Development of Item Banks to Measure Refractive Error-specific Quality-of-Life Parameters

by

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Table of Contents

List of Figures

List of Tables

Abstract

Refractive error is the most common cause of visual impairment. It can be corrected with spectacles, contact lenses or surgery. Refractive error itself or its correction may have quality-of-life (QoL) implications. Impact of refractive error on QoL can be explored using qualitative studies, and measured quantitatively using patient-reported outcome (PRO) instruments. The overarching aim of this doctoral study was to develop a technologically advanced PRO instrument, in the form of item-banking to be administered through computer adaptive testing (CAT) system, to measure QoL parameters in refractive error.

Through a systematic review of literature, I found that there was no published qualitative study exploring QoL in adults with refractive error. Similarly, a need for a comprehensive and scientifically robust refractive error-specific PRO instrument was identified. The existing PRO instruments in refractive error were paper-based questionnaires. They were limited in content and psychometric properties. None of them provided a comprehensive measurement of QoL in all refractive error sub-groups. The ‘Quality of Life Impact of Refractive Correction’, the ‘Quality of Vision’ and the ‘Contact Lens Impact on Quality of life’ had comparatively better psychometric quality with some limitations compared to the other PRO instruments. The superior quality PRO instruments were developed using Rasch analysis, a modern psychometric method.

I conducted two qualitative studies to explore the impact of refractive error on QoL in adults. In Australia, 48 semi-structured in-depth interviews were conducted. Thematic analysis resulted in six themes including concerns about refractive error and its implications, inconvenience rendered in daily life and difficulties in day-to-day activities. The second study was conducted in Nepal using similar methodology to explore impact of refractive error on QoL from a low- and middle-income country perspective. A total of 101 participants were interviewed including 47 participants with uncorrected refractive error. During thematic analysis, seven major themes emerged: Activity limitation, Inconvenience, Health concerns, Psycho-social impact, Economic impact, General- and ocular-comfort symptoms, and Visual symptoms. From both studies, multidimensional impact of refractive error on people’s QoL was identified.

Content (QoL domains and items) of the refractive error-specific item banks were identified from literature (existing questionnaire and grey literature) and the qualitative studies. The content identification and refinement process consisted of systematic criteria for binning, winnowing, expert panel review and cognitive testing. This iterative process resulted into item-pool (Australia) with 443 items and item-pool (Nepal) with 392 items.

The Item-pool (Nepal) was interviewer-administered to 305 participants with refractive error.

Psychometric properties of the item-pools were assessed, and optimized when required, using Rasch analysis. Rasch iterations resulted into 13 refractive error-specific item banks with 366 items. On CAT simulation, the mean number of items required for achieving high and moderate precision were 9.67 and 4.97 respectively. The final item banks were used to evaluate quality-of-life parameters across refractive error sub-groups. The item banks demonstrated good known-group validity by differentiating various sub-groups of refractive error. Overall, the findings provided promising evidence on the applicability of the refractive error-specific item banks to comprehensively and accurately evaluate quality-of-life parameters.

Declaration

I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Himal Kandel

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Publications, Conference presentations, Awards

Refereed publications: Review articles:

1. **Kandel H,** Khadka J, Lundstrom M, Goggin M, Pesudovs K. Questionnaires for measuring refractive surgery outcomes. *Journal of Refractive Surgery* 2017;33(6):416-24
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4. **Kandel H,** Khadka J, Shrestha MK, Sharma S, Neupane Kandel S, Dhungana P, Pradhan K, Nepal B, Thapa S, Pesudovs K. Uncorrected and corrected refractive error experiences of Nepalese adults: A qualitative study. *Ophthalmic Epidemiology*, 2018;25(2):147-61
5. **Kandel H,** Khadka J, Fenwick E, Sharma S, Sharma B, Kafle K, Kharal A, Kaiti R, Dhungana P, Shrestha MK, Nepal B, Thapa S, Lamoureux E, Pesudovs K. Constructing item banks for measuring quality-of-life in refractive error. *Optometry and Vision Science* 2018;95(7):575-87

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7. **Kandel H,** Khadka J, Pesudovs, K. Intensive blood-pressure treatment and patient-reported outcomes. New England Journal of Medicine 2017;377:2096-97

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1. Pesudovs K, Khadka J, Prem Senthil M, **Kandel H**, Kumaran SE, Fenwick E, EL Lamoureux. Disease-specificity and internationalization of ophthalmic quality-of-life item banks. ARVO 2018

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2. Pesudovs K, Khadka J, Prem Senthil M, **Kandel H**, Kumaran SE, Fenwick E, EL Lamoureux. The Eye-tem Bank project: the future of ophthalmic patient-reported outcomes in the form of item banking and computer adaptive testing system. XXXV Congress of the European Society of Cataract and Refractive Surgeons, 7-11 October 2017.
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Preface

Disclosure: There are no conflicts of interest or proprietary interest. I am responsible for the content and writing of the thesis. No editor was deployed in this thesis.

1. Inclusion of co-authored papers: publications arising directly from this thesis:

Five multi-authored papers have been published directly from this thesis on which I was the first author. The published text is moderately similar to the text in the thesis (Chapters 2, 3, and 4). Text from Chapter 1 has been published in the introduction sections of these papers. I designed all the published studies, collected data, analysed, wrote the first drafts, and revised the manuscripts with comments from the co-authors; reviewers and editors of the journals. I have described the contribution of every author in each publication below:

Paper I: **Kandel H,** Khadka J, Goggin M, Pesudovs K. Patient-reported outcomes for assessment of quality-of-life in refractive error: A Systematic Review. *Optometry and Vision Science* 2017; 94(12):1102-19

Co-author contributions:

- Khadka J: Study concept and design, Supervision, Critical revision of the manuscript
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- Pesudovs K: Study concept and design, Supervision, Critical revision of the manuscript, Funding acquisition

2. Co-author contributions to the additional publications related to this thesis:

Paper VI: **Kandel H,** Khadka J, Pesudovs, K. Intensive Blood-Pressure Treatment and Patient-Reported Outcomes. New England Journal of Medicine 2017; 377: 2096-97 [Correspondence]

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3. Inclusion of single-authored paper, publications arising directly from this thesis:

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Glossary of abbreviations

ACHIEVE	Adolescent and Child Health Initiative to Encourage Vision Empowerment
ADVS	Activities of Daily Vision Scale
AL	Activity limitation domain
AQOL	Assessment of Quality of Life
CAT	Computer adaptive testing
CFA	Confirmatory factor analysis
CLDEQ	Contact Lens Dry Eye Questionnaire
CLIQ	Contact Lens Impact on Quality of Life
CLUE	Contact Lens User Experience scales
COSMIN	Consensus based Standards for the selection of health status Measurement Instruments
CP	Coping domain
CPC	Category probability curves
CRE	Corrected refractive error
CSB	Comfort symptoms – bothersome
CSF	Comfort symptoms – frequency
CSS	Comfort symptoms – severity
CTT	Classical test theory
CV	Convenience domain
D	Dioptre
DEQ	Dry Eye Questionnaire
DESS	Dry Eye questionnaire and Scoring System
DIF	Differential item functioning
DV	Driving domain
EAP	*Expected A Posteriori*
EC	Economic domain
EFA	Exploratory factor analysis
EM	Emotional domain
EQ-5D	EuroQoL Health Questionnaire
FDA	Food and Drug Administration
FGVS	Freedom from Glasses Value Scale
GPCM	Generalized partial credit model
GRM	Graded response model
GS	General symptoms
GSB	General symptoms – bothersome

GSF	General symptoms – frequency
GSS	General symptoms – severity
HADS	Hospital Anxiety and Depression Scale
HC	Health concerns
HIC	High-income country
HRQoL	Health-related quality-of-life
ICC	Intra-class correlation co-efficient
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health (ICF)
ICL	Implantable Collamer lens
IOL	Intra-ocular lens
IRT	Item response theory
IVI	Impact of Vision Impairment
JMLE	Joint Maximum Likelihood Estimation
KMO	Kaiser-Mayer-Olkin
KW	KRUSKAL
LASEK	Laser epithelial keratomileusis
LASIK	Laser Assissted Keratomileusis In Situ
LID	Local item dependency
LMIC	Low- and middle-income
LoA	Limits of agreement
Logit	Log of the odds unit
logMAR	Logarithm of the Minimum Angle of Resolution
MB	Mobility domain
MCMC	Markov Chain Monte Carlo
MHRM	Metropolis-Hastings Robbins-Monro
MID	Minimally important difference
MML	Marginal maximum likelihood
MnSq	Mean square
MP	Measurement precision
MPWI	Maximum Posterior Weighted Info
MQLM	Multidimensional Quality of Life for Myopia questionnaire
MQLQ	Myopia-specific Quality of Life Questionnaire[111111111]
NAVQ	Near Activity Visual Questionnaire

NEI-RQL	National Eye Institute Refractive Quality of Life questionnaire
NEI-VFQ	National Eye Institute Vision Function Questionnaire
NHVQoL	Nursing Home Vision-targeted health-related Quality of Life
NVQL	Near Vision-related Quality of Life questionnaire
OCI	Ocular Comfort Index
OS	Ocular-comfort symptoms
OSB	Ocular-comfort symptoms – bothersome
OSDI	Ocular Surface Disease Index
OSF	Ocular-comfort symptoms – frequency
OSS	Ocular-comfort symptoms - severity
PCA	Principal components analysis
PCM	Partial credit method
PERK	Prospective Evaluation of Radial Keratotomy study questionnaire
PIADS	Paediatric Impact Of Assistive Devices Scale
PREM	Patient-reported experience measure
PREP	Paediatric Refractive Error Profile
PRK	Photorefractive keratectomy
PROWL	Patient-Reported Outcomes With Laser In Situ Keratomileusis questionnaire
PRO	Patient-reported outcome
PROMIS	Patient-reported outcome measurement system
PRSIQ	Patient Reported Spectacle Independence Questionnaire
PSI	Person separation index
PW	Person-weighting
QIRC	Quality of life Impact of Refractive Correction questionnaire
QoL	Quality-of-life
QoV	Quality of Vision
QVQ	Quality of Vision Questionnaire
REQ-Thai	Refractive Error Quality of life scale
ROC	Receiver operating characteristic
RSM	Rating scale model

RSVP	Refractive Status and Vision Profile questionnaire
SC	Social domain
SANDE	Symptom Assessment iN Dry Eye
SEEQ	Salisbury Eye Evaluation Questionnaire
SEM	Standard error of measurement
SF-36	Short-form 36 questionnaire
SG	Standard Gamble
SMILE	Small incision lenticule extraction
SREEQ	Student Refractive Error and Eyeglass Questionnaire
SS	Spectacle Survey
SVI	Subjective Vision Index
SVQ	Subjective Vision Questionnaire
TTO	Time Trade-Off
URE	Uncorrected Refractive Error
VAS	Visual Analogue Scale
VCM1	Vision Quality-of-life Core Measure-1 (previously known as VQoL)
VF-14	Visual function index - 14
VFQoL	Visual Function and Quality of Life questionnaire
VisQoL	Vision and Quality of Life Index
VQoL	Vision related effect on Quality of Life (later known as VCM1)
VS	Visual symptoms
VSB	Visual symptoms – bothersome
VSF	Visual symptoms – frequency
VSS	Visual symptoms – severity
WHO	World Health Organisation

Chapter 1. Introduction

The aim of this doctoral study was to develop technologically advanced and comprehensive patient-reported outcome (PRO) instruments to measure refractive error-specific quality-of-life (QoL). Item banks (large collections of items calibrated by modern psychometric methods such as Rasch analysis), developed through rigorous multi-phase qualitative and quantitative methods, may offer comprehensive and precise measurement of QoL parameters in refractive error. This chapter consists of an overview of the background, rationale, objectives and general methods of the doctoral study.

1.1 Background

Refractive error is one of the five priority conditions of the global initiative for the elimination of avoidable blindness, Vision 2020: The Right to Sight.[2, 3] Uncorrected refractive error (URE) is the leading cause of visual impairment, and the second leading cause of blindness worldwide.[4-6] In a recent study, Flaxman *et al.* estimated that in 2015 about 54% (n = 116.3 million) of global moderate and severe visual impairment was due to URE.[4] Recently, it was estimated that 1,095 million people had functional presbyopia.[7] Thus, including presbyopia, the magnitude of refractive error is much higher.[7, 8] Refractive error affects people for a greater number of years of their life than other common eye diseases such as cataract and glaucoma which usually onset in old age. The burden of URE is greater in countries with a low human development index.[9] The highest prevalence of URE lies in South Asia.[6]

The International Classification of Diseases, 10th revision (ICD-10) defines refractive error (H52) as a defect in the focusing of the light on the retina, resulting in blurred vision.[10] In myopia, the light is focused in front of the retina. In hyperopia, the light is focused behind the retina.[10, 11] Astigmatism is caused by the differential focusing of light rays in different meridians.[11] The physiology of presbyopia is different: due to age related changes, the eyes are not able to focus light-rays coming from objects near to the eye. Refractive errors can be optically corrected by using convex or concave lenses (Figure 1.1). Refractive error is different from other eye conditions such as cataract in several ways. Unlike general blur experienced in cataract patients, an uncorrected myope may have good near vision but poor distance vision. An uncorrected presbyope has difficulty reading at near but may have clearer vision at distance.[12] For activities such as driving, watching television and using a mobile phone, there is a ‘dynamic visual demand’ for rapidly alternating far and near vision.

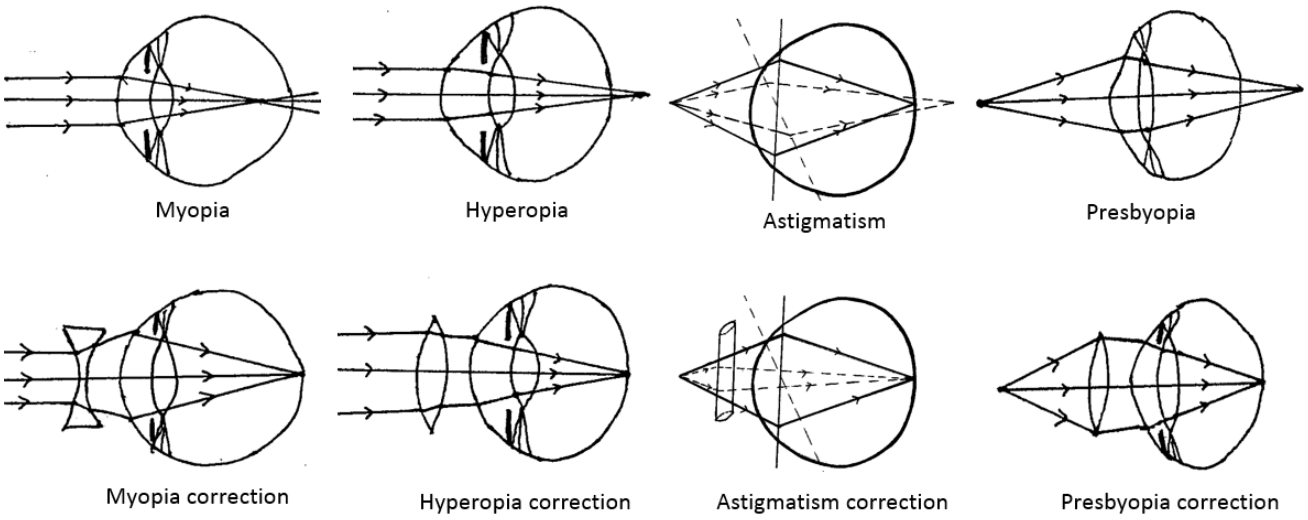

Figure 1.1 Types of refractive error and optical correction

Refractive error can easily be corrected with spectacles, contact lenses or surgery.[2] It is relatively more easily corrected than other eye conditions. However, several barriers to refractive correction (e.g. cost, availability of refraction services, and socio-cultural issues) makes URE the most common cause of visual impairment.[8, 13] The issue of non-compliance (e.g. in the use of spectacles) may be more in refractive error compared to other eye conditions such as cataract.

With advances in technology, a range of options from simple to the sophisticated, are available for each type of refractive error correction. There has been a rapid development in available designs as well as increase on the number of people using contact lenses and refractive surgery. Valid and reliable outcome measures are therefore crucial in determining refractive surgery and contact lens outcomes. Refractive error or its correction methods may have significant QoL implications. For instance, despite excellent visual outcomes offered by different types of contact lenses or new techniques for refractive surgery, complications such as dry eye are common.[14-16] The choice of correction method may depend upon several factors such as prescription, lifestyles, economic issues, and personality.[17] The impact of refractive error or its correction method on an individual's life can be explored qualitatively through in-depth interviews or focus group discussions. The PRO instruments are required to measure or quantify the QoL impact.[15, 16, 18] The standard objective measures used to assess the outcomes of refractive correction include visual acuity, residual refractive error and aberrometry.[19-21] The importance of PROs as clinical and research endpoints to assess the real-world impact of refractive error and its corrections on peoples' lives have been increasingly realised.[22-25]

A PRO is described as any report that comes directly from an individual regarding the impact of the condition, and the outcome of an intervention.[23-25] The PROs provide valuable information on understanding and promoting a person's health and have a number of uses in research and clinical practice.[18, 23-26] Patients' viewpoints are crucial in understanding refractive error, in promoting uptake of refraction services and in making the best choice for their refractive correction.[18, 22, 26-28] PROs are also helpful to compare the effectiveness of alternative intervention modalities from patients' perspectives.[23, 25] PROs are increasingly being used as a primary or secondary outcome measure in clinical trials while developing new products and techniques. This is particularly important for refractive surgery and contact lenses where new products and methods are continually emerging. Hence, PROs can have a crucial role in planning intervention and informing health policy. In optometry and ophthalmology, a number of PRO instruments have been developed to measure QoL.[18, 22]

Quality-of-life is a multidimensional construct, which comprises physical, environmental, social, emotional and economic factors. Ophthalmic QoL domains include Activity limitation, Mobility, Convenience, Health concerns, Visual symptoms, Ocular-comfort symptoms, General symptoms, Emotional well-being, Social and Economic issues.[29, 30] Similarly, refractive error-specific QoL is a complex multidimensional construct. It is determined by assessing the impact of refractive error or its correction method on an individual's physical, social or emotional well-being. The ultimate aim of refractive correction, like any other health care, is to address the QoL impacts of refractive error or its corrections.[14] Numerous PRO instruments are available for assessing QoL domains[29-32] in refractive error[1, 28, 33-45] including those specifically developed for refractive surgery[1, 40-42], contact lens[46, 47] and spectacles.[48, 49]

The existing refractive error-specific PRO instruments are of varying standard. A robust PRO instrument should be patient-relevant, comprehensive, psychometrically sound, valid, reliable and responsive to change.[26, 29] Comprehensive patient consultation is one of the most important processes in the development of a PRO instrument.[18, 26] This ensures all the relevant domains and items are included to measure an intended concept in a specific population. This process also avoids over-emphasis given to some QoL domains (Symptoms and Activity limitation) by clinicians. For instance, about 60% of the Refractive Status and Vision Profile questionnaire, which was developed with only minimal patient consultation, are on Activity limitation and Symptoms domains.[38] Whereas, a recent qualitative study found that health concerns and inconvenience are more important issues in people with refractive correction.[14] Similarly, tests for assessing psychometric properties, validity, reliability and responsiveness identify whether or not the PRO instrument has shortcomings.[18, 25, 26, 50]

While there are many existing PRO instruments in refractive error, they have several limitations. None are applicable to the entire spectrum of the refractive error population, which includes different severity levels of sub-types (myopia, hyperopia, astigmatism and presbyopia), and different types of correction. Similarly, many instruments purporting to measure QoL actually cover only one or two QoL domains, and none of them provide comprehensive measurement of each QoL domain (Table 1.1).[14-16, 18, 51] Moreover, some of the existing PRO instruments have been found to have issues with their psychometric properties, including validity and reliability.[15, 16, 18] Finally, findings from studies employing existing PRO instruments are not easily comparable due to heterogeneity in the studies in concept measured, definitions, methods, and populations. Therefore, there is a need to develop a comprehensive and psychometrically robust PRO instrument to measure QoL in refractive error which is applicable across a wide range of populations.[15, 16]

Table 1.1 Population and construct measured by current refractive error-specific PRO instruments

		Constructs claimed to be measured by current PRO instruments				
		Quality-of-life	Quality of vision / Symptoms	Satisfaction	Activity limitation	Spectacle independence
Population	Adults with uncorrected refractive error	**VFQoL**[a] *(AL-6, MB-2, VS-1, OS-2, HC-2, EM-2, SC-1)*				
	Adults with refractive correction (myopia, hyperopia, presbyopia; spectacles, contact lens, refractive surgery)	**NEI-RQL** *(AL-12, VS-9, OS-6, GS-1, HC-8, CV-5, EM-1)* **RSVP** *(AL-13, VS-10, OS-4, HC-2, CV-9, EM-2, SC-2)* **QIRC**[b] *(AL-1, OS-1, HC-4, CV-5, EM-7, EC-2)* **REQ-Thai**[a, c]	**QoV** *(VS-30)* **QVQ** *(AL-27, VS-34, OS-4, HC-17, CV-1)*	**PERK** *(VS-9, HC-7)*		
	Pre-presbyopic adults with myopia (spectacles, contact lens, refractive surgery)	**MQLM** *(AL-9, VS-11, OS-6, HC-4, EM-4, SC-4, CP-7)*				
	Adults with refractive surgery for hyperopia, myopia, astigmatism	**PROWL** *(AL-19, VS-41, OS-5, HC-17, EC-6)*				
	Adults with refractive surgery for myopia	**MQLQ** *(AL-12, MB-1, VS-7, OS-5, HC-5, CV-1, EM-1, SC-2)*	**SVQ** *(AL-13, VS-11)*			
	Adults with contact lenses (myopia, hyperopia)	**CLIQ** *(AL-2, VS-2, OS-2, HC-6, CV-5, EM-8, EC-3)*	**CLDEQ**[d] *(VS-9, OS-44, CP-2)*			
	Presbyopia (uncorrected, spectacles)	**NVQL**[a] *(AL-13)*				
	Presbyopia (spectacles, contact lens, refractive surgery)				**NAVQ** *(AL-10)*	

Presbyopia with refractive surgery		**FGVS** *(OS-1, HC-7, CV-9, EM-4)* **PRSIQ** *(CV-6, AL-3)*
Children wearing spectacles (myopia, hyperopia, astigmatism)	**SREEQ** *(AL-12, VS-10, OS-3, GS-4, HC-8, CV-1)*	**SS**[d] *(AL-5, OS-2, HC-24, CV-4, EM-2)*
Children with myopia	**PREP**[d] *(AL-5, VS-4, OS-4, HC-10, CV-3),*	

Note: In the parenthesis, number of items for each QoL domain are given (AL = Activity limitation, CP = Coping, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, OS = Ocular-comfort symptoms, SC = Social, VS = Visual symptoms). PRO = Patient-reported outcome; [a]PRO instrument for low and middle-income country setting; [b]QIRC was developed in pre-presbyopic population, but has also been tested with presbyopia. [c]Content of the REQ-Thai could not be retrieved. [d]Non-validated PRO instrument; **PRO instruments:** CLDEQ = Contact Lens Dry Eye Questionnaire[52], CLIQ = Contact Lens Impact on Quality of Life questionnaire[46], FGVS = Freedom from Glasses Value Scale[53], MQLM = Multidimensional Quality of Life for Myopia questionnaire[43], MQLQ = Myopia-specific Quality of Life Questionnaire[1], NAVQ = Near activity visual questionnaire[34], NEI-RQL = National Eye Institute Refractive Quality of Life questionnaire[35], NVQL = Near Vision-related Quality of Life questionnaire[54], PERK = Prospective Evaluation of Radial Keratotomy study questionnaire [41], PREP = Paediatric Refractive Error Profile[48], PROWL[55] = Patient-Reported Outcomes With Laser In Situ Keratomileusis questionnaire, PRSIQ = Patient Reported Spectacle Independence Questionnaire [56], QIRC = Quality of life Impact of Refractive Correction questionnaire[28], QoV = Quality of Vision questionnaire[33], QVQ = Quality of Vision Questionnaire[40], REQ-Thai = Refractive Error Quality of life scale[44], RSVP = Refractive Status and Vision Profile questionnaire[37], SREEQ = Student Refractive Error and Eyeglass Questionnaire[49], SS = Spectacle Survey[48], SVQ = Subjective Vision Questionnaire[42], VFQoL = Visual Function and Quality of Life questionnaire[12]

Initially, PRO instruments in refractive error were developed using classical test theory (CTT) [36, 37, 40-43], while subsequent instruments have used modern psychometric theory such as Rasch analysis.[12, 28, 33, 34, 46, 49] In both cases, the PRO instruments are paper- and pencil-based and thus have a fixed set of items which must be administered to all individuals irrespective of their characteristics such as ability levels. In other words, the existing PRO instruments are static and inflexible. Therefore, they either measure a low range of the assessed trait, or have poor precision if they measure a wide range of trait levels. They are often poorly targeted to patients at the extreme ends of the spectrum of refractive error. For example, a PRO instrument developed for a pre-presbyopic population may not be relevant for a presbyopic population. An item bank administered through a computer adaptive testing (CAT) system is a new generation PRO instrument that may address most of the limitations of the existing paper- and pencil-based PRO instruments.[23] Item banking has recently become popular in various areas of health.[30, 57-61]

An item bank has a relatively larger number of items compared to traditional paper- and pencil-based instruments, calibrated by using modern psychometric methods such as Rasch Analysis.[16] Therefore, it is more likely to have content relevant to diverse settings unlike short questionnaires. An item bank with a CAT system administers individually tailored items. Only the most informative

and targeted items are administered to an individual, thus decreasing respondent burden. Therefore, using just a few items, QoL domains can be precisely measured.[15, 16, 18, 30] The CAT can provide a real-time measurement with immediate feedback to the clinicians or patients.[16, 62]

This doctoral study is a part of the ‘Eye-tem bank project’ which is developing item banks for ophthalmic conditions. Figure 1.2 illustrates the progress of different modules of the ‘Eye-tem Bank’ project, including Refractive error module.

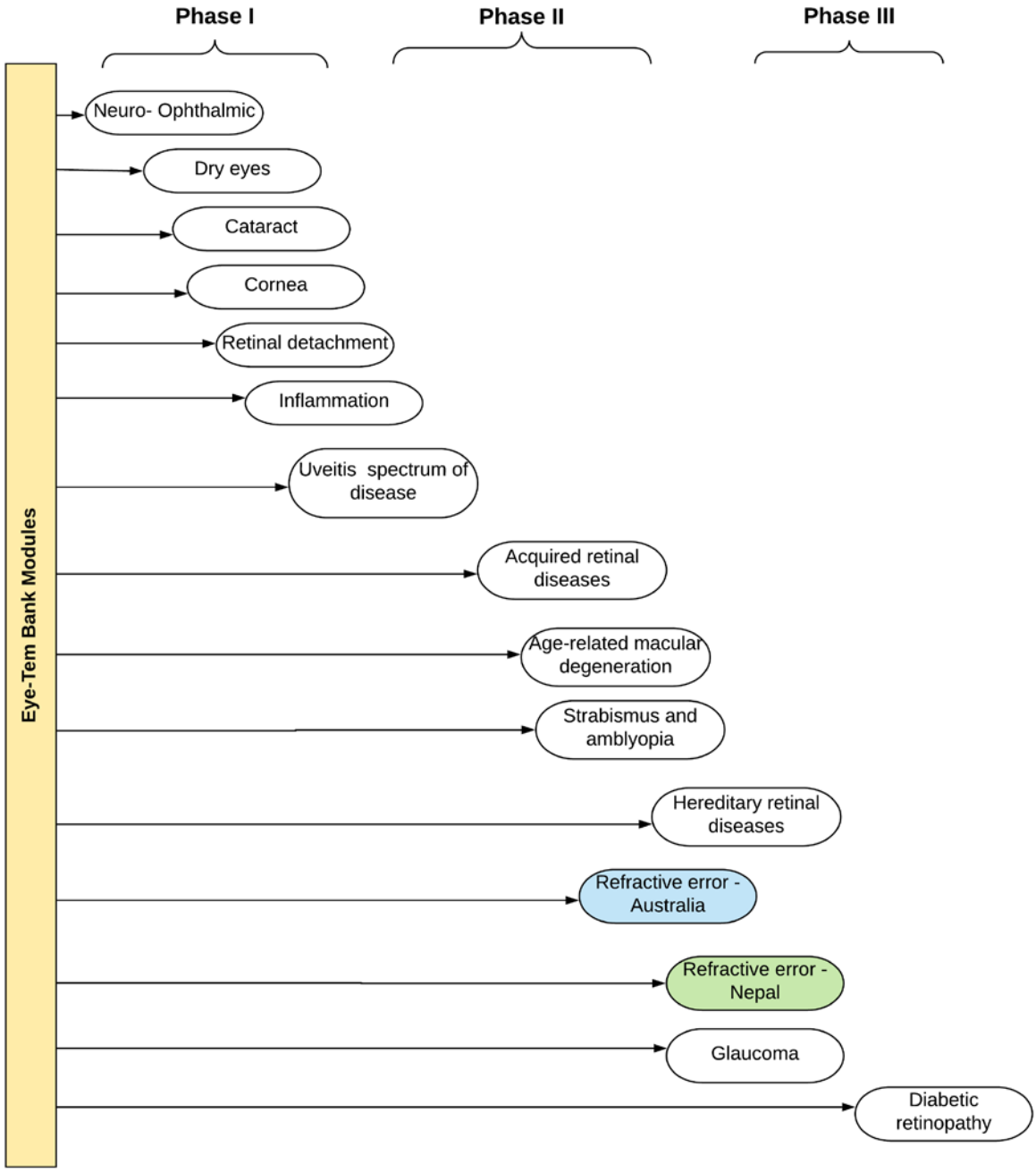

Figure 1.2 Refractive error module as a part of Eye-tem Bank project
Note: arrow-heads represent the location of developmental phase for the disease modules.

1.2 Aims and specific objectives

Aims and specific objectives for this doctoral thesis were:

Phase I–Australia and Nepal (Chapters 3, 4 and 5 describe literature review, qualitative studies and content identification process, respectively.)

- **Aim 1:** The aim of Phase I was to identify domains and items for measuring refractive error-specific QoL, through extensive literature review, qualitative studies and systematic content refinement process.
- **Specific objectives:**
- The specific objectives of the literature review were:
    1. to identify all the existing PRO instruments used in refractive error populations.
    2. to assess quality of the existing refractive error-specific PRO instruments in regard to content development, psychometric properties, validity, reliability and responsiveness, and determine the superior quality existing PRO instruments.
    3. to identify the content coverage of the identified PRO instruments in terms of QoL domains, and identify their limitations.
    4. to compare the status of refractive error-specific QoL measures between high and low- and middle-income countries.
- The specific objective of the 'Qualitative study I: In-depth interviews in Australia' was:
    5. to qualitatively explore and identify the issues that affect QoL of people with refractive error.
- The specific objectives of the 'Qualitative study II: In-depth interviews in Nepal were:
    6. to explore the impact of refractive error (including uncorrected refractive error) on QoL of adults in a low-income country setting.
    7. to identify the unique QoL impact issues in adults with uncorrected refractive error and various types of refractive correction, and to compare the QoL impact of refractive error between these sub-groups.
- The specific objective of the 'Content identification and refinement process' was:
    8. to identify minimally representative, informative and efficient sets of items for measuring refractive error-specific QoL in both high-income (Australia) and low-income country (Nepal) settings, and determine if two different item banks are needed for these settings.
- **Phase I, Hypotheses:**
    1. The existing PRO instruments in refractive error have limitations in content coverage and/or psychometric properties.
    2. Multidimensional impact of refractive error on QoL can be explored through qualitative studies.
    3. Refractive error item banks will have several QoL domains and a large number of items in each domain.

Phase II–Nepal (Chapters 6 and 7):

- **Aim 2:** The aim of Phase II (Nepal) was to develop refractive error item banks using Rasch analysis, and to assess the performance of the item banks for evaluating refractive error-specific QoL parameters
- Specific objectives of Phase II (Nepal) were:
    9. to calibrate the items in the 'Item pool (Nepal)' to develop refractive error item banks using Rasch analysis.
    10. to test the performance of the refractive error item banks in CAT system using CAT simulation tests.
    11. to measure and compare the QoL impact of refractive error between refractive error sub-groups by demographical and clinical characteristics.
- **Phase II, Hypotheses:**
    - Refractive error item banks will have satisfactory psychometric properties.
    - Refractive error item banks can be successfully administered by CAT system.
    - Impact of refractive error or correction methods on QoL can be evaluated using the refractive error item banks.
    - Refractive error item banks will demonstrate good known-group validity by differentiating refractive error sub-groups by differences in QoL impact.
    - QoL impact of refractive error varies by demographical and clinical characteristics.

1.3 Methodology

This doctoral study is a multi-phase prospective study consisting of qualitative and quantitative methods. It has four developmental phases (Figure 1.3). This thesis consists of the first two phases of the refractive error item bank module.

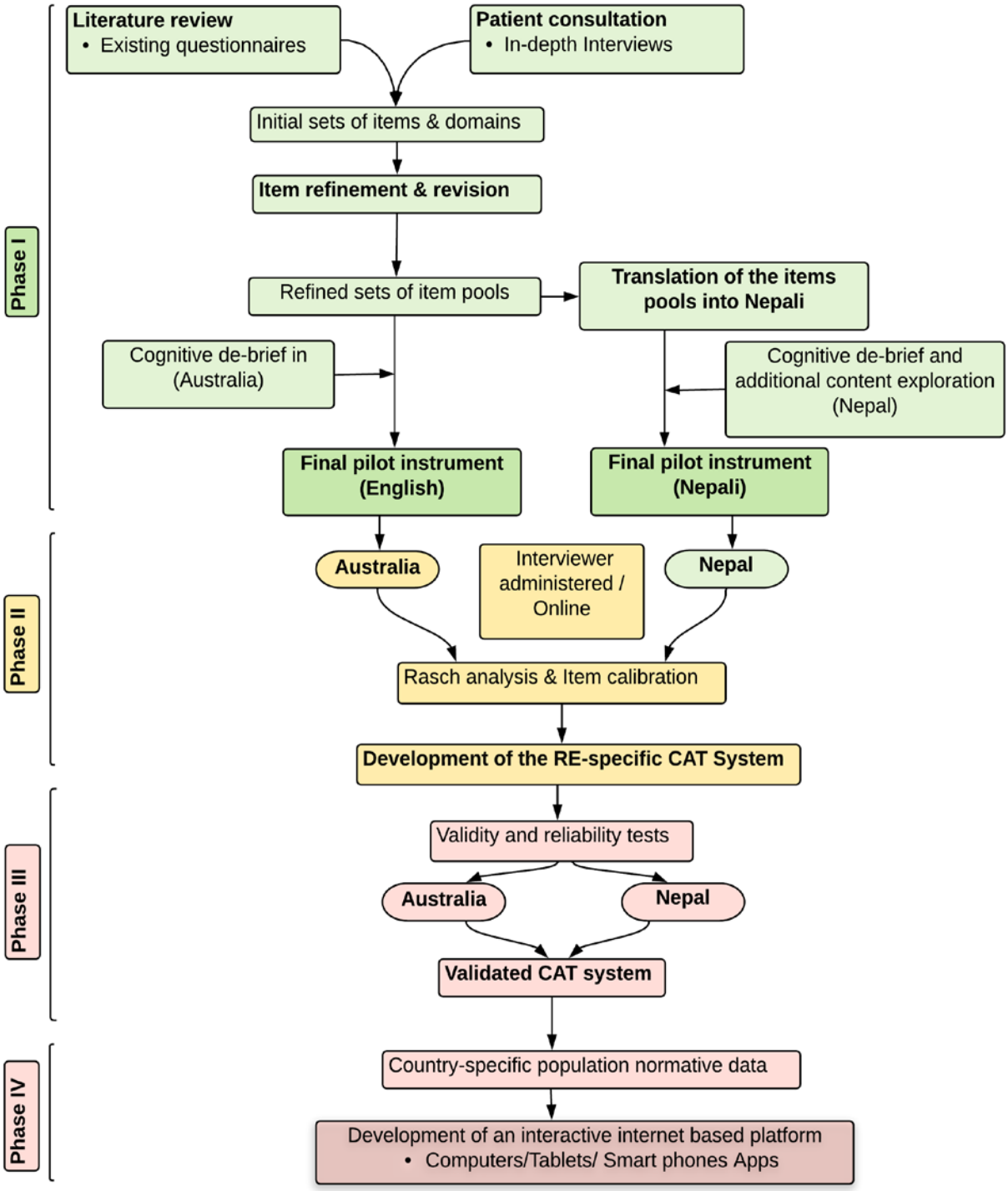

Figure 1.3 Methods for development of refractive error-specific item banks with a CAT system
Note: Green colour represents completed work, yellow colour represents ongoing work and red colour represents future work. CAT = Computer adaptive testing, RE = Refractive error.

Phase I: Content of the refractive error-specific item banks was identified in Phase I through extensive literature review and qualitative studies. Existing items were extracted from the existing PRO instruments in refractive error.[15, 16] For the qualitative studies, the participants with refractive

error were recruited from eye care centres and from the community. The in-depth interviews were conducted, transcribed and analysed to identify new content.[14, 63] All content was then aggregated and refined into questionnaires through a systematic process of binning and winnowing by a panel consensus, followed by cognitive testing. Phase I resulted into two questionnaires (item-pools), one for Australia (a high-income country setting) and the other for Nepal (a low-income country setting).[64]

Phase II: The primary objective of the second phase of the study was to calibrate items into the item banks using Rasch analysis. This included administration of the questionnaires (item-pools) and subsequent quantitative analysis of the questionnaire-data. Phase II has been completed for Nepal, and is ongoing for Australia. However, Phase II - Australia is not included in this thesis. The item-pools were administered to individuals with uncorrected and corrected refractive error who were recruited from the community and eye-care centres. Rasch analysis was performed to calibrate items into the item banks. Preliminary analysis was then conducted to test the performance of item banks in the CAT system by CAT simulation tests. The preliminary data was also used to evaluate QoL parameters across various refractive error groups. In addition, the preliminary analysis provided evidence on known-group validity, and the performance of the item banks as outcome measures.

Phase III: The third phase will include validation of the item banks implemented via the CAT system. The validation of the CAT system will include assessment for construct validity, discriminant validity, convergent validity, known-group validity, criterion validity and test-retest reliability.[30]

Phase IV: Comprehensive evaluation of refractive error-specific QoL using the item banks will be conducted at the fourth phase. This includes collecting normative data, determining thresholds (setting cut-offs) and categorizing people with low, moderate and severe impact on QoL parameters. In addition, responsiveness and sensitivity (ability to detect clinically significant changes) of the CAT system will be evaluated.[30]

Ethics approval for this study was obtained from the Southern Adelaide Clinical Human Research Ethics Committee, South Australia; the Institutional Review Committee, Kathmandu University School of Medical Sciences, Nepal; and the Institutional Review Committee, Tilganga Institute of Ophthalmology, Nepal (Appendix A). A written informed-consent was obtained from each participant. The study adhered to the tenets of Declaration of Helsinki.

1.4 Contribution to knowledge

Each stage of this doctoral study has contributed to knowledge towards understanding, measuring, monitoring and improving refractive error-specific QoL. This work may contribute to improve refractive error care to the billions of people affected by refractive error and presbyopia.

First, the literature review identified the existing PRO instruments in refractive error and graded their quality. This will guide the researchers in selection of an appropriate PRO instrument. Literature review also established the need for a comprehensive and scientifically robust PRO instrument in refractive error.

Second, two qualitative studies conducted were perhaps the first qualitative studies in adults to explore the comprehensive impact of refractive error on their QoL. Both the studies identified a number of ways how refractive error could impact on people's QoL.

Third, 13 item banks were developed to assess convenience, concerns, activity limitation, mobility problems, social problems, emotional impact, economic impact and frequency, severity and bothersome attributes of visual symptoms and comfort symptoms. The content of the item banks was identified and finalized using systematic methods for item extraction and refinement, and Rasch analysis, respectively. CAT simulations indicated that utilizing only few Items from the item banks may provide comprehensive yet precise measurement of QoL domains. The application of item banks administered through a CAT system is a new approach of measuring QoL impact of refractive error and its correction methods.

Fourth, the item banks were used to evaluate QoL domains in various sub-groups of refractive error quantitatively. The findings also demonstrated the known-group validity of the item banks by differentiating different demographic and clinical sub-groups of refractive error.

The qualitative and quantitative findings from this doctoral study may have high public health impact as refractive error and presbyopia affect billions of people worldwide, and may be useful to improve refraction services globally. Ultimately, the item-banks will be administered through the validated CAT systems, which will offer many advantages over currently existing paper-based PRO instruments. As only a few items tailored to individuals will be required to be administered, this approach decreases respondent burden and can save clinician's time. CAT system provides real time assessment with quick feedback, enabling immediate use of the PRO data. Thus, refractive error item banks administered through CAT system have a potential to be useful clinical tool. In the long run, refractive error item banks may be part of electronic health record systems enabling routine collection and documentation of PRO data in refractive error.

1.5 Thesis overview

This is a topic-based thesis which includes chapters with specific topics (Chapter 2 to Chapter 7) in between Introduction and conclusion chapters (chapter 1 and chapter 8, respectively).[65, 66] The epistemology for developing PRO instruments, with a focus on Rasch analysis, is briefly described in Chapter 2. The Chapter 3 provides a comprehensive literature review exploring the existing evidence on refractive error-specific QoL. Chapters 4 and 5 describe Phase I in Australia and Nepal. Similarly, Chapters 6 and 7 describe Phase II in Nepal. Chapter 8 provides an overall discussion and conclusions, with recommendations for future work. The topic-based chapters (Chapter 3 to Chapter 7) consist of text laid out in the IMRAD (Introduction - Methods - Results - and - Discussion) structure. The topic-based organisation is employed as this thesis comprises multiple studies.[66]

Chapter 2. The epistemology of PRO instrument development

Latent traits such as QoL cannot be directly measured unlike physical traits such as length and weight. PRO instruments such as questionnaires are widely used to measure latent traits. A PRO instrument typically has an item which consists of a question or a statement with two or more categorical response options. An item with two response options is called a dichotomous item. Whereas, an item with more than two response options is called a polytomous item.[67] The response options are also known as response categories.[68] Thresholds are the mid-points between the response categories in a polytomous rating scale. At threshold, there is a 50% probability of endorsing either of the adjacent response categories.[69] The number of response categories is always one more than the number of thresholds, for example, a rating scale with four thresholds have five response categories. A PRO instrument may consist of groups of items classified into domains or subscales.

A careful design of the instrument is crucial to ensure the content is relevant and represents what we purport to measure. Any instrument designed to measure QoL should be written in a clear and an unambiguous way. The measures created should be invariant for the populations they were developed for.[70] Subjective data should be carefully interpreted using psychometric methods for credibility and to avoid deriving false or misguided conclusions. Various theories and models have been developed to construct and evaluate PRO instruments, and to evaluate the data resulting their application. The goal is to develop comprehensive measures with high quality. Here, I briefly discuss Classical test theory (CTT) and Item response theory (IRT). In this doctoral study, I have used Rasch analysis which is a model based on the IRT. Aim of this chapter is to situate Rasch analysis in the wider theoretical models commonly used in instrument development in refractive error and to briefly describe key Rasch parameters.

2.1 Classical test theory

The CTT, also known as True score theory, is a traditional psychometric theory used in PRO instrument development and validation. The CTT employs a summary-scoring method which is the simple addition of ordinal values representing response options.[18, 22, 26, 28, 71] Internal consistency and factor analysis are commonly used correlation-based statistical measures in CTT.[1, 42-44, 54, 72]

Internal consistency refers to the extent the items measure the underlying construct.[73] In CTT, Cronbach's α is a commonly used statistic for assessing the internal consistency as a coefficient of reliability. Several studies have also used Cronbach's α as a surrogate measure of validity which is inappropriate.[1, 42-44, 54] Cronbach's α indicates how closely a set of items in a group are correlated

to each other (inter-item correlation). It may be inflated by redundant items.[73] Therefore, internal consistency is only a weak measure of reliability, and it does not say anything about validity (whether the instrument is measuring what it intends to measure).[73] While reliability does not imply validity of an instrument, poor reliability does indicate poor validity. For example, if a weighing scale gives five readings of a one Kg object as two, three, four, five and six; it is neither valid nor reliable. If it constantly gives a reading of six kg, it is not valid, but is reliable.

Internal consistency is not a measure of unidimensionality either. Dimensional structure of the items can be explored by exploratory factor analysis (EFA). The EFA is a method of multivariate analysis to explore the underlying structure or relationships between items. The EFA is useful to create a model. The factor structure can then be confirmed with confirmatory factor analysis (CFA). The CFA is useful to test if the hypothesized model is viable; how well the sample data fits the factor-model. In factor analysis, correlation between factors is calculated and the chi-square test is used to examine the significance of the difference between two factors.[74]

However, factor analysis in the CTT is based on correlation on ordinal level data, and has limitations in identifying multidimensionality. The standard error is unknown and ignored in correlations for factor analysis.[75] Factor analysis is sample dependent. It requires a complete data set, therefore is limited further by missing data. Practically, obtaining data free from missing data is unrealistic. As the factor analysis does not require linear interval-level data, it does not provide information on forming a linear measure.[76]

Imprecision or noise in CTT-based PRO measurement is exacerbated by floor and ceiling effects in the data. A floor effect occurs when the items are too difficult. For example, to an Activity limitation item ‘How much difficulty do you have swimming?’, most of the high myopes wearing spectacles may answer ‘Very difficult - can’t swim because of vision’. Whereas, a ceiling effect occurs when the items are too easy. For the same item on swimming (How much difficulty do you have swimming?), most of the participants who had undergone refractive surgery may answer “No difficulty at all”. Thus, extreme responses are likely to be endorsed when there is a large difference between item-difficulty and the person-ability, defined as poor targeting. The poor targeting causes a floor or a ceiling effect in the data.[77]

The CTT has been widely criticized in the recent years because of its false assumptions.[18, 22, 26, 28, 71] Summary scoring method assumes that response options are equidistant on a scale (Figure 2.1) and all items worth the same. Thus, CTT assumes ordinal level categorical data as interval level data.[72] These assumptions are inaccurate conceptually, and have been proven to be invalid by using IRT methods. So, these assumptions reduce precision in the measurement. Scoring with IRT

or Rasch analysis increases precision of measures up to ten fold.[3] Due to the noise in measurement, sensitivity of a PRO instrument is lowest when scored with summary scoring method. In addition, CTT does not provide information on how well do the items fit the trait being measured, and whether some items are answered differently by population sub-groups.[73] Thus, the approach using CTT doesn't provide insights at the items-level and does not allow scrutiny of individual items. It only provides sample-dependent test-level estimates.[78]

Figure 2.1 Erroneous assumption in summary scoring
Note: The distance between adjacent response options are assumed to be equal in summary scoring.

2.2 Item response theory

The IRT evolved from the CTT to overcome limitations of the latter.[78] It is based on the principle that the probability of an expected response is the function of person-ability and position on the latent trait, in terms of one or more parameters: difficulty, discrimination or guessing.[79] The person-ability is defined as zero logits (log odds units) when the probability of endorsing or achieving an item with mean difficulty (latent trait level) is 50%. Unlike CTT, IRT provides information on measurement precision as well.[78]

The IRT models are of three types based on the number of parameters they estimate. A three parameter IRT model estimates difficulty, discrimination and guessing parameters. A two parameter IRT model includes difficulty and discrimination parameters. An item with higher discrimination value is more likely to be endorsed (higher probability) although two items may have same difficulty values. The Graded response model (GRM) is a two parameter model.[74] One parameter model includes only the Difficulty parameter. Polytomous Rasch analysis is a unidimensional one-parameter model of the IRT which considers equal discrimination value for all items.[74]

The IRT models are usually unidimensional models. More recently, multidimensional models are

also described (e.g. multidimensional GRM). Multidimensional IRT models are applied when one latent trait is measured with many subscales.[80] Researchers may be tempted to measure QoL using a multidimensional model as QoL is a complex multidimensional trait. However, this approach has limitations. A single score may not provide any meaningful information on individual dimensions. For example, refractive surgery or contact lenses may minimize activity limitation, but may increase symptoms such as glare or dry eyes.[37, 47, 81, 82] Measuring symptoms and activity limitation in a single multidimensional scale therefore may not be appropriate in refractive error.

2.2.1 Estimation of parameters in item response theory

The parameters in IRT are estimated using various algorithms and techniques, available in various commercial software. Common algorithms are Expectation maximum (EM) algorithm, Markov Chain Monte Carlo (MCMC) algorithm and Metropolis-Hastings Robbins-Monro (MHRM) algorithm.[80] In Marginal maximum likelihood (MML), item parameters are estimated using EM algorithm. Person parameters are then estimated using the item estimates.[80] Similarly, fully Bayesian estimation methods employs MCMC algorithm. Whereas, MHRM method is a hybrid of MML and fully Bayesian estimation method which uses MHRM algorithm.[80] The Rasch model estimates are typically made by applying Joint Maximum Likelihood Estimation (JMLE) method, which is an unconditional maximum likelihood estimation method. The JMLE is relatively a flexible method.[83]

Rasch analysis estimations include calibrations of item-difficulty and person-ability, and estimation of fit.[76] Item-difficulty is estimated by the proportion of persons that endorsed each item, and person-ability is estimated by proportion of items each person endorsed or succeeded.[76]

2.3 Rasch analysis

Rasch analysis is an IRT-based one-parameter probabilistic model that estimates relative difficulty of items (item measures) and relative abilities of respondents (person measures), and align them in a single invariant interval-level scale. It is a probabilistic model based on the principle that a person with higher ability has greater chance of being successful in answering an item, and an item with less difficulty is more likely to be answered successfully than the item with more difficulty.[84] Probability (P) of endorsing an item accurately is the logistic function of difference between person-ability (B_n) and item-difficulty (D_i).[85]

$$P = f(B_n - D_i)$$

Rasch analysis transforms simple ordinal categorical data into interval level data with logarithmic transformation. Item and person estimates are placed in a single linear scale with logits (log odd

units). Interval sizes are determined by probabilities of item and person data.[85] Unit intervals in any locations of the scale have the same value or meaning.[79, 85]

Rasch analysis is based on the principle of conjoint measurement and measurement invariance, analogous to measurement of density. Density of a material is derived from the measurement of mass and volume. For a particular material, density is always the constant irrespective of the values for mass and volume. Analogous to this, Rasch analysis estimates probability of endorsing, achieving, agreeing to, or affirming an item as a function of person-ability and item-difficulty. Person-ability for different sub-groups of a population may vary, but the item hierarchy in the Rasch scale is invariant for a similar population, irrespective of the person abilities. Similarly, person-ability should be the same irrespective of which items from the Rasch scale are used to obtain the person-ability score.[86] Rasch analysis is based on complex mathematical modelling. However, in this thesis, application aspects of the Rasch Analysis are discussed with a problem-solving approach.

Rasch analysis describes, explains, measures and predicts the attributes based on a sound measurement philosophy.[70, 79, 86, 87] Rasch analysis can be applied at two stages: in constructing the measures and in evaluating the constructs, ideally for both.[70, 88-90] Both quantitative and qualitative analysis are crucial in Rasch analysis unlike CTT which ignores the subjectivity in answering the items.[70, 91] Unlike CTT, Rasch analysis only needs scientific density of data to enable calculations, and therefore is robust in handling missing data.[92, 93] More targeted data produce more precise measurement (less standard error).[92]

Researchers are divided on the preference of Rasch analysis over other IRT models.[94] Despite being a single-parameter model, Rasch analysis is superior to other IRT models because it is based on a sound measurement philosophy.[70, 79, 86, 87] Although human condition is exceptionally complex, Rasch analysis approximates physical measurement in measuring human attributes appreciating the idiosyncrasies between individuals.[70] Other IRT models are exploratory which aim to describe the variance within the data. two-parameter and three-parameter IRT models do this by attributing parameters such as discrimination and guessing to account for the variance.[92] However, Rasch analysis is a confirmatory model where data has to fit the model.[86, 87] In order to achieve an interval-level measurement, it is required that data fits the Rasch model requirements of unidimensionality, equal discrimination and local item independence.[76] Whereas, other IRT models are based on statistical modelling (rather than measurement philosophy). They aim to describe the data fitting them into their model, rather than aiming to develop measurement scales with fundamental measurement properties.[79, 86, 87]

In Rasch analysis, equal discrimination in items is assumed. Ideally, all the items have model-expected discrimination value of one. Item discrimination values from 0.50 to 1.50 are acceptable.[83] Guessing is an off-trait behaviour that can be detected through careful examination.[76] Rasch analysis has a strong quality control mechanism to diagnose any shortcomings and to ensure sound PRO measurement, such as assessment of measurement precision, dimensionality and fit statistics.[86]

Proponents of other IRT models may argue that the property of Rasch analysis requiring the data to fit into the Rasch model requirements (e.g. unidimensionality, local item independence, good fit statistics) to achieve a productive measurement may be unrealistic. In reality, data may never fit the model as the latent constructs aimed to measure are often complex. Response to this concern may be discussed with a well-known mathematical example as an analogy: Pythagorean Theorem. Pythagorean Theorem states that the square of the hypotenuse is the sum of squares of other two sides of the right-angled triangle. In reality, most of the triangles in nature are not right-angled triangles. Similar to this analogy, Rasch analysis should also be utilized to aim for a productive measurement although the data may not perfectly fit the Rasch model requirements.

Rasch model guides the development and selection of items in a PRO instrument. As the data has to fit the model in Rasch analysis, some items may have to be deleted. Item deletion is guided by Rasch diagnostic parameters (e.g. Item redundancy, Local item dependence, poor fit statistics, poor discrimination) discussed in detail in Section 2.3.1, and other parameters such as high percentage of missing data and item with low clinical importance.[95] Deleting items might cause reduction in content validity.[78] This is particularly important when a scale has few items only. It may not be a problem for item-banks as they usually have a large number of items. Supporters of Rasch analysis argue that the property ‘data has to fit the model’ is not a disadvantage. As long as all the items are measuring the same construct, which items are used to measure the construct does not matter.[96]

In summary, the focus of Rasch analysis is on scientific measurement, whereas, the focus of other IRT models is on simply describing the data parameters fitting in their models. Rasch analysis is particularly useful as *a priori* to form a sound measure comparable to measures in physical science such as measuring length, mass or density.[86] However, measurement of human conditions are more complex than measurement in physical science.[70] Nevertheless, our goal should be to approximate physical measurement standards while measuring QoL.

There are two common variants of Rasch model: partial credit model (PCM) and Rating scale model (RSM). The PCM is useful when differing number of response categories are used for

different items in the same scale. The PCM can mix dichotomous and polytomous data in the same observation. Different items have different threshold values. Each item in a scale has its own category-threshold structure, that may be different to other items.[97]

The RSM is one of the unidimensional IRT models used to analyse polytomous items (items with more than two response categories). RSM estimates both item-difficulty (or agreeability or endorsability) values as well as response category threshold (Tau) values.[91] Threshold step structure is calculated from the data.[91] Item-difficulty (and error value) is obtained by modelling the threshold values (and their errors) and their position in the item scale.[91] The RSM[98] was used in this study assuming rating scale were used by each item in a scale in a similar way. For each item in a scale (domain), same item-root (e.g. 'Because of having refractive error or its correction, how often…') and same response options were used. In RSM, all the items in a domain have similar structure (same set of threshold values for each item).[79] This is because, in order to calculate person and item parameters, the sum of raw scores associated with those parameters are used.

Group-rating scale model was used when a group of items in a scale were assumed to use a slightly different rating scale than the other items. For example, items on the Emotional domain were grouped based on positive (e.g. 'Because of having refractive correction, how often do you feel efficient?') or negative (e.g. 'Because of having refractive error, how often do you feel upset?') wording. The RSM has some advantages over the PCM. For example, the RSM may be useful when some response options of some items in the item bank are endorsed less than the minimum number of responses ($n < 10$) required for a stable threshold calibration.[99] In RSM, the functioning of an un-endorsed response category can be estimated from the functioning of the category for other items. Use of RSM therefore may reduce noise in the measurement. Fit statistics act as quality control tools to ensure that the individual data points contribute to the rating scale structure (minimizing noise).[83]

2.3.1 Rasch parameters

Rasch analysis provides insights into a series of important psychometric properties of a PRO instrument, known as Rasch parameters or diagnostic Rasch parameters. The parameters include response category functioning, dimensionality, fit statistics, targeting, measurement precision, local item dependency and differential item functioning. Alternatively, the data should meet the convergence to acceptable levels of the Rasch parameters (Rasch model requirements) in order to achieve an interval-level measurement.

The Rasch parameters act as diagnostic indicators used to select (include or exclude) items in constructing measures.[100] Rasch analysis is an iterative process where item or person estimate

cycles are repeated until essential or specified criteria or conditions are met (convergence). A well-targeted instrument has item and person means ideally at the same level of the scale. Each measurement scale should measure only one underlying construct (unidimensionality). Likewise, the trait values of the response options should increase monotonically in a scale with a uniform spacing between one to the next option (response category functioning). Person separation index or person reliability coefficients are the measures of measurement precision which estimate how many groups of people with different person-ability can be defined by the instrument. Similarly, item fit statistics indicate how well the items fit together to measure the underlying latent trait. Another component of Rasch analysis is the differential item functioning, which assesses if groups of people with similar latent traits respond differently.[18, 22, 23, 26, 71, 101]

It is essential to interpret qualitatively what the data and Rasch estimates mean while carrying out Rasch analysis.[70] Findings from the parameters (e.g. response category functioning, dimensionality, fit statistics) should be evaluated in combination.[102] Usually, improving one parameter improves the other. For example, addressing misfits may improve dimensionality, and vice versa. Meaningful and rational decisions should be taken, not just based on the guidelines and cut-offs. For example, deleting a misfitting item may need to be avoided if the item is clinically important. .[99] Rasch analysis requires the combination of quantitative and qualitative methods to make a scientific measure.[70]

2.3.1.1 Response category functioning

The aim of a rating scale framework should be to enable effective communication of latent trait by the responders.[99] To achieve this, a careful balance on the number of response options and the clarity of item and response options are essential. Appropriate number of response options is contextual and there is no ‘one size fits all’. In optometry and ophthalmology, four to five response options have been found to be optimum for measuring QoL domains.[103, 104] Too many response options muddles the definition of the construct being measured by the item.[99] This may also increase respondent burden leading to poor quality data. Improper rating scale design can lead to incomplete or false data.[99]

Any ambiguity in the item and response option wording may decrease reliability which in turn affects validity.[99] Careful construction of rating scale is therefore crucial. However, reliability is not sufficient to confirm validity of the rating scale which depends upon many factors such as type and purpose of rating scale, population, way of administration, and interpretation. The value of rating scale does depend upon the theoretical soundness which has to be further established empirically. Using Rasch analysis, how the rating scale performs can be empirically determined.[99] Rasch analysis also enables comparison between different categorizations with their impact on quality of

measures.[99]

Rasch analysis converts ordinal categorical data into interval-level data by logistic transformation. It provides estimates for threshold values of the response categories in logits. A threshold is a point where probability of endorsing adjacent categories is equal (i.e. 50%). Alternatively, the probability of endorsing switches at this point; i.e. the probability of endorsing the response option is higher after the threshold value if it was lower earlier, or vice versa.[79] The threshold values of the response categories (in logits) in a rating scale should increase monotonically (i.e. higher category should indicate higher ability/ stronger feeling/ higher latent trait).[104] Alternatively, ordered thresholds indicate that the response categories are utilized as intended in the order of functional ability.[105] The thresholds and category measures predicted by Rasch model are sample-free estimates.[106]

Before making a rating scale assessment using Rasch analysis, polarity of items should be made the same so that items are scaled in the same direction. Objectively, it can be investigated from point-measure (item-measure) correlations. This indicates how responses to an item align with the measure.[91] Item-point correlation coefficient higher than 0.4 indicates consistency in item polarity in the scale.[100] The empirical evidence of rating scale functioning can be derived from examining category frequency and average measures, category threshold progression and category fit statistics.[99]

Response categories with too low frequencies are problematic as the data may not be sufficient to provide stable threshold estimates.[99] Regular and near-normal distribution of response across the categories are desirable. At least ten responses are recommended per category.[99] Similarly, response categories (average measures for categories and response category thresholds) should advance monotonically with reasonable increments.[99, 100] This indicates persons with higher ability endorse higher response categories, and the persons with lower ability endorse lower response categories.[99, 105] This can be visually inspected from the category probability curves (CPC).

The CPC is a graph with category probabilities (y-axis) plotted against difference between person and item measures (x-axis) (Figure 2.2). In this example (Figure 2.2), the higher response option (response option ‘5. Not at all’) for an item from the Economic item bank is likely to be endorsed by people with higher economic status. In other words, Response 5 can be said the most difficult response option as only the most able participants i.e. Participants with higher economic status can endorse this category. Similarly, the threshold values should be neither too close nor to far apart. Generally accepted value for response category threshold step is between 1.4 logits and 5.0 logits.[91, 99] Likewise, infit and outfit mean square (MnSq) values 0.6-1.4 are considered productive

for rating scale measurement.[91] Whereas, MnSq values greater than 2.0 indicate more noise than information.[99] The steepness of the curves indicate the discrimination ability of the response category.[107]

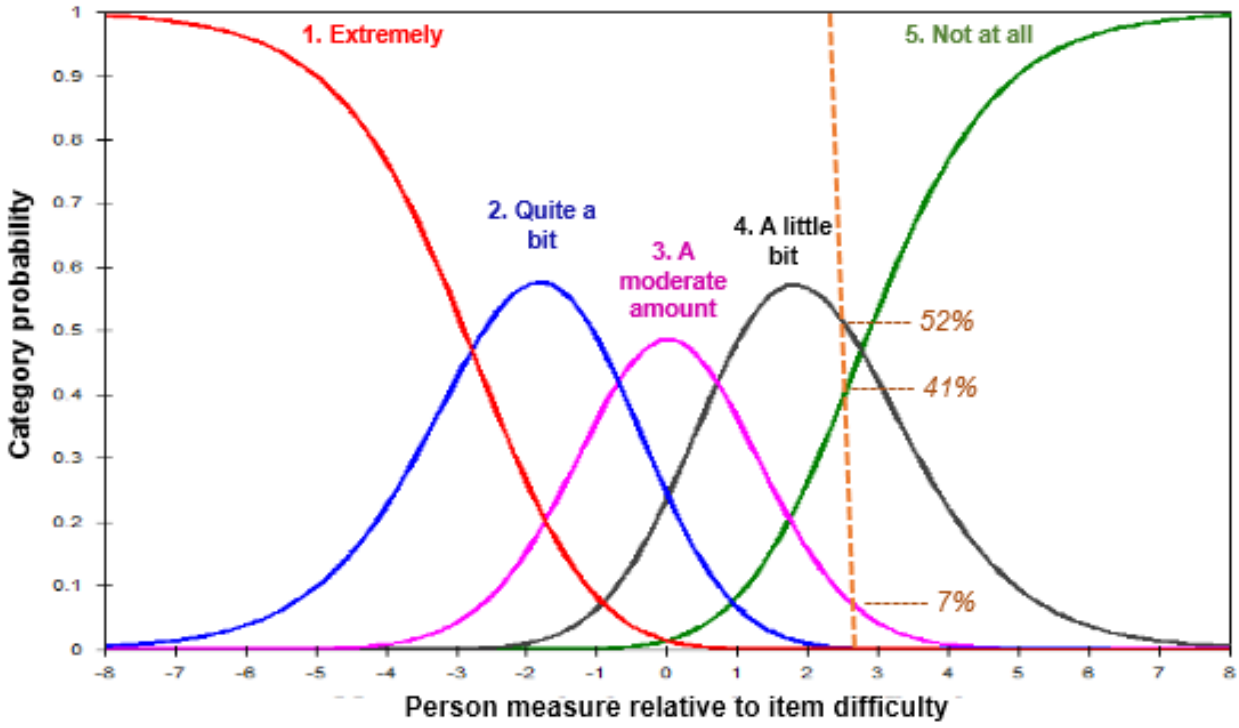

Figure 2.2 Category probability curves for the refractive error-specific Economic item bank
Note: Item example: 'EC2. How concerned are you about the initial and ongoing cost to buy your glasses?' Each curve represents the probability of endorsing a response option. For example, when the difference between person measure and item measure is 2.7 logits (i.e. at the location of brown dotted line), the probability of endorsing '3. A moderate amount', '4. A little bit' and '5. Not at all' response options were 7%, 52% and 41% respectively. At this point of the continuum, it was unlikely that the '1. Extremely' or '2. Quite a bit' would be endorsed.

Rating scale design affects item calibrations.[104] Items with same content but different rating scale design (types and number of response options) could have different item calibrations. When problems are detected, rating scales should be revised. Categories with low frequencies may have to be collapsed to the adjacent category. Similarly, adjacent or redundant categories should be collapsed if the thresholds are disordered (i.e. thresholds that do not advance monotonically) as they damage measurement .[100] Collapsing of the rating scale should be sensible. For example, it may not be good idea to collapse 'rarely' and 'often'. More regular frequency distribution should be aimed for. Each category should be the most probable response at some point of the measurement continuum.[89, 105] Similarly, impact on other Rasch parameters has to be considered. For example, if one categorization yields person separation of more than two and the other does not, former may have to be selected.[99] Similarly, we have to look at item misfits and ordering (does

theory matches with item ordering in one categorization than other?) while selecting an appropriate categorization.

The rating scale diagnostics discussed above (category frequency, category averages, threshold estimate values, threshold steps, category fit statistics) should be evaluated in combination. They provide similar information in different ways. If the rating scale is functioning well, revision should ensure maximum and accurate meaning is derived from the data using the measure.[99] Rating scale revision should be done at the pilot phase of developing a measure.[99] Well-functioning categories indicate successful use of polytomous Rasch analysis.[100] However, validity and reliability assessment are required to assess if the measure is functioning well or not on the whole.[99]

2.3.1.2 Dimensionality

Ideally, the criteria of unidimensionality should be met by a measurement scale, i.e. measurement scale should measure only one attribute (e.g. height, weight). This is a fundamental property of any scientific measurement. In reality, for PRO instruments, an absolute unidimensionality may not be possible. Unidimensionality cannot be strictly met as various factors such as cognitive and personality factors affect the performance of the responders.[74] For example, individual differences in adaptation to wearing glasses or contact lenses may affect the performance. Furthermore, definition of a dimension is provisional, defined to achieve a productive measurement. For example, mathematics may be a dimension although there may be questions on addition and subtraction which are very different skills. Analogously, activity limitation may be a single dimension when reading and playing are different types of activities.[76] Dimensionality can be assessed by multiple ways. Guidelines are provided that should be satisfied to call a scale as unidimensional.[74] However, aiming a productive measurement is more essential rather than obtaining acceptable values as per the guidelines.

Rasch factor analysis and Principal component analysis of Rasch residuals

Rasch factor analysis is the factor analysis of the ordinal level residuals that remain after the linear measure has been constructed.[76] After the linear measure is constructed, variance in the ordinal level residuals that is not explained by the primary Rasch measure (principal component) is identified.[76] The nature of the additional dimension has to be explored.[76] Whether the unexplained variance is systematic or random has to be studied.[91] Analogically, this can be understood as if we want to determine the weight of stones by how easily we can lift them, shape (round stones more difficult to lift) and wetness of hands (difficult to lift because of wet hands) may have to be controlled for.[76] Unidimensionality is assessed by principal component analysis (PCA) of the residuals.

Residuals are the deviations from the Rasch estimates. Residuals are the differences between observed data (observed scores) and the model estimates (Rasch predicted scores, expected data).[78] Raw residuals are standardised by using their variance.[76] Standardised residuals are the raw residuals divided by their standard error.[78] Evaluation of residuals is particularly important when sample size is too low or too high which affect statistical significance.[78] When the data fits the model well, standardised residuals are expected to be approximately normal. Alternatively, when the standardised residuals are normally distributed (approximately), this is an evidence of a good model fit.[78] Good fit statistics indicate unidimensionality.[108] However, good fit statistics is not sufficient to prove unidimensionality.[108] For example, detailed examination of Activity limitation domain may indicate multidimensionality with dimensions such as Reading and Lighting, although all items may fit together to measure activity limitation.

For a unidimensional measure, most of the variance should be explained by the principle factor (measure).[78] Raw variance explained by the first factor should be > 50%.[32] High proportion of variance explained by the measure means better performance of person and items.[100] PCA of the residuals identifies the items that have substantial variance in residuals that is not explained by the primary Rasch measure. Items clustered together with factor loadings for residuals significantly higher than zero (> 0.40) may cause disturbance in the measurement, and therefore have to be further investigated. The variance in the residuals of this group in relation to the primary Rasch measure indicates the viability of the second dimension. In this study, positively loaded items (mainly items with standardised PCA residuals loading > 0.40) with a meaningful second dimension were split from the main scale to evaluate if they formed a separate independent scale.

While assessing dimensionality, we have to determine what is causing the unexplained variance. Eigen-values (and variance for the eigen-values) explain systematic variance i.e. eigen-value two means at least two items are contributing to systematic variance of n%, i.e. indicating two items attributing to second dimension within the main dimension. In item banking, eigen-value less than three is acceptable.[57] When the unexplained variance explained by the first contrast is greater than three eigen-values, and/or when the ratio of variance explained by the items to the variance explained by first contrast is low, it indicates multidimensionality and further *post-hoc* investigations (correlations, limits of agreement) should be carried out.[57]

On Rasch PCA, if the correlation between two item-clusters is close to one, the items may be measuring the same dimension.[32] Pearson correlations between 0.57 and 0.82 suggest moderate correlations.[32] Disattenuated correlation is particularly important as it is calculated minimizing the effect of measurement error (noise) in the measurement.

However, two scales with high correlation does not necessarily imply that two scales are in agreement.[109] Correlation only evaluates linear relationship.[109] Limits of agreement can be determined by the Bland and Altman (B&A) agreement analysis. In the B&A plot, mean measures and difference between the paired observations in two scales are plotted in x and y axes respectively.[110, 111] Limits of agreement are calculated by the formulae: Difference ± (1.96*Standard deviation of the difference). If most of the observations are within the narrow limits of agreement, it implies that there is a good agreement.[110] Alternatively, wide limits of agreement suggest lower agreement.[109] This is more important than merely calculating correlation coefficient as the latter may be misleading.[110]

In sum, there are multiple ways to investigate dimensionality. First, Rasch factor or PCA of residuals, and fit statistics are evaluated. If this indicates multidimensionality, *post-hoc* tests such as disattenuated correlations, ratio between explained variance by items to unexplained variance, correlations and agreement analyses are conducted. In this study, the decision to split items or not were made qualitatively guided by these statistics in combination.

2.3.1.3 Fit statistics

The fit statistics indicate extent to which observed data adhere to the Rasch model estimates.[79] When there are misfits, Rasch estimates (item and person estimates) do not match with the sample data. Alternatively, the data where item and person estimates are coherent and integrated lead to good fit. Good fit statistics also indicate that the measure is unidimensional and has good construct validity.[85] Fit statistics act as quality control mechanism to determine if the data fits the Rasch model for measuring a unidimensional construct.[85] Fit statistics are calculated from the standardised residuals.[76] There are two types of fit statistics: infit and outfit statistics**.**

The infit statistics are information-weighted fit statistics (weighted by variance; the variance is larger for well-targeted responses and smaller for extreme responses).[76] Therefore, in calculating infit statistics, more weight is given to on-target observations.[79] Whereas, in calculating outfit statistics, equal weightage is given to on-target and off-target observations. Therefore, outfit statistics is influenced by off-target observations.[79]

Infit and outfit statistics are further of two types: unstandardised (infit MnSq; outfit MnSq) or standardised (infit zstd, outfit zstd) (Table 2.1).[79]

Table 2.1 Properties of infit and outfit statistics

	Standardised	Unstandardised	Weighted	Unweighted

Infit	**MnSq**		√	√		
	Zstd	√		√		
Outfit	**MnSq**		√		√	
	Zstd	√			√	

Note: MnSq = mean square, Zstd = z standardised

Infit or outfit MnSq values are calculated by chi-square statistics divided by their degree of freedom.[76] Alternatively, the MnSq values represent the ratio of observed variance to the expected variance.[108] The MnSq values are positive and range from zero to infinity, with an expected value of +1. The MnSq value 1.30 means 30% more variation in the observed data than the Rasch model predicted variation. MnSq values more than 1.30 are generally considered misfitting items (noisy items; introduce more noise than information in the instrument), and less than 0.70 are generally considered overfitting items (muted items; redundant items).[79, 100] However, items with infit and outfit MnSq values 0.5 to 1.50 provide useful information.[91] As long as the values are less than 2.0, the items do not damage the measures/scale.[93, 99]

Expected value for zstd fit statistics is close to 0. Positive values indicate more variation than model predicted variation. Negative values indicate less variation than model predicted variation. Acceptable values fall between +2 and -2, and are productive for measurement. Values more than infit zstd +2.0 are misfitting items (too erratic or haphazard to be useful; unpredictable; noisy), and less than infit zstd -2.0 are overfitting items (too good to be true; or too determined).[76, 79, 85]

Good fit statistics indicate that the more difficult items were less likely to be affirmed successfully, and the easier items were more likely to be affirmed successfully. For example, an easy item ‘How much difficulty do you have reading large prints?’ is expected to be answered ‘Not at all difficult’ by a person if he did not have any problem for reading fine prints (person with high person-ability). In contrary, misfitting or under-fitting items may indicate lack of consistency in interpretation of underlying measures.[91] For example, anomalous response of ‘no difficulty’ endorsed for relatively difficult items but ‘very difficult’ mentioned for relatively easier items is unexpected, and thus may lead to misfit.[74, 112] Misfitting items degrade quality of the measure. Misfitting items may be measuring some other constructs, or measuring multiple constructs. Use of double barrel items (e.g. item ‘Driving in glare conditions’ may be measuring a part of driving construct and a part of glare construct), use of poor item wording (causing cognitive errors) or items that apply only to some participants but not all, guessing, inattentiveness, carelessness, cheating, and ordering of items may cause poor fit due to random/erratic responses to an item.[74, 76, 85]

When item misfits is observed, it is important to investigate the nature of misfit and the context of measurement. Sometimes, just deleting unexpected responses (using PWeight command in Winsteps[113]), or removing correct responses of less able guessers or incorrect responses of highly able inattentive persons may reveal the reason for misfit.[114] At other times, deleting the items or temporarily deleting misfitting persons may improve the measure.[85, 100, 115] Fit statistics should guide the detection of a problem rather than guiding just to delete items.[76, 114]

Overfitting (muted) may be because of redundant (e.g. items similar in meaning) items or may indicate local dependence (heavily interrelated items).[76, 91] Overfitting items (infit MnSq < 0.7) do not degrade the measure, but may clearly point out misfitting (erratic) items. For example, deleting overfitting items may make the under-fitting item fit to the model, but this is not the correct approach to address item-misfits. Our aim is not to prove the data fits the model, but to address why some items are under-fitting (erratic). Overfitting items may cause misleading conclusions that the quality of the measure is better than it really is.[76] It may cause low standard errors and inflated separation indices.[76] Therefore, caution should be taken when making inferences.

It is important to recognise the influence of sample size on fit statistics. Zstd values depend upon sample size: even a small amount of misfit becomes significant (zstd > 2.0; $p < 0.05$) when the sample size is very large. Whereas, MnSq values are closer to 1 when sample size is very large**.**[76]

For this item-bank study, unnecessary deleting of misfitting items was avoided when possible by studying the nature of misfits. While constructing item banks, as many items as possible should be retained, unlike while constructing short-forms. I adopted more lenient criteria for item misfits: infit and outfit MnSq between 0.50 and 1.50 were considered satisfactory.[57, 116] First I tried to fix misfitting items by person-weighting. Participants with z residuals ≥ |4| were weighted zero when required, so that those respondents did not influence other participants' fit statistics. Person-weighting does not alter the dimensionality statistics. If this weighting did not improve fit statistics, other reasons for misfits (e.g. poor item wording, poor discrimination, i.e. item discrimination too less than Rasch assumed item discrimination of 1.0, low clinical relevance, narrow applicability, i.e. applicable only to a particular refractive error sub-group) were investigated, and the item was deleted if required.

2.3.1.4 Targeting

Targeting of a PRO instrument is determined by how well the item-difficulty matches the person-ability in the study sample. A well-targeted PRO instrument has a good balance of easy and difficult items. Poor targeting (no match between item difficulty and person-ability) results in large

standard errors. Thus, to produce maximum information (i.e. for precise measurement) while constructing a measure, item-difficulty has to be matched with the person-ability. Targeting can be studied by carefully observing person-item map (Figure 2.3) and/or by calculating the mean differences between mean item location and mean person location.

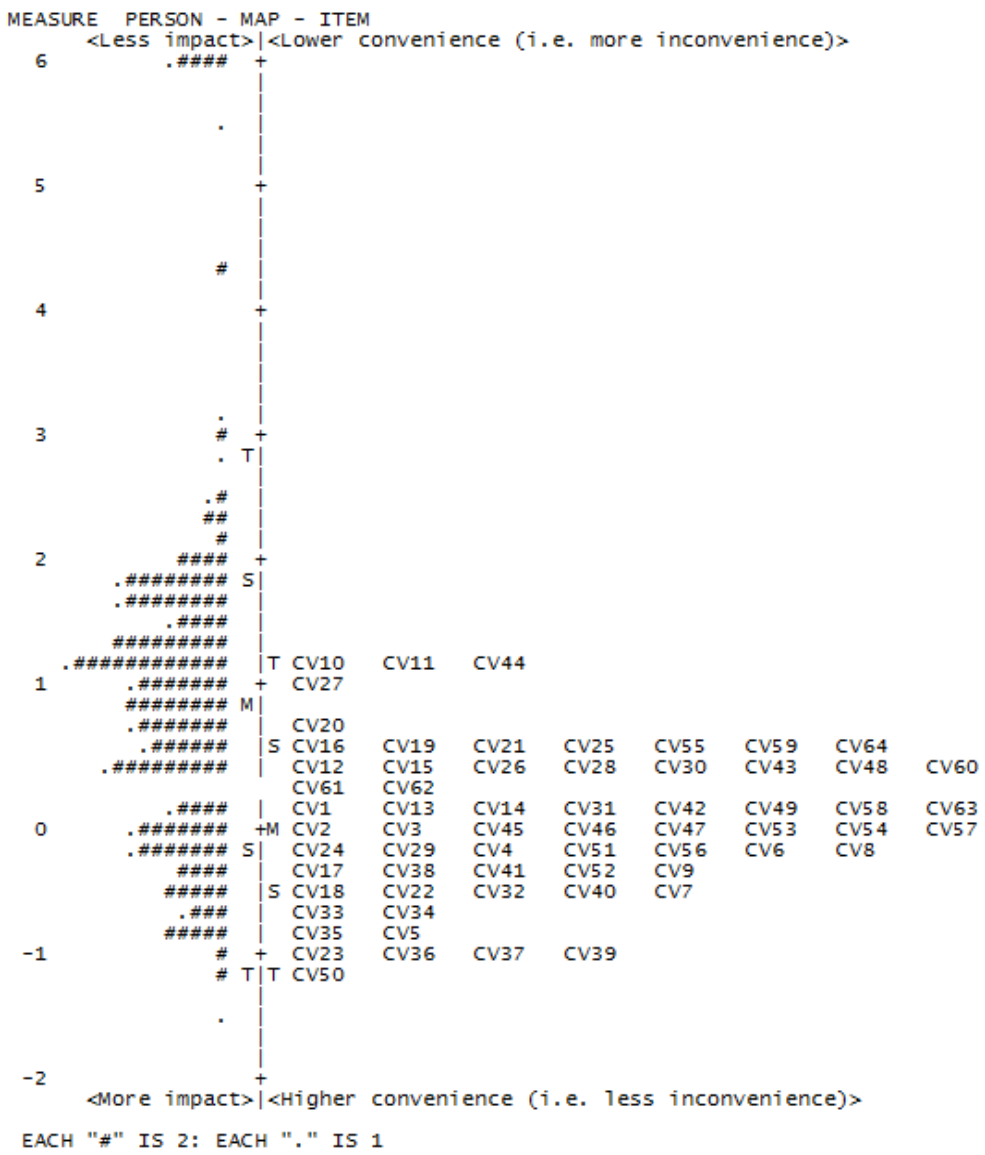

Figure 2.3 Person-item map for the refractive error-specific Convenience item-bank
Note: M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Person and item measures are the numerical representation of the performance of respondents and items on a measurement continuum.[112] In Rasch analysis research, 'person-ability' and 'item-difficulty' are the commonly used terms to denote person and item measures in the common measurement scale. While this is easily understood by the semantics in educational tests, it may be more difficult to conceptualize in QoL domains (Table 1.1). In the person-item maps, more

difficult items are better targeted to the persons with high ability (Figure 2.3).

Table 2.2 Definition of high person-ability and item-difficulty for quality-of-life domains

Quality-of-life domain	**High person-ability (high person measures)** i.e. persons with less impact from refractive error or its correction	**High item-difficulty (High item measures)** i.e. more difficult items for refractive error population
Convenience	Person with higher convenience (i.e. person with less inconvenience) due to refractive error or its correction	Item for less convenience (i.e. more inconvenience) due to refractive error
Health concerns	Person with less health concerns due to refractive error or its correction	Item for higher health concern due to refractive error or its correction
Economic	Person with less economic impact due to refractive error or its correction	Item for higher economic concern due to refractive error or its correction
Activity limitation	Person with higher ability due to refractive error or its correction	Item for higher difficulty due to refractive error or its correction
Mobility	Person with less mobility problems due to refractive error or its correction	Item for higher difficulty in mobility due to refractive error or its correction
Emotional	Person with less emotional impact due to refractive error or its correction	Item for higher emotional problem due to refractive error or its correction
Social	Person with less social impact due to refractive error or its correction	Item for higher social problem due to refractive error or its correction
Symptoms	Person with less symptoms due to refractive error or its correction	Item for higher symptom frequency, severity or bothersome due to refractive error or its correction

Targeting can be observed by examining Rasch-person-item map (Wright map) (Figure 2.3). The person-item map (Wright map) also tells us about the spread of the items, and gaps in the coverage. In the person-item maps, persons are located in the left. They are placed with their abilities in the latent traits from low (at the bottom) to high (at the top). Similarly, items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). If an item and person lie at the same level of the scale, there is a 50% probability for that person to endorse either of the response categories of a dichotomous item. For a polytomous item, there is a 50% probability for that person to endorse either higher or lower categories. Thus, person-item map enables us to visually inspect targeting and item-hierarchy. Mis-targeting occurs when items difficulty levels mismatch with the person-ability to endorse items. Mis-targeting can also occur if the spread of items is not similar to the person-ability levels or due to large gaps between the items which can be observed in the person-item map.[104]

Item mean is always placed at 0 logit value arbitrarily by default (analogy: 0 degree Celsius is arbitrarily assigned to the temperature of water's freezing point). Items with negative logit values are easier and the items with positive logit values are more difficult.[85] If an item has a trait level (difficulty) of 1.0 unit, and the person has a trait level (ability) of 1.0 unit, there is 50% of chance that person will get the item right (or endorse the item). By knowing the location of a person in the

person-item map, whether an item (or a QoL issue) might be problematic to him/her can be predicted.[112] Difference between mean person location and mean item location (0 logits) gives the mis-targeting value. Difference of more than 1.0 unit in person mean and item mean is notable mis-targeting.[26, 57]

2.3.1.5 Measurement precision and reliability

Errors in estimating Rasch parameters (person-ability and item-difficulty) determine the measurement precision.[85] Low errors lead to precise measurement. More targeted items produce more precise person measures and more targeted persons produce more precise item measures.[97] Uniform distribution is therefore desirable.

Person and item reliability indices indicate replicability of the persons and items placements respectively along the trait continuum.[100] Person reliability index indicates how consistently we would get similar person-ability estimates/personal ordering if we give parallel set of items (with same number and distribution of items) measuring the same construct.[85] For a productive measurement, person reliability > 0.80 (person separation index > 2.0) is necessary. Person reliability index is affected by errors in estimates (note: number of targeted items affect errors in estimates).[85] Similarly, item reliability index represents the replicability of item hierarchy if same items were endorsed by different group of persons with similar ability distribution. Item reliability is less if there are less number of persons at the level of some items' difficulty levels. For example, in the person-item map, if there are no persons at the levels of some items, item locations at that place cannot be reliable.[85] Ideally, item separation index (ISI) should be greater than 3.0 (reliability > 0.90).[105, 113, 117] This indicates that the person distribution is sufficient to generate reliable item hierarchy, and the items have a wide range of difficulties.[93, 113]

In this item-bank study, extreme responses were dropped when the PSI of the original scale was below acceptable range (i.e. PSI less than 2.0 or person reliability < 0.8). If the precision does not improve to the acceptable level even after removing the extreme responses, sample size may have to be increased with more appropriate data in order to improve measurement precision for item estimates. For example, if there is a ceiling effect in the data (current participants find the items too easy), more data has to be collected with population who finds the item difficult. Similarly, in order to improve person estimates, more items may have to be added in a particular section of the scale, matching person abilities at those levels.[85]

2.3.1.6 Local Item Dependency

The IRT models (e.g. Rasch analysis) assume that items are independent of each other. Response to one item should not influence response to another. This is important to get accurate parameter

estimations and to achieve unidimensionality.

If items are highly correlated to each other, it suggests redundancy. If the items have too low correlation between each other, they may be measuring different traits. There should be no or very weak correlation between items after underlying trait are accounted for. Local item dependency (LID) is suggested when correlation among the residuals is significant (≥ 0.30). LID can inflate estimates, therefore one item in a pair may have to be deleted, particularly for creating short-forms. In this item-bank study, correlation between item-residuals ≥ 0.30 were considered significant, and one of the items of each pair was temporarily deleted during calibration for obtaining the person measures.[57] These LID-free person measures were anchored and the Rasch analysis was re-run in the overall measures.

2.3.1.7 Measurement invariance and Differential item functioning

Fundamental properties of an instrument should be retained when measuring a construct of interest at various situations. This is called measurement invariance. This can be explained using an analogy of temperature measurement. Temperature is measured indirectly by measuring its effect on expansion of mercury/alcohol. However, expansion of the liquid also depends upon pressure. Therefore, if pressure is not adjusted for, boiling point of water at Mount Everest and at the sea level will be different (not 100 degree Celsius), and therefore measurement invariance is not achieved. Therefore, mercury is kept on a sealed tube where effect of pressure will be controlled. This analogy further emphasizes the importance of unidimensionality in measurement invariance.

Ideally, same measurement model should apply to all the respondents. The differential item functioning (DIF), also known as item bias, evaluates whether invariance in item-difficulty estimates exist between sub-groups of the sample while keeping the person measures equivalent. The DIF is a difference between sample estimates and population estimates because of some parameter other than the parameter of interest (e.g. gender).[79] The DIF occurs when two groups of participants with same latent traits or disability respond differently to an item.[102] For example males may underreport their actual anxiety levels compared to females.[118] Similarly, appearance with spectacles may be a greater concern (harder item) to female participants than to the male participants. Similarly, population sub-groups (e.g. age groups) may respond differently to some items. If the DIF exists, it may damage measures. Similar to the temperature measurement analogy, DIF may be addressed by anchoring. Items with a significant DIF value may require separate calibrations for different refractive error sub-groups. In this item-bank study, DIF will be addressed during CAT algorithm development in the next phase (post-PhD).

Item and person invariance are violated when DIF exists. Alternatively, when item and person estimates vary by more than the standard error, DIF exists. While DIF is directly related with measurement invariance, it should be noted that the instrument should have fundamental measurement properties such as unidimensionality, good fit statistics, local item independence, good targeting, and well-functioning response categories for measurement invariance. Appropriate targeting of items and persons reduce errors in estimating item-difficulty and person-ability. Error estimates and reliability indices (person and item) determine invariance (stability and replicability).[85] DIF is affected by sample size.

In this item-bank study, statistically significant ($p < 0.05$) DIF with a difference (DIF contrast) more than one was considered notable.[57] Rasch-Welch t test method, based on logistic regression, was used to determine the significance of the DIF contrast.

2.3.2 Validity and reliability

In addition to psychometric properties (Rasch parameters), validity, reliability and responsiveness of the PRO instruments should be considered (Table 2.3). Validity of a PRO instruments informs how well a PRO instrument measures a latent trait it aims to measure.[26, 37, 67] Similarly, reliability is the consistency in measuring the trait.[37] Responsiveness of a PRO instrument is the ability of an instrument to detect PRO changes over time. Whereas, sensitivity of a PRO instruments informs if the PRO instrument can detect differences between respondent groups (cross-sectional). Other important considerations in PRO development are respondent burden and mode of administration.

Table 2.3 Validity and reliability of patient-reported outcome instruments

	Performance of instrument (Validity and Reliability)
Construct validity	It is the extent to which the instrument measures what it purports to measure. It can be assessed using techniques such as principal component analysis along with inferential arguments.[67]
Content validity	It is the measure of how comprehensive and relevant the instrument is to the intended population. It indicates the appropriateness of the choice of items to measure a particular construct. It can be evaluated using techniques such as internal consistency along with inferential arguments.[67]
Convergent validity	The measure should correlate with another related measure (believed to be valid by the researcher) measuring a similar construct. For example, scores for Visual symptoms item bank should correlate with the Quality of Vision questionnaire[33] scores.
Discriminant validity	The measure should not correlate with another measure measuring a different construct. For example, scores for 'Social' item bank should not correlate with scores for 'Economic' item bank.
Concurrent validity	The measure should correlate with an appropriate clinical measure (e.g. correlation between visual acuity and activity limitation in uncorrected refractive error) to demonstrate concurrent validity.[18]

Known-group validity	It is the extent to which the measure can differentiate between two meaningful clinically different groups. For example, 'Convenience' item bank should be able to differentiate people who are wearing spectacles and people who underwent refractive surgery.
Predictive validity	It is the extent to which the measure can predict an event or performance in the future. For example, people with high inconvenience (low 'Convenience' item bank score) prior to refractive surgery may be more satisfied with refractive surgery outcomes.
Internal consistency coefficient	It is a measure of reliability or measurement variability. A commonly used measure of internal consistency is Cronbach's α. A value between 0.70 and 0.90 is considered desirable. If the Cronbach's α is more than 0.90, it implies redundancy.[67]
Test-retest agreement	It is a measure of reliability or measurement variability. It is the extent to which the results are repeatable when measured in the same participants at two time-points. The desired Intra-class correlation (ICC) is > 0.8.[18]
Inter-observer agreement	It is an analytic method of assessing reliability or measurement variability. It is the extent to which the results are repeatable when taken by the different observers. The desired weighted kappa is > 0.8.[26]
Inter-mode agreement	It is a measure of reliability or measurement variability. The extent to which the results are repeatable when taken by different modes of administration. Desired inter-mode correlation is > 0.7.[26]
Responsiveness	The extent to which an instrument can detect clinically important changes over time.[37]

In summary, CTT and Rasch analysis are the two commonly-used psychometric methods to develop PRO instruments or to assess the psychometric properties of the existing PRO instruments. In the next chapter (Chapter 3), the existing PRO instruments in refractive error are evaluated based on their performance on both CTT and Rasch analysis-based criteria. Rasch analysis used in this item-bank study is one of the modern psychometric methods based on a sound measurement philosophy. Its use to construct item banks is described in details in Chapter 6.

Chapter 3. Literature review

This chapter describes the literature review on the available evidence on refractive error-specific QoL. It consists of three major parts. The first part (Section 3.1) is on overview of refractive error and PROs. First the epidemiology and correction methods of refractive error are described. Then the types, modes of administration, importance, and challenges of implementing PRO instruments are discussed, with a focus on PROs in refractive error. The second part (Section 3.2) consists of systematic review of PRO instruments in refractive error and the available evidence on outcomes of refractive error or correction based on the use of the PRO instruments. This part consists of moderately changed text from the two published systematic reviews laid out in the IMRAD (Introduction, methods, results and discussion) structure.[15, 16] The aim of the systematic review was to assess the content, psychometric properties, validity, reliability, and responsiveness of the PRO instruments used in refractive error. The final section (Section 3.3) briefly situates this doctoral study into the literature review context.

3.1 Patient-reported outcomes in refractive error

In this section, the epidemiology of refractive error and refractive correction methods are briefly described. Then the types, mode of administration, importance and challenges in implementing PRO instruments are discussed with a focus on refractive error.

3.1.1 Epidemiology of refractive error

As discussed in Chapter 1, URE is the most common cause of visual impairment globally.[4-6] In addition, almost everyone over mid-forties has presbyopia. With an increase in the ageing population, the prevalence of presbyopia is ever-increasing.[7] Bourne *et al.* estimated that 1,095 million people had functional presbyopia in 2015.[7] Recently, Fricke *et al.* used a slightly different modelling approach and estimated that 1.8 billion people worldwide had presbyopia in 2015; about 45% of them had near visual impairment.[119] Similarly, there is an epidemic of myopia. Recently, it was estimated that 22.9% of the world population (n = 1,406 million) had myopia in 2000. It was estimated that the prevalence of myopia will increase to 49.8% (n = 4,758 million) by 2050.[120] The burden of refractive error is greatest in low-income countries and in disadvantaged groups of high-income countries.[8, 121, 122] The burden is higher in females, older people and people with lower socio-economic status.[9, 123] Refractive error and presbyopia is a public health problem with a huge societal cost implication.[124-126]

Possible roles of genetic and environmental factors in the cause of refractive error is widely studied, yet not clear.[120, 127] Familial clustering indicates the role of genetics on myopia, but the

temporal trends on rapid increase of myopia prevalence cannot be explained by genetics.[127] The role of several environmental factors such as lifestyle changes in children (e.g. decreased outdoor time, increased near work, use of electronic devices) may explain the temporal trends.[127] With urbanization and modernization, these changes continue to grow, resulting in an increase in the prevalence of refractive error. Several efforts have been made globally to reduce or prevent myopia. This includes optical or pharmacological interventions, orthokeratology, or vision therapy. The success of these interventions in reducing the prevalence of refractive error is yet to be observed.[128]

The epidemiology of hyperopia and astigmatism is less widely studied than that of myopia. Katz *et al.* reported that the prevalence of hyperopia and astigmatism increased with age in contrast to the prevalence of myopia that decreased with age.[129] The prevalence of hyperopia decreased with increase in number of years of education, which is opposite to that of myopia.[129] They reported that black men were less likely to be hyperopic than black women, or white men or women.[129] Similar to myopia, familial aggregation of hyperopia has been reported, indicating a role of genetics in the aetiology of hyperopia.[130] Therefore, ethnic differences and family history should be considered for both myopia and hyperopia.

Refractive error, although not described as an ocular disease, is not an isolated entity. Developmentally significant refractive error (0-6 years) may affect emmetropization, and lead to amblyopia or strabismus if not corrected early.[131] Strabismus and amblyopia may in turn have further life-time QoL implications.[132] Similarly, high myopia may lead to potentially blinding complications such as retinal detachment, macular degeneration, glaucoma and cataract.[120, 127] Likewise, hyperopia is an important risk factor for accommodative esotropia and angle-closure glaucoma.[130] Refractive error is also associated with many systemic conditions such as Down syndrome and Marfan's syndrome.[133, 134]

3.1.1.1 Definition and classification of refractive error

The definition and classification of refractive error is not uniform in the literature. The World Health Organization and the Global burden of disease study define refractive error based on the presenting visual acuity of less than 6/18 that can be improved by refractive correction.[5, 6, 135] This definition is meaningful for setting global goals to reduce refractive blindness and visual impairment. However, refractive error services should be aiming for achieving the best QoL results rather than merely improving vision at low thresholds. A person with visual acuity of 6/12, classified as normal in the above definitions, may function far better after refractive correction. Therefore, more holistically, if someone needs refractive correction, it should be defined as refractive error.

Refractive error differs according to types, and is usually distance dependent. A person with presbyopia may have a problem with near vision, but no problem with distance vision. On the other hand, a person with myopia may have problems with distance vision, but no problem with near vision. In this study, refractive error includes myopia, hyperopia, astigmatism and presbyopia. Refractive error and presbyopia are in fact different entities with different physiologies. However, they are often discussed together under 'Disorders of refraction and accommodation (ICD-10 code: H52)'.[10] Both refractive error and presbyopia are identified by objective and/or subjective refraction, and both can easily be corrected in a similar way i.e. with the use of spectacles, contact lenses or refractive surgery.

Refractive error is determined by standard objective and subjective refraction techniques. Objective refraction is performed using a retinoscope, an autorefractor or a wavefront analyser. Subjective refraction is performed with client's feedback using a trial frame or a phoropter.[128, 136] Distance refractive error is determined when accommodation is relaxed. If an individual is presbyopic, the near-addition power required is determined for the reading or working distance at near preferred by the client.[128] Typically, the goal of a clinical refraction is to achieve clarity with due considerations to preference, adaptation and comfort of the client.[136]

The spherical equivalent refractive error is often (and in this study) used to classify participants under myopia or hyperopia. It is calculated by adding spherical refraction to half of the cylinder.[127] Although refractive error of magnitude ±0.50 dioptre (D) is generally (and in this study) considered significant, the level of significance or need for refractive correction may vary with individuals. At times, myopia as little as -0.25D may require correction. At other times, relatively higher refractive error may not be problematic. If asymptomatic, low refractive error is often not corrected. Generally, moderate and severe refractive error may require correction for good vision. The aim of refractive correction should be improving visual function and QoL,[128] although achieving perfect vision is often the aim of clinicians.

Given this context, an inclusive definition to define and classify refractive error was used in this study. Refractive error was defined as myopia if the spherical equivalent refractive error was less than -0.5 D (Low: ≥ -3.0 D; Moderate: -3.25 to -6.0 D; High: < -6.0 D), and hyperopia if the spherical equivalent refractive error was higher than +0.5 D (Low: ≤+2.0 D, Moderate: +2.25 to +5.0 D High: > +5.0 D).[14, 63, 129, 137] If the prescription had cylinder component (> 0.5D), it was defined as a presence of astigmatism.[129] Refractive error also included presbyopia. If the prescription had near addition power, it was defined as presbyopia. If the participants were under-corrected by |0.50| D or more, they were included in the URE group. The eye with lesser absolute refractive error magnitude was considered for classification as this may better correspond to the

binocular visual status of an individual than the eye with higher magnitude of refractive error.

In this study, the participants' habitual (real-life) status of wearing spectacles or contact lenses was considered to classify as corrected or uncorrected refractive error. A person with refractive error may be mostly corrected with spectacles but be uncorrected for doing some tasks like swimming and taking a shower. Refractive error is thus different from other ocular conditions such as cataract where there is a permanent blur. Similarly, some participants in this study were classified under URE based on their habitual status, but they had used spectacles in the past.

3.1.2 Patient-reported outcomes

The Food and Drug Administration (FDA) defines PRO as any report of patient's health status that comes directly from the patient, without interpretation by the clinician or the researcher.[25, 138] PRO data are systematically collected using PRO instruments, such as questionnaire or item bank. PRO instrument is the medium to measure QoL parameters. Improving people's QoL is one of the most important outcomes of health care.[139]

QoL is a complex multidimensional construct. Measurement of QoL is not straightforward as it is dynamic and varies by several factors. There is no clear understanding in what are the factors that may contribute to the QoL. Depending upon the time, standards of measurement or measurement conditions, and meaning of the concepts, change in subjective valuation of the QoL constructs (response shift) may occur. QoL dimensions include health, education, economy, living conditions or environment, and physical safety/security.[140] The Eye-tem bank project had previously identified 10 ophthalmic QoL domains to measure the impact of ophthalmic conditions on QoL: Activity limitation, Mobility, Visual symptoms, Ocular-comfort symptoms, General symptoms, Convenience, Health concerns, Social, Emotional, and Economic, from patients' perspectives.[29, 30] Building on this evidence, this doctoral study describes the development of content (items and domains) to measure QoL parameters in refractive error.

In the literature, several other types of patient reports are included in PRO instruments that intend to measure refractive error outcomes. Not necessarily, all patient reports are about the status of patient's health or about their QoL. Table 3.1 shows some examples of misclassified items in some existing PRO instruments. As shown in the table, some of the items of different questionnaires claiming to measure QoL do not tap into QoL constructs. Some PRO instruments claim to measure constructs such as needs or expectations that are not clearly measurable. Ideally, PRO instruments should have each item corresponding to a measurable construct. Reports other than PROs may provide only indirect information on PROs or QoL. For instance, the patient-reported experience measures (PREMs) are important for assessing quality of care (e.g. satisfaction or

dissatisfaction with waiting times, quality of communication with doctor, support) in patients' perspectives, rather than for measuring QoL. A person with progressing high myopia may have poor QoL but good experience (satisfaction) with health care. In this case, PREMs may not correlate to PRO measures. Whereas, a person with refractive surgery complications may not be happy with the services they received. In this case PREMs may correlate with PRO measures. Therefore, a distinction between different types of patient reports is crucial (Table 3.1).

Table 3.1 Types of patient reports in refractive error

Types of patient reports	Examples
Patient-reported outcomes	**QIRC**[28] **(Convenience) item:** "3. How much trouble is not being able to use off-the-shelf (non-prescription) sunglasses?" **QoV**[33] **(Visual symptoms – frequency) item:** "1. How often do you experience glare?" **CLIQ**[46] **(Health concerns) item: "**17. How concerned are you about medical complications from your contact lenses?" **NAVQ**[34] **(Difficulty) item:** "1. How much difficulty do you have reading small print, such as newspaper articles, items on a menu, telephone directories?" **PROWL**[55] **(Driving) item:** "35. Because of your vision, how much difficulty do you have driving during the daytime in familiar places?"
Patient-reported experience measures (PREMs)	**CLUE**[141] **item (Handling and packaging):** "It was easy to open a new packet of [contact] lenses." **CLUE**[141] **item (Comfort):** "I have experienced red eyes." **PROWL**[55] **item (Satisfaction with LASIK surgery): "**Would you recommend LASIK surgery to a friend or family member?" **FGVS**[53] **item:** "21. Willingness to recommend to others" **QVQ**[40] **item:** "25. Before the operation, my eyes were sensitive to light."
Utilities	**NEI-RQL**[35] **(Expectation) items:** "1. If you had perfect vision without glasses, contact lenses, or any type of vision correction, how different would your life be?" "28. If you had perfect vision without glasses, contacts, or any other type of vision correction, how much do you think your life would change?" **RSVP**[37] **(Expectation) item: "**23. Please respond to the questions as they apply to you over the past month: I could accept less than perfect vision if I didn't need glasses or contact lenses anymore."
No meaningful measurement of the underlying construct	**NEIRQL**[35] **(Dependence on correction) item:** "15. When driving at night, do you need to wear glasses or contacts?" [**Note**: this item by itself doesn't say anything about the impact on QoL, although this might be related to inconvenience due to having to rely on spectacles or contact lenses. Many people are perfectly happy and satisfied wearing spectacles or contact lenses, as long as they can see well. Wearing spectacles or contact lenses has become their habit, and they do not even realise they are wearing spectacles or contact lenses most of the times.] **PROWL**[55] **(Work productivity and activity impairment) item:** "34. If you gave up driving, was that mainly because of your vision, mainly for some other reason, or because of both your vision and other reasons?" **PRSIQ**[56] **item: "**4. During the last 7 days, how often did you wear glasses or contacts for distance vision (5 or more feet away)?" **Demographic or clinical information items, or items related to health behaviour:** Contact lens complications, e.g. microbial keratitis; frequency of spectacles wear; use of safety eye wear.

Note: CLIQ = Contact Lens Impact on Quality of Life questionnaire[46], CLUE = Contact Lens User Experience scales, FGVS = Freedom from Glasses Value Scale[53], LASIK = Laser Assisted In-Situ Keratomileusis, NAVQ = Near activity visual questionnaire[34], NEI-RQL = National Eye Institute Refractive Quality of Life

questionnaire[35], PROWL = Patient-Reported Outcomes With Laser In Situ Keratomileusis questionnaire[55], PRSIQ = Patient-reported Spectacle Independence Questionnaire [56], QIRC = Quality of life Impact of Refractive Correction questionnaire[28], QoV = Quality of Vision questionnaire[33], QVQ = Quality of Vision Questionnaire[40], and RSVP = Refractive Status and Vision Profile questionnaire[37]

3.1.2.1 Utilities in refractive error

Utility is an indirect measure of QoL derived from people's report on preferences of living in a particular health state over another.[142] In this section, the utilities are briefly described. However, utility studies are not the focus of this thesis as a utility is not a direct measure of QoL. The rating scale of the utility measure is assumed to be interval-level scale, anchored between 0 (death) and 1.0 (perfect health).[142] The utility values closer to 1.0 indicate better QoL.[143] The utility values can be derived from direct or indirect methods.

Direct methods of deriving utility values include Standard Gamble (SG), Time-Trade-Off (TTO), and Visual Analogue Scale (VAS). An example of the Standard Gamble method may be choosing between "Wearing spectacles for life time" or "Taking a risk of undergoing refractive surgery that may provide good outcomes or sight-threatening complications". The percentage of risk is varied until when the person cannot decide which option to choose. If the person is willing to take higher risk, he has lower utility (worse QoL). The TTO method explores the number of years of life a person is ready to trade-off if the URE is corrected. If the person is willing to trade-off higher number of years, his utility is less. VAS is a rating scale or a category scale with defined anchors (e.g. 0 to 1). Unlike in TTO and Standard Gamble methods, no preferences (choices or risk) are involved in the VAS method, and therefore usually not considered as utility measures.[142, 144]

Common indirect methods (that require two steps) for eliciting utility values are multi-attribute instruments such as the EuroQoL-5 dimension (EQ-5D) questionnaire and the Assessment of Quality of Life (AQoL) questionnaire. These instruments are similar to PRO instruments for measuring QoL, and generally have items related to QoL domains. Typically, they have Likert-scale response categories. The scores are aggregated an converted into utility value in 0-1 scale.[142, 144]

Important conclusions on QoL impact of refractive error have been derived based on the utility studies. Utilities are often employed in economic assessments. Tahhan *et al.* have reported that both distance and near visual impairment elicited similar reduction of QoL (in terms of utility) in uncorrected distance refractive error and uncorrected presbyopia. Having both distance URE and uncorrected presbyopia further decreased utility values.[142] The authors also reported a 40 times higher cost-effectiveness of correcting refractive error than correcting cataract, while cataract itself has one of the most cost-effective interventions worldwide.[142] The utilities thus are useful to compare impact of different health conditions.

3.1.3 Refractive error correction

The need and choice of refractive error correction are influenced by individual factors such as visual, occupational and recreational needs, and preferences. In general, spectacles are the simplest, commonest and safest type of refractive correction. Other than for refractive correction, spectacles are also used to manage orthoptic problems such as convergence insufficiency or intermittent exotropia, or for ocular protection.[128] At times, a particular type of refractive correction is indicated e.g. contact lenses may be recommended to people with symptomatic anisometropia or aniseikonia, or people with irregular cornea.[128] At other times, a particular refractive correction is not recommended, e.g. contact lens wear is not recommended in presence of keratoconjunctivitis or other corneal abnormalities, dusty environment setting, or poor hygiene, to avoid potential sight-threatening complications such as microbial keratitis.[128] Not only for correcting refractive error, contact lenses may be used for therapeutic purpose in treatment of ocular surface problems.[128]

Use of contact lenses or refractive surgery for correcting refractive error is growing in low-, middle-, and high-income settings.[63, 128, 145-149] However, there are only a few reports on the number of people wearing contact lenses or number of refractive surgeries performed globally. In the mid-2000s, it was estimated that more than 140 million people world-wide used contact lenses, and the number continues to grow.[128, 150, 151] Over 36 million people in the USA used contact lenses in 2005.[128] Similar to contact lenses, refractive surgery is now a common method of refractive correction, particularly in middle- and high-income settings. The popularity of refractive surgery is growing in low-income settings as well.[145]

In 2001, refractive surgery was reported to be the second most common surgical procedure after cataract surgery in Singapore.[152] Similarly, in China, about 950,000 laser refractive surgeries were conducted in 2012. It has been estimated that 2.89 million eyes will undergo refractive surgery in China by 2023.[148] Over 8.5 million people in the USA had undergone refractive surgery between 1995 and 2010.[128] In Iran, the rate of excimer laser refractive surgery per million population increased form 2,764 in 2010 to 3,582 in 2014.[148] These data show that refractive surgery is growing as a popular method of refractive error correction globally.

Although popularity of refractive surgery is generally increasing, trends have seen ups and downs in the popularity.[149] The surgery rate would perhaps be much higher if there were no complications. The impact of complications on QoL can be studied using a responsive PRO instrument which is sensitive to complications.

Spectacles are the most common method of refractive correction. A simple pair of spectacles may correct refractive error and avoid huge productivity loss.[124, 126] However, cost, along with distance

to services, lack of information or awareness, poor quality of care, limited qualified human resources, gender-bias, older age and socio-cultural issues may be barriers to refractive correction.[3, 13, 136, 153, 154] In a study by Thompson *et al*., cost was identified as a barrier for both economically advantaged and disadvantaged groups in Mozambique.[13] Low utilization of ready-made spectacles in low- and middle-income countries is reported although they may be available at a low cost.[155] Similarly, Thompson *et al.* reported that the elderly patients were more likely to report distance as a barrier.[13] They also reported that the participants from the rural areas were more likely to be unaware of the problem.[13] In addition to these barriers, limitations from refractive correction such as inconveniences rendered from wearing spectacles or contact lenses may result into low compliance.[14, 63] These latent constructs can be measured using PRO instruments.

3.1.4 Types of PRO instruments

The PRO instruments may be classified based on various factors such as mode of administration (paper-based vs electronic), development theory (CTT vs IRT-based PRO instruments), applicability and content (generic vs targeted (domain, condition or intervention specific, or a mix of these sub-types)), flexibility (static e.g. questionnaires vs dynamic e.g. item bank administered by a CAT system). The common broad classification of PRO instruments done based on construct and intended population is: ‘Generic’ vs ‘Disease or condition-specific’ (Table 3.2).

The generic PRO instruments have broad content area to measure health related QoL.[37] They can be used with both healthy and disease populations, and enable comparison between them.[156] They also enable comparisons between various disease groups. They are commonly used for effectiveness analysis for appropriate resource allocation across diseases.[156] However, generic measures may not be sensitive enough to capture condition-specific issues and therefore may fail to measure disease-specific impact.[16, 25, 37, 156] They may also be culturally insensitive. In this thesis, all non-disease-specific PRO instruments are referred to as generic PRO instruments for simplicity. Therefore, generic PRO instruments also include domain or dimension-specific (e.g. pain, fatigue, physical function) PRO instrument if that PRO instrument is not intended for a particular disease.

The disease-specific PRO instruments include issues and concerns related to a particular disease. The importance of disease-specific PRO instruments can be explained with the analogy of history taking. During history taking, specific questions are asked related to a condition to move towards a diagnosis. Disease-specific issues are more important than other issues. In a similar way, condition or disease-specific PRO instruments are more comprehensive and sensitive to measure disease impacts at an individual level.[157] For example, ophthalmic PRO instruments such as the Impact of

Vision Impairment (IVI) may be more sensitive to ophthalmic conditions than generic PRO instruments.[158] Further distinctions within ophthalmic PRO instruments may be made. Refractive error-specific PRO instruments such as the Quality of Life Impact of Refractive Correction (QIRC)[28] may be more sensitive, relevant and more acceptable to measure the refractive error-specific issues than the IVI. Furthermore, the Contact Lens Impact of Quality of Life (CLIQ)[46] may be more sensitive to contact lens wear related issues than the QIRC. However, the CLIQ is applicable to a narrow spectrum of refractive error, i.e. only to the contact lens wearers. It does not enable comparison between QoL impacts of different types of refractive correction. Trade-off between 'Splitting' vs 'Lumping' conditions or diseases together is a challenge in a PRO development, which should be guided by the research purpose.

Whether to use generic or disease-specific PRO instrument depends upon research purpose, study population and/or concept being measured, and the psychometric quality and validity of the available PRO instruments. For example, in order to compare pain during Laser Assisted In-Situ Keratomileusis (LASIK) surgery and pain during tonsillectomy, Patient-reported outcome measurement system (PROMIS) Pain questionnaire may be the right choice.[159] Generic PRO instruments may be more appropriate to enable cross-conditions comparisons. Whereas, disease-specific PRO instruments are more sensitive to measure the impact of a disease or treatment in question. Depending upon the research questions, both generic and disease-specific PRO instrument may have to be used in combination.[37]

Similarly, selection of a particular domain or dimension-specific PRO instrument should be guided by research purpose, study population and/or concept being measured, and the psychometric quality and validity of the available PRO instruments. While improving QoL is the overall aim of any interventions, measuring some domains may be more important in some conditions. For example, measuring convenience may be important in refractive correction, whereas, measuring visual symptoms and activity limitation may be more important in URE.[63]

Table 3.2 Types of patient-reported outcomes in refractive error

Types	Sub-types	Examples
Generic	HR-QoL	Short-Form (SF-36) Questionnaire[160]
	Domain-specific	**Anxiety and depression:** Hospital Anxiety and Depression Scale (HADS)[161]
	Intervention-specific	**Assistive devices (e.g. contact lenses, spectacles):** Paediatric Impact of Assistive Devices Scale (PIADS)[162]
Ophthalmic (non-refractive error-specific)	Ophthalmic-QoL	National Eye Institute Visual Function Questionnaire (NEI-VFQ)[163]
	Domain-specific	**Symptoms (dry eye):** Ocular Surface Disease Index (OSDI) questionnaire[164] **Activity limitation:** Visual Function Index-14 (VF-14)[165]
	Utilities	Vision Quality of Life index (VISQoL)[166]

Refractive error-specific	Refractive error-specific QoL	Quality of life Impact of Refractive Correction (QIRC) questionnaire[28]; National Eye Institute Refractive Quality of Life (NEI-RQL) questionnaire[35]; Refractive Status and Vision Profile (RSVP) questionnaire[37]; Refractive Error Quality of life scale (REQ-Thai)[44]
	Intervention-specific	**Spectacles:** Spectacle Survey (SS)[48]; Student Refractive Error and Eyeglass Questionnaire (SREEQ)[49] **Contact lens:** Contact Lens Dry Eye Questionnaire (CLDEQ)[52]; Contact Lens Impact on Quality of Life (CLIQ) questionnaire[46] **Refractive surgery:** Patient-Reported Outcomes With Laser In Situ Keratomileusis (PROWL) questionnaire[55]; Prospective Evaluation of Radial Keratotomy (PERK) study questionnaire [41]; Quality of Vision Questionnaire (QVQ)[40]; Subjective Vision Questionnaire (SVQ)[42]; **Uncorrected refractive error:** Visual Function and Quality of Life (VFQoL) questionnaire[12]
	Domain-specific	**Activity limitations:** Near Activity Visual Questionnaire (NAVQ)[34]; Near Vision-related Quality of Life (NVQL) questionnaire[54] **Symptoms:** Contact Lens Dry Eye Questionnaire (CLDEQ)[52]

Note: HRQoL = Health related quality of life

3.1.5 Mode of administration of PRO instruments

PRO instruments may be self-administered or interviewer-administered (through face-to-face interviews or telephone interviews). They are administered either in paper or electronically. Paper-and pencil-based questionnaires are the most common types of PRO instruments. In other fields of health care, there is a movement of PRO measurement from paper-based PROs to electronic PROs (ePROs).[167] The influence has been new to ophthalmology, but has started with refractive error.[55, 168, 169] The electronic PRO instruments are administered either online (web-based survey or automated telephone survey[170]) or offline (using computer, iPad / tablets, mobile). They could be static (fixed number or order of items) or dynamic (e.g. a CAT system administers individually tailored items). For static PRO instruments, it has been reported that computer administered PRO instruments are equivalent to the paper-based PRO instruments.[171] However, electronic PRO instruments may offer several other advantages. Some of these advantages include easily accessible data and no requirement of data entry staff (if self-reported). PROs such as electronic patient diary may reduce recall bias.[25] Similarly, electronic PROs have an advantage that they can be easily added to the electronic health records.[167] This is one of the main reasons for growing popularity of electronic PROs as electronic health records are increasingly common even in the remote low-income country settings.[172] The internet-based electronic PRO measures have further advantage that patient may not have to come to hospital for the assessment. Even after assessment, interventions such as educational materials can be tailored online to the patients' PRO scores. Such PRO instrument could be used as a screening tool for early detection of complications, or for assessing symptoms and encouraging patients to seek for health services when required. The most advanced electronic PRO instruments are the item banks administered through internet-based CAT system.[30, 57, 59-61, 159, 173-177]

Figure 3.1 Symbolic diagram of refractive error-specific computer adaptive testing system

3.1.6 Importance of patient-reported outcomes

Patients are the centre, and priority of health care. All the stake-holders of health care (patients themselves, health care providers/clinicians, payers, regulatory bodies, policy makers) work to help patients. PROs are the outcomes that the patients value the most. PROs are extremely useful to ensure that everything we do benefits patients and address their concerns and needs.

Importance of PROs can be further explained with an example of importance of history taking in clinical practice. History taking is one of the main parts of clinical assessment. History taking may be considered as a primitive PRO assessment method, which is not usually systematic and comprehensive. Often history taking is focused to find out signs of disease, not giving any attention to the comprehensive impact of the disease on QoL. Symptoms are given more priority. Therefore, this example indicates the importance of PROs which may be much higher than the importance of history taking. PRO data are collected systematically using PRO instruments. PROs may have number of benefits or advantages. Below, a number of uses of PROs are discussed with a focus on refractive error correction outcomes. Most of the time, the listed advantages are inter-related, all aimed at providing holistic patient-centred care.

3.1.6.1 Communication between patients and clinicians

Participants experience latent traits (trait that is not directly observable) and researchers aim to measure that. PRO Instrument acts as a communication media between the participants (subjects) and the researchers or clinicians. PRO data can in fact be the conversation starters, and can give more voice to the patients in their health care.[178]

3.1.6.2 Respecting patient values and interests

Refractive correction outcomes that clinicians report are mainly based on objective assessments such as visual acuity or refractive error magnitude. However, functional assessment may be more crucial as patients visit optometrists to address their functional needs (e.g. myopia: 'objects at far look blurred'; presbyopia: 'unable to read small print'; people who want to have laser refractive surgery: 'inconvenience handling spectacles and contact lenses').[179] The evidence that exists based on clinical findings may not represent patient choices. For example, spectacle wearers opt for having laser refractive surgery despite the latter has known complications. Similarly, if X refractive surgery offers better visual outcomes than the Y surgery, but if X causes more symptoms such as dryness, the patient may prefer 'Y', especially if one does not have high visual demands. Improvement in clinical outcomes (e.g. reducing myopia progression) may not be a direct goal of spectacle wearers. Whereas, limitations in functionality such as not being able to swim may be more devastating to them. Therefore, PROs are the outcomes that are most valued by the patients, and the PROs are essential for increasing the value of our health care.[179]

3.1.6.3 Reducing disparity between clinician and patient perspective

Among QoL domains, visual symptoms and activity limitation are overemphasized by the clinicians in clinical practice. However, concerns and inconveniences may be more influential in people with refractive correction.[14, 63] Even the symptoms are often not noticed or not documented well by clinicians.[180] PRO instruments may be instrumental in reducing this gap.

3.1.6.4 Patients can best assess themselves about the impact of a disease

The patient is the recipient of health care. The patient knows the most, therefore is the expert, about the impact of a disease or its treatment on their QoL. All other stake holders in health care may just be the proxy measures to determine the impact of a disease in a patient. For example, symptoms and physical impairments are commonly missed out by health care providers.[180] Symptoms assessment made by the clinicians may not be reliable.[181] In fact, it is reported that patients experience symptoms sooner and with higher severity before clinical findings are detected by the clinicians.[182] PRO instruments enable accurate assessment of symptoms. Regular documentation of symptoms using PRO instruments may assist in monitoring of symptoms.[183] Longitudinal monitoring of symptoms may be particularly important for refractive surgery and contact lens wearers for monitoring dry eye symptoms. PROs may therefore be of tremendous value for assessing present health status achieved and sustainability of the benefits achieved, and for ensuring sustained benefits of refractive error intervention outcomes. The impact of refractive error or its intervention on QoL can therefore be best assessed by the patients themselves with the help of PRO instruments.

3.1.6.5 Part of comprehensive outcome assessment

PROs provide additional information that cannot be obtained by standard clinical tests. PROs can explain the unexplained variance in the clinical visual function.[184] Based on standard clinical objective outcome measures, an intervention may have good outcomes. For example, Schein *et al.* reported excellent outcomes of refractive surgery based on visual acuity and magnitude of refractive error. However, the outcomes were worse in terms of symptoms and driving performance.[37] The PROs may therefore help to identify room for improvement. The PROs are patient-centred outcomes that should be part of comprehensive outcome assessments complementing clinical objective outcomes.[157]

Use of PROs as a part of comprehensive outcome assessment is recommended by the regulatory bodies such as the Food and Drug Administration (FDA).[25] A robust PRO instrument enables accurate measurement of the impact of a disease on people's QoL. PROs inform us whether health care intervention is able to address symptoms, activity limitation or comprehensive QoL impact of a disease. A person wearing thick spectacles may be traumatized psychologically despite having good visual acuity. Based on standard clinical objective outcome measures, two types of surgeries may have similar outcomes. PRO instruments may determine which method provides the greatest QoL benefits. With such crucial advantages, the PRO instruments are now increasingly used as a part of comprehensive outcome assessment tools.

3.1.6.6 Comparative effectiveness research

There is a growing recognition of the importance of PROs as outcome measures in clinical trials. PRO instruments are increasingly being used as primary or secondary end points of the clinical trials comparing effectiveness of interventions. In refractive error, PRO instruments help us answer research questions such as:

- Which laser refractive surgery (LASIK or Small incision lenticule extraction (SMILE) or a novel surgery method) causes less dryness?
- Which type of contact lens causes less adverse effects?
- Were new pair of spectacles effective/able to address symptoms of headache and ocular pain?

PRO data may assist to improve refractive surgery, contact lens or spectacles designs. For example, newer spectacles or contact lenses may be customized for special situations such as night driving or prolonged computer works based on the PRO data.

3.1.6.7 Raising missed out patient issues

During qualitative interviews, I found many people live with huge psycho-social impacts from

refractive error.[14, 63] Some of the participants were so devastated that they burst into tears during the interviews. Clinicians often do not address the psycho-social implications of having refractive error or correction. PRO instruments may bring these issues to clinician's attention. This is particularly an advantage in less-expressive people. Similarly, reports discuss that the patients share sensitive issues through self-administered PRO instruments which would otherwise have been never discovered by the clinicians.[178] Appropriate referrals to needy patients (e.g. referral of patients with high emotional impact to mental health counselling service) may then follow. Self-reported PRO instruments may be the best medium to capture sensitive or other-wise missed out patient issues in systematic ways.

3.1.6.8 Shared clinical decision making

The use of PROs in clinical practice is an opportunity to involve patients in their own care. As discussed above, through PRO instruments, patients provide invaluable information about their condition they know the best. PRO data can assist clinicians in making appropriate decisions. For example, it is probably better to provide more educational materials to the patients with poorer PROs (more problems). PRO data may guide refractive surgeon to decide if LASIK or SMILE is likely to be a better intervention for the patient. PROs may also assist a clinician to recommend an appropriate type (good-value option) of refractive correction (cheap or expensive spectacles; spectacles, contact lenses or refractive surgery). In a setting where resources and time are limited, PRO data can guide clinicians to make better decisions. For example, people experiencing a lot of inconvenience related to spectacles wear may be advised for contact lenses or refractive surgery. In contrast, if a person does not have any problem with spectacles, laser refractive surgery may not be a good decision. A person seriously affected by the inconvenience of wearing spectacles or contact lenses may be a good candidate for refractive surgery. From a population level PRO data, clinicians can discuss existing evidence (e.g. evidence on PROs of refractive surgery) in discussing outcomes of interventions with their patients. Hence, use of PROs may enhance shared decision making by clinicians and patients.[178]

3.1.6.9 Improved quality of care

It has been reported that the use of PRO instruments in clinical practice has increased frequency of discussion of patient outcomes (e.g. symptoms) during clinical examinations/consultations.[183] Evidence from population level PRO data can provide crucial information such as which refractive service facility, refractive surgeon, or refractive intervention may yield better PROs. As a part of comprehensive outcome assessment, PRO data can help determine the cause of variation in patient care. For example, if the same refractive surgery techniques in similar settings and populations are giving two different types of PRO data in two centres, surgeon's techniques or

skills may need to be improved. Although PROs depend upon the underlying medical condition, a person with similar health status may be emotionally drained or coping well in life. Individual-level PRO data are therefore crucial in managing disease implications. While population level PRO data may be more useful for developing guidelines or policies, individual PRO data may be more crucial for effective comprehensive patient care.

3.1.6.10 Predicting post-intervention outcomes

PRO data can inform clinicians and patients on what to expect after an intervention. For example, PROs and clinical tests in combination may enable predicting which patients are more likely to develop dry eye.[185] This is particularly important in new contact lens wearers as apparently asymptomatic new contact lens wearers may develop dry eye symptoms after contact lens wear.[185] Similarly, pre-operative PRO data (e.g. psychosocial status) can predict post-surgical outcomes.[186] For example, Morse *et al.* found that the patients with depressive symptoms were less likely to be satisfied after refractive surgery.[187] In another study, Schein *et al.* reported that the patients with higher activity limitation and symptoms preoperatively were more likely to be less satisfied post-operatively.[188] Likewise, a study using the NEI-RQL found that hyperopes with presbyopia had larger improvements in QoL than their myopic counterparts after multifocal intra-ocular lens (IOL) implantation.[189] Using this evidence from the use of PRO data, a clinician may prioritize hyperopes to myopes for multifocal IOL implantation. PRO data can also inform patients about what to expect post-surgery, and therefore enhances patient satisfaction.[186] For example, large PRO data can inform about recovery process of laser refractive surgery, and when they can expect to carry out activities such as driving.

3.1.6.11 Surveillance or vigilance about potential adverse effects

PROs, especially self-administered electronic PROs, may be used to monitor if a novel refractive surgery or contact lens causes complications such as dry eye in the long run.[157] Electronic PROs can be designed in such a way that report of a particular symptom or complication can be flagged to draw attention of the clinicians. This can save clinician time and enhance clinical care. Thus, PROs may be useful to monitor refractive error correction outcomes.

3.1.6.12 Screening

PRO instruments can also be used to screen people for an intervention. For instance, people with low scores (more impact) on emotional domain may benefit from psychological counselling.[74] Gothwal *et al.* reported that the McMonnies questionnaire could be used to assess the risk for the dry eye syndrome.[190]

3.1.6.13 Work-shifting

PROs can be self-administered, or assisted by staff during waiting time or at home. Clinicians may get important information about patients without spending much of their valuable time. This may be particularly useful in a low-resource setting where a clinician can spend only a little time with each patient.

3.1.6.14 Informing policies and resource allocation

Information on QoL impact of refractive error from patients' perspectives provides evidence for government and policy makers for appropriate allocation of resources. This also ensures that the policies are made in the best interest of patients.

There are several other advantages of PRO application in various fields of medicine. This includes reports of increased survival in cancer, better symptom management and improved QoL, improved doctor-patient relationship, and increased clinical workflow efficiency.[178] However, PROs should not be used as a replacement to clinician-patient interaction, nor as a replacement of sound science and objective measurements.[157, 191] In summary, goal should be to enhance the advantages of PROs. The PROs have potential of making both patients and clinicians happier.[178]

PRO instruments have increasing demand in health care. They are important elements of patient centred care. The value in using PRO instruments in research and clinical practice has been increasingly acknowledged in recent years. However, the PROs are not routinely collected or measured in refractive error. There are several challenges in application of PRO instruments.

3.1.7 Challenges and barriers in PRO instruments implementation

Measurement of PROs involves measuring latent traits (e.g. QoL domains) which is not straight forward like measuring length, weight or density. Not only the measurement involves complex science, logistical issues may be the reasons why the PRO data are not collected routinely in refractive error care. Some of the challenges and barriers include:

3.1.7.1 Respondent and clinician burden

Patient and clinician burden is one of the major challenges in the application of PRO instruments, especially when the PRO instruments have too many items.[16] Time and efforts for the patient to complete the PRO instrument (e.g. questionnaire), and for the clinician to administer the PRO instrument may be very high. It may cause a high opportunity cost, especially to the clinicians in resource constrained settings. In some situations where a single clinician has to look after a high number of patients, PRO data collection is not often a priority. To reduce respondent and clinician burden, paper-based questionnaires can only accommodate a few items, and researchers often

aim to have as fewer items as possible. This may limit wider applicability of the PRO instruments. There is a high trade-off between reducing the length of an instrument (to decrease clinician and respondent burden) and applicability to wider contexts or settings. Implementing PRO instruments without increasing burden for patients and clinicians is important.

3.1.7.2 Comparison between studies not possible

Although a large number of studies have used PRO instruments in refractive error as outcome measures, the studies are not easily comparable. Each PRO instrument aims to quantify QoL constructs. However, findings are not comparable due to the heterogeneity in the studies. The quality of PRO instruments varies widely. Even the terminology or definitions used are not consistent. The differences in the sample demographics further increases difficulty in comparison. Therefore, meta-analysis on the effect of refractive correction on QoL is challenging.

3.1.7.3 Abundance of poorly designed PRO instruments

Another challenge in PRO application is the availability of poor-quality PRO instruments. Many of them were developed without proper patient consultation. There is a paucity of qualitative studies and most of the PRO instruments are clinician driven. Patient consultation is important to ensure the measures reflect patients' issues.[15, 16] Many of the existing PRO instruments in refractive error were developed by using traditional CTT method which is based on erroneous assumptions such as considering Likert scale generated categorical data as an interval level data, and therefore has many limitations.[15, 16, 77] The limitations were discussed in Chapter 2. In addition, traditional methods cannot handle missing data, which is another challenge. Modern psychometric methods such as Rasch analysis is found to be powerful in handling missing data.[92] The developers of the poorly designed PRO instruments claim that their measures are valid and reliable without adequate evidence. Clinicians and researchers, who are not expert in PRO instrument development, are confused and often make improper selection of PRO instruments. They tend to choose a PRO instrument that is more widely used, and the one developed by reputed authors or institutions, not based on the quality of the instrument.[15, 16]

The PRO instrument development should conform to the regulatory guidelines.[25, 50]Other logistic issues important for selection of PRO instruments for pragmatic reasons are ease of use (CTT easier), low respondent burden, data collection options, cultural relevance, linguistic adaptation, respondent literacy level etc.[156] Recently published systematic reviews grade the quality of the PRO instruments and guide the users to select an appropriate refractive error-specific PRO instrument to fulfil their purpose (Section 3.2).[15, 16]

3.1.7.4 Non-standardisation

Standardisation on developing PRO instruments, collecting PRO data and using them is a demand of time.[179] Standardisation would enable comparison of PRO data from different settings. However, this is complex as choice of PRO instrument varies by concept being measured, population and intervention. There is no consensus for the frequency at which PRO data needs to be collected, and this is not straight forward. Frequency of PRO data collection varies by interventions, which is generally determined to address the research purpose. With electronic health records being more common, there is an opportunity for standardisation of the PRO instruments. High quality electronic PRO instruments may be a part of electronic health records enabling routine collection of PRO data in refractive error.[157] Incorporation of standard PRO instruments to the electronic health records or to the clinical workflow may save resources (as new PRO instrument need not be developed), time, money and expertise.

3.1.7.5 Lack of expertise

Expertise required for understanding and interpreting PRO data is another challenge. The PRO instruments developed using IRT models such as Rasch analysis are found to be superior to the traditional ones.[15, 16] However, expertise required for carrying out psychometric assessment using modern IRT-based methods is rare. In addition, the computer programs to run IRT models or Rasch analysis are not user-friendly.[74]

3.1.7.6 Real-time use of PRO data not possible

Real-time measurement and analysis of the existing PRO instruments in refractive error is not possible. Therefore, these PRO instruments may only be used as research tools rather than clinical tools.

3.1.7.7 Data security and privacy

Data security and confidentiality is particularly crucial for internet-based electronic PRO instruments, as in electronic health records.[172] There are no established standards on the ways to store PRO data maintaining data security and privacy.

3.1.7.8 Difficult to obtain normative data

Disease-specific PRO instruments have items relevant to people with a particular disease. These items may have low relevance in populations without that disease (i.e. normal population). Therefore, comparing the disease impact with the normal population may not be straight-forward.

Most of these barriers and challenges can be addressed by thoughtful approaches. The goal should be using PROs ensuring patients are not burdened, or staff assisting PRO data collection are not burdened. Evolution of PROs has led to different types of PRO instruments from paper-

and pencil-based questionnaires to CAT administered comprehensive item banks. Item banking with CAT is the use of technology to address the limitations of traditional measures. However, developing item banks and setting up a CAT system is a time and resource-intensive process.

Item banking and CAT system has been successfully applied in other areas of health (e.g. Orthopaedics, Cardiovascular rehabilitation).[186, 192] Technology was once perhaps a barrier, but is an opportunity now, with an access to iPads, internet, mobile phones, computers, and internet even in the rural areas. CAT can offer real-time, efficient and comprehensive measurement of QoL. Individually tailored items offer personalized care. PRO instruments can be administered during waiting times or at home, self-reported by patients or assisted by staff. However, caution should be taken not to use PROs as a replacement to clinician-patient interaction. It should be supportive tool in patient management. To sum up, PRO data, a more focused systematic data, can in fact save clinicians time. Making patient care better, and making it easier for clinicians, is the ultimate aim of PRO use.

3.2 Patient-reported outcome instruments for assessment of quality-of-life in refractive error: a systematic review

3.2.1 Introduction

A robust PRO instrument should be patient-relevant, comprehensive, psychometrically sound, valid, reliable and responsive to change.[26, 29] To the best of my knowledge, a comprehensive review of refractive error-specific PRO instruments evaluating their content, psychometric properties, validity, reliability, responsiveness and performance as outcome measure, has not been published earlier. Hence, this study was designed to systematically review all the PRO instruments that have been used in people (children and adults) with refractive error (both corrected and uncorrected), and assess their quality based on their content, psychometric properties, validity, reliability and responsiveness.[18] This systematic review had five objectives, (1) to identify all the existing PRO instruments used in refractive error populations; (2) to assess quality of the existing PRO instruments in terms of content development, psychometric properties, validity, reliability and responsiveness, and determine the superior quality existing PRO instruments for use in refractive error; (3) to identify the content coverage of the identified PRO instruments in terms of QoL domains, and identify their limitations; (4) to evaluate the performance of the PRO instruments in measuring refractive error outcomes; and (5) to compare the status of QoL measures between high-, and low- and middle-income countries.

3.2.2 Methods

The guidelines for conducting a systematic review proposed by Rudnicka *et al.* were followed.[193]

Potentially eligible studies were searched on 22 June 2016 on MEDLINE, PubMed, Scopus, Web of Science and Cochrane databases using strategies that combine the search terms for each database (Table 3.3, see Appendix B for syntaxes in details). The search was limited to English language only. The retrieved citations (N = 2,054 citations) were imported to EndNote™ software, version X8.0.1 (Clarivate analytics, Philadelphia, USA).

Table 3.3 Search keywords for each database

Condition	Refractive error/s, hyperopia, myopia, astigmatism, presbyopia, near sighted/ness, short sighted/ness, long sighted/ness
Management	Eyeglasses / glasses, spectacles, contact lenses, orthokeratology, silicone hydrogel contact lenses, rigid gas permeable contact lenses, disposable contact lenses, Refractive surgery, refractive surgical procedure/s, kerato-refractive surgery; laser refractive surgery, excimer laser, Keratomileusis Laser In Situ, LASIK, Epi-LASIK, PRK, LASEK, Laser epithelial keratomileusis; Non-laser refractive surgery; radial keratotomy, astigmatic keratotomy, epikeratoplasty, thermokeratoplasty, intrastromal corneal implants , phakic intra-ocular lenses, PRL, phakic intraocular lens implant/s; posterior chamber phakic intraocular lens, multifocal intraocular lens; foldable iris-fixated lens; Artiflex, Implantable contact lens, Lens implant/s, Premium lens implant/s; Inlay/s; intac/s, intracorneal ring segment/s, ICR; RLE, refractive lens exchange , CLE, clear lens exchange, clear lens extraction, PRELEX, presbyopic lens exchange, RLR, refractive lens replacement
Instrument & Technique	Patient-reported outcome/s, PRO, questionnaire/s, survey, self-report, instrument, measure, Rasch analysis
Outcome	Quality-of-life, vision related quality-of-life, well-being, satisfaction, self-esteem, emotional, psychological, psychosocial, social, visual performance, activity limitation, visual disability, symptom/s, complication/s, outcome/s, concerns, impact, dry eye

The search strategy used was an iterative process (Figure 3.2). First, the duplicates and citations without abstract (e.g. letter to editor) were removed. Then the abstracts were reviewed for initial screening of the studies to identify the potentially relevant articles. Original articles describing a PRO instrument aimed at people with refractive error or its correction were included. Articles describing refractive error-specific PRO instruments but used in other conditions such as Keratoconus were excluded. However, the studies on a mixed population of cataract and refractive error (e.g. presbyopia) where the major focus was refractive correction (e.g. multifocal intra-ocular lens (IOL) implantation) were included.[33, 45, 53]

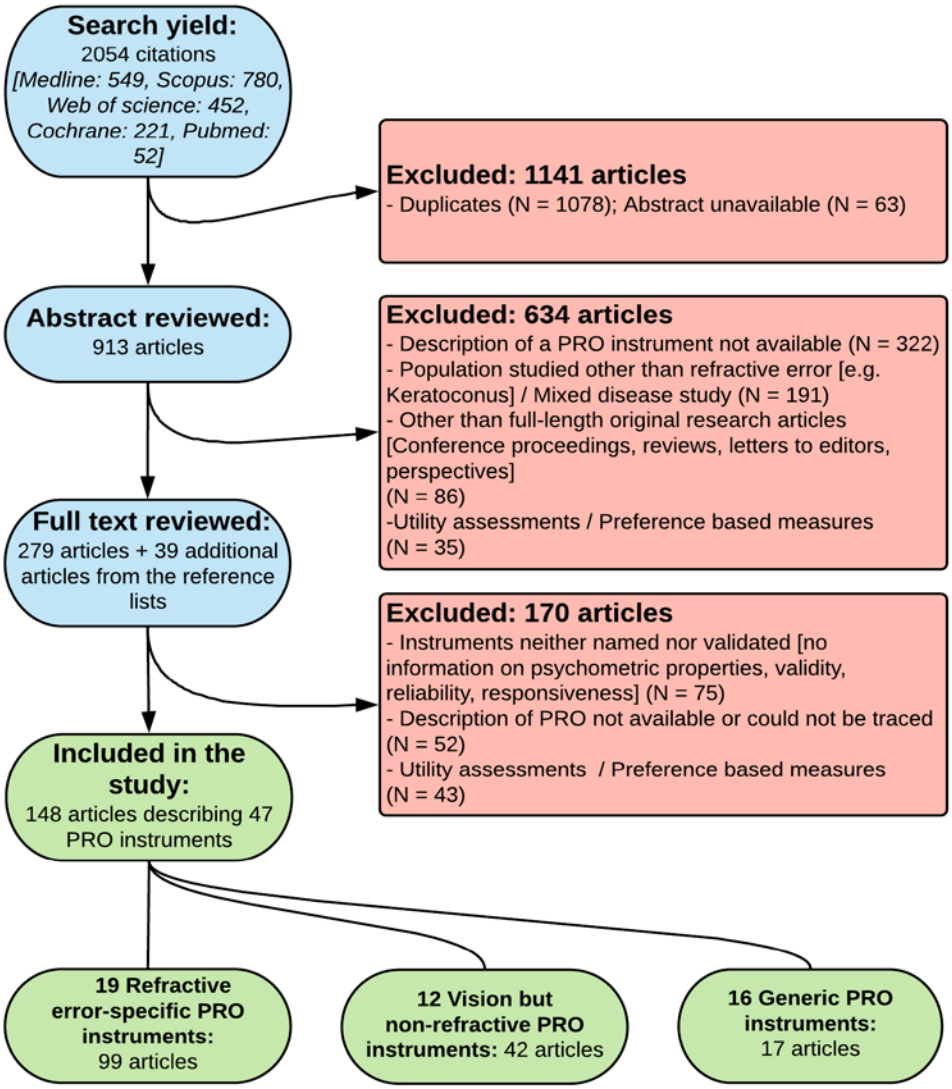

Figure 3.2 Search strategy
Note: PRO = Patient-reported outcome

After the initial screening, full text of the potentially relevant articles were obtained and reviewed in detail. The reference lists in the retrieved articles were hand-searched for additional relevant articles. The articles were excluded if description of the PRO instrument was not given or could not be traced. Similarly, the articles on utility and economic assessments of refractive correction were also excluded. The utility measures are preference-based measures. Although these measures (e.g. Vision Quality of Life index) indicate which group of people may have better QoL (e.g. people with higher utilities may have less economic impact), they do not directly quantify QoL.[166] The retrieved articles were grouped by types of PRO instruments described (Figure 3.2). Selection and classification of articles were done in consensus with my PhD supervisors.

The PRO instruments were classified as refractive error-specific, vision-specific non-refractive, or generic, based on the content and the population (disease group) on which they were developed and validated originally. The vision-specific PRO instruments were further grouped as 'Refractive' (e.g. the National Eye Institute Refractive Quality of Life questionnaire[35]) or 'Non-refractive' (e.g. the National Eye Institute Visual Function questionnaire[163]) based on content (if the content is specific to refractive error, e.g. inconveniences rendered by wearing spectacles, or not) and on whether they were developed for only refractive error populations or for general ophthalmic conditions respectively. Generic PRO instruments (non-disease-specific) cover broad aspects of QoL and health status and are intended to be used in wide range of disease conditions. They are useful for comparing outcomes across various health conditions. In this review, the domain-specific PRO instruments such as the Hospital Anxiety and Depression Scale[161] were also included in this category. The refractive error-specific, the vision-specific non-refractive, and the generic PRO instruments quantify how refractive error impacts on refractive error-specific, ophthalmic and general QoL, respectively.

In this review, a comprehensive assessment was made on the quality of the existing PRO instruments based on the quality criteria used previously (Table 3.4) for evaluating Rasch-based PRO instruments.[18] The revised criteria used in this study are applicable to assess both CTT- and Rasch-based PRO instruments. These criteria aligned with the guidelines proposed by the Consensus based Standards for the selection of health status Measurement Instruments (COSMIN) study[50] and the US Food and Drug Administration (FDA).[25] The COSMIN group has developed a checklist to evaluate quality of a study on measurement properties of an instrument. It guides development of an instrument, or reporting of the measurement properties of an instrument.[50] Similarly, the FDA guidelines describe how the FDA evaluates PRO instruments used to determine endpoints in clinical trials.[25] In this study, the quality assessment were made on content quality, psychometric information based on both traditional (CTT) and modern (IRT) methods, validity, reliability and responsiveness.

Table 3.4 Criteria for grading patient-reported outcome instruments[18]

Content Development	
Item identification	A: Comprehensive consultation with the patients and experts (interviews, focus group discussions), and literature review B: Minimal consultation with appropriate patients and experts, and literature review C: No consultation with patients
Item selection	A: Pilot instrument developed and tested with Rasch or factor analysis, Statistical justification for reducing items, Items with floor and ceiling effects removed, Missing data considered B: Only some of these techniques considered C: No pilot instrument, or no statistical justification of the items in the final instrument.

CTT-based psychometric properties	
Acceptability[72]	A: The percentage of missing data for majority of items: ≤ 5% B: The percentage of missing data for majority of items: > 5%; ≤ 40% C: The percentage of missing data for majority of items: > 40%
Targeting[72, 194]	A: End-point responses ≤ 5% for majority of items B: End-point responses > 5%; ≤40% for majority of items C: End-point responses > 40% for majority of items
Internal Consistency[174] [195]	A: 0.95 ≥ Cronbach's α ≥ 0.7 B: 0.7 > Cronbach's α ≥ 0.6, Or Cronbach's α > 0.95 C: Cronbach's α < 0.6
Item dependency[72]	A: Inter-item correlations < 0.3 B: Inter-item correlations ≥ 0.3; < 0.6 C: Inter-item correlations ≥ 0.6
Dimensionality[26, 196]	A: The first factor loading > 0.4 for all items; Principal component analysis (PCA) - variance explained by the measure > 60% and eigen-value of the first contrast < 2.0 B: Cronbach's α: 0.7 < α > 0.9; PCA - variance explained by the measure ≥ 50% to < 60%; and eigen-value < 2.0 C: Cronbach's α: 0.7 > α or α > 0.9; PCA-variance explained by the measure < 50%; and eigen-value > 2.0 (indicates multidimensionality)
Rasch analysis-based psychometric properties	
Response categories	A: All the categories were ordered or ordering of the categories were obtained after repairing disordered categories, and evenly spaced categories B: All the categories were ordered or ordering of the categories were obtained after repairing disordered categories, and categories were not evenly spaced. C: Unrepairable disordered categories
Unidimensionality	A: PCA of residuals: variance explained by the measure ≥ 60%; and eigen-value of the first contrast < 2.0 B: PCA of residuals: variance explained by the measure ≥ 50% to < 60%; and eigen-value < 2.0 C. PCA of residuals: variance explained by the measure < 50%; and eigen-value > 2.0
Measurement Precision	A: Person separation index (PSI) ≥ 2.5; Reliability > 0.85 B: PSI: 2.0 ≤ PSI < 2.50; 0.8 ≤ Reliability < 0.85 C: PSI < 2.0; Reliability < 0.80
Item fit statistics	A: All items with infit and outfit mean square between 0.70 and 1.30 B: One or two items within the 0.50 and 1.50 limit C: More than two items outside the 0.50 and 1.50 limit
Differential item functioning (DIF)	A: All items with DIF < 0.5 logits B: Some items 0.5 to 1.0 logits, and one at the most > 1.0 logits C: More than one item > 1.0 logit
Targeting	A: Difference between item and person means ≤ 1.0 logit B: > 1.0 to ≤ 2.0 logits C: > 2.0 logits
Validity	
Convergent validity	A: Tested against appropriate measure, and correlation: 0.3–0.9 B: Debatable choice of measure and correlation: 0.3–0.9 C: Correlation < 0.3 or > 0.9)
Discriminant validity	A: Tested with an appropriate measure, and correlation: <0.3 B: Debatable choice of measure, and correlation: <0.3 C: Correlation > 0.3
Concurrent validity	A: Tested with an appropriate measure and correlation: 0.3–0.9 B: Debatable choice of measure, and correlation: 0.3–0.9 C: Correlation < 0.3 or > 0.9

Known-group validity	A: Tested between appropriate clinical groups; significant difference between groups. B: Tested between debatable groups; significant difference between groups C: Not tested, or insignificant difference between groups
Repeatability or reproducibility / Responsiveness	
Test-retest agreement	A: Intra-class correlation (ICC) ≥ 0.8, B: 0.6 ≤ ICC < 0.8 C: ICC < 0.6
Inter-observer / inter-mode agreement[26]	A: Limits of agreement (LoA) < Minimally important difference (MID), Weighted kappa > 0.8, Inter-modal correlation > 0.7 B: LoA broader but still close to MID, Kappa: 0.6–0.79, inter-modal correlation 0.5–0.7 C: LoA >> MID, kappa < 0.6, inter-modal correlation < 0.5, or incorrect statistical test or inadequate sample (< 30)
Responsiveness [197]	A: Score changes over time > MID, or changes with intervention; Effect size (≥ 1) or responsiveness statistics given B: Changes over time but relationship to MID nor reported, effect size ≥ 0.5 to < 1; small sample, and inadequate time frame C: Score changes ≤ MID; effect size < 0.5

Note: A = Excellent; B = Fair/OK, C = Unsatisfactory

Details on CTT and IRT, two theories commonly used for developing the PRO instruments to measure QoL, was provided in Chapter 2. Rasch analysis is a widely used model of the IRT in outcome research. In brief, CTT is easy to use, but based on two erroneous assumptions: (1) all the items are of equal difficulty; and (2) change between response options is uniform, and thus the scores allocated to these response categories provide a valid summary score. Rasch analysis can be used to develop a new instrument, assess psychometric properties of a PRO instrument or re-engineer PRO instruments originally developed by using CTT[18, 23, 26, 28, 29] However, resources and expertise required for Rasch analysis limits its applicability. In this study, all PRO instruments were evaluated based on CTT and Rasch analysis-based criteria.

Grading each criterion of the PRO instruments was done at three levels: “A” for high quality, “B” for moderate quality and “C” for poor quality. The PRO instrument with the higher number of grade “A”s for the overall scale or for all the sub-scales was considered to be of a higher quality. Thirty articles provided exclusive information on these quality criteria. Among them, 29 studies described refractive error-specific PRO instruments and one study described a generic PRO instrument. The grading of each criteria for the PRO instrument they used is presented in Table 3.5 to Table 3.10.

3.2.3 Results

A total of 148 articles met the selection criteria (Figure 3.2). Forty-seven PRO instruments were identified (19 refractive error-specific, 12 vision-specific but non-refractive error-specific and 16 generic PRO instruments). Description of all PRO instruments used in refractive error is provided in Appendix C (due to length of this table, it is kept as an appendix). Most of the studies (n = 99, 66.9%) used refractive PRO instruments followed by vision but non-refractive (n = 42, 28.4%) and

generic (n = 17, 11.5%) PRO instruments. Ten studies (6.8%) used more than one type of PRO instrument. Among 47 PRO instruments, only 17 (16 refractive error-specific and one generic) were validated in refractive error populations; six of them were developed using Rasch analysis. In addition, two PRO instruments were evaluated with Rasch analysis although they were originally developed using the CTT (Table 3.5, Table 3.6).

3.2.4 A. Refractive error-specific PRO instruments

I reviewed 99 articles describing development, validation or use (as an outcome measure) of 19 refractive error-specific PRO instruments (Appendix C). Of them, 16 PRO instruments were named and validated (Table 3.5 to Table 3.10).

3.2.4.1 National Eye Institute Refractive Quality of Life (NEI-RQL)

I identified 29 articles that described the NEI-RQL.[17, 35, 36, 71, 82, 189, 198-220] Six articles provided information on quality criteria (Table 3.5).[36, 71, 198-201] The NEI-RQL was originally developed using CTT to measure comprehensive QoL.[35, 36] However, most of its items are for activity limitation and symptoms domains only. A comprehensive patient consultation was done but how the final items were selected was not reported. Sixteen different response categories are employed for 42 items making up 13 subscales. The NEI-RQL does not produce an overall score, but a score for each of the 13 subscales. Each subscale has a score from 0 to 100 with higher values indicating favourable outcome (better QoL).[36]

Table 3.5 Quality assessment of the National Eye Institute Refractive Quality of Life

SN	**Author (Date); Study population** (Country; Sample size; refractive error; refractive correction)	**Content quality / CTT-based psychometric properties** and/or **Rasch-based psychometric properties**	**Validity** / **Repeatability/ Responsiveness**
1	Hays (2003)[36]; USA; N = 1,161; Myopia, hyperopia, and emmetropia; Refractive surgery, contact lens, and spectacles	Content: Item identification: A; Item selection: C / CTT: Targeting: B; Internal consistency: A (10/12 subscales), B (2/12 subscales); Dimensionality: C	Convergent: A; Discriminant: C; Known-group: A (9/13 subscales), B (4/13 subscales) / Test-retest agreement: A (3 subscales), B (9 subscales), C (Suboptimal correction subscale)
2	Toker (2008)[198]; Turkey; N = 95; Emmetropia, myopia, and hyperopia; Spectacles and contact lens	Content: Item identification: A; Item selection: C / CTT: Internal consistency: A (9/12 subscales), B (3/12 subscales)	Convergent: A; Known-group: A (9/13 subscales), B (4/13 subscales) / Test-retest agreement: A (11/12 subscales), B (1/12 subscale)
3	McAlinden (2011)[71]; UK; N = 100; Refractive surgery patients preoperative (with spectacles or contact lens) and postoperative	Content: Item identification: A; Item selection: C / Rasch: Response category: C; Dimensionality: C; MP: C; Item fit statistics: C; DIF: C; Targeting: C	All: NR

4	Labiris (2012)[199]; Greece; N = 79; Emmetropia, myopia and hyperopia	Content: Item identification: A; Item selection: C / CTT: Acceptability: A; Targeting: C; Internal consistency: A (10/12 subscales), C (2/12 subscales); Dimensionality: B / Rasch: Item fit statistics: C	Convergent: A; Discriminant: B; Concurrent: C; Known-group: A (10/12 subscales), C (2/12 subscales) / Test-retest agreement: A (10/13 subscales), B (3/13 subscales)
5	Nichols (2003)[200]; USA; N = 79; Myopia, hyperopia, and emmetropia; Spectacles, contact lenses and without correction	Content: Item identification: A; Item selection: C / CTT: Internal consistency: A (9/12 subscales), B (2/12 subscales), C (Glare subscale)	Concurrent: C; Known-group: C / Test-retest agreement: A (3/13 subscales), B (3/13 subscales)
6	Kobashi (2014)[201]; Japan; N = 103; Myopia corrected with phakic intra-ocular lens implantation or with wavefront-guided LASIK	Content: Item identification: A; Item selection: C / CTT: Internal consistency: A (10/12 subscales), B (2/12 subscales)	Known-group: A (4/13 subscales), C (9/13 subscales) / Test-retest agreement: A (8/13 subscales), B (5/13 subscales)

Note: If the information on assessment criteria (Table 3.4) is not provided in this table, then either the test was not performed or the information was not provided. CTT = Classical test theory, DIF = Differential item functioning, LASIK = Laser Assisted Keratomileusis In Situ, MP = Measurement precision, NR = Not reported, PRO = Patient-reported outcome

Several studies have tested the psychometric properties of the NEI-RQL. Hays *et al.* reported up to 35% floor effect and up to 82% ceiling effect. The Cronbach's α ranged from 0.64 to 0.90. The test-retest intra-class correlation coefficient (ICC) ranged from 0.55 to 0.83.[36] Kobashi *et al.* reported similar results for the Japanese version of the NEI-RQL. Cronbach's α ranged from 0.61 to 0.90 for overall and all subscales. The ICC ranged from 0.73 to 0.94 for overall and all subscales (Table 3.5).[201] Similarly, in a study by Toker *et al.*, internal consistency of the NEI-RQL subscales and the overall scale ranged from 0.62 to 0.95, whereas, the ICC ranged from 0.61 to 0.95.[198] In another study, Nichols *et al.* reported good internal consistency (Cronbach's α = 0.91) and test-retest reliability (ICC = 0.91) for the overall NEI-RQL. The overall NEI-RQL score correlated with subjective refraction.[200] However, it has to be noted that the developers of the original NEI-RQL did not intend to produce an overall score.

The Greek version of the NEI-RQL has been tested using both CTT and Rasch analysis.[199] The CTT method showed that it is a valid and reliable instrument. However, the NEI-RQL had suboptimal psychometric properties when evaluated using Rasch analysis.[199] Similarly, using Rasch analysis, McAlinden *et al.* reported problems with the NEI-RQL in all of the psychometric properties tested, including misused or dysfunctional response categories, multidimensionality, poor measurement precision, poor item-fit statistics and notable differential item functioning (Table 3.5).[71]

Blaylock *et al.* found no significant correlation between post-operative refractive error with all the NEI-RQL scores.[218] In another study, Iijima *et al.* investigated correlations of the NEI-RQL scores with scattering from phakic IOL with a central hole (Hole ICL). Scattering moderately correlated

(Spearman's ρ = 0.58) with the glare subscale.[219]

In general, studies have found better NEI-RQL scores for refractive surgery compared to spectacles or contact lens wear. Hays *et al.* reported that patients with refractive surgery had better NEI-RQL scores than those wearing spectacles or contact lenses for 8/13 subscales. For the glare subscale, patients with refractive surgery had poorer score.[36] Similarly, Shams *et al.* reported that the patients with refractive surgery had better NEI-RQL scores for most of the subscales. However, the differences were only subtle for most of the subscales.[217] Queiros *et al.* also reported that the patients with LASIK had better NEI-RQL scores than spectacles, orthokeratology or soft contact lenses.[82] In another study comparing NEI-RQL scores between mono-vision (including surgical mono-vision) and single-vision correction, McDonnell *et al.* reported a difference in only 3 out of 13 subscales (expectations, dependence on correction, and appearance) favouring monovision.[17]

Nichols *et al.* demonstrated that the NEI-RQL could differentiate between myopes seeking LASIK from myopes not seeking LASIK, which could not be explained by differences in refractive error and visual acuity. Significant differences were observed for 4 out of 13 subscales: Expectations, Activity limitations, Appearance and Satisfaction subscales.[203] In another study, McDonnell *et al.* reported that after kerato-refractive surgery, there was improvement in all the subscales except glare subscale.[207] Effect size was low (0.09 to 0.38) for 3 out of 13 subscales, moderate (0.67 to 0.91) for 5 out of 13 scales and high (>1.0) for 5 out of 13 subscales. Changes were similar for myopes and hyperopes.[207] In another study, Blaylock *et al.* reported that in refractive lens exchange with multifocal IOL patients, significant improvement in the scores was achieved for 5 out of 13 subscales: expectations, activity limitations, dependence on correction, appearance, and satisfaction subscales. Glare subscales were significantly lower post-operatively. Larger improvement in near vision and dependence on correction was achieved in hyperopes compared to myopes.[189]

Several studies have compared outcomes of various refractive surgical procedures based on the NEI-RQL subscale scores. Pepose *et al.* found that the bilateral Crystalens group had more favourable outcomes than the combination of Crystalens, ReZoom or ReSTOR intra-ocular lenses.[220] Similarly, Kobashi *et al.* found that phakic IOL group scored better in 4 out of 13 (Activity limitations, Symptoms, Appearance and Satisfaction) subscales than the LASIK group 5-years post-operatively. There were no significant differences between the groups in 9 out of 13 subscales.[201] In another study, Pérez-Cambrodí *et al.* reported that phakic IOL implantations resulted to higher NEI-RQL scores except for the Glare subscale even in the presence of poor ocular aberrometric outcomes. The NEI-RQL subscale scores correlated with contrast sensitivity.[210] In another study, toric IOL implantation group had better NEI-RQL scores for 4 out of

13 subscales (Clarity of vision, Far vision, Glare and Satisfaction with correction) than the astigmatic IOL implantation group three months post-operatively.[208] In other two studies by Visser *et al.*.[214] and Lin *et al.*.[216], no significant difference was observed between different IOL implantation combinations. In summary, the studies report inconsistent findings for performance of the NEI-RQL subscales in measuring refractive surgery outcomes

Similarly, studies have used NEI-RQL as an outcome measure in contact lenses and spectacles wearers. Using NEI-RQL, Richdale *et al.* concluded that multifocal contact lenses offer better outcomes than monovision contact lens in patients with low astigmatic presbyopia.[211] In another study, Lipson *et al.* found that hybrid contact lenses offered better visual acuity but produced more ocular-comfort symptoms compared to soft-toric contact lenses. However, the differences in other NEI-RQL subscales (12 out of 13 subscales; subscales other than 'Symptoms') were not statistically significant.[204] Similarly, Bernsten *et al.* reported change in scores for only 3 of the 13 NEI-RQL subscales after the use of orthokeratology lenses.[202] In another study, Lipson *et al.* found no statistically significant difference in 9 out of 13 NEI-RQL subscale scores between orthokeratology lenses and soft contact lenses. Orthokeratology lenses had less activity limitations but more glare problems.[206] Similarly, Ritchey *et al.* reported no significant difference in NEI-RQL subscale scores between two types of overnight lens modalities.[212] In another study, Willen *et al.* found that there was no significant difference in NEI-RQL scores between placebo group and treatment group with cyclosporine, in contact lens wearers with dry eyes.[215] Thus, studies on contact lens wearers and spectacles wearers also report inconsistent findings on the performance of NEI-RQL as an outcome measure. Based on the study findings, it is difficult to generalize the performance of the NEI-RQL as an outcome measure in refractive error.

3.2.4.2 Refractive Status and Vision Profile (RSVP)

Thirteen articles that used the RSVP met the inclusion criteria.[37, 38, 90, 188, 200, 221-225] Six articles provided information on quality criteria (Table 3.6).[37, 90, 188, 200, 221, 222] The RSVP was originally developed using CTT, almost exclusively on a refractive surgery population. The developers aimed for measuring comprehensive refractive QoL.[37, 38] However, 31 (80%) out of 42 items in the RSVP are only for activity limitation, symptoms and convenience domains (Appendix C).[37, 38] The RSVP produces an overall score and eight subscale scores ranging from 0 to 100. Higher scores indicate more impairment.[37, 38]

The original RSVP was reported to have a good internal consistency (Cronbach's α: 0.70–0.93). The ICC for the group undergoing refractive surgery and the group not undergoing surgery were 0.61 and 0.88 respectively.[37, 38] Similarly, Nichols *et al.* reported satisfactory internal consistency (Cronbach's α = 0.81) and test-retest reliability (ICC = 0.76) for the overall RSVP. The overall

RSVP score did not correlate with subjective refraction.[200] In another study, Cronbach's α of the Persian RSVP ranged from 0.60 to 0.92. The ICC ranged from 0.51 to 0.95. Most of the RSVP subscale-scores weakly correlated with the clinical measures such as visual acuity and spherical equivalent refractive error. Similarly, the scores for most of the RSVP subscales were not significantly different for those seeking refractive surgery from those who had previously undergone refractive surgery.[221]

Using Rasch analysis, Garamendi *et al.* unravelled that the RSVP had poor targeting and underutilized response categories. The Rasch analysis guided 20-item revised version of the RSVP was then developed which had an acceptable precision (person separation: 2.01). For the RSVP-20, Cronbach's α was 0.90, and the ICC was 0.80.[222] In another study using Rasch analysis, only two subscales (driving and concerns) of the original RSVP showed adequate measurement precision (> 2.0). However, both the subscales suffered from poor targeting and differential item functioning. Targeting was worse (7.02 logits) for driving subscale (Table 3.6).[90]

Table 3.6 Quality assessment of the Refractive Status and Vision Profile

SN	**Author (Date); Study population** (Country; Sample size; refractive error; refractive correction)	**Content quality / CTT-based psychometric properties** and/or **Rasch-based psychometric properties**	**Validity / Repeatability/ Responsiveness**
1	Schein (2000)[37]; USA; N = 550; (N = 176 for assessing responsiveness); Myopia and hyperopia; Refractive surgery, spectacles and contact lenses	Content: Item identification: A; Item selection: B/ CTT: Internal consistency: A	Concurrent: A/ Test-retest agreement: B (Refractive surgery population); A (Not undergoing surgery) / Responsiveness: A
2	Schein (2001)[188]; USA; N = 176; Refractive surgery patients *[myopia (97%) and hyperopia (3%); PRK or LASIK]*	Content: Item identification: A; Item selection: B/ CTT: Internal consistency: A	Concurrent: C; Known-group: C/ Responsiveness: A
3	Nichols (2003)[200]; USA; N = 79; Hyperopia, myopia, and emmetropia; Spectacles, contact lens, or without correction	Content: Item identification: A; Item selection: B/ CTT: Internal consistency: A (Overall score and 6/8 subscales), B (Glare subscale), C (Corrective lens problems subscale)	Concurrent: C; Known-group: B (Overall and 3/8 subscales), C (5/8 subscales)/ Test-retest agreement: A (concern subscale), B 6/8 subscales and overall), C (Corrective lens problems subscale) / Responsiveness: C

4	Kadkhoda (2006)[221]; Iran; N = 73; Refractive surgery patients (pre- and post-op); *[mostly myopic; mainly wearing spectacles or no correction]*	Content: Item identification: A; Item selection: B/ CTT: Internal consistency: A (7/8 subscales), B (Expectation subscale)	Concurrent: A (3/8 subscales), Known-group: B (3/8 subscales and overall score), C (5/8 subscales)/ Test-retest agreement: A (overall and 6/8 subscales), B (glare subscale), C (optical problems subscale)
5	Garamendi (2006)[222]; UK; Myopia *[refractive surgery clinic (91) and general optometric practice (91)]*	Content: Item identification: A Item selection: B/ CTT: Acceptability: B (RSVP-20) Targeting: C (RSVP-20 & RSVP-42) Internal consistency: B for RSVP-42, A for RSVP-20/ Rasch: MP: C (RSVP-42), B (RSVP-20); Item-fit statistics: C (RSVP-20 & RSVP-42); Targeting: C (RSVP-42), B (RSVP-20)	All: NR
6	Gothwal (2010)[90]; UK; N=200; Patients from a refractive surgery clinic and a general optometry practice	Content: Item identification: A Item selection: B/ Rasch: Dimensionality: A$^{\alpha}$; MP: B$^{\alpha}$; Item fit statistics: A$^{\alpha}$ *[$^{\alpha}$For both Health concerns and Driving subscales; Note: MP for other 6 subscales of the RSVP: C]* Targeting: B (Concerns); C (Driving) subscales	All: NR

Note: If the information on assessment criteria (Table 3.4) is not provided in this table, then either the test was not performed or the information was not provided. CTT = Classical test theory, DIF = Differential item functioning, LASIK = Laser Assisted Keratomileusis In Situ, MP = Measurement precision, NR = Not reported, PRK = Photorefractive keratectomy; PRO = Patient-reported outcome

The RSVP has been used as an outcome measure in various types of refractive surgery including LASIK[226] and phakic IOL implantation.[225] Schein *et al.* reported that the RSVP is responsive to QoL changes after refractive surgery (effect size: 1.2 to 1.4). Improvement (reduced mean RSVP scores) were observed in overall scale and all subscales. The majority of patients had significant improvements in overall scale and 2/8 subscales (Concern and Functioning subscales). The overall RSVP scores significantly improved in 66.5% of the patients and significantly decreased in 4.5% patients.[188] Similarly, Lane and Waycaster reported moderate responsiveness of the overall RSVP for phakic IOL implantation for high myopia. The overall effect size value was 0.80 at three post-operative assessments. The effect size for individual subscales ranged from 0.3 to 1.4: 0.3 for Glare, 0.4 for Optical problems, 0.5 to 0.6 for Driving, 0.6 for Ocular symptoms, 0.6 to 0.8 for Physical / social functioning, 0.7 to 0.9 for Problems with corrective lenses, and 1.3 to 1.4 for Concerns.[225] Similar to the NEI-RQL, the performance of the RSVP in measuring refractive surgery outcomes is inconsistent in the literature.

Although RSVP was originally developed in a predominantly refractive surgery sample, it has been

used as an outcome measure for spectacles or contact lens wear. Esteso *et al.* reported significant improvement in QoL parameters after distribution of free spectacles, and thus provided evidence of known-group validity of the RSVP.[227] Whereas, Savage *et al.* found no significant differences in RSVP scores between presbyopes with or without low astigmatism.[224] Similarly, Nichols *et al.* reported no significant differences in RSVP scores between people with daily disposable and extended wear disposable contact lenses. They further concluded that RSVP would not be an appropriate outcome measure in contact lens trials as large sample size would be required.[223] Thus, the findings suggest that the RSVP may not be a good outcome-measure for spectacles and contact lens wearers.

3.2.4.3 Quality of life Impact of Refractive Correction (QIRC)

Eight articles were identified that described the QIRC.[19, 27, 28, 228-232] Three articles provided information on quality criteria (Table 3.7).[19, 28, 232] The QIRC was developed and validated using Rasch analysis.[28] Comprehensive consultation was done with people with myopia, hyperopia and astigmatism, along with literature review and expert opinion. It has high quality content with wide coverage of QoL domains including activity limitation, symptoms, convenience, economic issues, health concerns and well-being. With less items (n = 20), the QIRC has low respondent burden compared to other widely used refractive questionnaires (the NEI-RQL and the RSVP). The QIRC score is reported on a Rasch converted 0-100 scale. Higher score represents better QoL, and the average score is close to 50 units.[28]

The QIRC has demonstrated promising psychometric properties such as measurement precision (Person separation: 2.03) and fit statistics (infit: 0.70-1.24; outfit: 0.78-1.32). It was free from floor and ceiling effects. The test-retest ICC was 0.88. Internal consistency (Cronbach's α) was 0.78 (Table 3.7).[28] For the Greek version of the QIRC, Cronbach's α ranged from 0.88 to 0.92 for the surgery group, and the ICC was 0.98.[19] However, in a recent study, the original 20-item QIRC was reported to be multidimensional and it was split into two unidimensional scales: Functional scale (items: 1, 3, 7-13) and Emotional scale (items 14, 15, 17-19).[232]

The QIRC has been used to evaluate outcomes in spectacles, contact lenses or refractive surgery. Pesudovs *et al.* found that the refractive surgery patients had higher QIRC QoL scores than spectacles or contact lens wearers.[27] Likewise, Ieong *et al.* reported higher QIRC QoL scores for ICL implantation over contact lens wear.[233] In brief, studies using QIRC as an outcome measure report that refractive surgery offer better outcomes than spectacles or contact lens.

Table 3.7 Quality assessment of the QIRC and the CLIQ

SN	Name of the PRO / Author (Date); Study population (Country; Sample size; refractive error; refractive correction)	Content quality / CTT-based psychometric properties and/or Rasch-based psychometric properties	Validity / Repeatability/ Responsiveness
1	QIRC / Pesudovs (2004)[28]; UK; N = 312; Pre-presbyopic patients with refractive corrections (spectacles, contact lens, post-refractive surgery)	Content: Item identification: A; Item selection: A CTT: Internal consistency: A Rasch: Response category: A; Measurement precision: B; Item fit statistics: A; Targeting: A	Test-retest agreement: A; Responsiveness: B
2	QIRC / Meidani (2012)[19]; UK; N = 190; Pre-presbyopic myopes; Femtosecond LASIK (n = 92), Controls (contact lenses and spectacles; n = 98)	Content: Item identification: A; Item selection: A / CTT: Targeting: A; Internal consistency: A	Convergent: B; Concurrent: A; Known-group: A / Test-retest agreement: A; Responsiveness: A
3	QIRC / Ang (2015)[232]; Singapore; N = 50; LASIK (n = 25), Small incision lenticule extraction (SMILE, n = 25)	Content: Item identification: A Item selection: A Rasch: Response category: A^{ω}; Dimensionality: A^{ω}; Measurement precision: B^{ω}; DIF: A^{ω} *[$^{\omega}$For both Functional and Emotional scales]* Item fit statistics: B (Functional), A (Emotional); Targeting: C (Functional), A (Emotional)	All: NR
4	CLIQ / Pesudovs (2006)[46]; UK; N=128; Pre-presbyopic contact lens wearers	Content: Item identification: A; Item selection: A Rasch: Response categories: A; Measurement precision: B; Item fit statistics: A; Targeting: A	Test-retest agreement: A

Note: If the information on assessment criteria (Table 3.4) is not provided in this table, then either the test was not performed or the information was not provided. CLIQ = Contact Lens Impact on Quality of Life, CTT = Classical test theory, DIF = Differential item functioning, LASIK = Laser Assisted Keratomileusis In Situ, NR = Not reported, PRO = Patient-reported outcome, QIRC = Quality of Life Impact of Refractive Correction SMILE = Small incision lenticule extraction

The QIRC has been reported to be responsive to different refractive surgery procedures including LASIK, Laser epithelial keratomileusis (LASEK), Implantable Collamer lens (ICL) implantation, multi-focal IOL and SMILE.[19, 27, 28, 228-230, 232, 233] In a study by Garamendi *et al.*., the QIRC was responsive to detect change in QoL after LASIK. Improvement in the scores were observed for all the 20 items, of which 16 were statistically significant. Only a small number of patients who had complications had decreased QIRC scores.[228] McAlinden and Moore[230], and Ieong *et al.*[229] reported improvement in QIRC score after multifocal-IOL implantation and ICL implantation respectively. Similarly, using Greek version of the QIRC, Meidani *et al.* found that Femtosecond LASIK significantly improves QoL. Ang *et al.* found no differences between the QIRC scores three months after LASIK and SMILE. However, the authors indicated that a study with a larger sample size and a longer follow-up period is required to confirm their findings.[232]

To conclude, the QIRC has been proven responsive to changes in refractive error outcomes (including refractive surgery complications), and it enables comparison between effectiveness of various refractive error interventions.

3.2.4.4 Quality of Vision (QoV)

Five articles describing the QoV were reviewed.[33, 234-237] The QoV was developed using Rasch analysis to measure visual symptoms.[33] The content of the QoV was derived from consultation with patients. It has 30 items for 10 symptoms (glare, halos, starbursts, hazy vision, blurred vision, distortion, double or multiple images, fluctuation in vision, focusing difficulties, and difficulty judging distance or depth perception) with their three attributes: severity, frequency and bothersome subscales.[33] The QoV subscale-scores range from 0 to 100. Higher scores indicate poorer quality of vision.[33] The three subscales of the QoV have been reported to be non-interchangeable.[236]

Overall, the QoV has excellent psychometric properties (Table 3.8). The variance explained by the principal component was > 60%. The unexplained variance explained by the first contrast was < 2.0 eigen-values for all three scales. Similarly, for all three scales, mean square infit and outfit were within 0.81 to 1.27, and the person separation was > 2.0. There was a strong correlation of the QoV scores with visual acuity and contrast sensitivity. The ICC was 0.87. However, differential item functioning was observed for 8/30 items. The QoV had good content quality and psychometric properties except it suffers from poor targeting and differential item functioning.[33]

Table 3.8 Quality assessment of domain-specific PRO instruments in refractive error

SN	Name of the PRO / Author (Date); Study population (Country; Sample size; refractive error; refractive correction)	Content quality / CTT-based psychometric properties and/or Rasch-based psychometric properties	Validity / Repeatability/ Responsiveness
1	Quality of Vision (QoV) / McAlinden (2010) [33]; UK; N=900; Contact lenses (n = 150), Spectacle (n = 150), Laser refractive surgery (n = 300), Intraocular lens implantation (n = 150), cataract (n = 150)	Content: Item identification: A; Item selection: A / Rasch: Response category: A; Dimensionality: A; MP: B Item fit statistics: A; DIF: C Targeting: C (Bothersome), B (Others)	Concurrent: A; Known-group: A / Test-retest agreement: A; Responsiveness: B
2	Canadian Refractive Surgery Research Group Quality of Vision Questionnaire (QVQ)/ Brunette (2000)[39, 40]; Canada; N=690; Patients who underwent bilateral photorefractive keratectomy for myopia	Content: Item identification: C; Item selection: B/ CTT: Acceptability: B; Internal consistency: A (6/7 scales), B (1/7 scale)	Discriminant: C; Concurrent: C; Test-retest agreement: C (Global satisfaction), A (Other scales)
3	Prospective Evaluation of Radial Keratotomy (PERK) Study Questionnaire / Bourque (1986)[41]; USA; N= 354; Myopic patients who had undergone radial keratotomy	Content: Item identification: C; Item selection: B / CTT: Internal consistency: A (for all 3 subscales)	Concurrent: B

4	Student Refractive Error and Eyeglass Questionnaire (SREEQ) / Crescioni (2014)[49]; USA; N = 181; Myopia, astigmatism and hyperopia; Spectacle wearers	Content: Item identification: B; Item selection: C / Rasch: [For 10 matching items:] Response categories: B MP: B (Part A), C (Part B); Item fit statistics: A; DIF: C	All: NR
5	Freedom from Glass Value Scale (FGVS) / Berdeux (2010); France and Spain; N = 304 (152 French, 152 Spanish); Cataract or presbyopia surgery with multifocal intraocular lens	Content: Item identification: B; Item selection: B / CTT: Acceptability: A; Targeting: B; Internal consistency: A; Item dependency: B; Dimensionality: C	Known-group: B
6	Near Activity Visual Questionnaire (NAVQ) / Buckhurst (2012)[34]; UK; N=150; Presbyopia; Intraocular lenses (Monofocal, multifocal, accommodating), Multifocal contact lenses and Varifocal spectacles	Content: Item identification: B; Item selection: A / CTT: Internal consistency: A Rasch: Response category: A; MP: A; Item fit statistics: C; Targeting: C	Concurrent: B; Known-group: A; Test-retest agreement: B
7	Paediatric Impact of Assistive Devices Scale (PIADS)/ Day (1996)[162]; Canada; N = 307; Spectacles and contact lenses	Content: Item identification: B; Item selection: B / CTT: Internal consistency: B; Item dependency: B; Unidimensionality: C	Convergent: B; Discriminant: B; Known-group: B; Test-retest agreement: A

Note: If the information on assessment criteria (Table 3.4) is not provided in this table, then either the test was not performed or the information was not provided. CTT = Classical test theory, DIF = Differential item functioning, MP = Measurement precision, NR = Not reported, PRO = Patient-reported outcome

The QoV has been used to assess symptoms after various types of refractive surgical procedures. McAlinden reported worsening of symptoms after LASEK, which subsequently improved to better than the pre-operative levels by 3 months post-operatively.[235] Luger *et al.* reported that the QoV scores worsened (mainly increase in halos, blurred vision and double vision symptoms) after presbyopic LASIK before three months and remained stable after that.[237] In another study, Maurino *et al.* reported no significant difference between the QoV scores between two types of multifocal IOL implantation (bilateral implantation with the AT LISA 809M IOL or ReSTOR SN6AD1 IOL). A small but clinically significant minority of patients remained symptomatic (particularly halo being more bothersome).[234] To sum up, the QoV performs satisfactorily as an outcome measure in refractive error surgery.

3.2.4.5 Canadian Refractive Surgery Research Group Quality of Vision Questionnaire (QVQ)

Four articles on the QVQ were reviewed.[39, 40, 238, 239] The QVQ was developed using CTT to assess quality of vision after photorefractive keratectomy.[39, 40] The content of the QVQ was derived from the Prospective Evaluation of Radial Keratotomy (PERK) Study questionnaire and the Visual Functioning Index (VF-14).[41, 240] It has items on activity limitation, symptoms, health concerns and emotional well-being. The QVQ employs five-point Likert scales. The QVQ had rudimentary validity and reliability (Table 3.8).[39, 40] The Cronbach's α ranged from 0.83 to 0.96. The ICC ranged from 0.21 to 0.92.[40]

The QVQ was responsive to the PRK[39], LASIK[238] and phakic IOL implantation.[239] A high level of satisfaction was reported after each surgery. However, glare and night vision problems were reported to be more problematic. Night vision symptoms included stars around lights, halos, fog, or haze around streetlights, double outline of images, ghost images, and distortion of details.[39, 238, 239]

3.2.4.6 PERK Study Questionnaire

The PERK Study Questionnaire was developed to measure satisfaction after radial keratotomy in 1986 using the CTT.[41] It was perhaps the first published PRO instrument to systematically assess QoL domains in refractive error in patients' perspectives. It consists of items on emotional well-being, health concerns and symptoms. Only the elementary validation (internal consistency) was carried out (Table 3.8).[41] The Cronbach's α ranged from 0.89 to 0.90. The item-sum correlations were between 0.60 and 0.80.[41] Using the PERK study questionnaire as an outcome measure, the authors found that less than half of the participants were satisfied with the radial keratotomy outcomes.[41]

3.2.4.7 Multidimensional Quality of Life for Myopia scale (MQLM)

The Institute for Eye Research MQLM scale was developed using CTT to evaluate QoL related to myopia correction.[43, 241, 242] Most of the items are related to symptoms, activity limitation and emotional well-being. It has a few items on coping strategies as well. Only the rudimentary validation (international consistency) of the MQLM was carried out (Table 3.9).[43] The Cronbach's α ranged from 0.76 to 0.92. The ICC was 0.75.[43]

Table 3.9 Quality assessment of the myopia-specific patient-reported outcome instruments

SN	Name of the PRO / Author (Date); Study population (Country; Sample size; refractive error; refractive correction)	Content quality / Psychometric properties	Validity / Repeatability/ Responsiveness
1	Institute for Eye Research Multidimensional Quality of Life for Myopia (MQLM) / Erickson (2004)[43]; Australia; N = 1647; Myopia; Contact lens, spectacles and LASIK	Content: Item identification: B; Item selection: C / CTT: Internal consistency: B (cosmesis subscale), A (other subscales and overall scale) Dimensionality: C	Known-group: A / Test-retest agreement: C
2	Myopia-specific Quality of Life Questionnaire (MQLQ) / Lee (2005)[1]; South Korea; N = 288; Post LASIK	Content: Item identification: B; Item selection: A CTT: Acceptability: A; Internal consistency: A; Item dependency: B; Dimensionality: B	Concurrent: A
3	Subjective Vision Questionnaire (SVQ)/ Fraenkel (2004)[42]; Australia; N = 128; Myopia and myopic astigmatism; pre- and post LASIK	Content: Item identification: A; Item selection: A CTT: Internal consistency: A; Dimensionality: A	Test-retest agreement: A

Note: If the information on assessment criteria (Table 3.4) is not provided in this table, then either the test was not performed or the information was not provided. CTT = Classical test theory, LASIK = Laser Assisted

Keratomileusis In Situ, PRO = Patient-reported outcome

The MQLM was responsive to changes in frequency of visual symptoms, psychological state and in overall satisfaction with uncorrected visual acuity after LASIK. However, no statistically significant differences were detected for the tolerance of symptoms, cosmesis and extraversion/introversion subscales.[242]

3.2.4.8 Myopia-specific Quality of Life Questionnaire (MQLQ)

The MQLQ was developed using the CTT to measure QoL in Korean myopic population who had Laser in situ Keratomileusis (LASIK).[1] The items were derived from the existing questionnaires. Most of the items are for symptoms and activity limitation. All items are rated on a scale ranging from one (maximal dysfunction) to five (minimal dysfunction).[1] Only rudimentary validation (internal consistency) has been carried out (Table 3.9).[1] The Cronbach's α ranged from 0.70 to 0.95.[1] Using MQLQ as an outcome measure, it was reported that the LASIK improved QoL in myopia. Patients reporting adverse symptoms after LASIK had reduced overall QoL scores.[1]

3.2.4.9 Subjective Vision Questionnaire (SVQ)

The SVQ was developed using CTT to measure quality of vision in myopes seeking LASIK.[42] It consists of items related to activity limitation and symptoms.[220] It utilizes a visual analogue scale (10 cm line anchored with descriptive adjectives). Subjective vision index (SVI) is calculated where 0 is very poor and 100 is a perfect SVI.[42] Only rudimentary validation was conducted (Table 3.9).[42] The Cronbach's α was 0.94, and the test-retest correlation was 0.79.[42] The final 24 items accounted for 67.5% variance on principal component analysis. Using SVQ as an outcome measure, it was reported that the bilateral Crystalens group had more favourable outcomes than the combination of Crystalens, ReZoom or ReSTOR intra-ocular lenses.[220]

3.2.4.10 Visual Function and Quality of Life (VFQoL)

The 16-item VFQoL was developed and validated in low- and middle-income countries context (India) using Rasch analysis.[12, 243] It was developed using the Garamendi-modified RSVP[222] and the Fletcher QoL[244] instruments. The intended population was URE. Most of the items of the VFQoL are on activity limitation and symptoms.

The VFQoL had satisfactory psychometric properties with ordered response categories and good item-fit statistics. On Rasch analysis, the initial five responses categories were reduced to four due to underuse of 'moderate' and 'severe' categories although all five response categories were reported to be ordered.[12] The final VFQoL had satisfactory measurement precision (PSI, 2.27).[12] There was no significant DIF. Targeting was slightly poor (difference between person and item means: 1.06).[12] Sufficient statistics for dimensionality (e.g. PCA variance explained by measure,

eigen-value of the first contrast) were not reported (Table 3.10).[12]

Table 3.10 Quality assessment of the refractive error-specific PRO instruments for LMIC settings

SN	Name of the PRO / Author (Date); Study population (Country; Sample size; refractive error; refractive correction)	Content quality / CTT-based psychometric properties and/or Rasch-based psychometric properties	Validity / Repeatability/ Responsiveness
1	Visual Function and Quality of Life (VFQoL) / Brady (2010)[12]; Urban India; N = 400; People with refractive error	Content: Item identification: C; Item selection: A Rasch: Response categories: A; MP: B; Item fit statistics: A; DIF: A; Targeting: B	Concurrent: A; Known-group: B
2	Refractive error Quality of Life scale–Long form (REQ-Thai -87)/ Sukhawarn (2011)[44] Thailand; N = 424; Emmetropia, myopia and hyperopia; Post-refractive surgery, Spectacles and Contact lens	Content: Item identification: C; Item selection: B / CTT: Internal consistency: A (4/6 subscales), B (2/6 subscales); Dimensionality: B	Concurrent: C; Known-group: C; Test-retest agreement: A
3	Near vision-related Quality of Life (NVQL) / Patel (2006)[54]; Tanzania; N = 1,564; Presbyopia; With or without spectacles	Content: Item identification: C Item selection: B / CTT: Acceptability: B; Targeting: C; Internal consistency: A; Item dependency: B	All: NR

Note: If the information on assessment criteria (Table 3.4) is not provided in this table, then either the test was not performed or the information was not provided. CTT = Classical test theory, DIF = Differential item functioning, LMIC = Low- and middle-income country, MP = Measurement precision, NR = Not reported, PRO = Patient-reported outcome

It was reported that the increase in VFQoL scores after use of ready-made or custom-made spectacles were large. However, custom-made spectacles offered slightly higher increase. Particularly, the participants with high astigmatism benefitted more from the custom-made spectacles.[243]

3.2.4.11 Contact lens Impact on Quality of Life (CLIQ)

The CLIQ was developed and validated using Rasch analysis.[46] Out of its 28 items, 16 are the same as in the QIRC.[28] The remaining 12 items are for issues specific to contact lens wear. Five response categories are employed.[46] Unlike in other previous refractive error-specific instruments (the RSVP[37], the NEI-RQL[36]) there are only two items on activity limitation indicating the possibility that other issues are more important for contact lens wearers. Scoring of the CLIQ was done in such a way that the higher score represents better QoL.[46] It had ordered response categories, satisfactory measurement precision (person separation index / PSI, 2.02), good fit-statistics, good targeting and good test-retest agreement (test -retest intra-class correlation coefficient, 0.86).[46] However, the dimensionality of the CLIQ was not reported (Table 3.7). The CLIQ has not been used as an outcome measure.

3.2.4.12 Student Refractive Error and Eyeglass Questionnaire (SREEQ)

The SREEQ was the only validated PRO instrument to assess the impact of refractive correction in children.[49] It was developed using Rasch analysis, on the framework of the PREP[48] to measure QoL in school-aged-children wearing spectacles.[49] The majority of the items are for assessing activity limitation and symptoms. The SREEQ has two parts. The first part consists of items on perceptions about uncorrected vision, and the second part consists of the items on perceptions about vision corrected with spectacles. The SREEQ consists of 10 matching items for both parts. The original 4-point rating scale was modified into 3-point rating scale after combining 'most of the times' and 'some of the times' to 'some/most of the times', as the rating scale for the items on corrected vision perceptions had disordered thresholds.[49]

Interestingly, despite the study sample being predominantly corrected with spectacles, the person separation index (PSI) was very low (0.57) for the items on corrected vision. Although the PSI for the items on uncorrected vision was satisfactory, this may be of little value as the respondents were predominantly corrected with spectacles. With this low PSI, further statistical analysis on item and person measures may not imply meaningful information as it indicates high level of noise in the measurement.[49] The developers reported that the SREEQ had satisfactory item-fit statistics but significant differential item functioning (Table 3.8). Dimensionality of the SREEQ was not reported.[49] They have also proposed a new shorter version of the instrument: SREEQ-R with 20 items. However, the SREEQ-R has not been validated yet.

3.2.4.13 Refractive Error Quality of Life Scale (REQ-Thai)

The REQ-Thai was developed using CTT for Thai adults with refractive error.[44] The content was derived from the existing questionnaires.[1, 28, 35, 36, 38, 40, 42, 43] The initial version consists of 87 items. A shorter version was also developed which consists of 48 items. The items could not be traced. Only a rudimentary validation has been reported (Table 3.10).[44] Cronbach's α ranged from 0.74 to 0.99 for five dimensions for the long version, and from 0.69 to 0.94 for the short version. The test-retest ICC was 0.92.[44] The REQ-Thai has not been used as an outcome measure.

3.2.4.14 The Freedom from Glasses Value Scale (FGVS)

The FGVS was developed using CTT to measure independence from spectacles after multifocal IOL surgery.[45, 53] It has items related to convenience, health concerns and emotional well-being. The FGVS has minimal content quality, as a comprehensive consultation with the patients was not done. Scores for each item range from one to five, higher score meaning a more positive evaluation.

The FGVS had a weak to moderate psychometric properties (Table 3.8). Low missing data

reported indicate good acceptability of the FGVS. However, a ceiling effect was observed in all five subscales. Cronbach's α ranged from 0.78 to 0.93. Scale-scale correlations between five subscales ranged between 0.27 and 0.66, and item to scale correlations ranged from 0.52 to 0.85.[45] Using FGVS as an outcome measure, it was reported that the participants not wearing spectacles had higher scores than those wearing spectacles after surgery.[45]

3.2.4.15 Near Activity Visual Questionnaire (NAVQ)

Three articles were reviewed on the NAVQ.[34, 237, 245] It was developed for presbyopic population with varifocal spectacles, multifocal contact lenses and different types of IOLs.[34] It has been tested by both CTT and Rasch analysis. All the items are on activity limitation. Initial items were derived from literature with minimal patient consultation.[34, 246] Higher NAVQ scores indicate worse visual function.

The NAVQ had good internal consistency, ordered response categories and good measurement precision. It could discriminate between people with and without near vision difficulty (person separation index = 2.92; area under receiver operating characteristic (ROC) curve = 0.91). The correlation coefficient of the questionnaire score with near visual acuity and critical print size were 0.32 and 0.27 respectively. The ICC was 0.72 and the Cronbach's α was 0.95.[34] Dimensionality, targeting and repeatability of the NAVQ were not reported (Table 3.8).[34]The NAVQ was responsive to the improvement in the outcomes from the presbyopic LASIK surgery. The scores remained stable after three months.[237]

3.2.4.16 Near Vision-related Quality of Life (NVQL)

The NVQL is predominantly an activity limitation PRO instrument developed for presbyopic population in a rural Tanzania.[54, 247] The items were derived from the NEI-VFQ [248] and the RSVP[38] and from the interviews with the key-informants. Patient consultation was not undertaken. Only elementary validation has been carried out; Cronbach's α was 0.83 (Table 3.10).[54] Using NVQL as an outcome measure, studies reported that presbyopes had more activity limitations in near tasks than non-presbyopes.[54, 247] The increasing difficulty of near tasks was associated with the magnitude of presbyopia.[54]

3.2.4.17 Named but non-validated PROs instruments

I reviewed 21 articles describing three named PROs whose psychometric properties, validity and reliability assessments have not been carried out: the Paediatric Refractive Error Profile (PREP) [48, 249-252] the Spectacle Survey[48] and the Contact Lens Dry Eye Questionnaire (CLDEQ and CLDEQ-8).[47, 52, 81, 185, 253-264] The content development (i.e. item identification) of these instruments was also not reported. The PREP aims to measure myopia-specific QoL in children. Most of its items are on

symptoms and health concerns. The Spectacle Survey aims to measure activity limitation in children when wearing or not wearing spectacles.[249] Similarly, the CLDEQ is the only dry eye questionnaire specific to refractive error i.e. to contact lens wear. It has items predominantly related to activity limitation, health concerns and emotional well-being.[48] Several other dry eye questionnaires are also used for assessing dryness related to contact lenses and refractive surgery, but none of them was originally developed for contact lenses or refractive surgery.[81, 265-269]

3.2.5 B. Vision but non-refractive PRO instruments

I identified 42 articles describing the use of 12 vision-specific but not refractive error-specific PRO instruments (Appendix C). However, none of them has been validated in refractive error populations. Most of these articles (n = 25) describe dry eye related questionnaires, mainly used to assess dry eye in contact lens and refractive surgery populations. These include the Ocular Surface Disease Index (OSDI)[164, 185, 265, 267, 270-279], the McMonnies questionnaire[81, 253, 264, 266, 280, 281], the Ocular Comfort Index (OCI)[81, 271, 282], the Dry Eye Questionnaire (DEQ)[52, 271], the Symptom Assessment iN Dry Eye (SANDE)[267], the Salisbury Eye Evaluation Questionnaire (SEEQ) for dry eye symptoms[269] and the Dry Eye questionnaire and Scoring System (DESS).[268, 283] Similarly, the Visual Function Index (VF-14 or VF-7)[160, 165, 284-288] and the Activities of Daily Vision Scale (ADVS)[289] have been employed to measure refractive error-specific activity limitation. Likewise, the other PRO instruments used to measure refractive QoL were the National Eye Institute Visual Function Questionnaire (NEI-VFQ)[161, 163, 290-295], the Vision related effect on Quality of Life (VQoL, later known as VCM1)[165, 296], and the Nursing Home Vision-targeted health-related Quality of Life questionnaire (NHVQoL)[160] (Appendix C).

3.2.6 C. Generic PRO instruments

I identified 17 articles describing the use of 16 generic PRO instruments as outcome measures in refractive error (Appendix C). All the PRO instruments were developed based on CTT and use traditional summary scoring. The majority of the generic PRO instruments (n = 12) have been used for studying the mental health status, emotion and other psychological aspects related to refractive correction (Appendix C).[48, 160-162, 187, 289, 297-303] Other generic PRO instruments have been used to assess general symptoms (pain)[304-307] and overall QoL.[160] The Psychosocial Impact of Assistive Devices Scale (PIADS) is the only non-refractive PRO instrument validated in refractive error (Table 3.8).[162, 297, 298]

3.2.7 Quality assessment of the PRO instruments

Approximately one-third (n = 17) of all the PRO instruments identified have been validated in refractive populations. Ideally, before using an instrument as an outcome measure, its

psychometric properties, validity, reliability and responsiveness should be carefully evaluated and proven adequate.[50] I extracted information on quality assessment (item identification, psychometric properties, validity, reliability and responsiveness) of these 17 instruments from 30 studies (Table 3.5 to Table 3.10). Based on the grades, the QoV (scores: 8 As, 2 Bs), the QIRC (scores: 7 As, 2 Bs) and the CLIQ (score: 6 As, 1 B) were the top-three existing PRO instruments in refractive error.

Table 3.11 Recommended superior quality existing PRO instruments in refractive error

Trait or concept being measured	Population	Patient-reported outcome instrument
Quality-of-life	Pre-presbyopic population with refractive correction	Quality of Life Impact of Refractive Correction (QIRC)[28]
Quality-of-life	Contact lens wearers	Contact Lens Impact on Quality of Life (CLIQ)[46]
Visual symptoms	Any refractive error populations	Quality of Vision (QoV)[33]
Activity Limitation	Presbyopia correction	Near Activity Visual Questionnaire (NAVQ)[34]

Note: PRO = Patient-reported outcome

3.2.8 Content coverage of the existing PRO instruments

From 18 of the 19 refractive error-specific PRO instruments, 590 items were extracted. About two-thirds (n = 392) of the items were for symptoms and activity limitation domains. The items were listed and grouped into 10 ophthalmic domains identified earlier.[30] The final list of unique items in these domains were obtained after merging the redundant items (i.e. items with the same colloquial meaning). The maximum reduction in number of items was obtained for the visual symptoms domain followed by the ocular-comfort symptoms. About 28% (n = 166) items were unique (Figure 3.3). Most of the unique items were on the activity limitation domain (47) followed by convenience (24), visual symptoms (20), health concerns (18), ocular-comfort symptoms (15) and emotional well-being (14) domains. A very few items exist in general symptoms, mobility, economic well-being and social well-being domains. Among the superior quality PRO instruments identified in this study, QIRC[28] and CLIQ[46] are the measures for comprehensive QoL with relatively wider coverage of QoL domains. However, they do not have sufficient number of items to evaluate each QoL domain independently. Majority of their items are on emotional, health concerns and convenience domains. They do not have items on general symptoms (e.g. headache due to refractive error), social well-being and mobility. Other PRO instruments that claim to measure comprehensive QoL also do not have items across all the domains of QoL.[1, 12, 36, 38, 43]

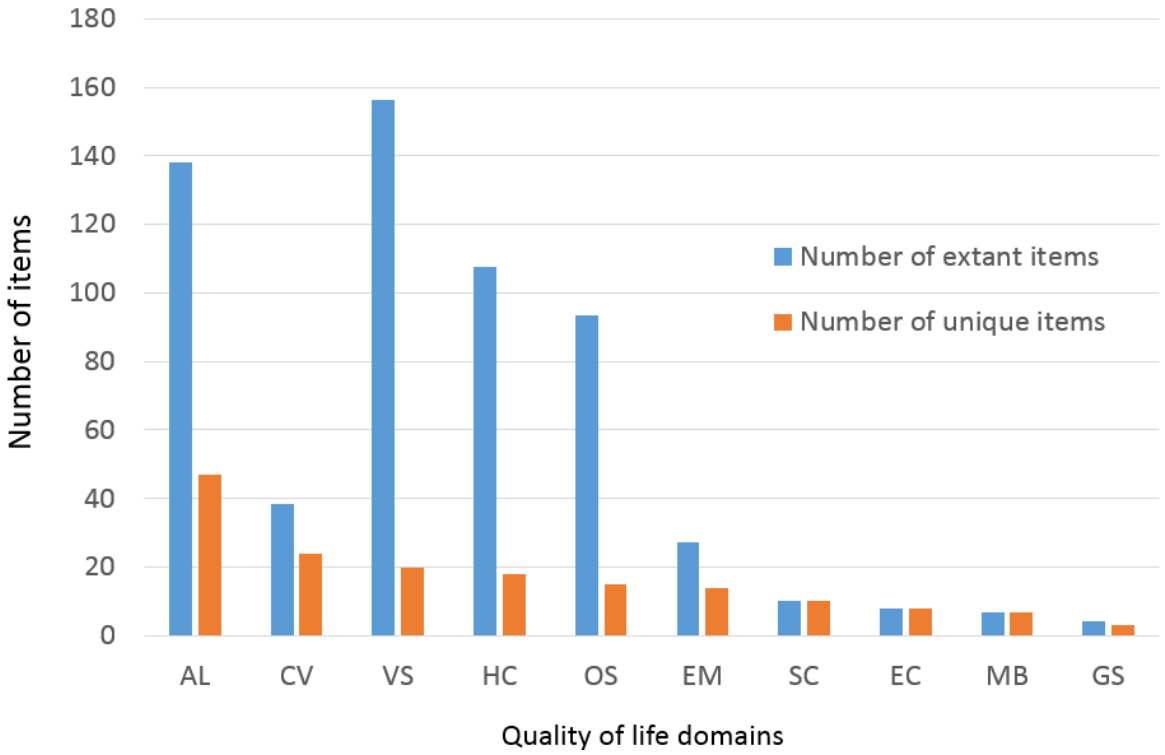

Figure 3.3 Number of the existing total and unique items by domain
Note: Number of total and uniqe items are represented by blue and orange bars respectively. AL = Activity limitation, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, OS = Ocular-comfort symptoms, SC = Social, VS = Visual symptoms

3.2.9 PROs for corrected and uncorrected refractive error

Almost all the PRO instruments were developed to assess outcome for refractive correction (Figure 3.4). The VFQoL[12] and the NVQL[54] were the only two PRO instruments targeted to URE. The NVQL has been used in both corrected and uncorrected populations. The items in the NVQL were adapted from the NEI-VFQ and the RSVP.[38, 248] Similarly, content of the VFQoL was derived from the Garamendi modified RSVP and the PRO developed by Fletcher *et al.*[222, 244]

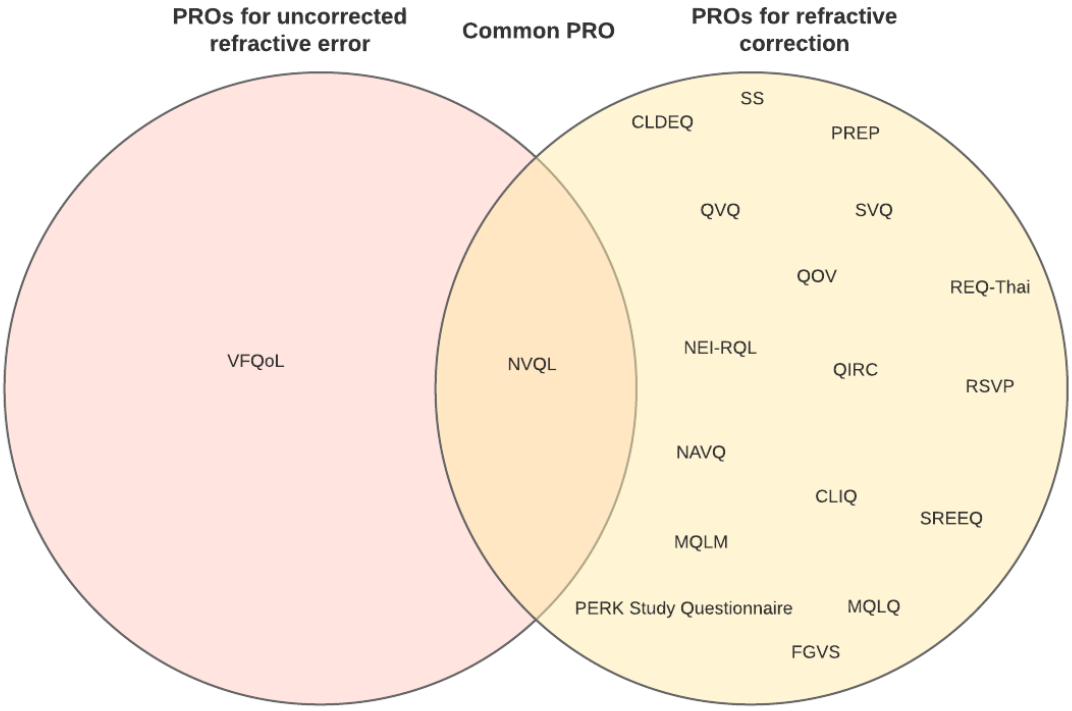

Figure 3.4 Patient-reported outcome instruments specific to uncorrected or corrected refractive error
Note: CLDEQ = Contact Lens Dry Eye Questionnaire, CLIQ = Contact Lens Impact on Quality of Life, FGVS = Freedom from Glasses Value Scale, MQLM = Multidimensional Quality of Life for Myopia, MQLQ = Myopia-specific Quality of Life Questionnaire, NAVQ = Near Activity Visual Questionnaire, NEI-RQL = National Eye Institute Refractive Quality of Life, NVQL = Near Vision-related Quality of Life, PERK = Prospective Evaluation of Radial Keratotomy, PREP = Paediatric Refractive Error Profile, QIRC = Quality of Life Impact of Refractive Correction, QoV = Quality of Vision, QVQ = Quality of Vision Questionnaire, REQ-Thai = Refractive Error Quality of Life Scale, RSVP = Refractive Status and Vision Profile, SREEQ = Student Refractive Error and Eyeglass Questionnaire, SS = Spectacle Survey, SVQ = Subjective Vision Questionnaire, VFQoL = Visual Function and Quality of Life

3.2.10 PROs for low- and middle-income country settings

Out of 149 studies reviewed, only six were carried out in low- and middle-income countries. These studies were from India,[12, 243, 283] Tanzania,[54] Rural China[247] and Thailand[44] for people with refractive error including presbyopia. The studies in low- and middle-income countries employed three refractive error-specific PRO instruments (the VFQoL,[12, 243] the REQ-Thai,[44] and the NVQL,[54, 247]) and one vision-specific non-refractive PRO instrument (the DESS[283]). Although the three refractive PROs were developed for the refractive error populations in low- and middle-income country settings, their items were derived from the other existing PRO instruments originally developed for high-income countries. They have items predominantly for assessing activity limitation although they claim to measure comprehensive QoL.[12, 54, 243, 247]

3.2.11 Discussion

A large number of PRO instruments were available for measuring refractive QoL (Appendix C). 19 refractive error-specific PRO instruments were identified. The NEI-RQL[36] and the RSVP[38] were the most widely used refractive error-specific PRO instruments. Several vision but non-refractive PRO instruments and the generic PRO instruments were also used in refractive populations. In this review, a significant number of studies used PRO instruments that have not been validated for refractive error populations. None of the non-refractive PROs were validated in the refractive error populations except the PIADS.[162] Among those PRO instruments validated in refractive error, most of them were validated using CTT and used summary scoring.

Based on the quality assessment criteria (Table 3.4), The QIRC[28], the QoV[33] and the CLIQ[46] ranked higher than the others (Table 3.11). All these three psychometrically superior PRO instruments were developed using Rasch analysis. This is in agreement with the literature that demonstrates that the questionnaires developed or rescaled using Rasch analysis produce better quality scales than those by CTT.[18, 19, 26, 68, 101, 308] This is probably because Rasch analysis can identify critical shortcomings and provides opportunities to improve them in a PRO instrument. However, even these best PRO instruments had limitations. The 20-item QIRC was reported to be multidimensional, and was split into two unidimensional scales.[232] The QoV suffered from poor targeting and differential item functioning.[33] Similarly, dimensionality and differential item functioning of the CLIQ has not been evaluated yet.[46] The most widely used instruments, the NEI-RQL and the RSVP, had problems in their psychometric properties. Both of them have subscales and claim to cover many domains of QoL. However, as they have a few items for each of the domains, they had poor measurement precision and targeting in general.[71, 90, 222] Poor quality instruments may provide incorrect or biased results leading to false conclusions.[50] This is even more important for PRO instruments due to the subjective nature of the constructs measured that are not directly measurable.[50] The selection of a PRO instrument in any study should be guided by its quality, not by how frequently it is used or by the reputation of the developers. In addition to the quality of the PRO instruments, objectives of the study and the target populations should be considered when choosing the appropriate PRO instrument.

Among the PRO instruments identified as superior to others, the QIRC and the QoV have performed well as outcome measures. The CLIQ has not yet been used as an outcome measure. The QIRC has been useful to detect differences in QoL impact from refractive corrections (spectacles, contact lenses and refractive surgery). The studies have demonstrated that refractive surgery offered better QoL results than spectacles or contact lens.[27, 233] The QIRC has also been proven to be responsive to various refractive surgical procedures and to surgery complications.[19,

[228-230] Similarly, the QoV has been proven to be responsive to various surgical procedures.[234, 235, 237]

New and technologically advanced methods are now available for refractive correction. The popularity of new types of contact lenses and refractive surgery is growing.[11, 309] Newer procedures claim to be better. However, QoL benefits from the newer treatment procedures should be demonstrated.[101, 197, 228] The importance of PRO instruments is indisputable for ongoing evaluation of the new technological procedures.[101, 197, 228] From the results of this review, it is evident that the PRO instruments may be sensitive to assess effect of complications on QoL.

Although an abundance of PRO instruments is available for measuring QoL in refractive error, most of them had shortcomings in terms of their content coverage. Among the PRO instruments that claimed to measure comprehensive QoL, their content was not the same. A majority of them had items predominantly for activity limitation and symptoms domains only (Appendix C).[1, 36, 38, 43, 49] The superior quality PROs: QIRC and CLIQ had relatively wider coverage of QoL domains, but their content was relevant only to the pre-presbyopic adults with refractive correction (not URE). And whether the content will be applicable to the low- and middle-income country settings is doubtful. Similarly, the vision but non-refractive PRO instruments were not developed specifically for refractive error. Therefore, the content in those PRO instruments may not represent issues that matter to the people with refractive error. Hence, they may not be able to capture refractive QoL issues. For instance, the NEI-VFQ has been reported to be insensitive in detecting QoL differences between refractive corrections.[163] Likewise, generic PRO instruments may not be sensitive enough to capture the QoL issues specific to refractive error.[50]

Uncorrected refractive error has always remained the major cause of visual impairment and a significant cause of blindness globally.[2, 5, 6] Despite the frequency and the magnitude of the URE burden, the PRO research in this arena is overlooked and underappreciated. The content of the two PROs for URE (the VFQoL and the NVQL) was derived from the existing PRO instruments for refractive correction or non-refractive populations. Hence, the issues important to people with URE may have been under-represented.

Similarly, the VFQoL[12] , the REQ-Thai[44], and the NVQL[54] were the only PRO instruments developed for the refractive error populations in low- and middle-income country settings. Their items were derived from the other existing PRO instruments developed for the high-income countries. Hence, these PROs may not capture unique QoL issues pertinent to low- and middle-income country populations (Appendix C). This may imply that there is a need for a refractive error-specific PRO instrument suitable for the low- and middle-income country setting.

This study comprehensively reviewed all the studies on PRO instruments in refractive error, in terms of types of PRO instruments (refractive error-specific, vision-specific but not refractive error-specific, and generic), and various types of refractive error populations (spectacles, contact lens, refractive surgery). The PRO instruments based on both CTT and Rasch analysis were assessed for quality. However, caution should be taken as the grading of the PRO instruments was purely based on the information provided in the reviewed articles only, and I have not performed any tests to independently verify the information published in those articles. Therefore, there is a chance that the PRO instruments that are classified as having poor quality, may in fact perform well if tested. One could argue that another limitation of this paper is not including utility measures. Utility measures were excluded as they do not directly measure QoL.

This systematic review identified that there is a need for a comprehensive and psychometrically sound PRO instrument to measure refractive QoL. Even the best existing PRO measures had limitations. The existing PRO measures in refractive error are paper- and pencil-based. Both types of PRO measures, either developed or validated by CTT or by IRT (e.g. Rasch analysis), have a fixed set of items administered to individuals with different levels of ability (static and inflexible). Therefore, they either measure low range of trait difficulty, or have low precision if they cover wide range of difficulty levels. They are often poorly targeted to the wide spectrum of refractive error. The way forward can be moving on from conventional questionnaires to item banking and from paper-and-pencil method of administration to Computer Adaptive Testing (CAT) system. [18, 23, 26, 30] An item bank has a large number of items on a latent trait (e.g. activity limitation, emotional well-being, symptoms, social well-being) calibrated on a measurement continuum by the modern psychometric methods such as Rasch Analysis.[23] An item bank can therefore cater for the QoL issues relevant to people across diverse spectrum of refractive error subtypes, correction types and socio-demographics. The CAT system is based on an adaptive technology. It is an advanced and efficient mode of administering individually tailored items matching item-difficulty to the person-ability. The CAT can be used in various electronic platforms such as computer, iPad or mobile phone. Only a few items are selected from a bank of items to obtain an accurate measurement. In essence, the final scores are determined by bracketing technique, analogous to the principle used by Humphrey perimeter to determine the threshold values.

Item banking with CAT can rapidly measure multiple domains of QoL as only a few items tailored to individuals are required to be administered. This decreases respondent burden and can save clinician's time. Another advantage of the CAT system is that it provides real time assessment with quick feedback enabling immediate use of the data. With rapid evolution of technology and growing use of electronic devices such as mobile phones even in the remote areas, concerns about

access, familiarity or representativeness (of the CAT / data) may not be a challenge.[18, 23, 29, 58, 310] In the long run, the application of the CAT may completely replace the use of paper- and pencil-based PRO instruments. However, developing a new PRO instrument is a lengthy process. Therefore, the PRO measures identified as of superior quality in this study are recommended to be used until technologically advanced CAT system is available and readily accessible to the clinicians or researchers. These PRO instruments are easily and freely available for use. However, they have to be culturally adapted and retested to check if they perform well or not before using as an outcome measure in a new population significantly different than the population they were originally validated to.[25]

3.3 Situating the doctoral thesis in the literature review context

Final section of the discussion section (Section 3.2.11) above highlighted the limitations of the existing research and indicated the direction for future research. The 'knowledge gap' was identified. Although refractive error-specific PROs have been widely studied, the current literature is not robust enough to provide clear information on the extent of impact of refractive error on QoL primarily due to the limitations of the existing PRO instruments. With a rapid proliferation of new PRO instruments, a PRO-active period has commenced with an increasing demand for measuring PROs in a robust manner. There is a need for scientific and comprehensive PRO instrument in refractive error. This justifies the overarching aim of this doctoral study: to develop technologically advanced PRO instruments in refractive error. Item banks administered through a CAT system may offer comprehensive, precise, and rapid evaluation of refractive error-specific QoL parameters. As outlined in Chapter 1, this thesis consists of first two phases of the item banks development project.

In this project, it is important to consider a balance between clinician's, researcher's, public health, and patients' perspectives as they may not be exactly the same. While all may have the common aim of measuring refractive error-specific QoL, the angle of looking at the scientific rigor of constructing this comprehensive measure may be different. For example, a clinician or a researcher working in myopia for decades may consider myopia a completely different entity than hyperopia and presbyopia, and may think measuring them together is not possible. Moreover, they may think measuring QoL of high myopia and mild myopia by a common scale is not possible. Similarly, researchers in myopia genetics may consider early onset myopia and late onset myopia very different entities. The same disparity may apply for hyperopia, astigmatism and presbyopia. However, there are several common issues in all refractive error sub-groups, particularly from patients and public health perspectives. For example, whether it is low or high myopia, hyperopia or presbyopia, people have to live with the inconveniences because of having to wear spectacles.

The decision on lumping and splitting of conditions to make a sensitive but comprehensive and practical measures is not straightforward and always debatable.[139] However, this should be guided by purpose and methodology. For instance, comprehensive refractive error-specific PRO instrument applicable to all refractive error sub-groups (spectacles, contact lens, refractive surgery; myopia, hyperopia, presbyopia) may not be an appropriate idea when we are developing a short questionnaire. A short questionnaire may not cater for all the important issues specific to each sub-group. An item bank which can include a large number of items may provide a unique opportunity to cater for the issues of all types of refractive error and correction sub-groups.

Moreover, being able to measure all sub-groups with a common PRO instrument offers several advantages. It enables effective comparison of QoL status between subgroups. Direct assessment of change in QoL status with an intervention can be measured by the same PRO instrument if it is developed for both URE and refractive correction populations.

As lumping and splitting items for various sub-groups is a challenge in PRO instrument development, whether an item bank should be developed for both adults and children is another debatable topic. Children (< 18 years old) were not included in this study. This study is a part of the Eye-tem bank project which is developing item-banks for all ophthalmic conditions only for adults.[30] QoL issues in children and adults are very different, and often not comparable. A single item bank may not be able to cater for the diverse QoL issues for both children and adults. Measurement of QoL in children is limited by their language skills and comprehension, and limited logical judgment, and therefore more difficult to measure. Moreover, QoL in children is interlinked with developmental aspects and with time their views about QoL changes. Often proxy measures (e.g. interviews with parents) are used to measure children's QoL. However, there may be discrepancies between children and their proxy in judgement of QoL issues, about refractive error outcomes (Figure 3.5).[311] Conducting qualitative studies to identify QoL issues would therefore be very complex if children were included in this study. Separate similar exercise has to be carried out for children to develop children-specific item bank in the future.

Figure 3.5 Child, parent and clinician disparity in refractive error correction outcomes

Some researchers may not be comfortable with terminology used in this study. I adopted the commonly used terminology: 'patient' reported outcomes (PROs) rather than 'client' reported outcomes. Refractive error is an ophthalmic condition, but not a disease. People with refractive error are not patients but 'clients'. However, I adopted the terminology to be consistent with the common usage.

In summary, this chapter established the need of a comprehensive and scientifically robust PRO instrument in refractive error. This justified the objective of this doctoral study, i.e. to develop item banks to measure QoL impact of refractive error. In the next chapter, qualitative studies which explore the QoL impact of refractive errors or their correction methods are described. These qualitative studies are the sources of content for the refractive error-specific item banks.

3.3.1 Outputs from this chapter

Two systematic reviews have been published from this chapter (Appendix D).[15, 16] Search for both studies was conducted in June 2016. The first published paper was the comprehensive review paper published in the Optometry and Vision Science journal.[16] The second systematic review paper was published in the Journal of Refractive Surgery.[15] This paper evaluated PRO instruments specifically focusing at the refractive surgery outcomes. The latter paper also won the Flinders University Vice Chancellor 'Best higher degree by research publication award'. This paper also attracted news coverage (Appendix E). The information regarding the refractive error outcomes in spectacles and contact lens wearers discussed in this chapter, is not yet published. In this chapter, results are discussed in more detail than in the published studies.

Chapter 4. Impact of refractive error on people's quality-of-life: a qualitative analysis

This chapter presents the qualitative findings from the interviews conducted with people with refractive error. Patient consultation (interviews and focus group discussions) is one of the most important steps in identifying content for a PRO instrument.[18, 25, 26] Identification of items from these interviews will be discussed in Chapter 5. Prior to that, this chapter aims to explore impact of refractive error and its corrections on QoL. It is essential to understand issues that are important to people with refractive error before embarking on to develop a PRO instrument to measure QoL for them.

This chapter has three parts. The first part (Section 4.1) presents qualitative study conducted in Australia, a high-income country setting. The second part (Section 4.2) presents the qualitative study conducted in Nepal, a low-income country setting. Both these sections are laid out in IMRAD (Introduction, Methods, Results and Discussion) structure. Rationale behind conducting these qualitative studies (and a reason for conducting second qualitative study in Nepal, after the first qualitative study was already conducted in Australia) are described in the introduction sections (Section 4.1.1 and Section 4.2.1). The third part of this chapter (Section 4.3) is the critical appraisal and conclusions of the qualitative findings from both the settings.

4.1 Impact of refractive error on quality-of-life: a qualitative study in a high-income country setting (Australia)

4.1.1 Introduction

As discussed in Chapter 3, there is an abundant literature that reports a huge impact of refractive error on people's QoL based on the clinical experience and quantitative measurements.[6, 8, 27, 28, 46, 235, 312] However, there exists a stark disparity in a clinician's and a patient's perspective (Figure 4.1).[313] Clinicians tend to believe that refractive correction (spectacles, contact lenses or refractive surgery) can address most of the issues of URE. However, similar to URE, refractive correction could impact on people's QoL.[15, 27, 28] Patients' viewpoints are therefore crucial in understanding refractive error, in promoting uptake of refraction services and in making choice of refractive corrections.[18, 22, 26-28] Understanding patient's viewpoints is essential in achieving goals of refractive error services, like any other health care services, which include reducing symptoms, minimising visual disability, and improving QoL.

Figure 4.1 Disparity between clinicians' and patients' perspectives

The impact of refractive error on people's lives, from their perspectives, can be explored quantitatively or qualitatively. The impact may be quantitatively measured by using PRO instruments (e.g. questionnaire, item-bank).[18, 314] Likewise, impact of refractive error on people's lives can be explored qualitatively through in-depth interviews or focus group discussions. Qualitative research often complements quantitative research.[315-317] It has more flexible methodology and therefore captures more comprehensive information compared to quantitative research that is restricted to responses to a structured questionnaire.

Despite the frequency and magnitude of the burden of refractive error, qualitative literature exploring impact of refractive error on QoL from patients' perspectives is sparse. Although quantitative studies may be important in measuring strengths of relationships between variables, qualitative studies are more important in capturing contextual information from peoples experiences on determining impact of refractive error on QoL.[318] Ideally, patient consultation through in-depth interviews or focus group discussions is one of the most important stage of developing the content of a high quality PRO instrument.[15, 16, 18, 26] Surprisingly, these preceding qualitative studies have not been discussed or published in detail for any of the publication that reported the development of the existing refractive-specific PRO instruments.[16] Thus, despite the high prevalence of refractive error, the subsequent implications on QoL from patients' perspectives are overlooked and underappreciated. Therefore, I designed this study to qualitatively explore the

issues that affect QoL of people with refractive error. The issues identified will be extracted to inform the content of the refractive error item banks; this process is described in Chapter 5.

4.1.2 Methods

In-depth telephone and face-to-face semi-structured interviews were conducted with 48 adults with refractive error including presbyopia. The participants were recruited from the Flinders Vision clinic, the Ashford Advanced Eye Care centre, and through community advertisements. The clinical details such as diagnosis, visual acuity and prescription were obtained from the clinical notes for those who were recruited from the clinics. For those recruited from the community, a detailed clinical assessment including objective refraction was carried out at Flinders Vision clinic to obtain necessary clinical details. Definition and classification of refractive error used in this study are described in Chapter 3 (Section 3.1.1.1). Refractive error of magnitude ±0.50 dioptre was considered significant.

Purposive sampling was done to include adults from diverse groups of refractive error and types of corrections. However, people with other ocular co-morbidity/ies which may significantly affect QoL, such as significant cataract, age-related macular degeneration were excluded from the study (Table 4.1).

Table 4.1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Refractive error with or without corrections (spectacles, contact lenses, refractive surgery)	• Any clinically significant ocular pathology that may impact on QoL domains
• 18 years old and above	• Mental health problem (insufficient cognitive awareness)
• Best corrected visual acuity > 6/18	• Not willing to participate
• Ability to understand and speak English language, and ability to give consent	
• Signed informed consent	

Informed written consent, and clinical and demographic information were obtained prior to the interviews using a background questionnaire (Appendix A). The background questionnaire also consisted of questions on frequency of wearing spectacles or contact lens, using a five-point Likert scale (very often, quite often, occasionally, rarely, never).

An interview guide was developed based on the literature review and clinical experience (Appendix F). It consisted of broad questions exploring refractive error-specific issues affecting QoL (Table 4.2). The interviews were conducted in English language and data were collected until the thematic saturation was achieved. Data saturation was defined when there was repetition of items/issues and new items were no longer obtained. The interviews were audio-recorded, transcribed

verbatim, coded and analysed.

Table 4.2 Sample questions in the interview guide

Broad concepts	Sample question
Symptoms	What are some of the symptoms you experience as a result of refractive error or its corrections (i.e. spectacles, contact lenses, laser refractive surgery)
Correction impacts	What are your experiences with having to wear spectacles?
Disadvantages	In your experience, what are the major inconveniences associated with having refractive error and having to wear corrections (i.e. spectacles, contact lenses) or undergo laser refractive surgery?
Finance	How does having refractive error impact you financially?
Perceptions	How do you feel about your refractive error?
Everyday tasks	What sort of difficulties do you experience in your day-to-day life because of refractive error and having to wear spectacles/contact lenses?

Coding process was an iterative process consisting coding and categorising as indicated by the data. Coding was done in the NVivo Software, Version 11 (QSR International Pty Ltd., Melbourne, Australia). Issues related to refractive error affecting QoL were identified in the transcripts and coded comprehensively. Thematic analysis was done by categorising the codes (discrete concepts) into categories and themes based on the semantic meaning of the codes (Figure 4.2). It was an iterative process consisting both deductive and inductive processes.[319] Initial codes and categories were generated from the interview guides (deductive process). New categories that consisted of similar codes were added as required to capture the participants' comments in detail (inductive process). During this inductive process, the themes were identified by techniques such as repetitions (the more the concept appears in the text, the more likely it is to be a theme), analogies, similarities and differences.[320]

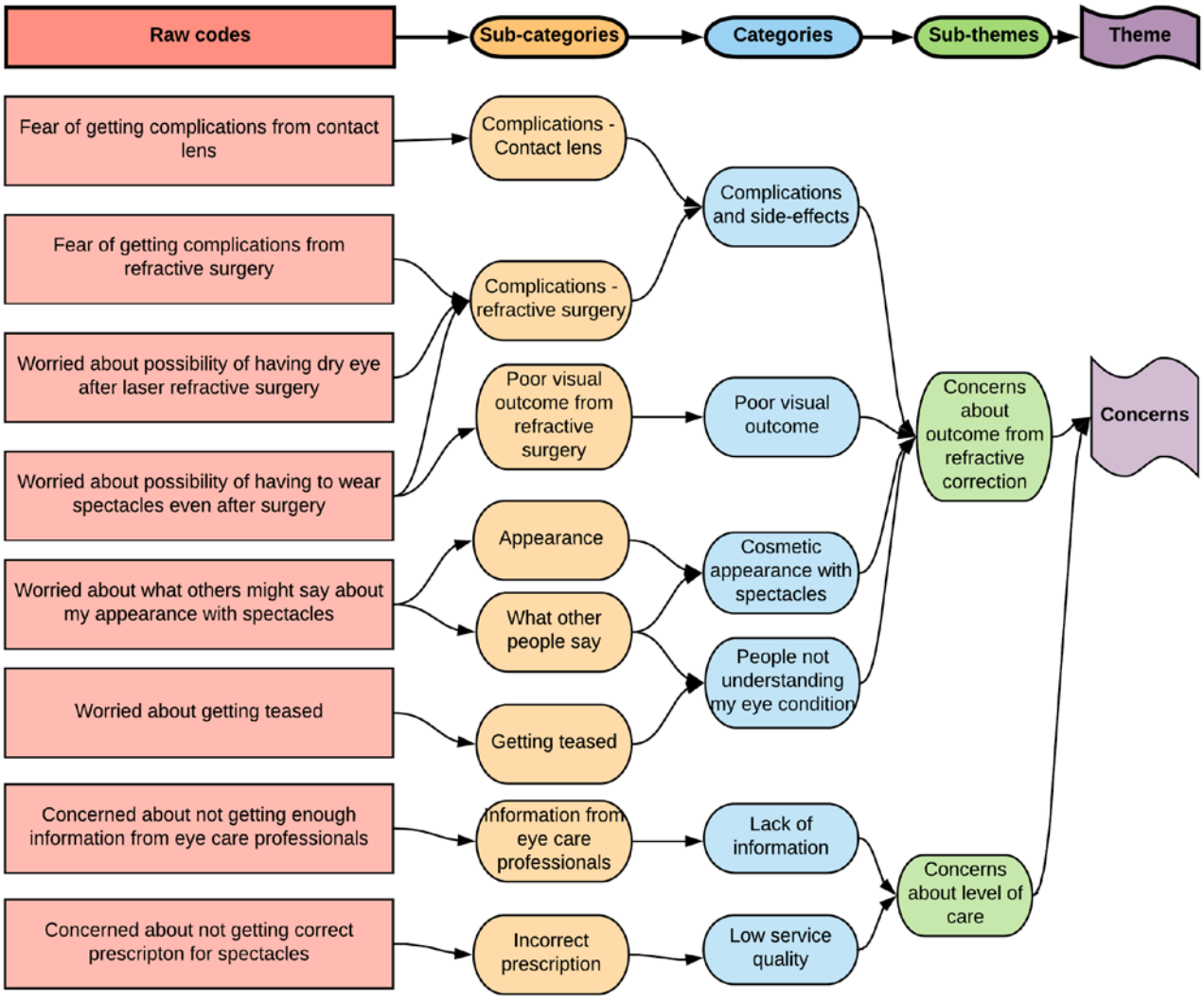

Figure 4.2 An example showing identification of categories and themes from raw codes

4.1.3 Results

Participants represented diverse age-groups, types of refractive error and refractive correction (Table 4.3). Median habitual visual acuity was 0 logMAR (Snellen equivalent 6/6) with all participants' visual acuity better than 0.30 logMAR (Snellen equivalent 6/12). The magnitude of myopia ranged from -0.62 D to -16.00 D spherical equivalent, and of hyperopia ranged from +0.75 to +12.0D spherical equivalent. All the contact lens wearers used spectacles as well. All the participants who had refractive surgery used spectacles prior to surgery. The coded segments, categories and sub-themes identified rooted to six major themes (Table 4.4, Figure 4.3). The major themes are described below with some supporting quotes extracted from the interviews.

Table 4.3 Demographic and clinical characteristics

Median age: [(Min, Q1, Q3, Max); years]	49 (22, 34.5, 59, 76)
Female [n (%)]	28 (58.3)
Country of birth [n (%)]	Australia 34(70.8), UK 5(10.4), Others 9(18.8)
Type of refractive error: (n = 48)[a]	
Myopia n (%), [Severity] [b]	31 (64.6) [Low = 13; Moderate = 8; High = 10]
Hyperopia n (%), [Severity] [b]	10 (20.8) Low = 6; Moderate = 3; High = 1]
Surgical emmetropia [n (%)]	7 (14.6)
Presbyopia [n (%)]	23 (47.9)
Astigmatism [n (%)]	22 (45.8)
Type of refractive correction[a]	
Spectacles [Frequency of use]	39 (81.3%) [Very often, 20: Occasionally, 15; Rarely, 4]
Contact lenses (Soft–daily wear / monthly / annual; Gas permeable; Orthokeratology) [Frequency of use]	17 (35.4%) [Very often, 9; Occasionally, 6; Rarely, 2]
Refractive surgery (Laser assisted in-situ Keratomileusis, Photorefractive keratectomy, Radial keratotomy)	17 (35.4%)

[a]Number or percentage of participants is more than the total number or 100% of participants as many had more than one type of refracrive error or correction.[b]Grading of severity of myopia and hyperopia (spherical equivalent) in dioptres: Low, |0.50| to |3.00|; Moderate |3.25| to |6.00|; High > |6.00|

Table 4.4 Major themes on refractive error-specific quality-of-life

Theme no	Major themes	Number of coded segments
Theme 1	People with refractive error were worried about their condition.	769
Theme 2	People with refractive error had difficulty doing physical, recreational and day-to-day activities.	471
Theme 3	People with refractive error were bothered by the inconveniences they had to live with.	326
Theme 4	People with refractive error lived with unwanted ocular and non-ocular symptoms.	319
Theme 5	Refractive error affected people's psycho-social well-being.	305
Theme 6	Refractive error had economic implications in people's lives.	177

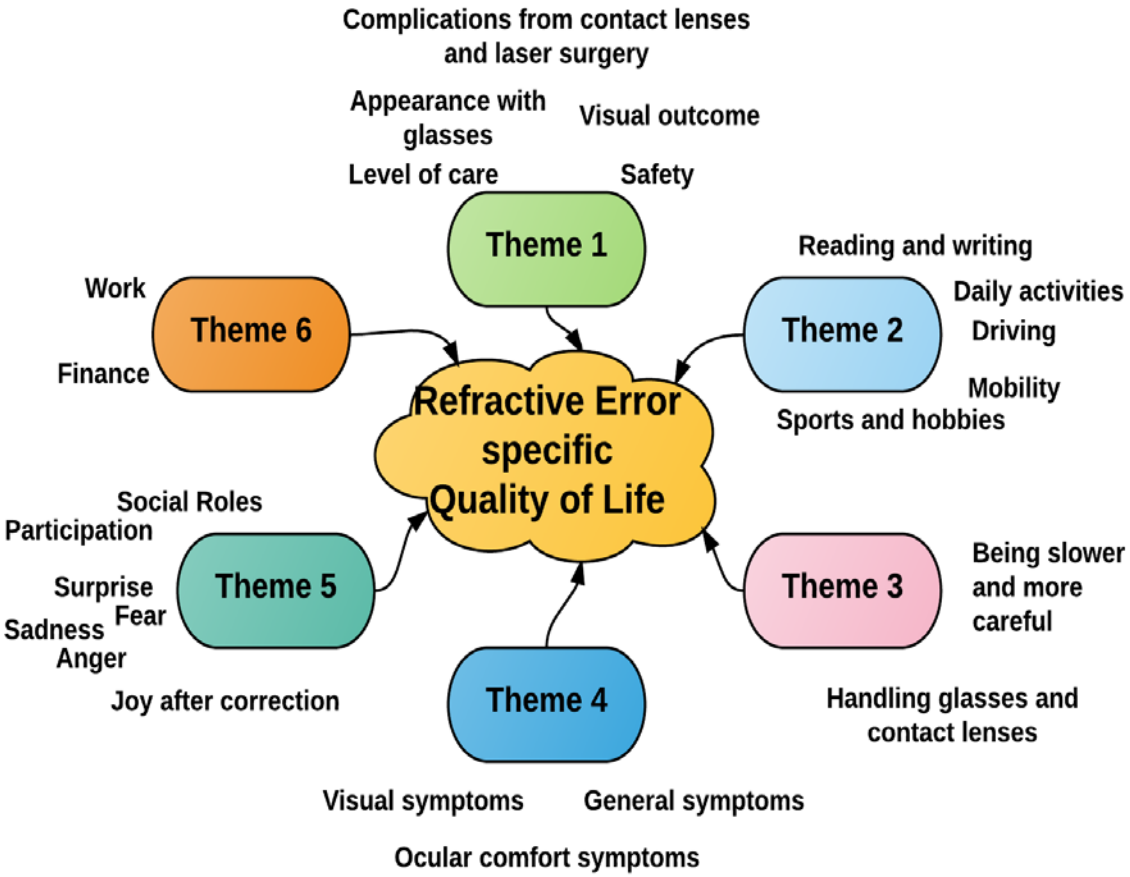

Figure 4.3 Categories contributing to the major themes

4.1.3.1 Theme 1: People with refractive error were worried about their condition

The most important theme identified based on the number of utterances was regarding the participants' concerns about their status resulting from refractive error. This included concerns about cosmetic appearance with spectacles, changing prescription, complications from contact lens wear or laser refractive surgery, outcomes of laser refractive surgery, ocular health and personal safety and refraction services (quotes 1-10).

The majority of participants wearing spectacles expressed concerns about their cosmetic appearance (quote 1). Many participants recalled stigma associated with the spectacles when they were purely worn as a medical device. Some reported that with time, spectacles had become a part of their fashion (quote 2). Others said that they got used to their appearance with spectacles. For some, the concerns about their cosmetic appearance with spectacles had disappeared with age (quote 3).

> *1. If you're going out for a night with friends, you know, you want to feel pretty, you want to not have your glasses. (028; high myopia; spectacles)*

> *2. Nowadays it's fashionable to wear glasses but it was very bad when I was younger. (048; myopia; spectacles)*

3. I just got to a point in my life where it was like 'oh I don't care. Those who love me, love me. Beauty is in the eye of the beholder and it doesn't mean that you don't have to wear glasses'… and certainly, priorities change with age. (018; high myopia; spectacles)

Most of the participants were concerned about their eyesight, ocular health and overall personal safety. Many expressed their concerns about the possibility of losing eyesight or worsening of prescription in the future (quote 4). Some of the participants, particularly those who considered having laser refractive surgery reported concerns about their continuously changing prescription. Similarly, participants were concerned about the potential unwanted sequel of refractive error (e.g. retinal detachment) (quote 5), and the potential complications of wearing contact lenses or having laser refractive surgery. A few of them expressed concerns for not being eligible for laser refractive surgery, or not being able to wear contact lenses because of their other eye condition such as severe dry eyes (quote 6). A few of them reported that they were worried about their personal safety due to poor eyesight (quote 7). Specific safety concerns included risk of falling or tripping. Participants wearing spectacles also mentioned their heightened injury concerns while playing sports. They were also concerned about breaking, dropping or scratching their spectacles.

4. It worries me when my prescription changes. (031; hyperopia, presbyopia; spectacles)

5. Because I'm so short sighted I'm now getting problems with these retinal tears and my eyes are falling apart. (024; high myopia; spectacles)

6. It's hard for me to find suitable contact lenses for me. I found one but I still couldn't wear them very often because of my dry eyes. (044; myopic astigmatism; spectacles, contact lens)

7. I'm a bit concerned about safety while driving at night. I don't want to be a burden or an accident waiting to happen (020; myopia; spectacles)

Many participants reported refractive correction and refractive service related issues (quote 8). Few of them expressed dilemma in choosing appropriate correction option (spectacles, contact lenses or surgery). Similarly, many complained about the negative way clinicians treated them, and about inadequate information provided to them by clinicians. A few of the participants also reported that they did not understand their condition well enough (quote 9). Other concerns included the possibility of losing independence in the future, being treated differently by others, and passing on refractive error to their children (quote 10).

8. People like me fall between the cracks. I'm not technically low vision although I find a lot of low vision strategies very helpful. (024; high myopia with floaters; spectacles)

9. I always, rightly or wrongly, thought that was only so much if you were–long sighted so that you needed [laser refractive surgery] for short stuff? (019; myopic astigmatism; spectacles)

10. I'm worried that my son will have to wear glasses. I think that [doctor] said like genes - you know, he said like I will inherit my eye problem to him. (006; myopic astigmatism; spectacles)

4.1.3.2 Theme 2: People with refractive error had difficulty doing physical, recreational and day-to-day activities.

All the participants reported that they had experienced limitations/difficulties in performing day-to-day activities because of refractive error. They expressed difficulty in reading, driving, sports and recreational activities, and other myriad of day-to-day activities. Refractive corrections generally reduced these limitations. However, specific issues were affected by type of correction e.g. wearing thick rimmed spectacles reduced peripheral vision making driving difficult (quotes 11-20).

Most of the participants reported difficulty with reading at near, intermediate or far distances. A few reported problems reading at variable distances (quote 11). Myopes had difficulty reading at far such as reading power-point projected slides and telling time from a wall clock (quote 12). Many recollected their memory of having trouble reading the board when they were in school. On the other hand, presbyopes and hyperopes had difficulty reading newspapers, books and magazines, restaurant menus, small print on medicine bottles, supermarket labels, or phone books at near (quote 13). Some of them reported reading problems especially in dim light. Similarly, older presbyopes had difficulty reading on computer screens. A significant number of participants who had refractive surgery or who used contact lenses reported difficulty using computer due to photophobia or dryness related symptoms.

> *11. I basically can only read at a fixed distance. If I'm trying to read a paper on the desk and then looking up and down at the computer I will get really severe headaches extremely quickly and I get very, very dizzy and quite nauseous. (024; high myopia; spectacles)*

> *12. In the lectures, I couldn't read the front board. (013; hyperopia; laser refractive surgery, spectacles, contact lens)*

> *13. No, my long vision's good, really good, but my short vision, when I read, when the phone rings or whatever, I can't see the number. When I read the paper, I can't see the words. (001; presbyopia; laser refractive surgery, spectacles)*

A majority of the participants said that they had problem with sports, or leisure activities. Many of them had difficulty playing outdoor sports such as football, cricket, volleyball, baseball, basketball, tennis, and hockey with spectacles on (quote 14). Some of them reported problems judging the ball when playing ball games like tennis and cricket. Majority of the participants, particularly those who wore spectacles, reported difficulty and inconvenience when swimming (e.g. not being able to find the way back, not seeing friends around them); a few of them said that they stopped swimming because they no longer enjoyed it due to trouble associated with navigating in and around the pool (quote 15). Many participants reported difficulty in doing recreational activities like playing other water-sports (snorkelling, skiing, scuba-diving, reef-water walking, playing water-polo, rowing), watching television, dancing, horse-riding, hiking and cycling (quote 16).

> *14. Wearing glasses and playing cricket isn't a good combination. (003; high myopia; spectacles)*

15. Went off and started doing swimming and things that–seriously I hadn't swum in a pool for years. (021; myopia; post-laser refractive surgery)

16. I could not lie on the lounge and watch TV because it skewed my vision through my graduates. (030; high myopia; spectacles)

About two-thirds of the participants had difficulty driving in various conditions (quote 17). Specific driving related tasks that were uttered to be difficult included reading road signs, judging distance between their vehicle and the vehicle in front, and seeing halos around lights. For a majority, driving at night was more problematic. Some of the participants reported difficulty noticing other cars or pedestrians while driving. Similarly, some of them expressed problem seeing their dash board (Satnav screen, speedometer) clearly.

17. Aberrations is more than the script really that I suffer from. I'm really finding its almost ridiculous driving at night. I don't drive at night unless I absolutely have to. (012; myopic astigmatism; spectacles)

Some participants had issues with activities of daily living especially when they were not wearing refractive correction. A few of them reported difficulty in kitchen works like cooking, cutting vegetables and discerning items in a plate. Many participants also reported difficulty recognising faces. Some reported problem in self-care activities such as difficulty taking a shower not being able to differentiate soap and a shampoo, putting make up on, and shaving (quote 18).

18. The frustrating thing is when you want to look in the mirror and brush your hair or do your makeup or something like that you think 'oh I can't do my eyes because I can't see to do my eyes'. (030; high myopia; spectacles)

Slightly less than one-third of the participants expressed difficulty in performing tasks related to mobility. This includes difficulty in using stairs, walking outdoors or indoors in familiar or unfamiliar places, walking in dim light, walking in crowded areas, using public transport, and negotiating pot-holes, curvatures, and obstacles when walking (quotes 19 and 20). In many instances, mobility problems were related to difficulty adjusting to spectacles (especially multifocals), or when not wearing any corrections.

19. It [graduated lenses] just didn't work so in the end I just had to sort of wear reading glasses all the time which isn't very good for when you're walking around a workshop. (002; presbyopia; laser refractive surgery, spectacles)

20. Walking to school or walking from the bus or whatever used to be so difficult when it was raining. I couldn't see anything because my glasses would be like a windshield with rain on it. (003; high myopia; laser refractive surgery)

4.1.3.3 Theme 3: People with refractive error were bothered by the inconveniences they had to live with.

All participants stated that they had to live with a number of inconveniences because of having refractive error (quotes 21-30). Most of the inconveniences uttered were from the spectacles and contact lens wearers. They complained of having trouble handling spectacles or contact lenses.

This includes carrying spectacles (quote 21), carrying cleaning supplies, swapping spectacles (presbyopes), putting spectacles on and off (quote 22), and putting in or removing contact lenses from eyes (quote 23-24). Other inconveniences expressed include having to rely on refractive corrections (quote 26), wearing spectacles or contact lenses in rainy, dusty, dry or windy environments.

> *21. I just don't like carting [spectacles] around with me. (001; presbyopia; laser refractive surgery, spectacles)*
>
> *22. It's frustrating because you always have to have a pair of glasses with you and particularly at work you're taking them on and off every five minutes. So, although it made the vision clearer it was frustrating in itself. (025; presbyopia; spectacles)*
>
> *23. I'd go out to a party or something like that; it started off as really good but then by the end of the night it'd be such a hassle getting [contact lenses] out. (005; myopia; contact lens)*
>
> *24. You can't wear [contact lenses] all the time, you've got to take them out every night, you've got to clean them; yeah, I didn't want to do that. (001, presbyopia; laser refractive surgery, spectacles)*
>
> *25. They've got dirt on them, they've got fingerprints on them, and when I put them on my face they fog up. I have to constantly clean them. (021; myopia; laser refractive surgery, spectacles)*
>
> *26. They say that even though they correct your distance, you'll need glasses for near. I think it was always just a pain to have to rely on something. (017; high myopia; spectacles)*

A number of participants expressed having their comfort or time compromised because of having refractive error. The comfort was reported to be compromised having to adjust to new refractive corrections (quote 27), having to look through wrong section or below or above spectacles (quote 28), having to hold reading material too close or too far, pressure of spectacles over nose (quote 29) or behind ears, having to wear spectacles while playing sports. Similarly, inconveniences resulting from time compromised were having to be slower and more careful (quote 30), needing longer time to do things, having to take longer breaks, having to wait for new pair of spectacles or contact lenses.

> *27. My prescription always kept changing and then, I'd get the ones which would make me feel sick when I put them on because the ground was so sloped. I'd get used to that eventually. (021; myopia; laser refractive surgery, spectacles)*
>
> *28. With multifocals, my eyes don't shift between the fields so well. I tend to look ahead as well as look down to my feet. So, I tend to take them off when I'm going down stairs. (042; presbyopia, hyperopic astigmatism; multifocal spectacles)*
>
> *29. Glasses were heavy and when I went out running a couple of weeks ago, I ran with them and I just had to keep pushing them up my nose all the time. They just kept sliding down my nose and the glass in them was just too heavy, it just wouldn't sit properly. (013; hyperopia; laser refractive surgery, spectacles, contact lens)*
>
> *30. You have to be so careful you don't scratch [spectacles] and all that and that's a nuisance with wearing glasses. (038; hyperopia, presbyopia; spectacles)*

4.1.3.4 Theme 4: People with refractive error lived with unwanted ocular and non-ocular symptoms

Most of the participants described blurred, hazy or cloudy vision at far, intermediate and near distances (quotes 31 and 32). Some of them reported difficulty shifting focus between near and far distances. Similarly, many described experiencing glare and halos particularly due to bright light sources. Few of them reported experiencing deteriorating vision, distorted vision (quote 33), loss of peripheral vision (due to thick frames) (quote 34), difficulty in depth perception, and things looking smaller, bigger or far away with spectacles. Other visual symptoms included difficulty distinguishing colour and distinguishing contrast, difficulty focusing eye, and fluctuating vision (quote 35).

> *31. I see far things far away and far things far away are blurred. (014; high myopia; spectacles)*
>
> *32. I have trouble, particularly with smaller print and things like that - blurry vision, having to hold it a bit further away to get a clear look. (025; presbyopia; spectacles)*
>
> *33. One eye was reading italics while the other one was reading bold. (021; myopia; laser refractive surgery, spectacles)*
>
> *34. Well, you also have to be careful with the wider frames too because that reduces your vision sort of to the side. If you've got a great, thick frame, it's like blinkers, isn't it? You imagine just blocking that. (038; hyperopia, presbyopia; spectacles)*
>
> *35. When I did try [monovision] with contact lenses it was pretty hard at work, just the computer screen is just kind of–it just makes it difficult to kind of switch from one to the other. (004; presbyopia; monovision contact lens)*

Most of the non-visual unwanted sensations in and around eyes were reported by the participants wearing contact lenses or those who had refractive surgery. This included ocular discomfort (quote 36), dryness, soreness in eyes (quote 37), and redness in eyes. Apart from that, the participants wearing contact lenses experienced watering and irritation in eyes. Similarly, participants who had undergone refractive surgery reported intense pain during the recovery period only. On the other hand, participants wearing spectacles complained of soreness over nose and behind ears due to pressure from spectacles. Similarly, participants reported squinting or squeezing their eyes when not wearing spectacles or contact lenses (quote 38). Other ocular-comfort symptoms reported were ocular fatigue and heaviness in eyes.

> *36. I can just feel there's something foreign in my eyes. I can feel the contacts in there and I suppose because I know they're there and I know they're causing irritation I could sort of feel them all the time. I don't know if it's mind over matter because I know that they're there, I just want them out. (013; hyperopia; laser refractive surgery, spectacles, contact lens)*
>
> *37. It was like having sand rubbed in your face and then lemon squeezed in your eyes. (005; myopia; laser refractive surgery)*
>
> *38. Just trying to squint, and I always sat at the back of the class and that never really helped the issue. (005; myopia; laser refractive surgery)*

Many participants reported having general symptoms such as headaches (quote 39). Generally, headache was reported to be present when not wearing refractive correction. However, a few participants said that they had a headache when they wore spectacles. Many participants also reported having dizziness, tiredness, nausea or vomiting, and motion-sickness or disorientedness. Dizziness and nausea were more common in the initial days of adaption particularly for multifocal spectacles.

> *39. Graduated lenses made me dizzy. …I got headaches and they sort of made me feel nauseous as well. (025; presbyopia; spectacles)*

4.1.3.5 Theme 5: Refractive error affected people's psycho-social well-being

Categories for emotional well-being were Surprise, Anger, Sadness, Fear and Joy after the first or correct corrections, in alignment with the primary emotions of the Parrott's inventory of emotions.[321] Many participants reported mixed emotions.

Many participants were surprised with how well they could see with refractive correction. Many among them were surprised to know how much they were missing out on before they had corrections (quote 40). Most of the participants expressed satisfaction with their refractive correction (quote 41). Participants who had undergone refractive surgery were mostly happy to be free from spectacles (quote 42).

> *40. I was quite amazed at how much I could see with [spectacles] on because, you know, you just don't realise that even trees and things, you know, they've got individual leaves and I remember thinking 'oh my gosh, what have I been missing out on?' (014; high myopia; spectacles, contact lenses)*

> *41. I was so effusive and so excited when I went back for my first check-up. I said to [Doctor] 'you have no idea how much you've changed my life' Honestly, I cannot be more happy, more pleased. I can't stop raving and driving everyone insane about the fact that I can see. It has changed my life. (022; hyperopia; laser refractive surgery)*

> *42. I'm elated with [laser refractive surgery]. I think it's just absolutely wonderful. I couldn't be happier. I was never happy with my spectacles. I feel sorry for people that have to wear them. (047; myopia; laser refractive surgery)*

Some participants expressed anger, frustration for not getting good vision (quote 43), or for not being able to do some tasks. A few of them reported frustration for not being able to adjust to spectacles (quote 44). Others expressed jealousy, restlessness and agony.

> *43. The doctor said there's nothing more that they can actually do at this point to correct it. It's frustrating. (018; high myopia; spectacles)*

> *44. I got really fed up because I can't get on with bifocals or graduated. (002; presbyopia; laser refractive surgery, spectacles)*

A majority of participants expressed 'Sadness'. This primary emotion includes feeling depressed, low self-esteem, lost, guilty, upset, lonely, unhappy, disappointed, helpless, embarrassed (quote 45), and insecure. Many of them felt different and singled out in their groups having to wear

spectacles (quote 46). Some of them were disappointed with their refractive corrections (quote 47). A few reported sadness for the frequent change in prescription (quote 48) and for passing refractive error on to their children.

> *45. If I have to go to parties, if I have to go to somewhere where I really want to flaunt myself and I put the glasses it really comes in between my self-esteem and I feel kind of self-conscious. (041; myopic astigmatism; spectacles, contact lens)*

> *46. It was hard being different. I think mainly for me it was being ostracised because I was different. You know, you didn't get picked in the teams and I suppose, it happens a lot with people with glasses. I was rather a loner as a result. (018; high myopia; spectacles)*

> *47. I was quite disappointed. I haven't had a perfect result. I've noticed my close-up vision isn't as good as it was and even after six months it doesn't seem to have gotten back to where it was. (017; high myopia; laser refractive surgery)*

> *48. My prescription was continuously changing, and I felt depressed about it. (021; myopia; laser refractive surgery; spectacles)*

Almost all the participants who considered having laser refractive surgery expressed fear and nervousness before, during or after the procedure (quote 49). Many of them were scared about the possibilities of getting complications such as dry eyes, halos around lights and even being blind. Some were anxious about the nature of the procedure itself and the newness of the technology. Participants who regularly wore spectacles felt vulnerable when they were not wearing spectacles occasionally such as when swimming. Similarly, those who were wearing contact lenses reported being nervous while handling their contact lenses.

> *49. Surgery just seems like a scary thing to do. I was like 'no, I don't want any flaps flapping around or anything like that'. They cut the cornea and then it has the flap that never really goes back down again and never really heals back down again. Too scary; I just couldn't bother. (027; myopia; spectacles)*

Participants expressed having refractive error affected their social roles and participation. Some of them reported difficulty in taking care of children or grandchildren (quote 50). Participating in team sports or social group activities was frequently reported taking part in such activities were difficult with spectacles. Similarly, many did not like to wear spectacles when attending social functions like parties as they did not find their appearance with their spectacles cosmetically aesthetic (quote 1). Many participants also raised social concerns about others not understanding issues people with refractive error have.

> *50. There have been a couple of times when I couldn't find my glasses. I certainly do not feel comfortable carrying an infant without my glasses on. (027; myopia; spectacles)*

Participants reported a series of coping strategies to confront with their conditions and the difficulties or inconveniences associated with that. Some of them include accepting the condition (quote 51), learning to live with it (quote 52), learning to do things differently than how they used to do before, seeking support from others and trying to be positive.

51. I'm used to the way that my face looks in glasses now. (011; myopic astigmatism; spectacles)

52. The short sightedness, because you have it from when you're young you just build your life and your career around it. (024; high myopia; spectacles)

4.1.3.6 Theme 6: Refractive error had economic implications.

Participants reported many direct and indirect costs involved with refractive correction. Although all the participants who had had refractive surgery reported it to be expensive (quotes 53 and 54), some participants said that contact lenses and spectacles were more expensive on the long run over laser refractive surgery which is just a one-off expenditure (quote 55). A few among them said that their insurance not covering laser refractive surgery was particularly an issue. Similarly, many participants expressed their concerns over the cost of buying spectacles, contact lenses and cost of maintaining them (quotes 56-58).

53. I kind of looked into [laser refractive surgery] a long time ago but it was pretty expensive. Well, that was a disincentive for a long time. (004; presbyopia; monovision laser refractive surgery)

58. I have the crazy position that it'll be really nice when I finally get cataracts because then I can go under the medical schemes and have the cataracts removed and lenses fixed at the same time at no cost whereas if I have it done now it's a huge cost to me. (018; high myopia; spectacles)

55. I was factoring in the cost of buying glasses over the next 20 to 30 years and thinking well, you know, this is actually quite good value. (030; myopia; laser refractive surgery)

56. It's always a bit of a shock when they tell you how much [price of spectacles] is, it's like 'oh my God, really?' (013; Hyperopia; laser refractive surgery, spectacles, contact lenses)

57. I was spending a fortune on contact lenses. (022; hyperopic astigmatism; laser refractive surgery)

58. I would love to wear just the normal pair of sunglasses and I know I can have a prescription pair made up but I just find the cost outweighs the use. (031; hyperopic astigmatism; spectacles)

Approximately one-third of the participants reported that having refractive error affected their career choices and work. A few of them reported difficulty doing their current professional jobs, e.g. job requiring to use computer for long time was reported to be difficult due to eye strain and watering (quote 59 and quote 60). Similarly, others expressed frustration not being able to choose the career of their choice (quote 61).

59. Well that's been very debilitating in terms of my ability to work. No, it's not good in my position. To have this sort of come on, slap bang in your supposed peak of your career, you know, I should be able to earn the peak money of my career for the next ten years, you know, I'm at the top bit. Yeah that's actually really difficult and annoying. (024; high myopia sequel–retinal tears; spectacles)

60. I'm a librarian and it became impossible to file books, you know, the little spine labels in the library, I couldn't–I had to get closer and closer to that little spine label to actually see where to put them in their right order. (028; high myopia; spectacles)

61. Well wearing glasses, the Air Force was a definite out, the Navy was a definite out. (029; hyperopia; spectacles)

4.1.4 Discussion

This study qualitatively explored the refractive error related issues that affect people's QoL. To the best of my knowledge, prior to this, no other studies had qualitatively explored living experience in terms of QoL impact in adults with refractive error. This study thus enriched the understanding of the QoL issues that are important to people with refractive error.

The most prominent theme was participants' concerns about their cosmetic appearance with spectacles, outcome with correction, complications from contact lenses and laser refractive surgery, ocular health and overall personal safety being affected. This is important to consider as clinicians tend to overemphasize visual functions and symptoms when examining their patients.[28, 101] This study findings provide further evidence that these concerns influence QoL in people with refractive error. This is consistent with the literature where convenience, cost, health concerns and well-being were reported to be more influential on QoL.[28, 46, 90]

Activity limitations (difficulties in performing day-to-day activities) as the result of refractive error have a huge impact on people's life. This is probably the major reason for people seeking refractive correction.[22] It is generally understood that spectacles, contact lenses or refractive surgery overcome the activity limitations caused. However, findings of this study suggest that this is not always the case. Rather, correction types do come with specific limitations such as problems in using computers after laser refractive surgery or contact lenses wear due to dryness. Similarly, spectacles were reported to hinder certain activities and hobbies such as swimming and other water sports. Likewise, participants expressed mobility problems particularly when adjusting to their spectacles.

The participants expressed many inconveniences related to refractive error such as handling their spectacles and contact lenses and having to be slower and more careful. Most of the inconveniences reported were due to spectacles or contact lens wear. This was in agreement with the studies that report less convenience issues in people who had refractive surgery than in spectacles or contact lens wearers.[27, 228]

People with refractive error may have problem seeing clearly at various distances. This is unique to other eye conditions where people experience general overall blur (e.g. cataract), or loss of visual fields in certain zones (e.g. glaucoma). In addition, refractive surgery or contact lens wear

may adversely impact people's well-being by unwanted symptoms such as dryness and ocular discomfort despite having the excellent visual outcomes, as reported by McAlinden *et al.*[33]

A range of positive and negative emotional reactions associated with refractive error were identified in this study. This includes feeling of sadness, surprise, fear, anger and joy with correction outcomes. Many participants reported various coping strategies in dealing with the negative emotions experienced. In a study conducted in low vision population in Australia, a significant impact of coping strategies on vision-related QoL has been reported.[322] Similar to low vision, refractive error is generally a chronic stressor warranting a need for examining a direct relationship between coping strategies and refractive QoL.

In this study, cost of refractive correction was one of the major concerns of people. This is consistent with the literature where billions of dollars' worth of direct and indirect economic loss is predicted due to refractive error.[124, 153] The cost was more of a concern to those considering laser refractive surgery. Unlike other surgeries, the Medicare and many private health covers do not cover it fully, considering it cosmetic rather than a functional requirement. All the participants who had laser refractive surgery expressed improvement in their QoL. This is again in alignment with many quantitative QoL studies.[28, 188, 207] Hence this study findings add evidence for the stake holders to rethink about considering laser refractive surgery as a functional requirement rather than merely a cosmetic need.

This study identified the important living experiences of people with refractive correction that are unique from other eye conditions. In other ophthalmic conditions such as cataract, diabetic retinopathy, and age related macular degeneration, vision-related activity limitations were reported to be the major QoL issues.[323-326] Whereas, activity limitation was not the most important theme for refractive error. This is probably because all the participants were corrected for refractive error which probably have improved their ability to carry out day-to-day activities. Moreover, I found that concerns about cosmetic appearance, inconveniences from having to wear and handle spectacles and contact lenses etc. were unique issues in people with refractive error.

One of the limitations of this study was that it did not have participants with URE. However, the participants recollected their past experiences regarding the difficulties in performing activities when their vision was uncorrected. In a typical high-resource setting like this, refractive error is expected to be corrected as most of the people have access to refractive services. However, millions of people with refractive error in low-income settings do not have access to refractive correction.[6] It can be expected that people with URE have poorer QoL and probably different QoL issues. These study findings therefore may not be generalized to all but indicate a strong need to

conduct a similar study in low- and middle-income country setting. A similar study including URE was later conducted in Nepal and is presented in the next section.

Another limitation was that children (< 18 years old) were not included in this study. This study is a part of the Eye-tem bank project which is developing item-banks for all ophthalmic conditions only for adults.[30] This is because children and adults are not comparable research participants for qualitative studies, and a single item bank would not be able to accommodate the diverse QoL issues for both children and adults (see Section 3.3 for details). Separate similar exercise has to be carried out for children to develop children-specific item bank in the future.

The purposive sampling employed in this study is a non-probability, non-representative sampling strategy which has limitations. The proportion of participants in various clinical and socio-demographic sub-groups in this study may not represent the refractive error population in this setting. However, this type of sampling strategy was adopted as the main aim was to identify the QoL issues in wide spectrum of refractive error, its correction types and socio-demographics. The goal was not to quantify the QoL impact of refractive error in this population but was rather to explore the ways how refractive error may impact people's QoL. Nevertheless, a caution should be taken while interpreting the findings due to short-comings of the purposive sampling strategy.

Another limitation of the study is the inherent bias entailed in the qualitative nature of the study due to reflexivity and preconceptions of the researcher. However, to minimize this bias and to maintain the qualitative rigour, the guidelines for qualitative research by Malterud *et al*. were followed.[317] Using open ended questions, maintaining a neutral position, avoiding direct questions, considering every response, assuring participants of the confidentiality, and acknowledging the limitations were some of the strategies employed.

This study presented more findings on how refractive error impacted people's QoL negatively compared to their positive experiences. This should not undermine the value of refractive corrections. This might partly be because the interview guide (Appendix F) contained more questions exploring the negative impact of refractive error or its correction on QoL. Nevertheless, the study also discussed positive experiences of having refractive correction (Examples: Theme 1: Spectacles as a part of fashion; Theme 2: Refractive corrections generally reduced activity limitations; Theme 5: Positive emotions like joy, surprise, happiness, and coping strategies). In general, when the participants compared their status with and without corrections, refractive corrections offered better QoL status. However, when the participants compared themselves with the people without refractive error, they reported having lower QoL status in general.

In conclusion, this study qualitatively explored the impact of refractive error on the QoL of adults, particularly after correction. The findings highlight that refractive correction does not always address these issues, and sometimes add issues. Concerns about cosmetic appearance with spectacles, personal health and safety, difficulties in day-to-day activities, and inconveniences rendered in daily life were identified as the most important issues in people with refractive correction. These wider perspectives should be considered while planning refraction services. This study is the foundation of the development of technologically advanced PRO for refractive error (Item banks) administered through a CAT system, particularly for high-income country settings.[15, 30]

4.2 Impact of refractive error on quality-of-life: a qualitative study in a low-income country setting (Nepal)

4.2.1 Introduction

In the above section (Section 4.1), I discussed the qualitative findings on how refractive correction impacts on QoL of adults in a high-income country setting with very high human development index (Australia).[14, 64] I have explicitly discussed limitations of that study. One of the limitations of the above study was that it did not include participants with URE. Having participants with URE is important as the PRO research so far is largely focused on the refractive correction only; not on the URE.[16] In addition, the QoL issues in low- and middle-income (LMIC) settings may be different to high-income country setting even for refractive correction. For instance, issues related to inconvenience doing manual agricultural works wearing spectacles may be more important to the low-income country settings than the to the high-income country settings.[14]

The second (current) qualitative study was conducted in Nepal, a low-income country in South Asia. The maximum burden of URE lies in South Asia.[6] Similar to other LMICs, URE including uncorrected presbyopia is a major public health problem in Nepal.[327-330] However, a little priority has been given to address refractive error related vision impairment. Nepalese eye care system is rather cataract focused.[328] There is a huge unmet need for refractive error services.[327, 328]

To the best of my knowledge, there was no published similar qualitative study exploring the impact of refractive error (including URE) on QoL of adults in the LMIC settings. Therefore, the current qualitative study was conducted to address this gap. The specific objectives were, to identify the unique QoL impact issues in adults with URE and various types of refractive correction, and to compare the QoL issues of refractive error between these sub-groups. This study provided formative data for the construction of item banks for measuring refractive error-specific QoL in adults in the LMIC settings, described in details in Chapter 5.[64]

4.2.2 Methods

The guidelines for conducting a qualitative study proposed by Malterud *et al.* were followed to maintain scientific quality and rigour, similar to the Australian study.[14, 317] Semi-structured, in-depth, face-to-face interviews were conducted with adults having refractive error, with or without correction. The participants were recruited form Tilganga Institute of Ophthalmology (TIO) and Dhulikhel Hospital, Nepal from September to November, 2016. TIO is the only place offering refractive surgery services in Nepal.

Purposive sampling was used to recruit participants across diverse spectrum of refractive error, corrections and socio-demographics. Definition and classification of refractive error used in this study were described in Chapter 3 (Section 3.1.1.1). Refractive error of magnitude ±0.50 dioptre was considered significant. Participant recruitment was done with the help of ophthalmic personnel (ophthalmologists, optometrists or ophthalmic assistants) delivering refractive care to the participants at refractive surgery clinic, contact lens clinic or refraction units.

The ophthalmic personnel referred potential participants to the interviewers (author and a registered nurse dedicated for conducting interviews) with an established diagnosis of refractive error. Participant selection criteria were similar to the Australian study[14] (Table 4.1) except that the participants had to be fluent in either Nepali or English language. All the interviews were conducted in Nepali language. Among the participants referred by the ophthalmic personnel, two persons did not meet the selection criteria (Table 4.1). One person was taking anti-depressant medication, and the other person did not want to participate not being comfortable with the interview being recorded. An informed written consent was obtained from the participants included in the study. Then the information on clinical (e.g. visual acuity, final subjective refraction, presence of any other ocular and systemic co-morbidities) and socio-demographical information was collected using a background questionnaire (Appendix A). Similar to the Australian study, the background questionnaire also consisted of questions on frequency of wearing spectacles or contact lens, using a five-point Likert scale (very often, quite often, occasionally, rarely, never). The participants were grouped into Indo-Nepalese or Tibeto-Nepalese ethnic groups as the prevalence of refractive error has ethnic variations.

The participants discussed how their refractive error or corrections impacted on their QoL. Interviews were mostly conducted during waiting times (e.g. during mydriasis for pre-operative exam for refractive surgery eligibility, waiting time for ophthalmologist consultation). The interview guide developed earlier was adapted (Appendix F).[14] The guide consisted of open ended broad non-leading questions worded in present tense, aiming to explore the habitual status (Table 4.2).

Habitual status was emphasized as the retrospective collection of PRO data may introduce recall bias.[157] The interviews were conducted in Nepali language by two interviewers fluent in Nepali. The data collection was carried out until thematic saturation occurred.

The interviews were audio recorded, transcribed verbatim to ensure accuracy, and coded and organised in NVivo software (Version 11). The interview transcripts were reviewed line by line looking for apparent concepts. Initial codes were derived from the concepts based on the semantic meaning of the comments from the participants. Then the coding was carried out by both interviewers. Any disagreements were handled with discussion. Any confusion was discussed with my PhD supervisor (JK), who had expertise in qualitative research.[325, 331] Discussions led to consensus between the three of us. Categories, sub-themes and themes were recurrent (frequent) as well as unifying ideas identified using an inductive approach. The descriptive codes were evaluated to find patterns and relationships (e.g. similarities) to derive categories, sub-themes and themes (bottom-up approach). Consistency in coding and categorising was maintained regularly comparing new and old codes and categories. All of us reviewed codes, categories and themes and approved the final coding framework. Thematic analysis was used with matrices produced to compare the occurrence of themes and categories across refractive error sub-groups.

4.2.3 Results

A total of 101 participants with refractive error, with or without correction, were interviewed. The participants had diverse socio-demographical and clinical characteristics (Table 4.5).

Table 4.5 General characteristics of the participants

Mean age ± SD	34.4 ± 15.2 (Minimum, 18; Maximum, 74) years
Male	55
Marital status	Married, 59; Never married, 41; Divorced, 1
Rural / Urban	Rural, 29; Urban, 72
Ethnicity	Indo-Nepalese, 71; Tibeto-Nepalese, 30
Education level	Illiterate, 16; Primary school level, 17; High school level, 22; Under-graduate level, 32; Post-graduate level, 13; Missing data, 1
Occupation	Student, 20; Manual agriculture/farming, 11; Teacher/lecturer, 9; House works, 9; Sales (sales person / cashier / accountant / sales manager), 7; Hotel works (receptionist, supervisor, cook, waiter), 7; Health personnel, 4; Information technology and computing, 4; Local business owner, 4; Unemployed, 4; Plumber/electrician / auto mechanic, 4; Tailor, 3; Religious preacher, 3; Others (social worker, nurse, bus-conductor, engineer, architect, garden designer, researcher), 12
Type of refractive error [a]	
Myopia [Severity][a]	56 [Low, 27; Moderate, 15; High, 14]
Hyperopia [Severity][a]	21 [Low, 12; Moderate, 3; High, 6]

Surgical emmetropia	19
Presbyopia	28
Type of refractive correction[b]	
Spectacles [Frequency of use]	60 [Very often, 31; Quite often, 9; Occasionally, 20]
Contact lenses [Frequency of use]	17 [Very often, 5; Quite often, 3; Occasionally, 6; Rarely, 3]
Refractive surgery	20
URE (Un/der-corrected)	47

Note: URE = Uncorrected refractive error. [a]Number or percentage of participants is more than the total number or 100% of participants as many had more than one type of refractive error or refractive correction. [b]Grading of severity of myopia and hyperopia (spherical equivalent) in dioptres: Low, |0.50| to |3.00|; Moderate |3.25| to |6.00|; High > |6.00|.

The participants had different levels of myopia (55.4%), hyperopia (20.8%), presbyopia (27.7%) and surgical emmetropia (18.8%) (Table 4.5, Table 4.6). All the participants with refractive surgery or wearing contact lenses were from urban areas. Similarly, the participants with refractive surgery or contact lenses had higher educational qualifications (Median number of years of formal education = 16 years) than others (Median number of years of formal education = 9 years) [Mann-Whitney U test, $p < 0.001$]. Likewise, participants with refractive surgery or contact lenses had lower mean age (26.7 ± 5.3 years) than others (39 ± 17.2 years) [Independent sample t test, $p < 0.001$].

Table 4.6 Distribution of participants by refractive error and refractive correction types

		Refractive error sub-types				**Total** [Frequency of using refractive correction]
		Myopia [Median, -3.75D SphEq (Min, -22.00 D; Max, -0.63 D][a]	**Hyperopia** [Median, +2.00D SphEq (Min, +0.75 D; Max, +16.50 D][a]	**Surgical emmetropia**	**Presbyopia**	
Refractive correction	**Spectacles** [Frequency of spectacle wear]	36 [Very often, 21; Quite often, 5; Occasionally, 10]	14 [Very often, 5; Quite often, 2; Occasionally, 7] [b]	n/a	19 [Very often, 5; Quite often, 3; Occasionally, 11]	60[b] [Very often, 31; Quite often, 9; Occasionally, 20]
	Contact lenses [Frequency of contact lens wear]	11 [Very often, 2; Quite often, 2; Occasionally, 4; Rarely, 3]	6 [Very often, 3; Quite often, 1; Occasionally,2]	n/a	0	17 [Very often, 5; Quite often, 3; Occasionally, 6; Rarely, 3]
	Refractive surgery	0	1	19	0	20
	Uncorrected	28	9	n/a	20	47[b,c]
Total [Degree of refractive error][a]		56[b,d] [High, 14; Moderate, 15; Low, 27]	21[b,d] [High, 6; Moderate, 3; Low, 12]	19[b]	28[b]	**101**[b]

[a]For calculating Median and degree of refractive error, the eye with less absolute value of refractive error

was considered. [b]Row totals and column totals are not the sum of individual cells in the corresponding rows or columns. This is because, a single participant might be included in multiple places. For example, a participant who had a history of refractive surgery has a hyperopia, for which he is wearing spectacles (occasionally) and contact lenses (quite often). Similarly, all the contact lens wearers also wore spectacles. Most of the presbyopes had refractive error for distance as well. [c]Classification of uncorrected or corrected refractive error was based on pre-dominant habitual status. For example, a person with presbyopia was classified under 'uncorrected refractive error' if one did not wear spectacles most of the time while doing near tasks. [d]Grading of severity of myopia and hyperopia (spherical equivalent) in dioptres: Low, |0.50| to |3.00|; Moderate |3.25| to |6.00|; High > |6.00|.

A total of 3,477 comments were coded into seven themes: Activity limitation, Inconvenience, Health concerns, Psychosocial impact, Economic impact, General- and ocular-comfort symptoms, and Visual symptoms. The most frequently uttered QoL issues for uncorrected and corrected refractive error are presented in Table 4.7. Below, I summarise the major findings with patterns of responses by their refractive error sub-types or corrections, and their socio-demographics. The findings are supported with a mix of representative and illustrative quotes in the text.

Table 4.7 Frequently reported quality-of-life issues for uncorrected and corrected refractive error

Uncorrected Refractive Error (URE)	Corrected Refractive error (CRE)
Theme 1. Activity limitation *[Comments, 848; Unique issues, 86 (URE, 75; CRE, 67)*	
Difficulty reading at far; Difficulty reading at near; Difficulty recognising people or objects at far; Difficulty watching television; Difficulty doing agricultural works Presbyopia: Difficulty reading and writing at near; Difficulty using a mobile phone; Difficulty threading a needle	Spectacles: Difficulty taking part in recreational activities e.g. dancing; Difficulty swimming; Difficulty doing agricultural works with spectacles (e.g. digging) High or moderate myopia: Difficulty washing face; Difficulty taking a shower; Difficulty identifying and recognising a tooth brush Presbyopia and high myopia: Difficulty reading in dim light High refractive error: Difficulty adjusting to dim light after being in bright light Female: Difficulty putting make-up on Contact lenses and refractive surgery: Difficulty using a computer
Theme 2. Inconvenience *[Comments, 684; Unique issues, 64 (URE, 44; CRE, 60)*	
Needing longer to do things; Having to be slower and more careful; Having to rely on others for help Myopia: Having to go closer to see things clearly Uncorrected presbyopia: Having to hold reading material too far Under-corrected refractive error: Having to travel long distance to have their eyes examined or to make spectacles Presbyopes from rural areas: Couldn't adapt to wearing spectacles	Spectacles: Breaking spectacles; Spectacles sliding down my nose or falling off my face, Fogging-up of spectacle lenses; Not being able to use off-the-shelf (non-prescription) sunglasses; Difficulty putting motorcycle helmet on; Wearing spectacles in rain Presbyopia: Forgetting to carry reading spectacles; Looking through wrong section or below or above my spectacles High refractive error: Wearing thick and heavy spectacles Contact lens: Putting in or removing contact lens from eyes, Cleaning or maintaining hygiene, Carrying cleaning kit, Having to carry spectacles even when wearing contact lens, not being able to wear contact lens as long as one wants to; Difficulty wearing contact lenses in dry, dirty or dusty environment Refractive surgery: Forgetting to carry eye drops; Having to take extra-precautions about eyes e.g. avoiding dust, not rubbing eyes
T**heme 3. Health Concerns** *[Comments, 492; Unique issues, 39 (URE, 28; CRE, 38)*	

People not understanding my eye condition; What other people might say (if I wear spectacles); Possibility of further deteriorating my vision in the future; Falling; Getting lost (not seeing the surrounding) when travelling Under-corrected: About quality of care offered by their health practitioners and about possibility of not having a proper refraction	Spectacles: Aesthetic appearance Female: Spectacles not going well with their dress or make-up; Reflections from spectacles when being photographed were annoying; Getting bumps or dents on the nose or behind the ears High refractive error: Possibility of going blind Contact lens: concerns about side effects or complications Refractive surgery (Pre-operative): Being eligible for surgery; Vision after laser refractive surgery; Possibility of having complications Refractive surgery (Post-operative): Possibility of having long term complications, or having to wear spectacles again due to relapse of refractive error
Theme 4. Psychosocial impact *[Comments, 352; Unique issues, 62 (URE, 40; CRE, 56)*	
Feel regretful or guilty about my eye care in the past; Feel disappointed; Feel humiliated	Spectacles: Feel embarrassed, Feel different from others, Feel self-conscious about one's looks, Feel frustrated, Feel weak and older than actual age; Feel disabled; Feel like being held back in life Spectacles - Female: Problem attending social functions like wedding, parties; Problem finding a life-partner and getting married Refractive surgery (Pre-operative): Feel excited about refractive surgery; Feel nervous or scared Refractive surgery (Post-operative): Feel free, more active, relaxed and gaining higher confidence.
Theme 5. Economic impact *[Comments, 270; Unique issues, 15 (URE, 10; CRE, 14)*	
Cost to buy spectacles; Needing longer time to do work; Not being able to work	Spectacles: Ongoing cost to buy spectacles Contact lens: Cost to contact lens, Cost involved in care and maintenance of contact lens Refractive surgery: Cost of having refractive surgery; Cost of buying eye drops
Theme 6. General- and ocular-comfort symptoms *[Comments, 536; Unique issues, 19 (URE, 17; CRE, 19)*	
Headache; Giddiness; Eye pain	Spectacles: Discomfort caused by spectacles Contact lens: Heaviness in eyes; Red eyes Refractive surgery: Dry eyes; Tired eyes; Burning in eyes
Theme 7. Visual symptoms *[Comments, 295; Unique issues, 23 (URE, 18; CRE, 23)*	
Blurred vision at distance; Blurred vision at near; Cloudy vision	Spectacles: Blurred vision in rain; Dazzled vision; Loss of peripheral vision; Distorted vision Refractive surgery: Glare from lights; Sensitivity to light; Difficulty focusing at things for a long time

4.2.3.1 Theme 1. People with refractive error experienced activity limitations

Difficulty in doing day-to-day activities due to having poor vision was the most prominent theme for the participants with URE. They reported difficulty reading at far or near, and difficulty recognising people or things at far, watching television and so on. Many of them reported that they had difficulty doing manual agricultural works wearing spectacles, especially when they had to bend down to do those activities, and therefore stopped using spectacles. These tasks included cutting grass, carrying loads (in Nepal, farmers typically carry grass in a bamboo basket "Doko" with the help of a strap "Namlo" on their head), cutting or collecting firewood, working in the fields such as digging (using a spade "Kodali") (quote 1). Likewise, the uncorrected presbyopes reported difficulty reading and writing at near. Many of them reported difficulty using a mobile phone; cutting food or vegetables; seeing hair, insects or dirt on food; beading necklace or chains; threading a needle; recognising faces and objects in a photograph; winnowing; and making cotton wicks (religious

reasons). The participants with URE reported difficulty cooking, travelling and playing sports due to having reduced vision. Whereas, spectacle wearers reported difficulty cooking due to fogging-up of spectacle lenses, and playing sports like football due to possibility of spectacles falling off the face. Similarly, contact lens wearers reported difficulty travelling due to difficulty handling them.

> *1. Working in the fields or in the forest is very difficult wearing spectacles. Digging and ploughing fields, collecting firewood, cutting grass, weeding, climbing trees, carrying grass on 'doko' with 'namlo' are difficult [bending down]. Spectacles drop down. I sometimes wear them, sometimes take them off which is very irritating. Sweating makes it even harder covering it up. Working in rain is difficult as well. Cleaning spectacles with soiled clothes doesn't help. When I dig without wearing spectacles, I cut roots of the plants. (013; 27/m; myopic astigmatism; mostly uncorrected)*

In addition, participants wearing spectacles reported difficulty in recreational activities like dancing, and said they often took spectacles off while doing those activities. Many participants reported swimming as a major problem as they could not wear their spectacles. Surgical emmetropes happily reported to be free from these problems (quote 2). Spectacle wearers also reported more problems in cycling, driving, riding a motorcycle or moped. They reported more of these problems, particularly at night. The participants with high or moderate myopia wearing spectacles reported difficulty washing face, taking a shower, and identifying and recognising a tooth brush. Female participants with spectacles reported difficulty putting make-up on, and were annoyed as spectacles would hide the make-up. Similarly, the participants with contact lenses or laser refractive surgery reported more problems using a computer. High refractive error cases reported difficulty adjusting to dim light after being in bright light. To conclude, almost all the participants (n = 98) reported activity limitation due to having refractive error or its correction.

> *2. You can't wear spectacles when taking a shower or when swimming. I used to go swimming with friends. After taking spectacles off, I couldn't see anything. I couldn't recognise my friends, and finding the way back was so difficult. I didn't enjoy swimming at all. (078; 28/f; surgical emmetropia [SMILE for high myopia])*

4.2.3.2 Theme 2. People with refractive error live with inconveniences

Inconvenience was the most important theme, particularly for spectacle wearers. They frequently reported spectacles breaking or slipping down the nose. Presbyopes, mainly male participants, reported forgetting to carry reading spectacles with them, or losing spectacles. All the residents of Kathmandu valley reported not being able to wear an air-filtering face mask as a major inconvenience, as Kathmandu was a dusty and polluted city.[332] Not being able to use normal sunglasses, difficulty wearing a motorcycle or moped helmet while wearing spectacles, having to be conscious about wearing spectacles all the time, looking through wrong section of the spectacles and looking for spectacles soon after waking up were other prominent inconveniences uttered. Interestingly, some participants reported forgetting to take off spectacles when washing face or taking shower. Participants with high refractive error reported that wearing thick and heavy spectacles was a nuisance. Some participants reported difficulty wearing spectacles in the rain.

Many participants reported inconvenience having to remove spectacles or contact lenses when doing some activities such as swimming. They also expressed inconvenience having to frequently go for eye check-ups, and frequently replacing spectacles or contact lenses. Participants who used both spectacles and contact lenses reported more inconvenience not finding or misplacing them.

Many participants using contact lenses reported inconvenience cleaning or maintaining hygiene. Many reported difficulties wearing contact lenses in dry, dirty or dusty environment. It was particularly reported to be bothersome when dirt or dust goes in eye while wearing contact lenses (quote 3). Many participants reported inconvenience carrying cleaning kit for contact lens, and having to carry spectacles even when wearing contact lenses. Some reported inconvenience putting in or removing contact lenses from eyes, and said that it was time-consuming. Similarly, not being able to wear contact lenses as long as they wanted was reported to be a disadvantage of wearing contact lenses.

> *3. As we know, Kathmandu is so polluted, it's really difficult to wear contact lenses. Because of dust everywhere, I started having irritation and a lot of watering. I drive a moped to my office, and if dust goes into my eye, it's very very uncomfortable, but I am in dilemma whether to remove contact lenses [off my eyes] as my hands are not clean. I feel like going to office as soon as possible so that I can remove my contact lenses. Therefore, I rarely wear contact lenses these days. (053; 21/m; myopia; occasional contact lens wearer)*

All the participants with refractive surgery expressed happiness for being free from spectacles and contact lenses (not having to rely on them). However, some reported inconvenience having to carry eye drops with them. Some participants said that after surgery, they had to take extra-precautions about eyes e.g. avoiding dust, not rubbing their eyes.

Many participants with URE said that they stopped using spectacles due to inconvenience. Some presbyopes, particularly from rural areas said it was difficult to adapt to spectacles, and therefore they stopped using them. Similarly, many participants reported problem wearing spectacles in warm and humid weather especially when doing manual agricultural works. Likewise, participants reported to have stopped using spectacles while doing some activities such as cooking or physical activities due to spectacle lenses getting fogged-up (quote 4). Many participants with URE reported inconvenience needing longer time to do things and having to depend upon others. URE participants, particularly myopes, reported inconvenience having to go closer to see things clearly. Whereas, uncorrected presbyopes reported inconvenience having to put things far to read. To sum up, more than 90% (n = 92) participants reported inconveniences due to having refractive error.

> *4. Spectacle lenses get steamed up while cooking. In our village, we cook on firewood and the problem is worse. It's difficult even to eat hot food. I don't wear spectacles in the kitchen. (016; 28/f; moderate myopia; spectacle wearer–mostly uncorrected while doing household works)*

4.2.3.3 Theme 3. People with refractive error have concerns about refractive error and its consequences

More than 85% (n = 86) participants reported one or more concerns about refractive error, its corrections and their consequences. Aesthetic appearance, the way of being treated by others, and vision or prescription getting worse were the most frequently uttered concerns. Typically, young female spectacle wearers with high refractive error from an urban area had maximum concern about appearance. Appearance was one of the major reasons for people deciding to wear contact lenses or to have refractive surgery. Female participants further added that spectacles did not go well with their dress or make-up, and reflections from spectacles when being photographed were annoying. Similarly, the participants with URE from rural areas who were prescribed spectacles for the first time were particularly worried about what other people might say (about their looks) (quote 5). Likewise, female spectacle wearers were particularly concerned about getting bumps or dents on the nose or behind the ears due to spectacles. Similarly, participants with high refractive errors showed more concerns about possibility of going blind.

> *5. I feel uncomfortable meeting people [in my village] wearing spectacles. Some people tease me. They call me "Char ankhe" (meaning 'a four-eyed person'). Even when they are talking about something else, I feel like they are talking about me wearing spectacles. People in my village don't understand this and they might say 'Why is he wearing spectacles?' Therefore, I don't always wear spectacles. But when I am not wearing spectacles, and I am not able to recognise my friends from far, they say in a sarcastic way "You didn't even recognise me. You are a big person now!" (047; 24/m; moderate myopia; spectacles)*

Most of the participants showed concerns about the possibility of worsening prescription or decreasing vision (quote 6). The URE participants expressed concerns about what others might say e.g. when not being able to recognise a person from far, or if they start wearing spectacles. Similarly, they expressed concerns about not getting or not understanding the information from the health practioners. The URE participants expressed concerns about personal safety being at risk by falling when walking or by getting lost (not seeing the surrounding) when travelling. Spectacle wearers, particularly the under-corrected cases, were more concerned about quality of care offered by their health practioners and about possibility of not having a proper refraction, compared to contact lens wearers or those who had refractive surgery. They were also worried about people not understanding their eye condition. Similarly, participants from rural areas showed concerns regarding the services they get during free eye camps (quote 7). Participants who wore spectacles, contact lenses or combination showed their concerns about side effects or complications of contact lens wear. Similarly, Participants who had considered laser refractive surgery (pre-operative participants) reported that they were greatly concerned about being eligible for surgery, vision after laser refractive surgery, and possibility of having complications. Participants who had undergone laser refractive surgery were also concerned about the possibility of having long term

complications.

> *6. My prescription is worsening since I was a child. There is no sign of it slowing down. I have to change my spectacles every six months when I go for an eye-check-up. I'm worried if in the future I can't see anything. (005; 18/m; moderate myopia; spectacles)*

> *7. I got spectacles from an eye camp. The spectacles were too big in size and looked ugly. I was not comfortable with them. I even got terrible headaches when wearing them. So, I stopped using them. (014; 37/m; moderate hyperopia; URE)*

4.2.3.4 Theme 4. Refractive error had profound psychosocial impact

Approximately 80% of the participants reported psychosocial impact of refractive error. The URE participants expressed mostly negative emotions such as feeling regretful about their own eye care in the past, feeling disappointed, feeling humiliated and so forth. Spectacle wearers expressed feeling embarrassed, different from others, self-conscious about one's looks, frustrated (e.g. wearing spectacles in a crowded public bus), weak (e.g. in social contexts) and older than actual age. They felt like crying and felt angry when others teased them for their looks. They also reported feeling disabled (e.g. not able to participate in physical activities like gymnastics) and being held back in life (e.g. socially rejected for group activities). On the other hand, the participants who considered having laser refractive surgery were excited about it, but at the same time nervous or scared of the potential complications. Likewise, the participants who had undergone refractive surgery expressed feeling free, more active, relaxed and gaining higher confidence (quote 8).

> *8. The very first day after surgery, I felt like 'oh my god, my eyes can see'. I wanted to share this with everyone. I felt like hugging my doctor. … I am living a happy life now free from spectacles. This has increased my confidence. I feel like I can do anything. (066; 24/f; surgical emmetropia)*

Nearly 40% of the participants reported having refractive error and its correction (particularly spectacles) affected their ability to fulfil their social roles and responsibilities (quote 9). A majority of the spectacle wearers reported problem with attending social functions like wedding, parties. Some participants with URE reported not getting enough support from the family members, others reported their family and friends being affected because of them having refractive error. Few participants reported problem finding a life-partner and getting married (quote 10). Approximately one-third of the participants reported various coping and adaptation strategies to deal with refractive error and its consequences (quote 11). The strategies include adaptive ones such as being positive, accepting the eye condition, learning to do things differently than one used to do them before, and getting professional or peer support. Some participants, particularly presbyopes reported using their family member's spectacles while doing some near tasks such as reading or threading a needle. Participants with URE or spectacle wearers reported mal-adaptive processes like not wearing spectacles to avoid being teased at, avoiding group activities or social functions (withdrawal), and pretending to be able to see clearly.

9. It is difficult carrying, playing with or looking after my children. They hit on my spectacles, hold my spectacles or pull my spectacles off my face. Without spectacles, I can't see anything. Sometimes, frame may also cause an injury to my little one's face. People may think that I don't even know how to look after my kids. (021; 38/f; high myopia; spectacles)

10. It is difficult to get married. [In an arranged marriage] Relatives of a girl get worried about the consequences of having high refractive error, thinking I may not be able to look after the bride very well in the future, and thinking I may pass my eye condition to our children in the future. (036; 24/m; high myopia; spectacles)

11. When I come to hospital, I pacify myself saying at least I can see with these spectacles. I am able to do well in my academic career as well. There are people with more severe problems. (036, 24/m; high myopia; spectacles)

4.2.3.5 Theme 5. Refractive error impacts on economic well-being

Three-quarters of participants reported economic impact from having refractive error. Cost of buying spectacles or contact lenses or laser refractive surgery, direct and indirect (e.g. travel) costs for getting eye check-up, cost of lubricant eye drops (particularly having to use it for a long time after refractive surgery), and refractive error affecting work were common issues uttered by the participants (quote 12). The cost of buying spectacles was more of a concern to the participants with URE. Whereas, concern for cost of buying contact lenses were reported by only the participants currently wearing contact lens. Few participants believed clinicians were only interested in making profits (selling spectacles or from other services) and therefore gave biased information. On the other hand, most of the participants who had laser refractive surgery said that it was expensive, but worth the value. On the whole, people with URE reported more adverse economic impacts of refractive error.

12. Spectacles are expensive particularly for high power like mine; comfortable spectacles are even more costly. I try to be very careful not to break them. In addition, travel cost to go to buy new spectacles: food, accommodation, bus fare is costly. I have to go to see a doctor every six month or a year. (003; 19/m; high myopic astigmatism; spectacles)

4.2.3.6 Theme 6. People with refractive error experienced general- and ocular-comfort symptoms

Nearly half of the participants reported general symptoms associated with refractive error such as headaches and giddiness (quote 13). They were reported to be more problematic by URE participants. On the other hand, participants who had refractive surgery or contact lenses reported more ocular-comfort symptoms. The most common ocular-comfort symptoms reported were itching, dryness, watering, burning and ocular discomfort (quote 14). Dry eye was more common in refractive surgery group. Interestingly, tired eyes was reported only by those who had refractive surgery. Similarly, heaviness in eyes was more common in contact lens wearers and in hyperopia. URE participants more frequently reported eye pain.

13. It's been four years since I'm having giddiness and headaches when reading small prints. I feel as if I am going to faint. (011; 45/f; mild hyperopia and presbyopia; URE)

14. When looking at my computer for quite some time, there is a burning sensation in eyes.

It causes discomfort and irritation, followed by watering…. Problem increases in when dust goes inside the eye [when wearing contact lens]. It gets itchy as well. Therefore, I rarely wear contact lenses these days. (049; 20/f; moderate myopia; spectacles and contact lens wearer)

4.2.3.7 Theme 7. People with refractive error experienced visual symptoms

Most of the participants reported blurred or cloudy vision at various distances. These symptoms predominantly came from the URE group (quote 15). However, many participants wearing spectacles or contact lenses also reported having these symptoms occasionally. Participants with myopia, and with laser refractive surgery had more glare and light sensitivity compared to hyperopes and other types of refractive corrections, respectively. Comparing between refractive error correction groups, distorted vision, blurred vision in rain, and loss of peripheral vision were reported by spectacle wearers only. Participants with laser refractive surgery reported difficulty focusing at things for a long time particularly in the initial days after surgery.

15. Letters and numbers written here [points to his mobile phone] are blurry. It becomes slightly clearer when I increase the brightness. The problem is worse in dim light or at dusk– everything is blurry. (020, 49/m, hyperopia and presbyopia, URE)

4.2.4 Discussion

This study qualitatively explored the impact of uncorrected and corrected refractive error in a low- and middle-income country setting from patient's perspectives. Based on the shared experiences of participants of the study, this research identified seven themes that determined the impact of refractive error on QoL of adults: Activity limitation, Inconvenience, Health concerns, Psychosocial impact, Economic concerns, General- and ocular-comfort symptoms, and Visual symptoms. Refractive error has a diverse spectrum, and therefore the significance of these themes varies across the sub-groups.

The majority of the limitations in day-to-day activities were reported by URE participants. Refractive correction also added limitations. For some activities, both groups reported limitation. However, nature of difficulty was different. For instance, URE participants had limitation in playing sports or cooking due to poor vision. Whereas, spectacle wearers had difficulty for these activities due to fogging up of spectacle lenses or spectacles falling off their face. While QoL issues may be common between groups, extent and mechanism of impact may vary.

Similarly, inconvenience was the most important issue in spectacles wearers. Many participants who were classified as URE in this study based on their habitual status, particularly from rural areas involved in manual agricultural works, had stopped wearing spectacles due to inconvenience. Even in high-income country setting, farmers and other manual workers have been reported to have used optical correction less frequently.[333, 334] Likewise, several participants in this study also reported inconvenience handling contact lens. One of the reasons for poor compliance

to contact lens care reported widely in the literature may be due to the inconvenience.[335]

Health and psycho-social impact varied between refractive sub-groups. Younger spectacle wearers, particularly female, were concerned about the aesthetics, as reported elsewhere.[336] Most of the negative emotional reactions expressed were related to spectacles wear and URE. Spectacle wearers reported more problems participating in the social functions mainly because of their appearance. This was the main reason why many of them used contact lenses for social occasions only. Possibilities of having side effects or complications were the major concerns for participants wearing contact lens. All the contact lens wearers reported these concerns as Kathmandu was polluted and dusty.[332] Because of this reason, most of them reported wearing contact lenses only occasionally. Similarly, concerns such as possibility of having to wear spectacles again due to relapse of refractive error were the major issues for the participants who had refractive surgery. Nonetheless, refractive surgery was found to be invaluable in addressing the socio-emotional issues related to spectacle wear.

Economic reason is widely recognised as a major barrier to accessing refraction services.[9, 124, 125, 153, 328, 334] In this study, cost related reasons were the major economic concerns particularly for URE, despite refractive correction being one of the most cost-effective way of correcting avoidable visual impairment.[334, 337] In this study, many participants reported difficulty doing manual agricultural works while wearing spectacles (owing to inconveniences such as spectacles falling off the face, or spectacle lenses fogging up). Economy of Nepal is largely based on agriculture where majority of people practise manual farming. Thus, refractive error may hugely impact on the country's economy. In Nepal, out-of-pocket payment is the most common way of getting eye examined or having refractive correction.[328] This is different in high-income countries where the participants generally have complete or partial insurance.[14, 336, 338] Moreover, in Nepal, people in the remote areas do not have good access to refraction services with cost implications for travel to eye centres.[327, 328, 339] In addition, beliefs of profit motives of the clinicians leading to biased information were observed in this study similar to reports elsewhere.[336] In this study, spectacles wearers did not express economic concerns for buying contact lens. Probably, inconvenience, health concerns and other reasons were more influential reasons for them to decide not to wear contact lens. Many participants were not aware about the availability or cost of contact lens, and in rural areas contact lenses are not readily available.[328]

Most of the general, ocular-comfort or visual symptoms discussed in this study were similar to the findings in the study conducted in Australia.[14] This is logical as symptoms mainly depend upon the pathophysiology of the condition. Headaches and giddiness were the most common general symptoms reported by the participants. The relationship between refractive error and headaches

has been widely discussed in the literature, but mechanism behind this is unclear.[340] Similarly, ocular-comfort symptoms were more prominent in participants with laser refractive surgery or with contact lens. Dry eye is a common side effect of refractive surgery and contact lens wear.[14, 15] Likewise, visual symptoms were more pronounced for URE. Interestingly, I found that wearing spectacles might add visual symptoms such as blurred vision in the rain and distorted vision.

In this study, participants with contact lenses and with refractive surgery mentioned preferences and reasons for choosing their refractive correction modality. Many participants chose to wear contact lenses despite their concerns about potential complications and ocular discomfort for aesthetic appearance. Similarly, many chose to have refractive surgery despite concerns about cost, and about potential short or long-term complications as they valued more for appearance without spectacles and the convenience that comes with not having to wear spectacles or contact lenses. However, as preferences are only indirect methods of assessing quality-of-life, they are not discussed in detail here.[16] Similarly, some participants shared their opinions about how their refractive error related issues could be addressed. For example, participants with high refractive error who complained of spectacles being thick and heavy causing marks over nose or ears, wished lighter spectacles to be cheaply available. In a similar note, since the aim of this study was to explore the current (habitual) impact of refractive error or refractive corrections, participants' perceptions and opinions are not discussed in detail. Alternatively, the study findings provide indirect information on the preferences, perceptions, compliance, and barriers to refractive error services.

Whilst positive outcomes of refractive correction have been reported in this study, the higher number of negative comments discussed in this study should not undermine the benefits of refractive corrections. In general, as reported elsewhere[14], participants with refractive correction had better QoL status compared to participants without correction. However, participants with refractive correction had poorer QoL when they compared their QoL status with the people without refractive error. This conclusion has been drawn qualitatively.[14] To determine the extent or quantify the QoL status, a comprehensive PRO measure with robust psychometric properties should be used.[15, 16]

This study explored the impact of refractive error on QoL of adults with their habitual correction status. The majority of participants in the URE group were not 'never-worn-spectacles' but did not habitually use spectacles. Many presbyopes, reported using their spouse's spectacles occasionally while doing some near tasks such as reading. Many participants reported they stopped using spectacles due to inconvenience, and the cost of new ones. Further, understandably, the participants who considered having refractive surgery had more concerns and dissatisfaction about

wearing spectacles or contact lens. Clinicians and health service providers should be aware about comprehensive impact of refractive error including inconvenience, health concerns, psychosocial and economic impacts, particularly of refractive correction. Otherwise, compliance and effectiveness of their services are doubtful.[328, 335]

The study had some limitations. The participants were recruited from hospital settings only. In Nepal, in addition to eye care facilities, a significant amount of refractive error services are provided in the outreach programs, as the eye centres are located mainly in the cities. People in remote locations may not have access to eye hospitals and perhaps their concerns and issues would be different.[327, 339, 341] However, this limitation is minimized by a careful selection of the study centres. The TIO is a reputed tertiary eye care centre in Kathmandu, with a large network of primary eye care centres outside Kathmandu valley. Although, the TIO is located in the capital city, its catchment area is not limited to Kathmandu city. In addition, it receives hundreds of referred cases from its primary eye care centres and other eye facilities.[328] Similarly, Dhulikhel Hospital is a community hospital with more direct reach to the rural communities. Having participants across a range of sociodemographic profile, using a purposive sampling, has further minimized this limitation.

Sample size in a qualitative study generally depends upon when the thematic saturation is reached.[317] This study has a relatively larger sample size than one would expect. This is because the aim was to achieve saturation within refractive error and correction subgroups. The overarching aim of this study was to develop item (question) banks (An item bank is a PRO instrument with a large number of items calibrated to measure a common construct). Therefore, in-depth interviews were conducted until there were repetition of items and no further new issue was obtained. After data saturation was reached, further interviews with 2-3 participants were conducted in each sub-group for validity. Fewer number of interviews would be sufficient to study only the most important aspects. Interestingly, less-expressiveness was observed in Nepalese adults with refractive error compared to their Australian counterpart indicating need for larger sample size.[14] A new study looking at differences in expressing impact of a condition in low- and high-resource settings would be interesting.

The purposive sampling was employed to gather perspectives of diverse groups of refractive error by its sub-types, correction types and socio-demographics. It is a sampling technique commonly used in qualitative studies.[315, 317] Refractive error is a heterogeneous condition including people with different levels of myopia, hyperopia, astigmatism and presbyopia. Similarly, refractive correction ranges from simple spectacles to sophisticated refractive surgery procedures. However, purposive sampling is a non-probability, non-representative sampling which has several short-

comings. It may introduce selection bias. The proportion of participants in this study may not represent the proportion of types of refractive error, or types of refractive correction in Nepalese communities. For example, about one-fifth of the participants in this study had refractive surgery, whilst refractive surgery is rarely used as a method of refractive correction in Nepal, even in urban settings. Despite these limitations, purposive sampling was useful for the purpose to explore QoL impact of wide spectrum of refractive error and its socio-demographics. This is a qualitative study with a phenomenological approach exploring the ways by which refractive error can impact people's QoL, rather than measuring or quantifying the extent of impact of refractive error. Quantitative study may be more important to study the extent of impact.[316] Therefore, readers should exercise a caution while making inferences. To minimize the inherent biases of using purposive sampling, I have described findings of this study qualitatively, keeping numbers to a minimum.[342], Numbers or percentages are only for illustrating the overview of the qualitative material. [317, 342]

Another potential bias in a qualitative study is the researcher bias. In a qualitative study, investigator actively participates to increase understanding of a phenomenon (constructionism).[316, 317] Analysis may depend upon the angle at which investigator interprets the data. Textual interpretation in turn depends upon preconceptions and reflexivity.[317] In this study, I tried to maintain a neutral position while conducting interviews and analysing the data. However, perfect neutralism is not possible.[317] I conducted a similar study in Australia (Section 4.1) just before this study. I acknowledged this limitation before starting the study. Therefore, to minimize this bias, I trained a nurse (SNK) to conduct interviews and code the data. SNK also interviewed and coded the data. Interviews and coding by both the researchers were qualitatively compared. The audio files and transcripts were regularly audited by my PhD supervisor (JK) to minimise the effect of preconceptions and reflexivity. In addition, in the current study I used inductive method of analysis unlike the deductive followed by inductive method in Australia. First the codes were identified. Based on the relationships between the codes, other structures were finalized.

In addition, some findings of this study may not be similar for other LMIC settings as QoL is a multidimensional concept that depends on many socio-cultural factors. The specific issues vary in different places although concepts may be similar. This limits external validity, particularly generalizability of the conclusions. One could argue that another limitation of the study is in the methodology that only in-depth interviews (no focus group discussions) were carried out, for convenience and easier logistics.

Despite these limitations, qualitative study is important to comprehensively understand a disease or a condition along with its contextual information.[315, 316] It creates useful knowledge to aid clinical

practice. It addresses limitations of quantitative research which is confined to areas that can be quantified or analysed using statistics.[315, 316] A person's life, feelings and experiences may not merely be translated into statistics.[316] Quantitative research often misses out doctor-patient interaction, opinions and experiences.[316] In order to understand impact of refractive error, it is essential to understand people who are the primary subjects living and experiencing refractive error.[316] For example, when a surgeon is doing a refractive surgery, he is not just treating refractive error, but treating a person with refractive error living in a socio-cultural environment. A qualitative analysis, which involves textual interpretation rather than statistical analysis, enables comprehensive assessment including context.[315, 317]

In conclusion, this study added evidence to the sparse literature on impact of URE or its correction on QoL in LMIC settings.[16] The findings adhere to the literature that report refractive correction do not always address all the QoL issues of URE, but often adds issues such as psychosocial impact, inconvenience and concerns.[14] In general, spectacles and contact lens wearers had more QoL issues than the refractive surgery group as reported earlier.[14, 27] Services should be tailored to individuals based on their refractive error subtypes, correction types and their socio-demographics. The improved understanding of the ways how refractive error impact on QoL are important for promoting valued refractive care. Another significance of this study is that the QoL issues identified will be used to develop item banks to comprehensively and scientifically assess refractive error-specific QoL in LMIC settings.[14-16, 51, 343, 344]

4.3 Critical appraisal of the qualitative findings–Australia and Nepal

Several interesting similarities and differences in QoL issues were identified between the two settings. Table 4.8 shows the comparison of number of unique quality-of-life issues between Australia and Nepal. From the interviews conducted in Australia, 2,367 comments from the interviews were coded to 294 unique issues. Similarly, about 3,477 comments from the interviews in Nepal were coded to 308 unique issues. Overall, only about 45% of the unique issues were common to both the settings.

Table 4.8 Comparison of unique issues between Australia and Nepal

	AL	MB	VS	OS	GS	HC	CV	EM	SC	EC	CP	Total
Australia	60	18	25	14	8	41	43	41	14	17	13	**294**
Common issues	37	10	18	12	3	30	33	16	9	10	10	**188 (45.4%)**
Nepal	72	14	23	14	5	39	64	32	16	15	14	**308**

Note: AL = Activity limitation, CP = Coping, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, OS = Ocular-comfort symptoms, SC = Social, VS = Visual symptoms

Some common inconveniences reported were difficulty adapting to new pair of spectacles, not being able to wear normal sunglasses and having to go for frequent eye check-ups. In Nepal, most of the participants from the capital city (Kathmandu) reported that not being able to wear dust-mask when wearing spectacles was inconvenient. Similarly, many reported inconvenience having to travel long distance to have their eyes examined or to make spectacles as eye centres were located only in the urban areas. Contact lens related inconveniences were more prominent in Australia; in Nepal most of them used only occasionally due to pollution. The participants from Australia more frequently reported inconvenience having to wear goggles over their spectacles while snorkeling or watching 3D movies.

The most common concerns raised were regarding the cosmetic appearance with spectacles, and prescription of spectacles getting worse. Participants considering refractive surgery were worried about possibilities of having to wear spectacles even after laser refractive surgery. Contact lens participants in Nepal were particularly worried about getting complications from contact lens wear, again due to pollution. Participants in Nepal were also concerned about their facial appearance in photographs due to spectacles. They were also concerned about what other people might say about them when wearing spectacles, and were concerned that they might get insulted. Participants from Australia who had considered laser refractive surgery were concerned about having complications from laser refractive surgery e.g. infection and scarring.

The participants with URE predominantly reported difficulty in doing day-to-day activities due to having refractive error. Many reported difficulties doing manual agricultural works such as cutting grass and collecting firewood wearing spectacles. Therefore, many said they stopped using spectacles. Uncorrected presbyopes reported difficulty in near tasks such as threading a needle. In Australia, participants reported difficulty doing sports, leisure or recreational activities. They reported difficulty particularly for swimming. Driving was more important issue for the participants in Australia. Similarly, some participants in both settings reported mobility problems such as difficulty using stairs particularly when wearing multifocal spectacles. For some activities, different groups experienced similar issues, but the extent of impact and reason behind the impact were different. For example, URE participants found it difficult to play sports due to poor vision, whereas, spectacle wearers found it difficult to play ball games as the spectacles would keep falling off their faces.

Many participants in both the settings reported feeling embarrassed wearing spectacles, and they said they felt older than their actual age wearing spectacles. Many participants in Nepal reported feeling regretful about their eye care in the past. Similarly, many participants from both settings reported problem attending social functions due to their appearance with spectacles, and many

wore contact lenses only on those occasions. Many participants in Nepal, particularly female participants reported difficulty getting a life-partner or getting married due to having refractive error. Participants from both the settings reported several coping techniques to deal with their refractive error such as squinting or squeezing their eyes to see clearly.

Cost of spectacles and contact lenses were reported to be concerns in both the countries. Most of the participants in Nepal reported concerns for direct and indirect cost for eye check-up as insurance system is not common in Nepal. Most of the symptoms reported in Australia and Nepal were common, as symptoms mainly depend upon the pathophysiology. Few symptoms were more common in either of the two settings, such as itchy eyes was more common in Nepal perhaps due to pollution. Blurred vision was more commonly reported in Nepal mainly by the URE participants.

Both these qualitative studies showed different ways how refractive error could impact on people's QoL. Impact of refractive error on QoL is multi-dimensional, and influenced by various socio-cultural factors. Because of refractive error, people live with a number of inconveniences. They are concerned about their refractive error and its direct and indirect consequences. Likewise, they experience problems in day-to-day activities, mobility and social issues. Similarly, they live with visual, ocular-comfort or general symptoms owing to having refractive error or its correction. Likewise, they reported experiencing economic and emotional impact. Many participants also reported adopting several coping strategies to deal with the consequences of refractive error. Patients' aims for refractive correction may be beyond achieving good visual acuity (Figure 4.4).

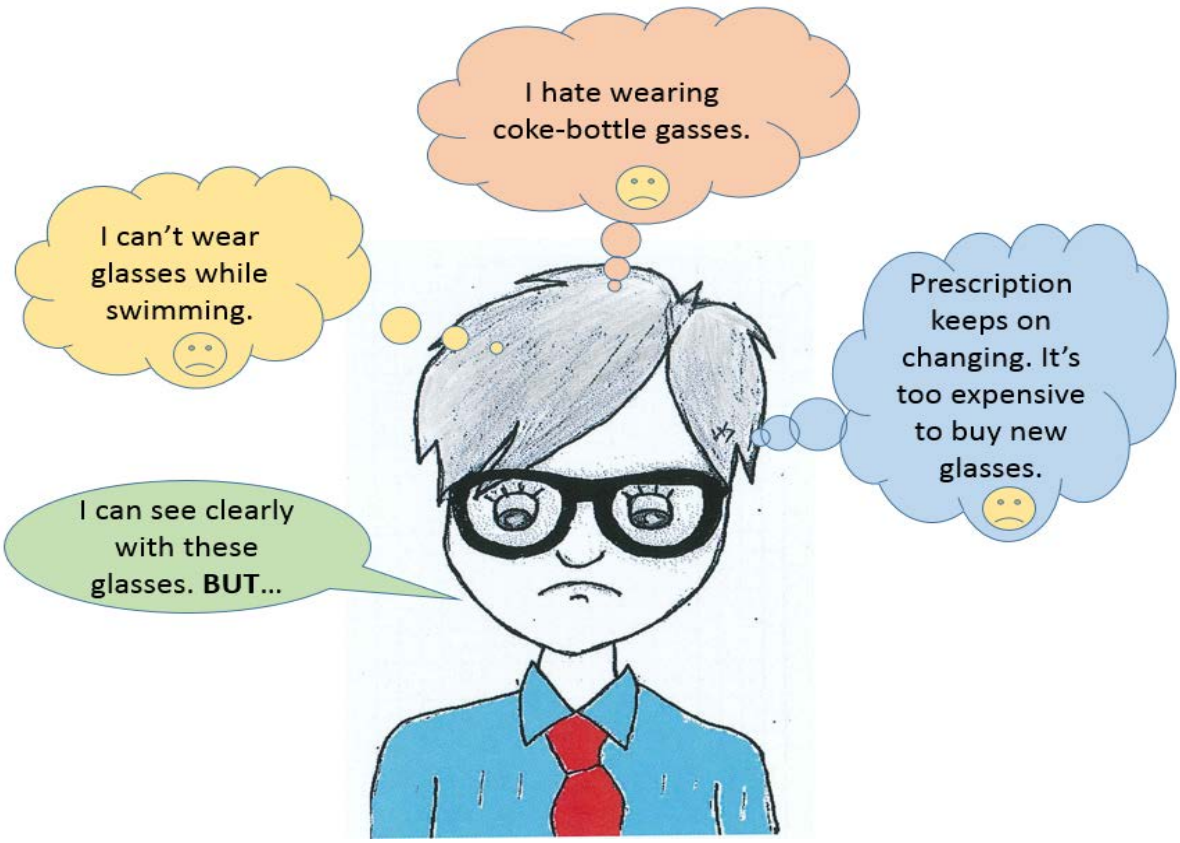

Figure 4.4 Patient's aim is beyond achieving good visual acuity

In both the studies, interesting similarities and differences in QoL impact of refractive error were observed between refractive error sub-groups. Interestingly, in both studies, I found that refractive correction not always addresses all the QoL issues of URE, but often adds issues. For example, many participants, particularly young females, wearing spectacles were highly concerned about their cosmetic appearance with spectacles. In general, spectacles and contact lens wearers had more QoL issues than refractive surgery group as reported earlier.[14, 27]

The limitations of qualitative studies such as bias owing to reflexivity and preconceptions of the researcher and efforts to minimise bias, limitations due to purposive sampling and justification why it was adopted, and issues about generalisability were explicitly discussed in discussion sections of both the studies (Sections 4.1.4 and 4.2.4). Similarly, more number of negative comments discussed in both studies should not undermine the benefits of refractive corrections: this has also been discussed in discussion section of both studies. One of the other important limitations of the Australian study was that it did not have any participants with URE. It was a typical high-resource setting scenario where refractive error is expected to be corrected.

Both these studies may have important implications. To my knowledge, there is no other published

study that has qualitatively explored the impact of refractive error on QoL in adults. Being the first of their kind, they provide useful insights about refractive error-specific QoL to refraction service providers (e.g. clinicians, managers, and non-governmental organisations.), researchers and policy makers. Most of the existing literature on refractive error-specific QoL is from high-resource setting. Similarly, QoL implications of URE is under-researched. Therefore, the study findings are especially useful to understand QoL implications of people with URE, particularly from the low- and middle-income country settings. As discussed in Chapter 3, even the studies quantitatively reporting QoL implications of refractive error are not reliable because of the use of poor quality PRO instruments.[16] Both current study results highlight that refractive service providers should tailor their services to the socio-economic, cultural and individual characteristics for achieving a better compliance. There is no 'one size fits all' when it comes to refractive correction.

These qualitative studies are the foundation of the development of technologically advanced PRO for refractive error (Item banking) administered through a CAT system.[15, 30] Qualitative analysis indicated a need for two separate item pools for Nepal and Australian settings, as more than half of the issues (54.6%) were unique to either of the settings. In chapter 5, I have explicitly discussed how I have extracted items from these qualitative studies to inform the content of the refractive error item banks. An item bank is new generation PRO measure. It has a large number of items (questions) calibrated to measure a common construct by using modern psychometric methods such as Rasch Analysis.[16] Therefore, it is more likely to have content relevant to diverse settings unlike short questionnaires. In addition, this is more likely as I have included diverse participants in terms of their clinical socio-demographical characteristics. Moreover, an item bank is a flexible PRO instrument. If a need for new items are felt, the new items may be anchored to the calibrated items.[74] Item banking implemented via the CAT system will then make it possible to rapidly and accurately measure refractive error-specific QoL in a valid and reliable way.[15, 23, 29, 31, 32] More details on item banking and CAT system are provided in the chapters 5, 6 and 7.

4.4 Outputs from this chapter

Both the qualitative studies have been published in reputed ophthalmology journals, and have been received well by the ophthalmic community and the general people (Appendix D).[14, 63] The study from Australia was published as a lead feature of the 2017, October/November issue of the Clinical and Experimental Ophthalmology journal, a leading international ophthalmology journal.[14] The article is the 'Editor's choice free article', available to the readers free of cost. A high-quality editorial was written for this article.[345] In addition, this article was selected for the Continued Professional Development points for the Royal College of Australian and New Zealand College of Ophthalmologists (RANZCO) Fellows[346, 347] This article was of interest to the general public as well,

and was covered by at least eight news media (Appendix E). Likewise, the study from Nepal was published in Ophthalmic Epidemiology journal, another leading international journal in ophthalmology.[63] A blog was published in the International Agency for Prevention of Blindness (IAPB)–standard list website and newsletter, from both qualitative studies (Appendix D).[348]

The results from the qualitative study in Australia were presented (poster) at the Australian Society for Medical Research – South Australia (ASMR-SA) Annual Scientific Meeting, June 2016, Adelaide, Australia. Similarly, the results from the qualitative study in Nepal was presented (oral) at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, May 2017, Baltimore, USA.[51] Likewise, a comparison of findings from these two qualitative studies was presented (oral) at the Flinders Health Research Week, September 2017 (Appendix D).

Chapter 5. Development of content for the refractive error-specific item banks

5.1 Introduction

This chapter describes the systematic multi-step process involved in the development of content for the item banks for measuring refractive error-specific QoL. The content for the item banks were identified from the existing PRO instruments and the qualitative studies. The content identification process is a part of Phase I of the overarching project of developing refractive error-specific item banks implemented through the CAT system.

The need for a comprehensive and scientifically robust PRO instrument for refractive error was identified from the literature review (Chapter 3). A PRO instrument should measure what the developers intended it to measure (content validity) in the target population.[349-351] Irrelevant or poorly designed content in a PRO instrument can result into poor quality data and false conclusions. Importantly, while the content validity of a PRO instrument may be proven psychometrically robust in one population, it may be poor for another population owing to issues with cross-cultural adaptation.[350] In practice, a PRO instrument is commonly used in settings that are different from which it was originally constructed.

Simultaneous content identification may be particularly important for refractive error as URE is mainly a problem of low- and middle-income countries, and refractive error is more likely to be corrected in high-income countries.[6, 290] I conducted a qualitative study in Australia, in a typical high-resource setting, and I could not recruit any participant with URE.[14] Therefore, a second qualitative study was conducted in Nepal which is a low-income country with a huge unmet need for refraction services, with abundance of URE population.[63, 327] The findings of the qualitative studies were discussed in detail in Chapter 4. The aim of the study described in this chapter (Chapter 5) was to identify minimally representative, informative and efficient sets of items for measuring refractive error-specific QoL in both high-income (Australia) and low-income country (Nepal) settings, and determine if two different item banks were needed for these disparate settings.

5.2 Methods

I followed the standard methods of PRO instrument development as per the guidelines provided by the Consensus based Standards for the selection of health status Measurement Instruments (COSMIN) study[50] and the US Food and Drug Administration (FDA).[25] The content of the refractive error item banks were derived from existing refractive error-specific questionnaires and in-depth

patient consultation. The methodology used in this study is aligned with the methods used in development of item banks for other eye or health conditions.[29, 57, 62, 352] First, the literature review and a qualitative study in Australia were conducted simultaneously, followed by a new qualitative study in Nepal. Subsequently, the content of the item banks was extracted from the literature and qualitative studies.

The content identification and refinement of the refractive error-specific item banks consisted of four steps: (1) Identification of extant items, (2) Development of items from new qualitative studies in patients with refractive error, (3) Item classification and selection, and (4) Cognitive interviews (Figure 5.1). This was an iterative process consisting of multiple sessions of review and revisions. First, a set of domains and items for refractive error-specific item bank was developed in Australia (Item-pool (Australia); Appendix G). The item-pool (Australia) was then translated into Nepali language. After that, the cognitive interviews in Nepal were conducted to test the adequacy and relevance of the Nepalese version of the Item-pool (Australia) in the Nepalese setting. During cognitive interviews, many new QoL issues were identified, indicating that the content of the Australian item-pools was not sufficient to cater for the QoL issues apparent in the Nepalese population. Therefore, a new qualitative study in the Nepalese population was conducted.[63] A set of domains and items for the refractive error-specific item bank for Nepal (Item-pool (Nepal); Appendix H) was then developed using similar methods as in Phase I Australia.

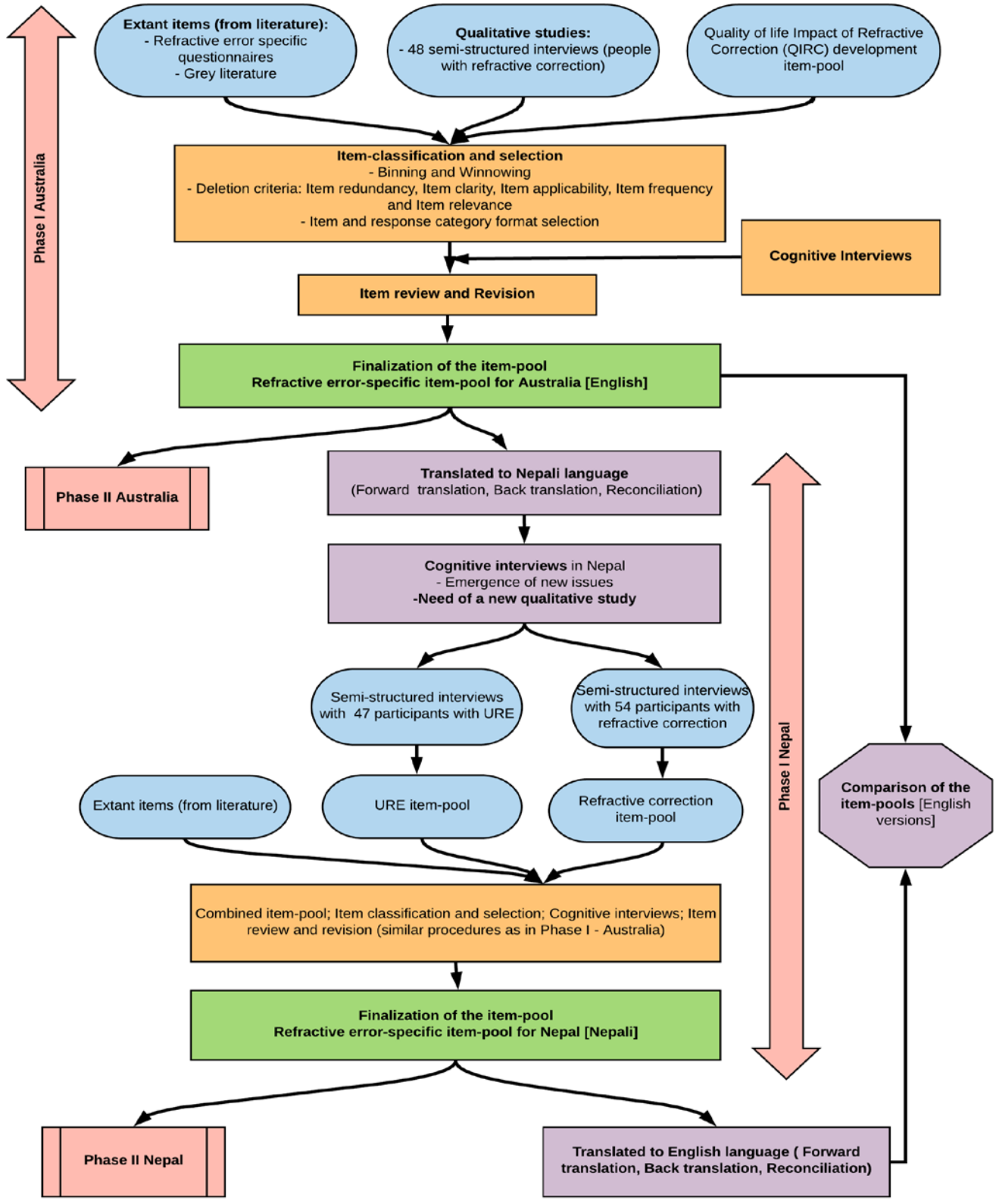

Figure 5.1 Steps for content identification in Australia and Nepal
Note: URE = Uncorrected refractive error

5.2.1.1 Identification of extant items

As discussed in Chapter 3 (Section 3.2.2), I conducted a comprehensive search for PRO instruments measuring QoL in refractive error in Medline on 22 June 2016. The search strategy was translated into PubMed, Scopus, Web of Science and Cochrane databases (Appendix B).[16] The search yielded a total of 2,054 articles.[16] Articles describing a refractive error-specific PRO instrument measuring QoL domains in refractive error were identified. This included validated and non-validated PRO instruments. Many included articles described PRO instruments that were neither validated nor named. In addition, how their items were derived was also not explained. Such instruments were regarded as grey literature in the search process.

5.2.1.2 Development of items from qualitative studies

Semi-structured telephone or face-to-face in-depth interviews with people with myopia, hyperopia, astigmatism and presbyopia, with or without correction were conducted. The extant items extracted from the PRO instruments were also used to design and interview guide to conduct in-depth interviews. For example, because most of the items in the existing PRO instruments were on activity limitation and symptoms, the interview guide consisted of broad open ended questions exploring all areas of QoL.[14, 63] The qualitative studies were conducted in Australia and in Nepal (for detailed qualitative findings, refer to Chapter 4).[14, 63] In Australia, 48 participants were recruited from the Flinders Vision clinic, the Ashford Advanced Eye Care centre, and through community advertisements. All the participants in Australia had refractive correction. This was a typical example of a high-resource setting where refractive error is expected to be corrected.[14] In Nepal, 101 participants were recruited from the Tilganga Institute of Ophthalmology (TIO) and the Dhulikhel Community Hospital (Table 5.1); almost half of them had URE.[51, 63] TIO, located at Kathmandu, is a tertiary eye care centre with a wide network of community eye care centres. It is the only place offering refractive surgery services in Nepal. Whereas, Dhulikhel hospital is located outside Kathmandu valley and has a direct access to a rural population. Clinical information was obtained from the participants' records.

Ocular examination including visual acuity and refraction was conducted when the information was not available in their clinical records. Some participants were classified under multiple categories on type of refractive error or type of refractive correction (Table 5.1). In both settings, all the contact lens wearers used spectacles as well. All the participants who underwent refractive surgery used spectacles prior to surgery. Some of the participants who underwent refractive surgery were currently using spectacles either for near, far or both. Similarly, the classification of uncorrected or corrected refractive error was based on predominant habitual status. For example, a person with presbyopia who did not use spectacles while doing near works most of the time was classified

under ‘uncorrected refractive error’.[14, 63]

The age distribution of the participants in the two samples (Table 5.1) was statistically significant (Mann-Whitney U test, $p < 0.001$). One of the reasons for this difference was that the participants in Nepal who used contact lenses or those who had undergone refractive surgery were in the younger age groups (Median age, 26 years; range 18 to 38 years) compared to their Australia counterparts (Median age, 42 years, range 22 to 60 years).

Table 5.1 Clinical and demographical characteristics of the interview participants

	Australia (N = 48)	**Nepal** (N = 101)
Median age: [(Min, Q1, Q3, Max); years]	49 (22, 34.5, 59, 76)	29 (18, 23, 45, 74)
Female [% (n)]	58.3 (28)	45.5 (46)
Country of birth [% (n)]	Australia 70.8 (34), UK 10.4 (5), Others 18.8 (9)	Nepal 99.0 (100), India 1.0 (1)
Type of refractive error		
Myopia % (n), [Severity (n)][a]	64.6 (31) [Low ,13; Moderate, 8; High, 10]	55.4 (56) [Low, 27; Moderate,15; High,14]
Hyperopia % (n), [Severity(n)][a]	10 (20.8) [Low, 6; Moderate, 3; High, 1]	21 [Low,12: Moderate,3; High,6]
Pre-presbyopic surgical emmetropia [% (n)]	14.6 (7)	18.8 (19)
Presbyopia [% (n)]	47.9 (23)	27.7 (28)
Astigmatism [% (n)]	45.8 (22)	40.5 (41)
Type of refractive correction		
Spectacles [% (n)] [Frequency of use (n)]	81.3 (39) [Very often, 20: Occasionally, 15; Rarely, 4]	59.4 (60) [Very often, 31; Quite often, 9; Occasionally, 20]
Contact lenses [% (n)] [Frequency of use (n)]	35.4(17) [Very often, 9; Occasionally, 6; Rarely, 2]	16.8 (17) [Very often, 5; Quite often, 3; Occasionally, 6; Rarely, 3]
Refractive surgery [% (n)]	35.4 (17)	19.8(20)
Un/under-corrected refractive error [% (n)]	0	46.5 (47)

Note: Some participants were classified under multiple categories on type of refractive error or refractive correction. In both settings, all contact lens wearers used glasses as well. All participants who underwent refractive surgery used glasses prior to surgery. Some who underwent refractive surgery were currently using glasses either for near, distance or both. Similarly, the classification of uncorrected or corrected refractive error was based on predominant habitual status. For example, a person with presbyopia who did not use glasses while doing near work most of the time was classified under ‘uncorrected refractive error’.
[a]Grading of severity of myopia and hyperopia (spherical equivalent) in dioptres: Low, |0.50| to |3.00|; Moderate |3.25| to |6.00|; High > |6.00|.

The interviews were conducted until no new themes emerged (thematic saturation).[14] I aimed for thematic saturation overall, and within types of refractive error and types of refractive correction. As reported in similar qualitative studies for other item banks,[29, 31] generally 10 to 20 interviews are adequate to obtain thematic saturation in a population sub-group. Although the number of

participants in refractive error sub-groups (e.g. male and female) were not equal in the current qualitative studies, thematic saturation was achieved for clinical and gender related issues. The difference in the number of participants across the groups was perhaps not a big concern as the primary aim was not to compare the extent of impact between groups, but rather to identify QoL issues. The interviews were audio-recorded, transcribed verbatim, and coded and analysed. The NVivo software, Version 11 (QSR International Pty Ltd.) was used for coding and data management.

I also obtained items from the Quality of Life Impact of Refractive Correction (QIRC) questionnaire development item-pool, which was developed in 2004 by Pesudovs *et al.*[28] The authors obtained the initial items from a literature search, retrospective analysis of case records at the University of Bradford Eye Clinic, UK, and from professional and lay focus group discussions. The professional focus groups had involved participants from refractive surgery, contact lens practice, optometry, ophthalmology, and psychology. The lay focus groups consisted of post-refractive surgery patients, contact lens wearers and spectacle wearers.[28]

5.2.1.3 Item classification and selection

Classification and selection of the items obtained from the literature and the qualitative studies were done based on systematic binning and winnowing criteria. Binning is the process of grouping items with a similar semantic meaning and which measure a similar latent trait (QoL domain). Winnowing is the systematic process of reducing a large number of binned items into a representative set of items.[62] Binning was done within the framework of 10 domains of Ophthalmic QoL identified during the thematic analysis of the qualitative interviews, namely: Activity limitation (AL), Mobility (MB), Visual symptoms (VS), Ocular-comfort symptoms (OS), General symptoms (GS), Health concerns (HC), Convenience (CV), Emotional (EM), Social (SC) and Economic (EC).[14, 32] A few items were binned into a new Coping (CP) domain. The QoL domains used in this study (Table 5.2) were consistent with the World Health Organisation guidelines, and have been published in earlier Eye-tem bank studies.[29-31] Many of the QoL domains identified in this study (e.g. Activity limitation, Symptoms, Emotional, Social, and Economic) are described in the Wilson and Cleary model or in the International Classification of Functioning, Disability and Health (ICF) framework.[353, 354]

Table 5.2 Explanatory examples of quality-of-life issues in refractive error for the identified domains

Domain	Examples of quality-of-life issues
Activity limitation	Difficulty reading at near, intermediate or far distances; Difficulty playing sports with spectacles on; Difficulty swimming; Difficulty driving at night
Mobility	Difficulty in going up or down stairs using multifocal spectacles
Visual symptoms	Glare after refractive surgery; Occasional blurred or hazy vision while wearing contact lens; Distorted vision with multifocal spectacles

Ocular-comfort symptoms	Dry eye after laser refractive surgery; Pain during recovery period of refractive surgery; Contact lens related redness in eye
General symptoms	Headache; Giddiness in the initial days of adaptation to spectacles
Health concerns	Worry about complications from contact lenses and laser refractive surgery; Worry about cosmetic appearance with spectacles; Concerns about visual outcomes with refractive corrections; Concerns about level of refractive care
Convenience	Handling spectacles and contact lenses; Having to hold reading material too far away; Wearing spectacles or contact lens in rainy, dry, windy or dusty environments; Not being able to use normal sunglasses
Emotional well-being	Surprised with how well I could see after laser refractive surgery; Happy to be free from spectacles after refractive surgery; Frustration about not being able to adapt to multifocal spectacles; Scared about possibility of having complications of refractive surgery
Social well-being	Difficulty taking care of, or playing with children (wearing spectacles); Self-conscious attending a wedding party (appearance with spectacles)
Economic	Cost of spectacles, contact lenses or refractive surgery; Cost to travel to hospital; Not being able to use computer at work for a long time (after laser refractive surgery)
Coping	Accepting the eye condition and getting used to my appearance with spectacles; Learning to live with high myopia and its consequences

Binning was followed by the winnowing process which used five deletion criteria: item redundancy (same meaning with other item), item clarity (confusing), item applicability (appropriate only for a narrow spectrum), item frequency (no or low recurrence in the literature or qualitative studies) and item relevance (of low importance or appropriateness to adults with refractive error or its correction, e.g. items from paediatric PRO instruments not relevant to adults were deleted).[30, 31]

5.2.1.4 Cognitive interviews with patients

Cognitive testing with patients was conducted to ensure that all the items were worded in a lay language, and were clear and comprehensible to the participants so that the items were interpreted correctly as intended (Table 5.3).[62, 355] The items were tested with participants across a wide range of refractive error conditions in Australia and in Nepal. In Nepal, cognitive interviews were conducted twice: first with the Nepalese version of the Item-pool (Australia) to test whether the same instrument would be applicable; second with the Item-pool (Nepal).

Table 5.3 Questions for cognitive testing

Criteria tested for	Questions
Comprehension	1. Do you have difficulty understanding the question/item? Yes/No; If yes…(probe)
Interpretation	2. What does the item/question mean to you in your own words? And how did you choose an answer?
Clarity and common language usage	3. Would you reword the question? If so, how? 4. Are the response choices consistent with the questions/items? 5. Is the question/item easy or difficult to answer?
Others	6. Are there any items too similar (redundancy)? 7. Is there any important issue not captured?

5.2.2 Item and response category format selection

Item and response category formats for each domain were selected iteratively during expert panel (my supervisors and I) revisions to enable use of items at a variety of literacy levels and remove ambiguity or cognitive processing difficulty. Patients' wordings during qualitative studies were given preference while phrasing the items.[349] Items were worded in the present tense. The National Institute of Health recommends that the patient materials should have readability below 8th grade reading levels.[356] In the item-pool (Australia), the range of Flesh-Kincaid scores for items in each domain correspond to fourth to eighth US school grade levels.[357] Lay introduction and instructions were provided in the first page of the item-pool, which included definition of refractive error and refractive correction (Appendix G). For the overall item-pool, the preceding phrase "Because of your refractive error and/or correction…" was used.

The foundation for the item and response category selection process was the domain item-root and response option formats used in other item-banks, and based on the other available evidence.[29-31, 103, 104] In a study on a refractive error population consisting participants with spectacles, contact lenses and refractive surgery, McAlinden *et al.* had found that the frequency, severity and bothersome subscales of visual symptoms were independent to each other.[236] Therefore, it was decided to have three subscales to measure frequency, severity and bothersome attributes of the symptoms domains. Similarly, four or five response options were used, along with a non-applicable option when required, for all domains (Table 5.4). If the number of response categories is too high, it increases cognitive burden. On the other hand, too few response categories provide less information about the item.[62, 103, 358] A simple and consistent item format with four to five response options has been recommended in the literature.[69, 103, 104] Items should be meaningful and easily understandable.[106] For example, an item with a double negative structure may not be good as it might increase confusion and respondent burden.[74] Consistency of the item wording style and uniform wording of the response categories has been reported to be important, particularly when using the CAT systems for reducing cognitive burden.[62, 103, 104, 358]

Table 5.4 Item roots and response categories

Domain(s)	Item root *Because of your refractive error and/or correction -----*	Response categories
VS, OS, GS (Frequency)	How often do you experience -----?	Never; Occasionally; Quite often; Very often
VS, OS, GS (Severity)	How severe is/are the -----?	Not at all; Mild; Moderate; Severe
VS, OS, GS (Bothersome)	How much of a problem is/are the -----?	None; A little; Quite a bit; A lot
AL, MB	How much difficulty do you have -----?	None; A little; Quite a bit; A lot; Unable to do because of my refractive error its correction

EM	How often do you -----?	None of the time; A little of the time; Some of the time; Most of the time; All the time
HC, EC	How concerned are you about -----?	Not at all; A little bit; A moderate amount; A lot; Extremely
SC	How much of a problem do you have -----?	None; A little; Quite a bit; A lot; Unable to do because of my refractive error or its correction
CV	How much trouble is -----?	None; A little bit; A moderate amount; Quite a lot; Extremely
CP	Do you cope by -----?	Not at all; A little bit; A moderate amount; A lot; Extremely

Note: AL = Activity limitation, CP = Coping, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, OS = Ocular-comfort symptoms, SC = Social, VS = Visual symptoms

5.2.3 Expert review and revision of items

Each step described above was done following consensus among a panel (my supervisors and I: optometrists with internationally recognised expertise in PRO development).[15, 16, 18, 23, 26, 28-30, 33, 42, 46, 77, 116, 344, 359] During binning and winnowing, and after cognitive testing with the patients, the expert panel reassessed the items for the clarity and appropriateness based on five criteria outlined above. The expert panel review reduced bias in selecting, amending, or deleting items. In addition, I consulted other technical experts (five optometrists and two ophthalmologists) for their input on the relevance of the items before finalising the item-pools.

5.2.4 Linguistic translation and comparison of item-pools

The Item-pool (Australia) (Appendix G) was translated into the Nepali language using standard protocols of forward and back translation in order to adapt it to the Nepalese setting (Figure 5.2).[360] First, the English version was translated into the Nepali language independently by two people (HK and SNK (a nurse)) fluent in both English and Nepali. The translated versions (Nepali) were then reconciled via consensus between HK and SNK. The third Nepali native speaker (my supervisor, JK) with a good command of the English language reviewed and revised the translation. The translated Nepali version was then back translated into English by the fourth native Nepali speaker (AK). Finally, all translators reviewed the original and back translated version (English) and finalized the Nepali version of the Item-pool (Australia). Likewise, the Item-pool (Nepal) (Appendix H) was translated into English using similar procedures in order to compare the content with the Item-pool (Australia) (Figure 5.2).

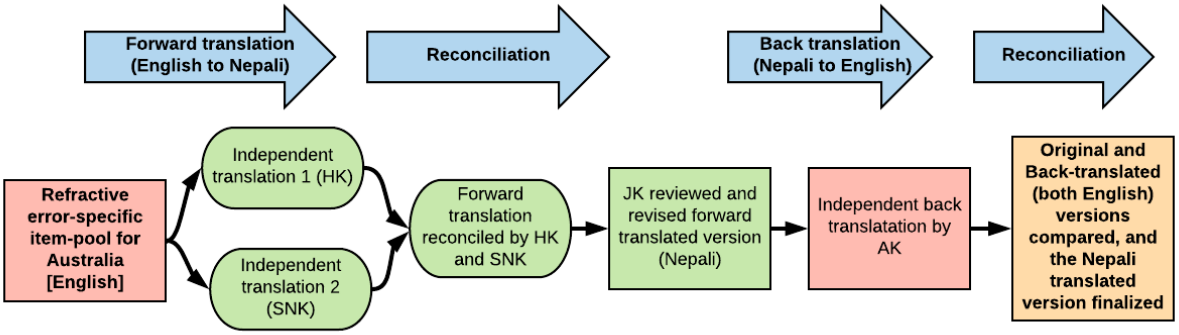

Figure 5.2 Translation of Item-pool (Australia) into Nepali language
Note: HK = Himal Kandel (author), JK = Jyoti Khadka (PhD Supervisor), AK = Anish Kharal (an optometrist fluent in English and Nepali), SNK = Sandhya Neupane Kandel (a nurse fluent in English and Nepali)

5.3 Results

5.3.1.1 Identification of extant items

I identified 19 refractive error-specific PRO instruments comprising a total of 677 items (Table 5.5). A total of 590 items from 18 PRO instruments were extracted as the content of the Refractive Error Quality of life scale (REQ-Thai) could not be retrieved.[44] Three of the PRO instruments (the REQ-Thai[44], the Visual Function and Quality of Life (VFQoL)[12] and the Near Vision-related Quality of Life (NVQL)[54]) were constructed in low- and middle-income country settings.[12, 44, 54] An additional 202 items from 21 articles describing 21 unvalidated refractive error-specific PRO instruments were retrieved.[361-381] About two-thirds of the extant items related to activity limitation and symptoms. Other items were about health concerns (18%), convenience (7%), emotional (5%), and others (4.1%).

Table 5.5 Refractive error-specific PRO instruments used to extract items for the initial item pool

Instrument / Author (Year)	No of items	Basis of original content development
PERK Study Questionnaire / Bourque (1986)[41]	16	Not reported
Canadian Refractive Surgery Research Group Quality of Vision Questionnaire (QVQ) / Brunette (2000)[40]	93	Other PRO instruments; expert input
Refractive Status and Vision Profile (RSVP) / Schein (2000)[37]	42	Literature review; patient and expert input
Contact Lens Dry Eye Questionnaire (CLDEQ) / Begley (2001)[52]	55	Another PRO instrument
National Eye Institute Refractive Quality of Life (NEI-RQL) / Berry (2003)[35]	42	Focus groups with patients
Institute for Eye Research Multidimensional Quality of Life for Myopia / Erickson (2004)[43]	45	Literature review; patient and expert input
Subjective Vision Questionnaire (SVQ) / Fraenkel (2004)[42]	24	Literature review; expert input
Quality of life Impact of Refractive Correction (QIRC) / Pesudovs (2004)[28]	20	Literature review; patient and expert input
Myopia-specific Quality of Life Questionnaire / Lee (2005)[1]	34	Other PRO instruments; patient and expert input

Spectacle Survey (ACHIEVE study) / Walline (2006)[48]	37	Not reported
Pediatric Refractive Error Profile (PREP-26) / Walline (2006)[48]	26	Not reported
Near Vision-related Quality of Life (NVQL) / Patel (2006)[54]	13	Other PRO instruments
Contact Lens Impact on Quality of Life (CLIQ) / Pesudovs (2006)[46]	28	Literature review; patient and expert input
Visual Function and Quality of Life (VFQoL) / Brady (2010)[12]	16	Other PRO instruments
Freedom from Glasses Value Scale(FGVS) / Levy (2010)[53]	21	Patient input
Quality of Vision (QoV) / McAlinden (2010)[33]	30	Literature review; patient and expert input
Refractive Error Quality of life scale (REQ-Thai) / Sukhawarn (2011)[44]	87	Other PRO instruments *[Note: Content could not be retrieved]*
Near Activity Visual Questionnaire (NAVQ) / Buckhurst (2012)[34]	10	Literature review; expert input
Student Refractive Error and Eyeglass Questionnaire (SREEQ) / Crescioni (2014)[49]	38	Other PRO instruments
Total	**677**	

Note: The PRO instruments are listed in the chronological order of development. ACHIEVE = Adolescent and Child Health Initiative to Encourage Vision Empowerment, PERK = Prospective Evaluation of Radial Keratotomy, PRO = Patient-reported outcome

Out of 792 items identified, 678 items were retained. 33 global (non-specific) items (e.g. QVQ[40] item: "I am satisfied with the results of my operation") were excluded. Similarly, 81 items on utility, patient-reported experience measure, non-measurable construct, demographic characteristics, clinical information, or items related to health behaviour, which did not directly measure QoL domains, were also excluded. Some of the examples of excluded items were: Refractive Status and Vision Profile (RSVP)[37] 'utility' item: "I could accept less than perfect vision if I didn't need glasses or contact lenses anymore."; Freedom from Glasses Value Scale (FGVS)[53] 'patient-reported experience measure' item: "Willingness to recommend to others"; National Eye Institute Refractive Quality of Life (NEI-RQL)[35] 'non-measurable construct' item: "When driving at night, do you need to wear glasses or contacts?". Only 27% of the retained items were unique (n = 184) to each other, and were included in the item-pools (Australia, 181; Nepal, 25). These items were supplemented with the new items derived from the qualitative studies.

5.3.1.2 Development of items from the qualitative studies

The participants with wide spectrum of refractive error in regards to their country of birth, age, gender, geography (low- and high-income countries, urban and rural), education level (illiterate to doctoral education), employment status, marital status, types of refractive error (various levels of myopia, hyperopia, astigmatism and presbyopia), types of refractive correction (URE, spectacles, contact lenses, refractive surgery), and frequency of spectacles or contact lens wear (Table 4.3, Table 4.5) were interviewed.[14, 63] In Australia, a total of 2,367 comments from the qualitative interviews were initially developed into 807 items.[14] Similarly, in Nepal, 3,477 comments were developed into 914 initial items.[63] Qualitative analysis indicated the need for two separate item banks for Nepal and Australian settings, as more than half of the issues (54.6%) were unique to

either of the settings. The Item-pool (Australia) was supplemented with the QIRC-item-pool, which consisted of 377 items.[28]

5.3.1.3 Item classification and selection

The initial item pool therefore consisted of 2,890 items (Table 5.6). The items were classified into 11 QoL domains for both Australia and Nepal. After the systematic binning and iterative winnowing process, the item-pool for Australia consisted of 343 items and 311 items for Nepal.

Table 5.6 Extraction of items from various sources

Source	No of items
A. Extant items	**792**
a. Refractive error-specific patient-reported outcome instruments	590
b. Grey literature	202
B. Qualitative Studies	**2,098**
a. Interviews, Australia	807
b. Interviews, Nepal	914
c. Quality of life Impact of Refractive Correction item-pool	377
Total number of initial items	**2,890**

5.3.1.4 Cognitive interviews with patients

Cognitive testing was done through in-depth interviews with 15 participants in Australia and 10 participants in Nepal for the Item-pool (Australia) and Item-pool (Nepal), respectively. The participants had representation from refractive errors sub-types (low, moderate and high myopia and hyperopia, astigmatism, and presbyopia), with refractive correction (spectacles, contact lenses and laser refractive surgery), gender, age and socio-economic status in the discrete cognitive testing groups. Three participants in Nepal had URE. Each respondent answered all items in the country-appropriate item pool and provided feedback for further refinement of items that helped ensure that item content, wording and phrasing was appropriate and relevant. Following the cognitive interviews, a total of 6 items were deleted and 25 items amended in Item-pool (Australia), and a total of 3 items deleted and 17 items amended in Item-pool (Nepal) (Table 5.7). Following the iterative process of content identification and refinement, a final set of 337 items for Item-pool (Australia) (Appendix G) and 308 items for Item-pool (Nepal) (Appendix H) were available.

Table 5.7 Examples of changes made from cognitive interviews (Australia)

Domain	Initial item	Type of change	Reason for change
Visual Symptoms	'How often do you experience difficulty with light/dark adaptation?'	Amended	The item was worded differently for clarity: "How often do you experience difficulty with adapting to changes in light [bright to dark (e.g. cinema) or dark to bright (e.g. driving through a tunnel)"

General Symptoms	"How often do you experience headaches due to your vision?"	Amended	All items in this domain were for assessing general symptoms 'due to refractive error or its correction'. This was explained in the instruction (first page of the questionnaire) as well. To avoid redundancy and to avoid confusions, the item was worded as: 'How often do you experience headaches?'
Emotional	'How often do you feel shy for having to wear glasses?'	Deleted	Item had a similar meaning to the other item 'How often do you feel embarrassed wearing glasses?'.
Emotional	'How often do you have suicidal thoughts?'	Deleted	This emotion was reported by the participants to be too strong, too negative and rare for people with refractive error.

5.3.2 Final set of items

When comparing item content, only 207 (47.3%) items were common to both the Item-pool (Australia) and Item-pool (Nepal) (Table 5.8) indicating that two separate set of item banks may be needed.

Table 5.8 Comparison between Item-pool (Australia) and Item-pool (Nepal)

	AL	MB	VS	OS	GS	HC	CV	EM	SC	EC	CP	Total
Item-pool (Australia) (Total)	80	19	27	16	10	41	44	53	16	18	13	**337**
Common items	**45**	**10**	**20**	**14**	**3**	**30**	**34**	**19**	**11**	**11**	**10**	**207 (47.3%)**
Item-pool (Nepal) (Total)	72	14	23	14	5	39	64	32	16	15	14	**308**

Note: AL = Activity limitation, CP = Coping, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, OS = Ocular-comfort symptoms, SC = Social, VS = Visual symptoms

On further sub-analysis of the Item-pool (Nepal), the majority of the items (65.3%) were common between uncorrected and corrected refractive error (Table 5.9). This indicated that a single comprehensive item bank may have content sufficient to measure QoL in uncorrected or corrected refractive errors. Furthermore, many of the items related to refractive correction (e.g. handling spectacles or contact lenses) would still be relevant to some URE participants as the participants with sub-optimal correction or under-correction were classified under URE.

Table 5.9 Comparison of items for uncorrected and corrected refractive error groups: Item-pool (Nepal)

	AL	MB	VS	OS	GS	HC	CV	EM	SC	EC	CP	Total
CRE (Total)	54	13	23	14	5	38	60	31	14	14	11	**277**
CRE (Unique)	10	1	5	2	0	11	20	14	4	5	4	**76**
Common items	**44**	**12**	**18**	**12**	**5**	**27**	**40**	**17**	**10**	**9**	**7**	**201 (65.3%)**
URE (Unique)	18	1	0	0	0	1	4	1	2	1	3	**31**

URE (Total)	62	13	18	12	5	28	44	18	12	10	10	**232**
Total - Item-pool (Nepal)	**72**	**14**	**23**	**14**	**5**	**39**	**64**	**32**	**16**	**15**	**14**	**308**

Note: AL = Activity limitation, CP = Coping, CRE = Corrected refractive error, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, OS = Ocular-comfort symptoms, SC = Social, URE = Uncorrected refractive error, VS = Visual symptoms

The source of majority of the items in the item-pools, particularly for Item-pool (Nepal) was from qualitative studies. About half of the items in Item-pool (Australia) were identified from both literature and qualitative studies (Figure 5.3). Other items were uniquely identified from qualitative studies (new qualitative studies or the QIRC item-pool, 46.3%) or literature (questionnaires or grey literature, 4.5%). Commonness in item-source ranged from 0% (coping) to 87.5% (ocular-comfort symptoms) (Table 5.10).

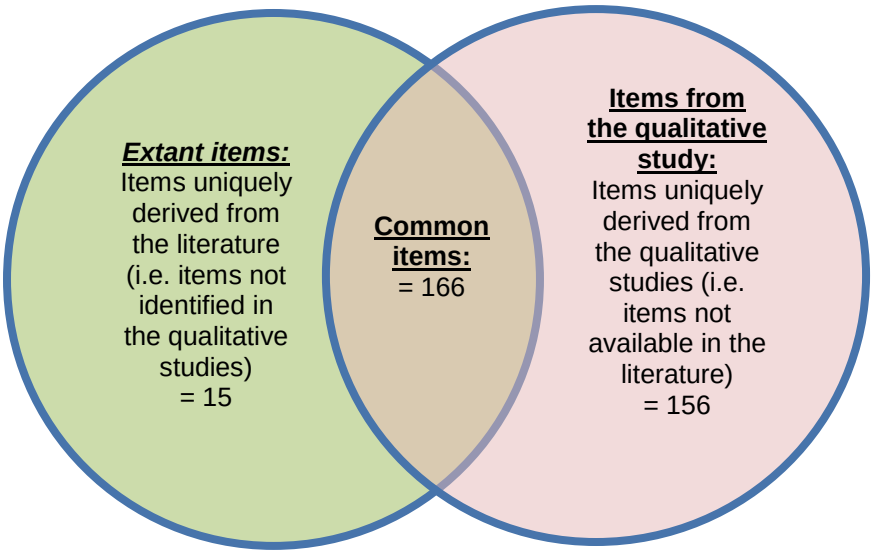

Figure 5.3 The source of items for Item-pool (Australia)

Table 5.10 Source of final items for Item-pool (Australia)

Source of items	VS	OS	GS	AL	MB	SC	EM	EC	CV	HC	CP	Total
Questionnaires	19	14	3	48	7	7	12	8	24	26	1	**169**
Grey literature	12	13	3	8	3	-	1	3	9	15	-	**67**
Extant items - Total	20	15	4	48	8	7	12	9	25	32	1	**181**
Extant items - Unique	1	1	0	6	0	2	3	0	1	0	1	**15**
Common items	19	14	4	42	8	5	9	9	24	32	0	**166**
Qualitative studies - Unique	7	1	6	32	11	9	41	9	19	9	12	**156**
Qualitative studies - Total	26	15	10	74	19	14	50	18	43	41	12	**322**
Interviews	25	14	9	63	18	13	38	17	43	41	12	**293**

QIRC Item-pool	14	9	7	54	10	5	35	10	24	16	2	**186**
Item-pool (Australia)	**27**	**16**	**10**	**80**	**19**	**16**	**53**	**18**	**44**	**41**	**13**	**337**

Note: AL = Activity limitation, CP = Coping, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, OS = Ocular-comfort symptoms, QIRC = Quality of life Impact of Refractive Correction, SC = Social, VS = Visual symptoms

For the Item-pool (Nepal), only 8.1% items were commonly identified from the literature and the qualitative studies. All items in the item-pool (91.2% unique) were identified from the qualitative studies (Figure 5.4). Commonness in item-source ranged from 0% (General symptoms, Convenience, Economic, Coping) to 25.8% (Activity limitation) (Table 5.11).

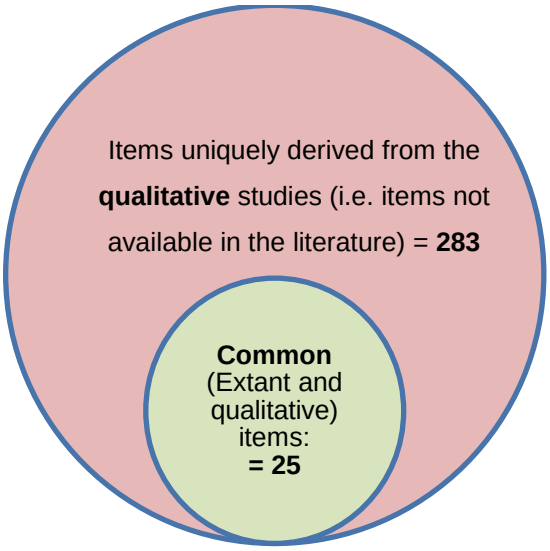

Figure 5.4 The source of items for Item-pool (Nepal)

Table 5.11 Source of final items for Item-pool (Nepal)

	AL	**MB**	**VS**	**OS**	**GS**	**HC**	**CV**	**EM**	**SC**	**EC**	**CP**	**Total**
Total extant items	17	1	1	2	-	2	-	1	1	-	-	**25**
Unique extant items	-	-	-	-	-	-	-	-	-	-	-	**-**
Common items	17	1	1	2	-	2	-	1	1	-	-	**25**
Unique items from qualitative study	55	13	22	12	5	37	64	31	15	-	-	**283**
Total items from qualitative study	72	14	23	14	5	39	64	32	16	15	14	**308**
Item-pool (Nepal)	**72**	**14**	**23**	**14**	**5**	**39**	**64**	**32**	**16**	**15**	**14**	**308**

Note: AL = Activity limitation, CP = Coping, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, OS = Ocular-comfort symptoms, SC = Social, VS = Visual symptoms

5.4 Discussion

The content for the refractive error-specific QoL item banks was identified through a multi-phase, rigorous and systematic process which ensures that item content is relevant and able to measure the QoL impact of uncorrected and corrected refractive errors. Due to less than 50% overlap of content between the Australian and Nepalese item-pools, two separate sets of item banks for Australia and Nepal may be required, which was supported by the qualitative findings (Chapter 4).[14, 63] The Item-pool (Australia) consisted of 337 items and Item-pool (Nepal) consisted of 308 items, both spanning same 11 QoL domains.

I was able to use extensive previous developmental work on measurement of PROs in refractive error, extracting almost 800 items from PRO instruments and grey literature. This also enabled assessment of the coverage of the existing instruments across QoL domains, and identification of gaps in content coverage and applicability of instruments to different population settings. For example, I found that about two-thirds of the extant items pertained to activity limitation and symptoms while few related to emotional or social issues. Additionally, very few PRO instruments were targeted for low resource settings and for URE. Moreover, the PRO instruments developed for low- and middle-income countries and URE used items derived from the PRO instruments originally developed for high-income countries and corrected refractive error.[12, 44, 54] Therefore, I was only able to apply very few extant items in the development of Item-pool (Nepal).

An important aspect of this work was that the extant items extracted for the item-pools were supplemented with the items crafted from the qualitative studies (Chapter 4).[14, 63] Comprehensive patient consultation is essential in constructing high quality PRO instruments to ensure that all relevant domains and items are included to comprehensively measure an intended construct. This reduces disparity between clinicians' and patients' perspectives.[14, 18, 26, 62, 349-351] Guidelines from regulatory bodies such as the FDA have stated that item generation is incomplete without patient consultation.[25] This is a limitation of most of existing PRO instruments in refractive error, which were developed with minimal or no patient consultation.[34, 40-42, 44, 49, 52, 54] Qualitative studies were also important in order to ensure there were sufficient items across all domains to obtain good measurement precision.[26, 351] Moreover, the qualitative findings showed many unique issues for low- and high-income country settings indicating the need for two separate sets of item banks. This aligned with the literature reporting that PRO instruments constructed for high-income countries may not be transferable to low- and middle-income countries in their original form.[12, 54] For Item-pool (Australia), items from the QIRC development item-pool were incorporated. The QIRC is a high quality and widely used instrument for measuring refractive error-specific QoL.[15, 18, 26, 28] The inclusion of the QIRC item-pool in this study will make the content of the item banks relevant to the

UK as well as Australian populations.

I found a high overlap (about two-thirds of the items common) in the items for uncorrected and corrected refractive error in Item-pool (Nepal), although their extent and the nature of impact may vary. For example, people with URE may have high difficulty playing sports due to poor vision. Whereas, people wearing spectacles may experience some difficulty playing sports because of inconveniences caused by wearing spectacles e.g. steaming up, slipping down on the nose, being bumped off by other players or because of the physical motion involved in the sport. This supported having a single comprehensive item bank which might be sensitive enough for both URE and corrected refractive error groups. URE and refractive correction may be located at different points in a latent trait continuum. One of the reasons for the high overlap might be that the URE group also included under-corrected cases and occasional spectacles or contact lens wearers, and thus they also had issues related to spectacles and contact lens wear (e.g. inconveniences due to wearing spectacles). Having a single item bank for uncorrected and corrected error groups offers many advantages. A population generally consists of people with both uncorrected and corrected refractive error. It is therefore desirable to use a single PRO instrument to assess QoL for pragmatic reasons. A common item bank with items for both uncorrected and corrected refractive error enables us to compare the QoL status among URE and various refractive intervention groups on the same continuum. In addition, developing two different CAT systems is expensive.

There were interesting differences in the findings between two qualitative studies due to economic, lifestyle related, cultural and religious, health services related, environmental, and social differences, in addition to the URE related issues identified in the Nepal study. In Nepal, many participants reported difficulty doing manual agricultural works such as cutting grass and collecting firewood while wearing their spectacles. Therefore, many said they stopped using spectacles. In Australia, participants expressed difficulty doing sports (e.g. swimming), leisure or recreational activities. Likewise, driving related issues were more prominent in Australia. Many elderly women in Nepal reported limitation in their near activities such as beading a necklace or making cotton wicks for religious reasons. Most of the participants from the capital city (Kathmandu) reported inconveniences by not being able to wear an air-filtering face mask when wearing spectacles. This was important because Kathmandu is dusty and heavily polluted. Similarly, many reported inconveniences having to travel long distance to have their eyes examined or to make spectacles as eye centres were located only in the urban areas. Contact lens related inconveniences were more prominent in Australia; in Nepal most of the contact lens wearers used them only occasionally due to the pollution. Contact lens participants in Nepal were particularly worried about

getting complications from contact lens wear. The participants from Australia more frequently reported inconvenience in having to wear goggles over their spectacles while snorkeling or watching 3D movies. Many participants in Nepal, particularly the female participants reported difficulty getting a life-partner or getting married due to their refractive error. Most of the symptoms reported in Australia and Nepal were common, as symptoms mainly depend upon the pathophysiology of refractive error. However, the frequency of some symptoms was more common in either settings, for example, 'itchy eyes' was more frequently reported in Nepal (perhaps due to pollution), whereas, 'dry eyes' was more frequently reported in Australia (refer to Chapter 4 (Section 4.3) for details on similarities and differences). These differences led to the differences in the items between the item-pool (Australia) and item-pool (Nepal).

One of the limitations of this study was that none of the participants interviewed in Australia had URE, although URE is one of the major eye problems of low-resource settings even in the high-income countries.[14, 296] Taylor *et al.* reported the URE accounted for more than half of the visual impairment in indigenous adults in Australia.[382] The Australian qualitative study did not have any indigenous participants. The limitation of not having participants with URE was minimized as the respondents recalled their past uncorrected status experiences.[14] Nevertheless, the impetus to conduct a new qualitative study in Nepal was due to not having participants with URE and participants from low resource settings in the Australian study. Some of the issues in item-pool (Nepal) may be relevant to low-resource settings in high-income countries. Future study comparing QoL issues (e.g. issues related to refraction services, emotional, social, economic, concerns) between low-resource settings of a HIC and a LMIC is required. The possibility to link item-pool (Australia) and item-pool (Nepal) to construct common item banks will be discussed in the next phase of the project (Chapter 8). The common item-banks may be relevant to high and low resource settings in HICs and LMICs.

Another limitation for this study could be the small sample size for cognitive testing. However, the participants had representation from refractive error and refractive correction sub-types, gender, age and socio-economic status. Other measures such as use of patients' wordings from qualitative studies, lay introduction and instructions, a simple and consistent item format, and expert panel consensus were employed to ensure that the items were clear and comprehensible to the participants so that the items were interpreted correctly as intended. As a result, only minor changes had to be made after the cognitive testing. A similar study to develop item banks for measuring QoL in diabetic retinopathy also used only eight cognitive interviews.[31]

One strength of this study was that Item-pool (Australia) may be applicable to other high-income country settings and Item-pool (Nepal) may be applicable to other low- and middle-income country

settings, although cognitive testing to ensure cross-cultural appropriateness is recommended. Even using a PRO developed in one high-income country (e.g. the US) in another high-income country (e.g. Australia) may be fraught with problems due to lexical or idiosyncratic differences in language. As discussed above, combining item pool (Australia) and item pool (Nepal) may result into a single PRO instrument applicable to both settings.

In conclusion, this chapter outlined our systematic procedure for the development of item banks for refractive error in Australian and Nepalese populations across the range of refractive errors and their correction methods. The item pools comprised 337 items for the Item-pool (Australia) and 308 items for the Item-pool (Nepal). The next chapter (Chapter 6) describes the psychometric assessment of the Item-pool (Nepal).

5.4.1 Outputs from this chapter

An original article highlighting the methods and findings of this chapter has been published in the Optometry and Vision Science journal.[383] In addition to the conference presentations for qualitative studies (Section 4.4), I made two presentations (oral) focusing on content identification and refinement process. I presented (oral) a paper at the the Association for Research in Vision and Ophthalmology–Asia (ARVO–Asia) Meeting, 08 February 2017, Brisbane, Australia (Appendix D). Similarly, I presented another paper at the Eye and Vision Collaborators' Day, 22 September 2017, Flinders Medical Centre, Adelaide, Australia.

Chapter 6. Phase II (Nepal): Assessment of psychometric properties

6.1 Introduction

Two sets of item pools for refractive error were developed, one for Australia and one for Nepal (Chapter 5). The content of the item pools were extracted from the literature[15, 16] (existing questionnaire and grey literature) and the qualitative studies.[14, 63] The initial framework consisted of a total of 11 domains (n = 17 when considering 3 item-pools each for visual, ocular-comfort and general symptoms, for measuring their frequency, severity and bothersome attributes, separately). The primary aim of the study described in this chapter was to calibrate the items in the Item-pool (Nepal) to develop refractive error-specific item banks, using Rasch analysis. The specific objectives were to test the psychometric properties of the item-pools for each domain separately, and to optimize the psychometric properties of the domains whenever required and whenever possible, to create unidimensional item-banks. This chapter is laid out in the IMRAD structure. The methods and results section are designed to answer the broad research question 'Can the item pools grouped by their content form valid and independent scales to measure refractive error-specific QoL parameters?'

6.2 Methods

The 392-item questionnaire was interviewer-administered to 305 people with refractive error (myopia, hyperopia, astigmatism and presbyopia, with or without correction). The participants were recruited from out-patient departments of Tilganga Institute of Ophthalmology (TIO) and Dhulikhel Hospital, Nepal. TIO, located in Kathmandu, is the only place offering refractive surgery services in Nepal.[145] Whereas, Dhulikhel hospital is located outside Kathmandu valley and has a direct access to rural population. Consecutive diagnosed cases of refractive error who met the selection criteria were requested to participate by ophthalmic personnel (optometrist, ophthalmologist or an ophthalmic assistant). Adults (> 18 years of age) with refractive error with or without corrections with best corrected visual acuity > 6/18, able to understand and speak Nepali language were included in the study. Participants with any clinically significant ocular pathology that might impact on QoL domains, and participants with mental health problem or insufficient cognitive awareness were excluded from the study. The ophthalmic personnel referred potentially eligible participants to the author (HK). The questionnaire was then interviewer-administered (face-to-face) by HK in Nepali language after taking an informed written consent.

The first page of the phase-II questionnaire consisted of introduction and general instructions

(Appendix H). The clinical (e.g. visual acuity, final subjective refraction, presence of any other ocular, and systemic co-morbidities) and socio-demographical data were collected using a background questionnaire (Appendix H). Definition and classification of refractive error used in this study were described in Chapter 3 (Section 3.1.1.1). Refractive error of magnitude ±0.50 dioptre was considered significant. The background questionnaire also consisted of questions on frequency of wearing spectacles or contact lens, using a 5-point Likert scale (very often, quite often, occasionally, rarely, never). Clinical data were obtained from the participants' clinical records. Detailed ocular examination including visual acuity and refraction was conducted when the information was not available in their clinical records. The participants were asked to answer the questionnaire considering their habitual status of wearing spectacles or contact lenses at the time of data collection. For example, if they used spectacles in the past but not at present, they were advised to answer the questions considering their present status which was "with no spectacles".

6.2.1 Data collation and statistical analysis

The questionnaire responses were entered into an Excel spreadsheet (Microsoft Corporation, Washington, USA), and the cleaned data was imported to the SPSS software, Version 23 (SPSS, Chicago, IL, USA). Responses for 'not applicable' option were deleted and considered as missing data for Rasch analysis. Descriptive statistical analysis was conducted in the SPSS software. Normality of the data was evaluated using the histogram and Kolmogorov-Smirnov test. The two-sided p value less than 0.05 was considered statistically significant. Rasch analysis was conducted using Winsteps software, Version 3.92.1 (MSEA Press, Chicago, IL, USA).[384]

The Rasch analysis was described in detail in Chapter 2. The Rating Scale Model of Rasch analysis was used in this study. While researchers are divided on the selection between Rasch or IRT models, Rasch analysis is based on sound measurement principles. It is relatively simpler than other (2 or 3 parameter) IRT Models. Evidence shows that information provided by Rasch analysis is powerful for unidimensional item bank calibrations.[192, 385] Rasch models are more robust than 2- or 3-parameters IRT models when the sample size is small[106, 107, 386] and homogenous.[386] Rasch model is robust in handling missing data.[92]

Unlike other IRT models which are exploratory and conform to the data, Rasch analysis is a strict confirmatory model where data should fit the model.[70] In real world, data can never fit the Rasch model which is a probabilistic model. Deviation from the model requirements to some extent may be expected.[387] Nevertheless, the goal should be to approximate Rasch model requirements. Lenient approach, using moderate threshold parameters, was therefore required in deleting items,

particularly for item banking.[388] The main goal of the Phase II study was to calibrate items in the item-banks, retaining as many items as possible. The Rasch parameters investigated in this study include response category functioning, measurement precision, unidimensionality, fit statistics, targeting and differential item functioning. Multiple Rasch iterations were performed when required and when possible to form valid scales.The criteria for Rasch model requirements used in this item-bank study are given on Table 6.1.

Table 6.1 Rasch model expectations for item banks

Parameters	Rasch model expectations
Disordered thresholds	No
Person separation index / Person reliability	> 2.0 / 0.80
Item separation index / Item reliability	> 3.0 / 0.90
PCA, variance by the first factor	> 50%
PCA, eigen-value for the first contrast (% unexplained variance in the first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0 (< 5%) / High
Ratio between PCA, % raw variance explained by items to variance by first contrast	High
Item infit (MnSq)	< 1.50
Item outfit (MnSq)	< 1.50
Local item dependency (LID)	No item-pairs with residual correlations ≥ 0.30
Differential item functioning (DIF)	< 1.0 and p < 0.05
Measurement range (logits)	Wide
Targeting, difference between person & item means (logits)	< 1.0 logits

Note: MnSq = Mean square, PCA = Principal component analysis

6.3 Results

A total of 305 people with refractive error were included in this study (Table 6.2). All the contact lens wearers used spectacles as well at various frequency. All the participants who had undergone refractive surgery (age range: 22 to 37 years) and contact lens wearers (age range: 19 to 36 years) were younger than others. Age-wise group-analysis was not done as the presbyopic group represented the older age-group.

Table 6.2 Demographic and clinical characteristics

Parameters	
Mean age (min-max) years	30.5 ± 14.07 (18-83)
Male	154 (50.5%)
Rural	45 (14.8%)
Median visual acuity (range)	Median, 0 logMAR (Snellen equivalent: 6/6); Range, -0.08 logMAR (Snellen equivalent: 6/4) to +1.18 logMAR (Snellen equivalent: 4/60)
Refractive error	

Mean SphEq refractive error (range) in dioptres	-2.40 ± 2.93 (Min -15.00 to Max: +11.00)
Myopia[&]	227 (High, 29; Moderate, 71; Mild, 127)
Hyperopia[&]	39 (High, 4; Moderate, 12; Mild, 23)
Astigmatism	65*
Presbyopia	48[#]
Refractive correction	
Spectacles	257 (Very often, 160; Quite often, 53; Occasionally, 44; Never, 47[$])
Contact lens	37 (Very often, 9; Quite often, 6; Occasionally, 22; Never, 267[+])
Laser refractive surgery	25
Uncorrected refractive error	57[@]

Note: Total number of participants = 305. MAR = Minimum angle of resolution, SphEq = Spherical equivalent; [#]32 [including 23 surgical emmetropes] of them did not have any refractive error for distance. [&]Grading of severity of myopia and hyperopia (spherical equivalent) in dioptres: Low, |0.50| to |3.00|; Moderate |3.25| to |6.00|; High > |6.00|. *4 out of 65 participants had mixed astigmatism with non-significant spherical equivalent refractive error. [$]23 of the participants in the 'Never' category used spectacles in the past. [+]14 of the participants in the 'Never' category used contact lenses in the past. [@]Participants are classified into this group based on their habitual correction status. For example, even if the participants had proper refractive correction, if they did not use the correction most of the times, they are categorized as having uncorrected refractive error. Similarly, if the participants used spectacles all the time but were under-corrected, they are classified under the uncorrected refractive error group.

6.3.1 Convenience

The original Convenience domain (CV) had 64 items. Each item started with 'How much of a problem do you have….?', with a 5-point 'Problem' rating scale and two other possible responses: 'This is not relevant to me' and 'Refuse to answer'. The responses were coded from 1 to 5 with higher scores for higher convenience levels. Alternatively, as the level of inconvenience increased, the score decreased. Category structure statistics of the original Convenience domain are given in Table 6.3.

Table 6.3 Category structure statistics for the original Convenience domain

Category	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. Extremely	692	5	1.23	1.40	None	(-2.78)[*]
2. Quite a lot	1,918	15	0.97	1.11	-1.49	-1.10
3. A moderate amount	2,893	22	0.91	0.84	-0.33	0.04
4. A little bit	3,494	27	0.91	0.81	0.49	1.12
5. None	4,097	31	1.06	1.06	1.33	(2.68)
Missing data[#]	5,402	29				

Note: MnSq = mean square; [*]As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes. [#]Missing data = Missing data+ This is not relevant to me + Refuse to answer

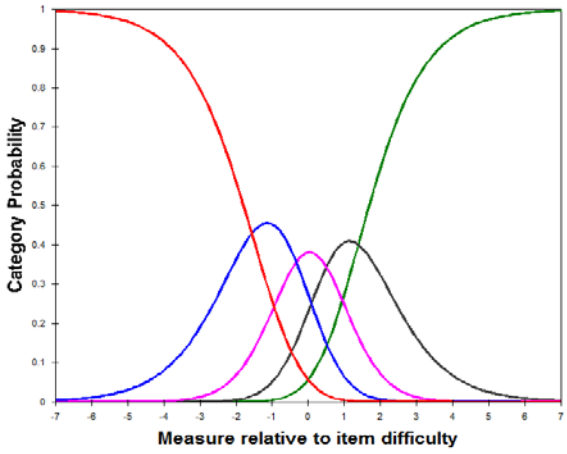

Figure 6.1 Category probability curves for the Convenience item bank
Note: red = 1. Extreme, blue = 2. Quite a lot, pink = 3. Moderate amount, black = 4. A little bit, green = 5. None

The thresholds and the category measures were ordered (Figure 6.1, Table 6.3). The category fit statistics were satisfactory. The frequency count for the category 1 was low suggesting fewer participants in the lowest convenience (i.e. highest inconvenience) category. However, the frequency count for the category 1 was much higher than the minimum number of responses required for a stable threshold calibration.[99]

Table 6.4 Rasch parameters of the Convenience domain iterations

Parameters	**Rasch model expectations**	**First iteration (Original)**	**Final iteration:** [PW: CV58, CV61, CV23, CV31, CV57][&]
Disordered thresholds		No	**No**
No. of items (Ni) / No of persons (Np)		Ni = 64 / Np = 289	**Ni = 64 / Np = 289**
PSI (person reliability)	>2.0 (>0.80)	2.97 (0.90)	**2.90 (0.89)**
ISI (item reliability)	>3.0 (>0.90)	5.10 (0.96)	**5.05 (0.96)**
PCA, variance by first factor	>50%	48.8%	**48.8%**
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	6.3 (5.1%) / r_d = 0.92	**6.3 (5%) / r_d = 0.90**
PCA, % raw variance explained by items	-	15.1 %	**15.1 %**
Item infit (MnSq)	<1.5	Item CV23	**0**
Item outfit (MnSq)	<1.5	4 items (CV58, CV61, CV17, CV23)	**0**
Local item dependency (LID)	>0.3		**81 (4%) pairs; 38 LID items**
Measurement range (logits)	-	1.20 to -1.10	**1.23 to -1.13**
Targeting, difference between person & item means	<1.0 logits	0.99 logits	**0.96 logits**
Items with PCA standardised residual loadings > 0.40		8 items (CV7, CV32-CV37, CV39)	**8 items** (CV7, CV32-CV37, CV39)

Note: Values in red font represent poor fit to the Rasch model. CV = Convenience ISI = Item separation index, PCA = Principal component analysis, PSI = Person separation index, MnSq = Mean square;

&PW: person weighting was done such that persons with erratic responses (residuals ≥ |4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations.

The final Convenience scale had good fit statistics (Appendix I) after person weighting for the erratic responses on five items. The measurement precision was excellent. However, eigen-value of the first contrast suggested that a cluster of more than six items might form a secondary dimension. Eight items had PCA standardised residual loadings >0.40 logits. However, those items did not conceptually form a separate meaningful construct. Despite a high eigen-value of the first contrast, a single construct for the Convenience item bank was proposed based on other multiple factors which indicated that the overall scale was essentially a unidimensional measure. These factors included satisfactory PCA variance explained by the first factor, high disattenuated correlation between the first and second item-clusters, good fit statistics, and high ratio of explained variance by items to unexplained variance in the first contrast (Table 6.4).

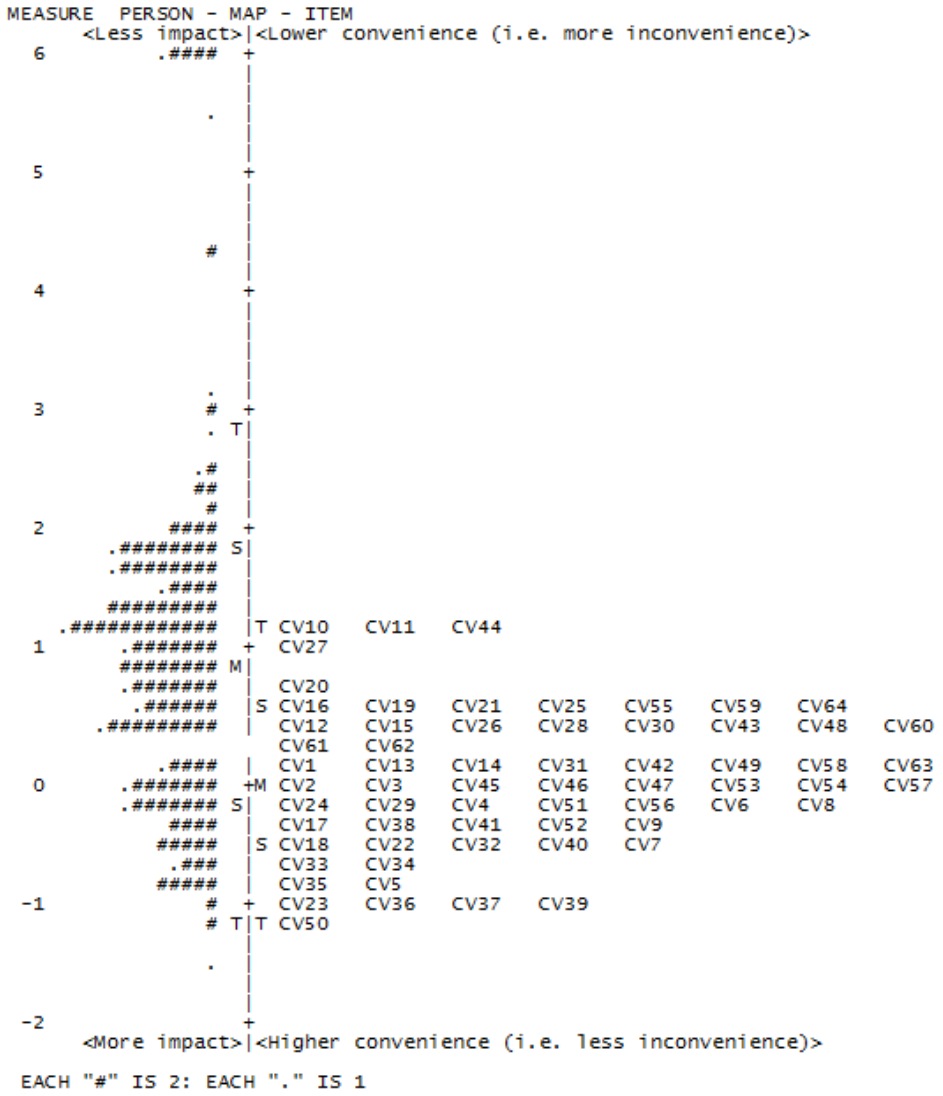

Figure 6.2 Person-item map for the refractive error-specific Convenience item-bank
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Targeting of person-ability and item-difficulty was within an acceptable range (Figure 6.2, Table 6.4). Higher person measures in logits represented a higher convenience level (lower inconvenience). Whereas, items with lower convenience level (i.e. higher inconvenience levels) had higher item measures in logits. Items related to handling spectacles or contact lenses (e.g. losing or misplacing spectacles or contact lenses, forgetting to carry spectacles) were perceived as the most troublesome issues (i.e. the items with highest item-measures).

6.3.2 Health Concerns

The Health concerns (HC) domain had 39 items. Each item started with 'How concerned are you about ….?', with a 5-point 'Concerns' rating scale with two other possible responses: 'This issue is not relevant to me' and 'Refuse to answer' The responses were coded from 1 to 5 with higher scores for better status or outcomes (i.e. less concerns). Alternatively, as the level of trait (concern) increased, the score decreased. The category structure statistics of the original Health concerns domain are given in Table 6.5.

Table 6.5 Category structure statistics for the Health concerns domain

Category	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. Extremely	366	4	1.20	1.50	None	(-2.21)*
2. A lot	771	9	1.02	1.00	-0.82	-0.81
3. A moderate amount	1,235	14	0.88	0.78	-0.14	0.02
4. A little	2,124	23	0.90	0.78	0.26	0.82
5. Not at all	4,547	50	1.10	1.07	0.70	(2.14)*
Missing data#	2,267	20				

Note: MnSq = Mean square. *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes. #Missing data = Missing data + 'This issue is not relevant to me' + 'Refuse to answer'

The thresholds and the category measures were ordered. The response categories had satisfactory fit statistics. The frequency count for the category 1 was low suggesting a fewer participants in the highest concern category. Whereas, half of the responses were for Category 5 indicating that there was a ceiling effect, i.e. most of the participants had little or no health concerns. This was also evident from the category probability curves and poor targeting as seen in the person-item map (Figure 6.6).

The Health concerns scale had good fit statistics (Appendix I) after person weighting for the erratic responses on item HC15. The measurement precision was also good. However, on the PCA, eigen-value of the first contrast suggested that a cluster of more than four items might form a secondary dimension. The PCA standardised residuals for six items (HC21, HC23, HC19, HC17, HC22, HC24) loaded > 0.40, and the residuals for HC20 loaded 0.40. These items were related to concerns about contact lenses and laser refractive surgery. A separate Rasch analysis was performed to test whether these items could form an independent valid scale (Table 6.6).

Table 6.6 Rasch parameters of the Health concerns domain iterations

Parameters	Model expectations	HC Original	First dimension (HC_1)	Second dimension HC_2)#	Final iteration (PW: 15)&
Disordered thresholds		No	No	No (wide spaced)	**No**

No. of items (Ni) / No of persons (Np)	-	Ni = 39 / Np = 290	Ni = 32 / Np=290	Ni = 7 / Np=110[#]	**Ni = 39 / Np = 290**
PSI (person reliability)	>2.0 (>0.80)	2.40	2.30	2.18	2.41(0.85)
ISI (item reliability)	>3.0 (>0.90)		5.94 (0.97)	1.25 (0.61)	6.15 (0.97)
PCA, variance by first factor	>50%	42.2%	40.8%	70.8%	**42.2%**
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	4.62 (6.9%) / r_d = 0.89	3.86 (7.1%) / / r_d = 0.67	2.07 (8.6%) / r_d = 1.0	**4.64 (6.9%) / r_d = 0.89**
PCA, % raw variance explained by items	-	12.7%	11.3%	20.9%	**12.7%**
Item infit (MnSq)	<1.5	0	0	0	**0**
Item outfit (MnSq)	<1.5	1 (HC15)	0	0	**0**
Local item dependency (LID)	>0.3				**42/741 pairs; 20 LID items**
Measurement range (logits)	-	0.85 to -1.35	0.79 to -1.22	0.37 to -0.45	**0.85 to -1.35**
Targeting, difference between person & item means (logits)	<1.0 logits	1.22	1.38	0.28	**1.22**
Items with PCA standardised residual loadings > 0.40		6 items (HC21, HC23, HC19, HC17, HC22, HC24)	5 items (HC26, HC27, HC1, HC18, HC3)	2 items (HC 23, HC24)	**6 items** (HC21, HC23, HC19, HC17, HC22, HC24

Note: Values in red font represent poor fit to the Rasch model. HC = Health concerns, ISI = Item separation index, MnSq = Mean square; PCA = Principal component analysis, PSI = Person separation index; [&]PW: Person weighting was done such that persons with erratic responses (residuals >|4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations. [#] 29 extreme responses were dropped/removed.

The first contrast (possible secondary dimension, HC_2) had seven items with responses from 139 participants. The PCA variance explained by the measure was high. However, the PSI was only 1.93. After dropping 29 extreme responders, the PSI improved to acceptable levels. A low number of participants (n = 110) to these items was a concern because these items were not relevant to most (62.1%) of the study participants. Further participants had to be dropped to obtain acceptable precision. And this scale had a very narrow range of measurement (0.37 to -0.45 logits). Due to these reasons (low sample size or narrow measurement range or both), item-reliability was also poor. Low item-reliability implies a poor construct validity. It indicates inability to precisely establish item hierarchy.[384] Although the difference between mean person measures and mean item measures was low (before dropping extreme responses, 0.83 logits; after dropping extreme responses, 0.28 logits), person-item map (Figure 6.4) shows that the targeting was poor based on the distribution of persons and items. Therefore, only a marginal benefit may be there by having separate scales.

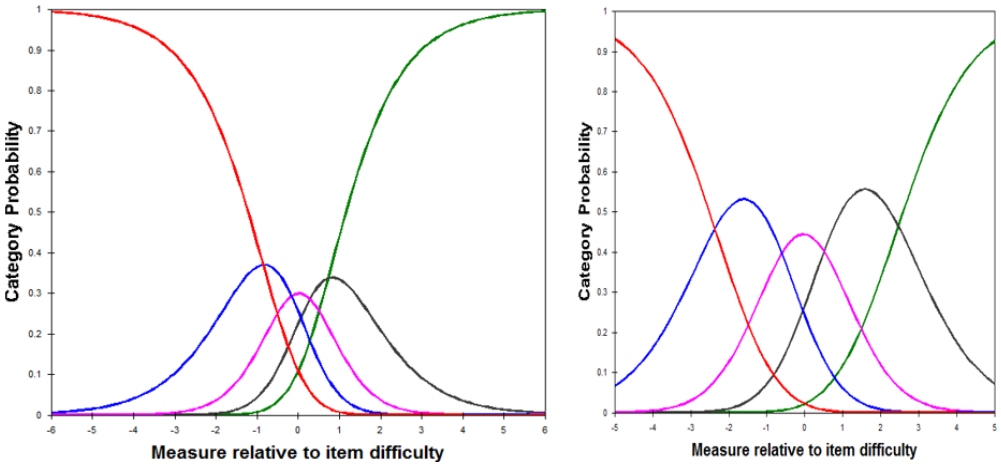

Figure 6.3 Category probability curves for a. HC_1 and b. HC_2
Note: red = 1. Extremely, blue = 2. A lot, pink = 3. A moderate amount, black = 4. A little bit, green = 5. Not at all

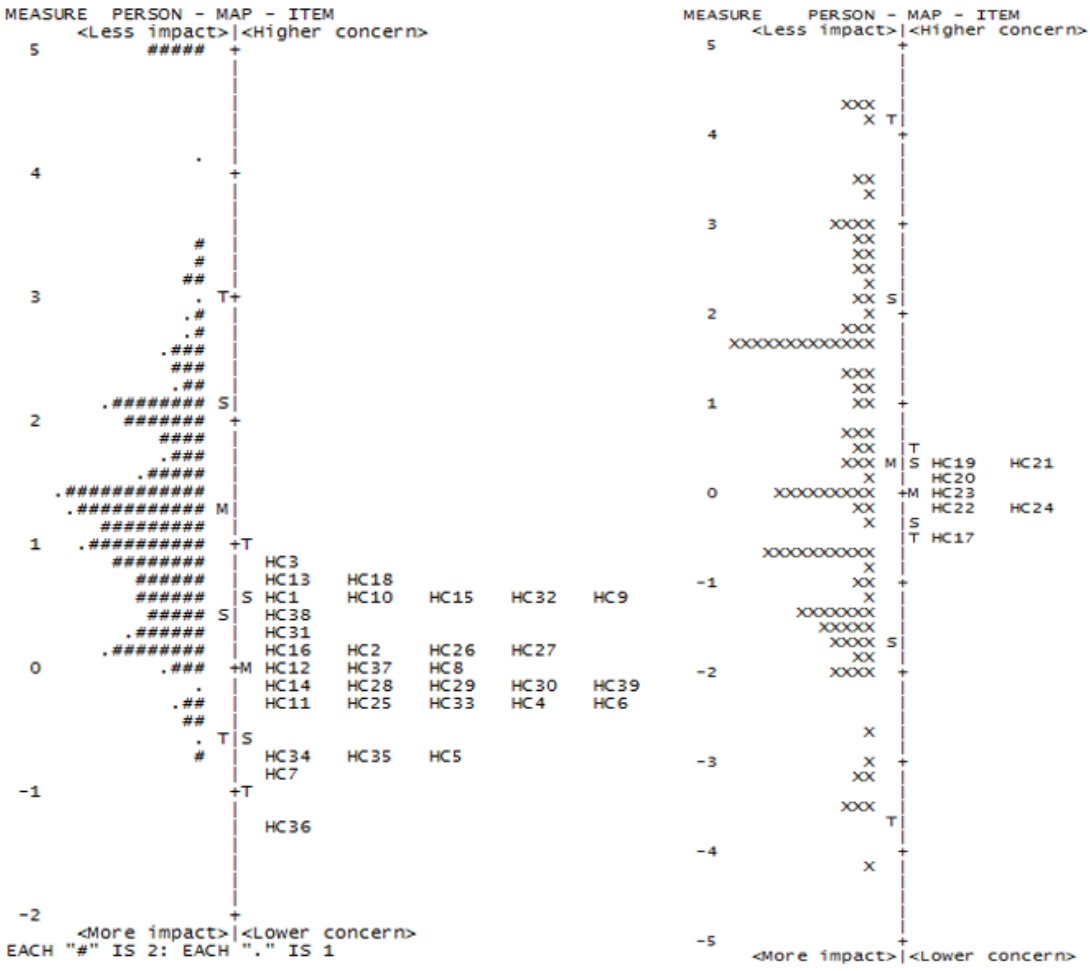

Figure 6.4 Person-item map for a. HC_1 and b. HC_2
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Some of the important parameters of the original scale worsened after removing the first contrast. The PCA variance explained by the measure, targeting and the PSI worsened. There was only a slight reduction in the eigen-value of the first contrast. However, the eigen-value of the first contrast (3.86) was still higher than the acceptable value (Table 6.6). Then the Bland and Altman test was performed to evaluate the agreement between two dimensions (Figure 6.5).

Agreement analysis between Health concerns subscales:

The Bland and Altman plot for the agreement between HC_1 and HC_2 (N = 110) was carried out (Figure 6.5). The distribution was normal (Kolmogorov-Smirnov test, p = 0.110). The mean difference between HC_1 and HC_2 was 0.82 logits (Paired t test, p < 0.001). And, the limits of agreement were wide (upper limit of agreement: 4.13 ± 0.28; lower limit of agreement: -2.49 ± 0.28 logits). The Pearson correlation coefficient was 0.50.

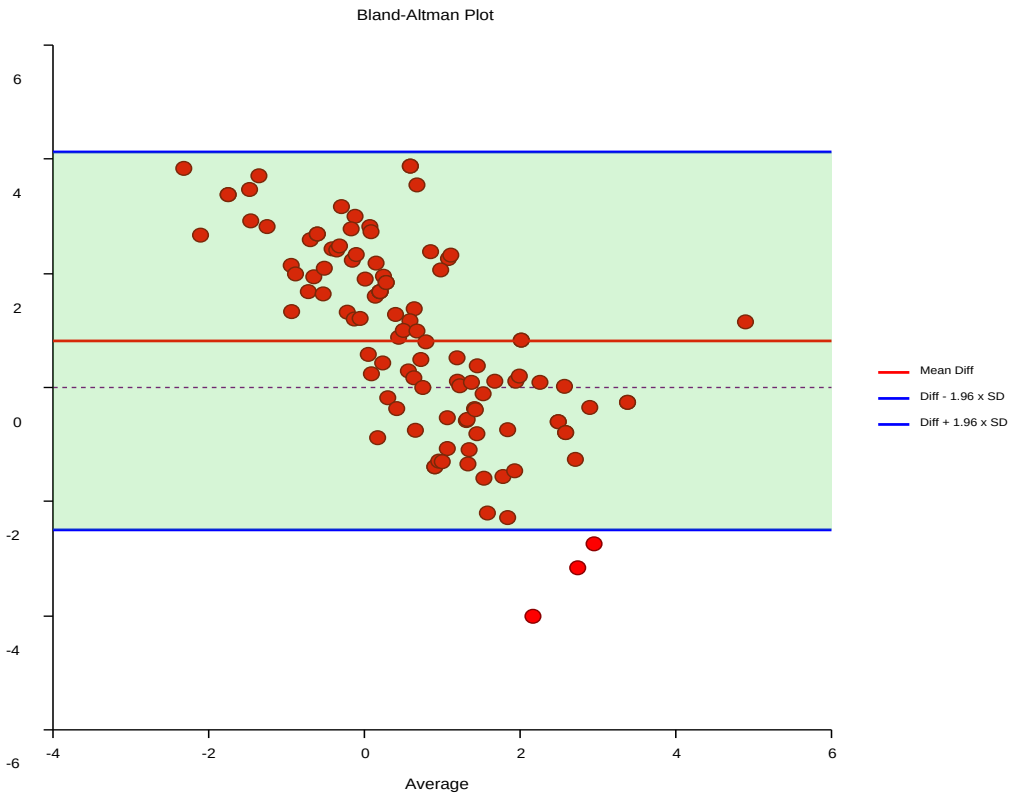

Figure 6.5 Bland and Altman plot: HC_1 vs HC_2

Decision making and final Health concerns item bank:

As discussed above, the secondary dimension (first contrast) had limitations. In addition, removing this did not significantly improve the parameters of the remaining items (first dimension). Conceptually, all the items measured the same construct ‘Concerns’. The disattenuated correlation

between the first and the second clusters of items was high (Table 6.6). In the Bland and Altman analysis, the mean difference between the subscales was less than 1.0 logits. Therefore, despite having a high eigen-value of the first contrast (4.6) and wide limits of agreement between two groups of items, a single ‘Health concerns’ scale was proposed considering multiple factors in combination as discussed above.

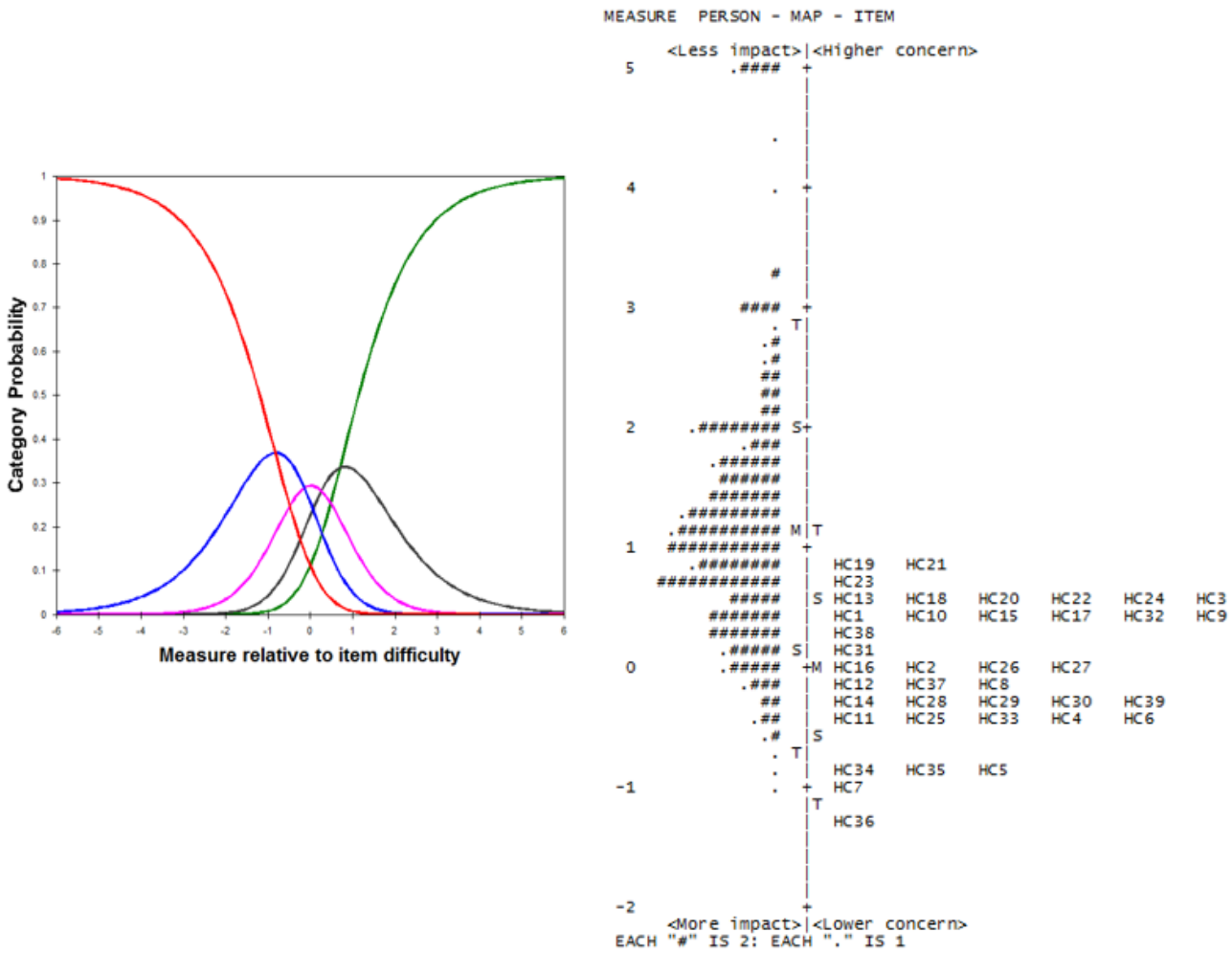

Figure 6.6 Final Health concerns item bank: a. Category probability curves b. Person-item maps
Note: In figure a, red = 1. Extremely, blue = 2. A lot, pink = 3. A moderate amount, black = 4. A little bit, green = 5. Not at all. In figure b, persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

In the final Health concerns item bank, targeting of person-ability and item-difficulty was slightly outside an acceptable range (Figure 6.6, Table 6.6.). People with less health concerns due to refractive error had higher person measures in logits. Whereas, the items with higher health concerns had higher item measures. Items related to concerns about outcomes of refractive correction (e.g. side effects and complications from refractive surgery) had higher item-measures.

Whereas, items for concerns about safety and way of being treated by others were perceived as the items with less concerns than other items.

6.3.3 Economic

The economic impact was identified as one of the most important QoL domains during Phase I qualitative analysis (Chapter 4). Initially, the Economic domain had 15 items. Each item started with 'How concerned are you about ….?', with a 5-point 'concern' rating scale and two other possible responses: 'This issue is not relevant to me' and 'Refuse to answer'. The responses were coded from 1 to 5 with lower scores implying worse economic impact (Table 6.7).

Table 6.7 Category structure and use statistics for the original Economic domain

Category number	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. Extremely	83	2	1.77	1.80	None	(-3.18)*
2. Quite a bit	245	7	0.93	0.88	-1.92	-1.40
3. A moderate amount	465	14	0.82	0.69	-0.57	-0.06
4. A little bit	904	26	0.96	0.88	0.39	1.38
5. Not at all	1,727	50	1.07	1.04	2.10	(3.32)*
Missing data#	956	22				

Note: Values in red font represent poor fit to the Rasch model. MnSq = Mean square; *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes. #Missing data = Missing data + This task is not relevant to me / don't do the task + Refuse to answer

First, the response category frequency and functioning was assessed (Table 6.7). The thresholds and category measures were ordered and advanced monotonically. Initially, the categories 2 to 5 had acceptable fit statistics but the category 1 had poor fit statistics. In the final iteration, the category fit statistics for all the categories were satisfactory. The width between the thresholds was excellent (Figure 2.2). The frequency count on category 1 was very low suggesting only a few participants were on the highest concern category. However, the frequency count for category 1 is above the minimum number of responses required for a threshold calibration.[99] In contrast, half of the responses were for Category 5 (Not at all) indicating that there was a ceiling effect i.e. most of the participants had low or no economic impact from refractive error.

Table 6.8 Rasch parameters of the Economic domain iterations

Parameters	Model expectations	Original	First dimension (Work): [deleted EC8; PW:EC9]&	Second dimension (Finance): (PW: EC5)&	Final (Combined) [deleted EC 8; PW: EC9, EC5]&
Disordered thresholds		No	No	No	**No**
No. of items (Ni)/ No of persons (Np)		Ni = 15 / Np = 192)	Ni = 7 / Np = 158#	Ni = 7/ Np = 292	**Ni = 14 / Np = 292**
PSI (person reliability)	>2.0 (>0.80)	2.04 (0.81)	2.28 (0.84)	2.55 (0.87)	**2.12 (0.82)**

ISI (item reliability)	>3.0 (>0.90)	6.15 (0.97)	2.96 (0.90)	5.75 (0.97)	**6.47 (0.98)**
PCA, variance by first factor	>50%	58.7%	62.0%	71.9%	**60.6%**
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	4.04 (11.1%) / r_d = 0.865	1.97 (10.7%) / r_d = 1	2.06 (8.3%) / r_d = 1	**4.02 (11.3%) / r_d = 1**
PCA, % raw variance explained by items	-	12.9%	16.5%	9.1%	**13.3%**
Item infit (MnSq)	<1.5	2 (8, 5)	0	0	**0**
Item outfit (MnSq)	<1.5	2 (8, 5)	0	0	**0**
Local item dependency (LID)	>0.3				**7/91 pairs; 5 LID items** (EC1, EC4, EC11, EC12, EC15)
Measurement range (logits)	-	1.60 to -1.08	0.74 to -0.67	1.95 to -1.98	**1.81 to -1.30**
Targeting, difference between person & item means	<1.0 logits	2.36	2.29	2.94	**2.90**
Items with PCA standardised residual loadings > 0.40		3 items: EC1, EC2, EC6 (EC3, EC5, EC7 loaded close to 0.40)	2 items: EC14, EC15	2 items: EC2, EC3	**3 items:** EC1, EC2, EC6 (EC3, EC5, EC7 loaded close to 0.40)

Note: The values in red font represent poor fit to the Rasch model. EC = Economic, ISI = Item separation index, MnSq = Mean square, PCA = Principal component analysis, PSI = Person separation index; # 125 participants with extreme responses were dropped/removed. &PW: person weighting was done such that persons with erratic responses (residuals ≥ |4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations.

Measurement precision of the original Economic domain was good. However, it had two misfitting items (EC5 and EC8). On the PCA, the eigen-value of the first contrast suggested that a cluster of more than four items might form a secondary dimension. PCA standardised residuals for most of the items on finance loaded greater than or close to 0.40. The ability of the first contrast (EC_2-Finance; secondary dimension) to form an independent valid scale was assessed performing a separate Rasch analysis. Similarly, the ability of the remaining items, after removing the finance items, to form an independent scale was evaluated.

The' EC_2-Finance' dimension had seven items (Items EC1- EC7). All of them fit well to Rasch model, after person-weighting was done to mute the erratic responses for EC5. The EC_2-Finance scale was a unidimensional measure with high variance explained by the measure. The PSI was better than that of the original Economic scale. However, targeting was slightly poorer than the original Economic scale (Table 6.8).

The first dimension (EC_1-Work) had low precision (PSI 1.44). Therefore, the extreme responses from 125 (44.1%) participants were dropped. In the EC_1-Work dimension, item EC8 (Your optical correction restricting your choice of career e.g. air force, army, navy) was a misfitting item (infit MnSq, 2.22; outfit MnSq, 2.10). This item might have been relevant for the participants in the past, but perhaps less relevant at the current habitual status of the participants. Misfitting of EC8 could not be fixed with person-weighting or by deleting misfitting persons. Therefore, EC8 was deleted. Targeting of EC_1-Work was poorer than the original Economic domain. It would have been poorer (4.25 logits) if the extreme responses were not dropped (Table 6.8).

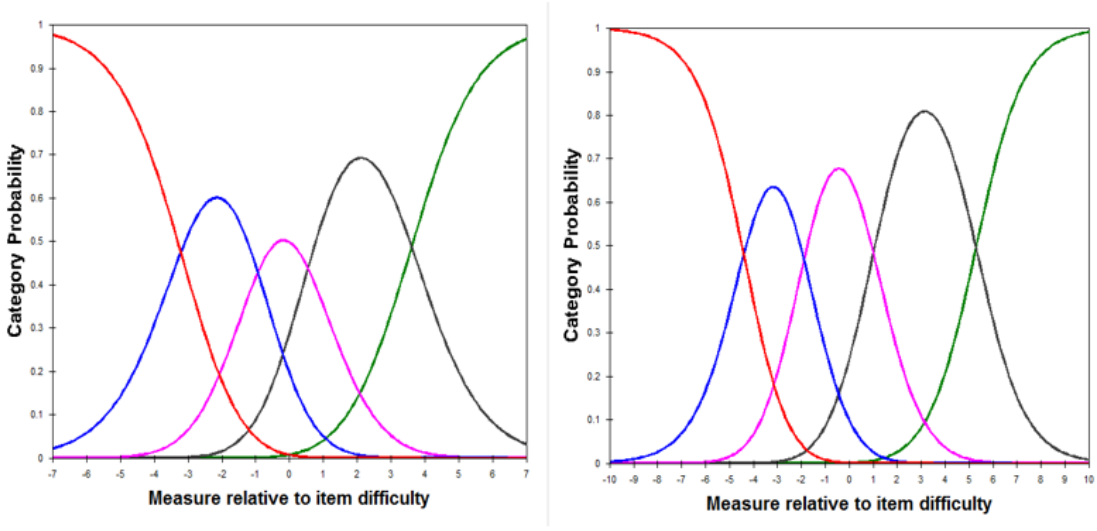

Figure 6.7 Category probability curves for a. EC_1-Work and b. EC_2-Finance
Note: red = 1. Extremely, blue = 2. Quite a bit, pink = 3. A moderate amount, black = 4. A little bit, green = 5. Not at all

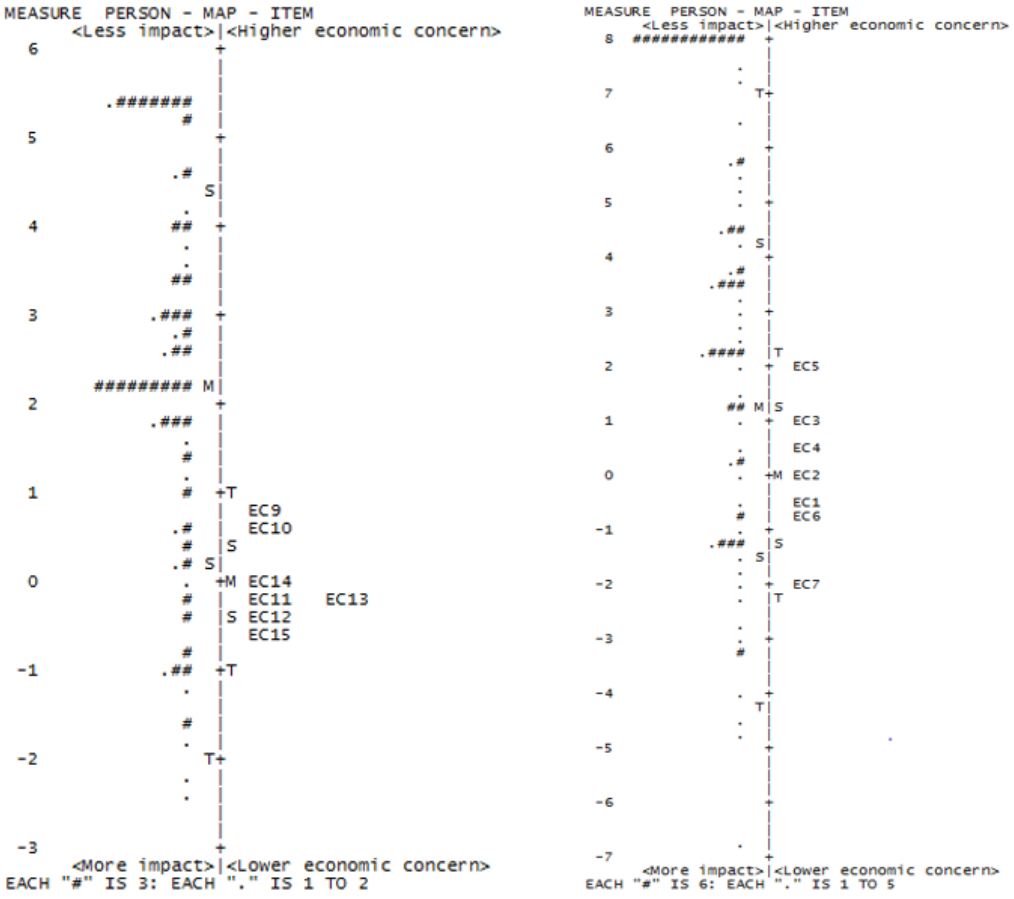

Figure 6.8 Person-item map for a. EC_1-Work and b. EC_2-Finance
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Agreement analysis between EC_1-Work and EC_2-Finance

The Bland and Altman agreement analysis between EC_1-Work and EC_2-Finance (N = 158) was carried out (Figure 6.9). The distribution was normal (Kolmogorov-Smirnov test; $p = 0.20$). The mean difference between EC_1-Work and EC_2-Finance was 0.84 ± 2.73 logits (paired t test, $p < 0.001$). In the person-item map for the final combined scale, all the EC_2-Finance items are of more concern than the EC_1-Work items. This may explain the difference. The limits of agreement were wide (upper limit of agreement: 6.21 ± 0.37; lower limit of agreement: -4.52 ± 0.37 logits). The correlation coefficient was 0.57.

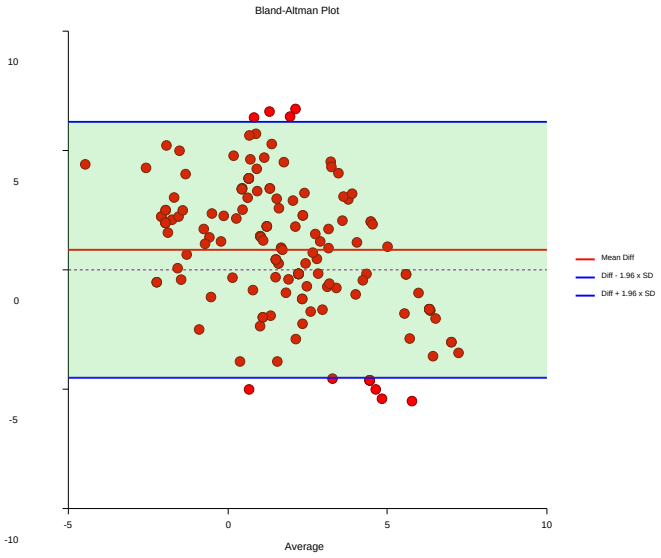

Figure 6.9 Bland and Altman plot: EC_1-Work vs EC_2-Finance

Decision making for the Economic item bank

Despite wide limits of agreement between EC_1-Work and EC_2-Finance, it was decided to have a single scale based on multiple factors. All items of the Economic domain measured the same construct 'Economic impact' conceptually. The PCA variance explained by the measure was excellent (60.8%) for the combined scale. All the items had satisfactory fit statistics (Appendix I). On Bland and Altman agreement analysis, the mean difference between the subscales was <1.0 logits (Figure 6.9). About half of the persons had to be dropped to obtain acceptable precision for the first dimension (EC-Work), and this scale had a very narrow range of measurement (0.74 to -0.67 logits). Poor targeting of EC-work was clearly evident from the person-item map (Figure 6.8). Therefore, a single Economic scale was proposed, although eigen-value and wide limits of agreement on Bland and Altman plot indicated possibility of forming a secondary dimension. Hierarchy of the items was maintained while combining these Economic subscales (Figure 6.8, Figure 6.10).

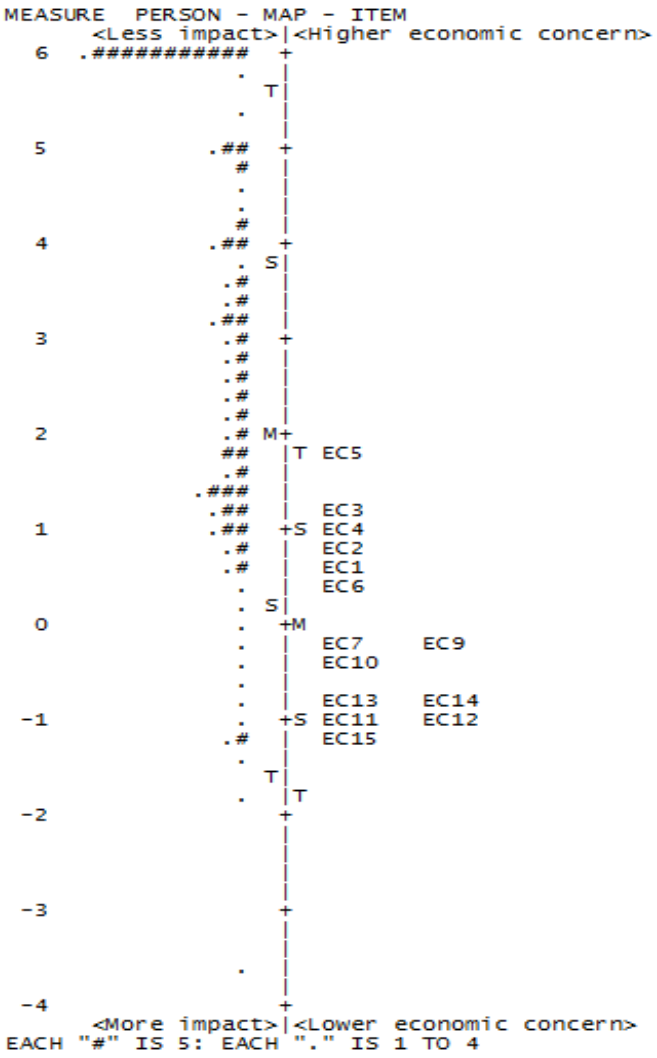

Figure 6.10 Person-item map for the final iteration of the Economic item bank
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

The final Economic item bank had good measurement precision and good fit statistics (Appendix I) after deleting EC8 and person-weighting erratic responses for EC9 and EC5. The variance explained by the first factor was excellent. However, targeting between person-ability and item-difficulty was outside an acceptable range (Table 6.8, Figure 6.10). The higher person measures in logits represented the lesser economic impact owing to impact of refractive error on work or finance related issues. Whereas, the items with higher economic impact had higher item measures. Items related to concerns about cost of having refractive surgery, contact lenses or glasses were perceived as the items with higher economic concerns levels than other items. Whereas items related to impact of refractive error on work were perceived as the items with less trait level. This indicates that the economic impact of refractive error may be less on work-related issues than on finance-related issues.

6.3.4 Activity Limitation

The original Activity limitation (AL) domain had 72 items. Each item had a 5-point 'difficulty' rating scale with two other possible responses: 'This task is not relevant to me / don't do the task' and 'Refuse to answer'. The responses were coded from 1 to 5 with higher scores for higher ability levels. Alternatively, as the level of difficulty increased, score decreased. Category structure statistics of the original Activity limitation domain are given in Table 6.9.

Table 6.9 Category structure statistics for the Activity limitation domain

Category	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	**Category measure**
1. Unable to do because of my vision	182	1	1.29	1.45	None	(-2.85)*
2. A lot	845	5	1.24	1.87	-1.61	-1.00
3. Quite a bit	1,590	9	0.98	1.05	-0.03	0.16
4. A little	2,960	17	0.98	0.66	0.71	1.09
5. None	12,082	68	0.97	0.99	0.94	(2.43)*
Missing data#	3,653	17				

Note: Values in red font represent poor fit to the Rasch model. MnSq = Mean square; *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes. #Missing data = Missing data + This task is not relevant to me / do not do the task + Refuse to answer

The thresholds and category measures were ordered. Initially, the category 2 had a poor outfit MnSq. In the final iteration, the category fit statistics for all the categories were satisfactory (infit and outfit MnSq: 0.7 to 1.4 in all cases). Frequency count in the category 1 was very low suggesting very few participants in the higher difficulty category. However, the frequency count for category 1 was higher than the minimum number of responses required for a stable threshold calibration.[99] In contrast, 68% of the responses were for Category 5 indicating that there was a ceiling effect i.e. most of the participants had a little activity limitation. This is also evident from the category probability curves and poor targeting as seen in the person-item map (Figure 6.11).

Measurement precision of the original Activity limitation scale was excellent. However, it had nine misfitting items. On the PCA, eigen-value of the first contrast suggested that a cluster of more than six items might form a secondary dimension (Table 6.10). The PCA standardised residuals for ten items on 'Reading and writing for near (eight items)' and 'Other near works (two items)' loaded >0.40. Ten items put together, PSI was 1.52 (N = 296). After dropping the extreme responses (n = 147), the PSI improved to 2.38. However, removing responses of nearly half of the respondents was a concern. After this step, we performed a series of Rasch analyses to assess the potentiality of relevant concepts to form valid scales, and assess the impact of removing these scales from the original Activity limitation scale. These are presented in Table 6.11 and Table 6.10 respectively.

Table 6.10 Rasch parameters of the Activity limitation domain iterations

Parameters	**Model expectations**	**AL-original**	**Iteration I:** AL minus 'Reading and writing at near'; del AL25; [additional PW.14, 51 1][&]	**Iteration II:** AL minus 'Reading and writing at near' and 'Other near works'; [additional PW.14, 51, 1][&]	**Iteration III:** AL minus 'Reading and writing at near', 'Other near works', and 'Far-distance works' [additional PW.14 51 1][&]	**Iteration IV:** AL minus 'Reading and writing at near', 'Other near works', 'Far-distance works' and 'Physical activities'	**AL Final iteration**: Del AL25 [PW 25, 54, 30, 57, 14, 56, 9, 53][&]
Disordered thresholds		None	None	None	None	None	**None**
No. of items (Ni) / No of persons (Np)	-	Ni = 72 / Np = 296	Ni = 61/ Np = 296	Ni = 48 / Np = 296	Ni = 38 / Np = 296	Ni = 28 / Np = 296	Ni = **71 / Np = 296**
PSI (person reliability)	>2.0 (>0.80)	2.85 (0.89)	2.98 (0.90)	2.81 (0.89)	2.36 (0.85)	2.15 (0.82)	**3.09 (0.91)**
ISI (item reliability)	>3.0 (>0.90)	7.19 (0.98)	7.27 (0.98)	7.67 (0.98)	7.86 (0.98)	8.35 (0.99)	**7.30 (0.98)**
PCA, variance by first factor	>50%	47.8%	49.8%	50.5%	50.2%	53.7%	**48.8%**
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	6.60 (4.8%) / r_d = 1	4.62 (3.8%) / r_d = 1	4.89 (5.0%) / r_d = 0.98	3.64(4.8%) / r_d = 0.95	2.69 (4.5%) / r_d = 0.89	**6.59 (4.8%) / r_d = 1**
PCA, % raw variance explained by items	-	17.1%	18.0%	18.2%	22.4%	24.9%	**17.5%**
Item infit (MnSq)	<1.5	6 (25, 29, 54, 56, 57)	0	0	0	59: 1.63	**0**
Item outfit (MnSq)	<1.5	9 (25, 29, 22, 54, 56, 57, 53, 30, 9)	0	0	0	59: 1.78	**0**
Local item dependency (LID)	>0.3						**125 (5%) pairs; 38 LID items**
Measurement range (logits)	-	1.85 to -2.00	2.13 to -2.32	1.95 to -2.42	2.07 to -2.34	2.28 to -2.30	**2.14 to -2.25**
Targeting, difference between person & item means	<1.0 logits	2.37	2.40	2.30	2.43	2.66	**2.49**
Items with PCA standardised residual loadings > 0.40		8 items [13, 11, 16, 5, 10, 19, 18, 20]; close to 0.40: 12, 36, 32; mainly items on reading and writing at near]	6 items [36, 35, 32; loadings close to 0.40: 41, 33, 42) Mainly items on 'other near works'	7 items [3, 4, 1, 2, 24, 21, 39; items on 'Far-distance works'	5 items [56 53 69 54 57; Items on physical activities]	3 items [70, 71, 72; Driving]	**8 items** [13, 11, 16, 5, 10, 19, 18, 20]; close to 0.40: 12, 36, 32; mainly items on reading and writing at near]

Note: Values in red font represent poor fit to the Rasch model. AL = Activity limitation, ISI = Item separation index, PCA = Principal component analysis, PSI = Person separation index

MnSq = Mean square; [&]PW: person weighting was done such that persons with erratic responses (residuals ≥|4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations.

Table 6.11 Sub-scales of Activity limitation

Parameters	**Model expectations**	**First group: 'Reading and writing for Near'**	**Second group: 'Other near works'** (PW: AL51, AL26, AL37, AL45)[&]	**Third group: 'Far-distance works'**	**Fourth group: 'Physical activities'**
Disordered thresholds		No	No	No	No
No. of items (Ni) / No of persons (Np)	-	Ni = 10 Np = 197[#]	Ni = 13 Np = 157[#]	Ni = 10 Np = 216[#]	Ni = 10 Np = 213[#]
PSI (person reliability)	>2.0 (>0.80)	2.19 (0.83)	2.01 (0.80)	2.57 (0.87)	1.83 (0.77)
ISI (item reliability)	>3.0 (>0.90)	8.41 (0.99)	5.54 (0.97)	6.72 (0.98)	7.75 (0.98)
PCA, variance by first factor	>50%	67.7%	65.3%	67.2%	61.2%
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	2.38 (7.7%) r_d = 0.80	2.07 (5.5%) r_d = 1	2.21 (7.3%) r_d = 1	1.68 (6.6%) r_d = 1
PCA, % raw variance explained by items	-	19.5%	16.8%	12.8%	26.1%
Item infit (MnSq)	<1.5	0	0	0	0
Item outfit (MnSq)	<1.5	0	0	0	0
Measurement range (logits)		2.52 to -2.40	2.32 to -2.03	1.05 to -1.67	1.90 to -1.78
Targeting, difference between person & item means	<1.0 logits	4.0	3.04	2.24	1.48

Note: Values in red font represent poor fit to the Rasch model. AL = Activity limitation, MnSq = Mean square, PCA = Principal component analysis; [#] Extreme responses were dropped/removed. [&]PW: person weighting was done such that persons with erratic responses (residuals ≥|4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations.

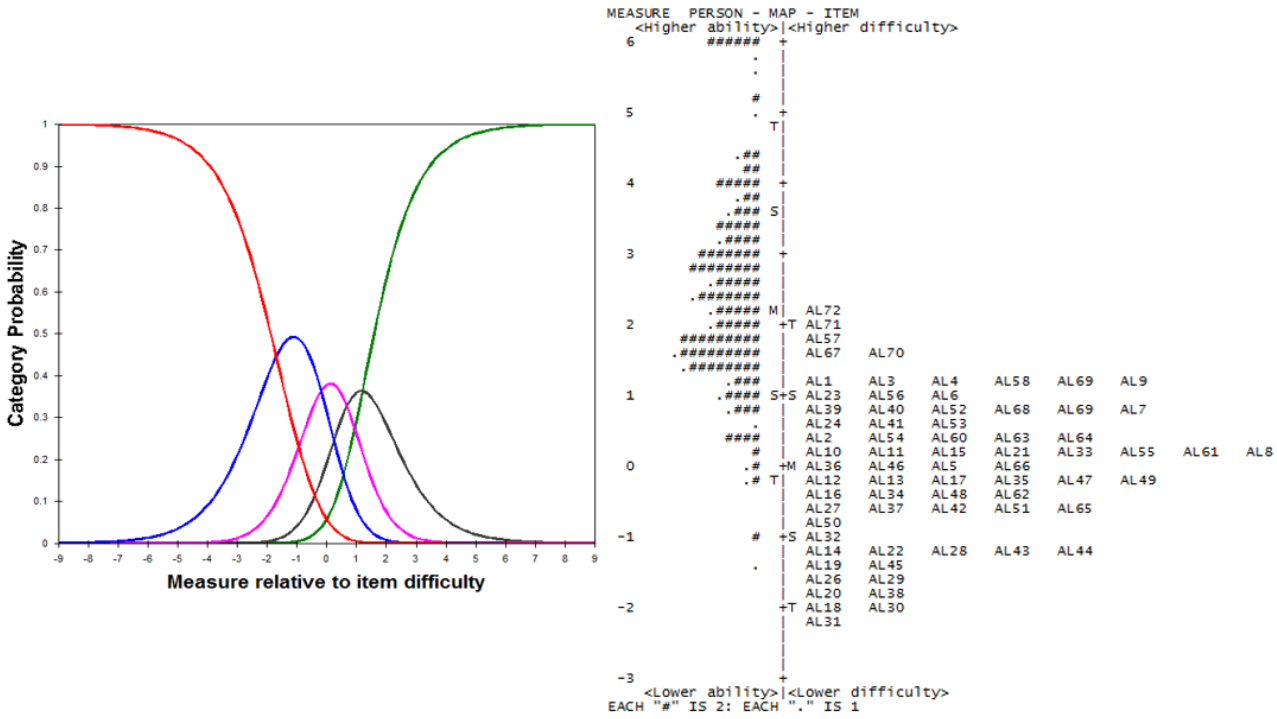

Figure 6.11 Final 71-item Activity limitation item-bank: a. Category probability curves b. Person-item map

Note: In figure a, red = 1. Unable to do because of my vision, blue = 2. A lot, pink = 3. Quite a bit, black = 4. A little, green = 5. None. In figure b, persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

First group: Reading and writing at near

As most of the items with PCA standardised residual loading > 0.40 in the original Activity limitation scale were on reading and writing at near, we grouped all the items relevant to this concept. Ten items (Items: AL5, AL6, AL8, AL10, AL11, AL13, AL16, AL18, AL19, AL20) related to this concept were grouped. The PSI was low (1.52) that improved to 2.19 after dropping extreme responders. However, about one-third of the persons (n = 95, 32.5%) had to be dropped. Targeting of this scale was poor (difference between person and item means: 4.00 logits) (Table 6.11).

After removing these 10 items, only a little improvement occurred in the main Activity limitation scale: (little improvement in the PCA variance explained by measure, slight reduction in eigen-value of the first contrast, slight improvement in targeting). There was a reduction on the measurement precision. The PCA standardised residuals for six items on ‘Other near works’ loaded >0.40 on the main scale (Table 6.10).

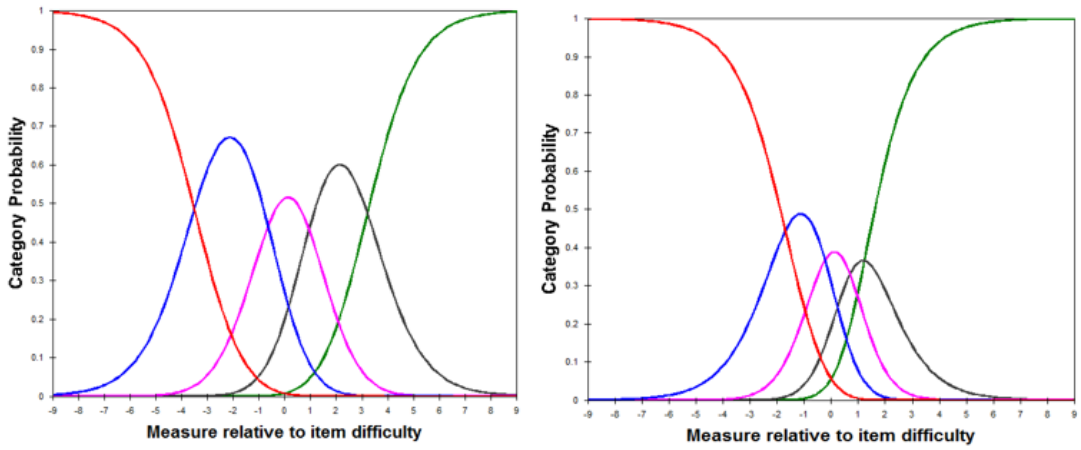

Figure 6.12 Category probability curves for a. Reading and writing at near and b. AL–first iteration
Note: red = 1. Unable to do because of my vision, blue = 2. A lot, pink = 3. Quite a bit, black = 4. A little, green = 5. None

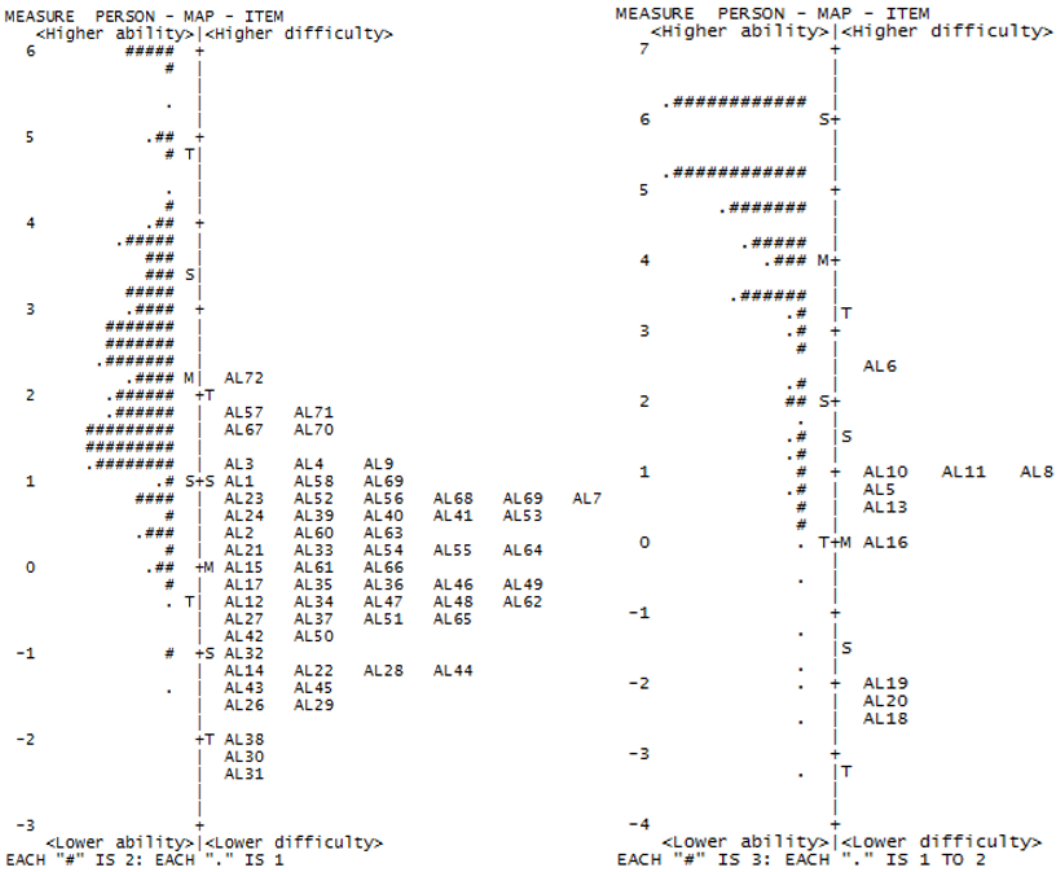

Figure 6.13 Person-item maps for a. AL–first iteration and b. 'Reading and writing at near'
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Agreement analysis between 'Reading and writing at near' and AL–first iteration:

The Bland and Altman analysis for the agreement between 'Reading and writing at near' and first iteration (N = 197) was performed (Figure 6.14). The distribution was normal (Kolmogorov-Smirnov test: 0.20). The mean difference was -2.21 ± 1.69 logits (paired t test, p < 0.001). The limits of agreement were wide (upper limit of agreement: 1.21 ± 0.20 logits; lower limit of agreement: -5.43 ± 0.20 logits). The Pearson correlation coefficient was 0.52.

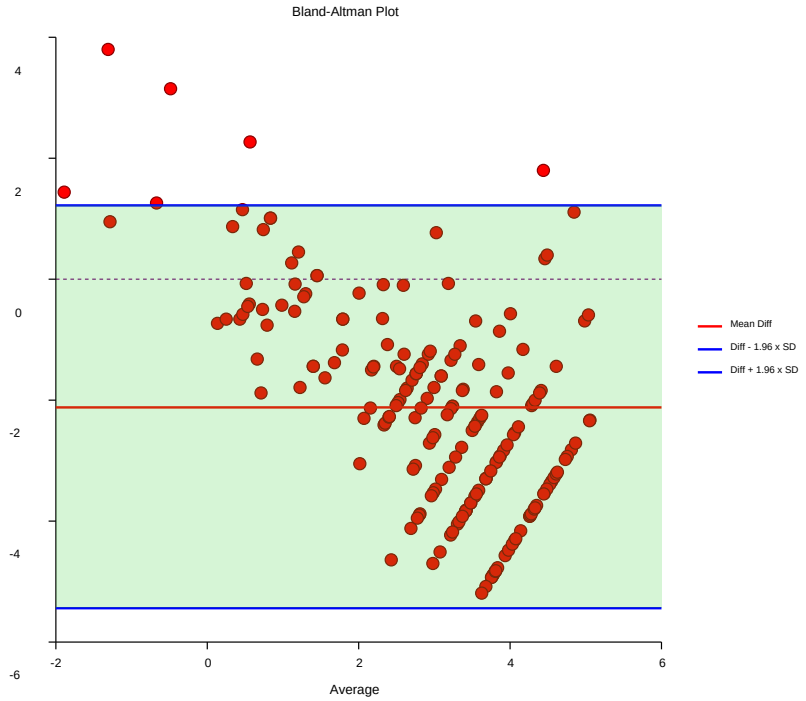

Figure 6.14 Bland and Altman plot: 'AL–first iteration' vs First group 'Reading and writing at near'

A notable bias and wide limits of agreement was observed in the Bland and Altman plot. However, this difference may be because the AL–contrast had poorer targeting (Figure 6.13; difference between person and item means for first contrast, 4.0 logits; and for first iteration, 2.40 logits) with higher ceiling effect. Alternatively, mean difficulty of items for the first contrast 'Reading and writing at near' was less than for the first iteration. Furthermore, the mean difference in the Bland and Altman plot might have been even worse if the extreme responses were not dropped (difference between person mean and item mean for the first contrast would have been 5.17).

Second group: Other near works

Thirteen items on near works other than ‘Reading and writing at near’ (i.e. other than the first group of items) were grouped together (AL26, AL32, AL33, AL34, AL35, AL36, AL37, AL41, AL42, AL45, AL46, AL47, AL51). Similar to the first group of items ‘Reading and writing at near’, PSI of this scale was low (1.20). After dropping 138 extreme responders, the PSI improved to 2.01. Removing almost half (46.8%) of the respondents was a concern. Targeting of the ‘Other near works’ scale was poor (3.04 logits) (Table 6.11).

After removing these 13 items, only a little improvement occurred in the main Activity limitation scale (a little increase in the PCA variance explained by measure, only a slight improvement in targeting). There was an increase in the eigen-value of the first contrast and decrease in the PSI. After removing these items, PCA standardised residuals for seven items on ‘Far-distance works’ loaded >0.40 (Table 6.10).

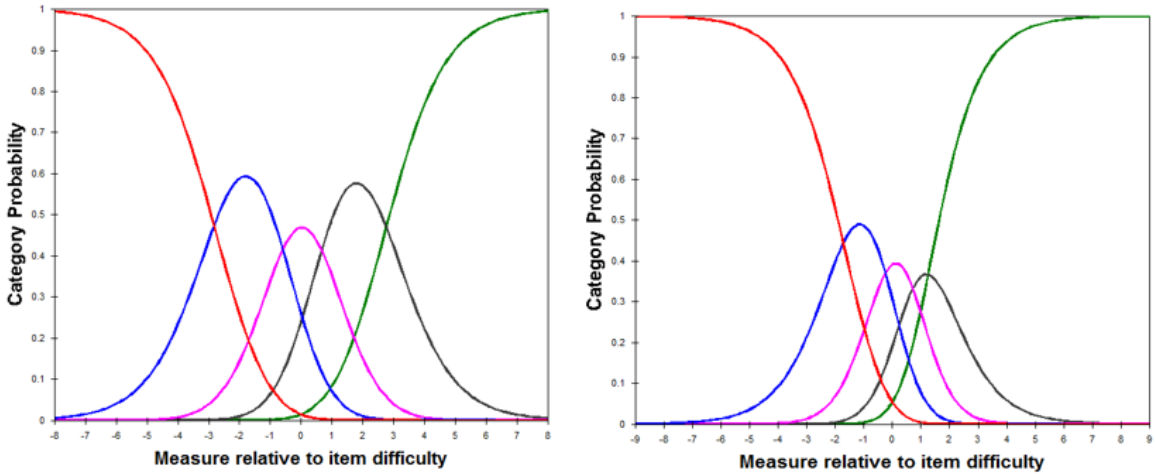

Figure 6.15 Category probability curves for a. Other near works and b. AL–second iteration
Note: red = 1. Unable to do because of my vision, blue = 2. A lot, pink = 3. Quite a bit, black = 4. A little, green = 5. None

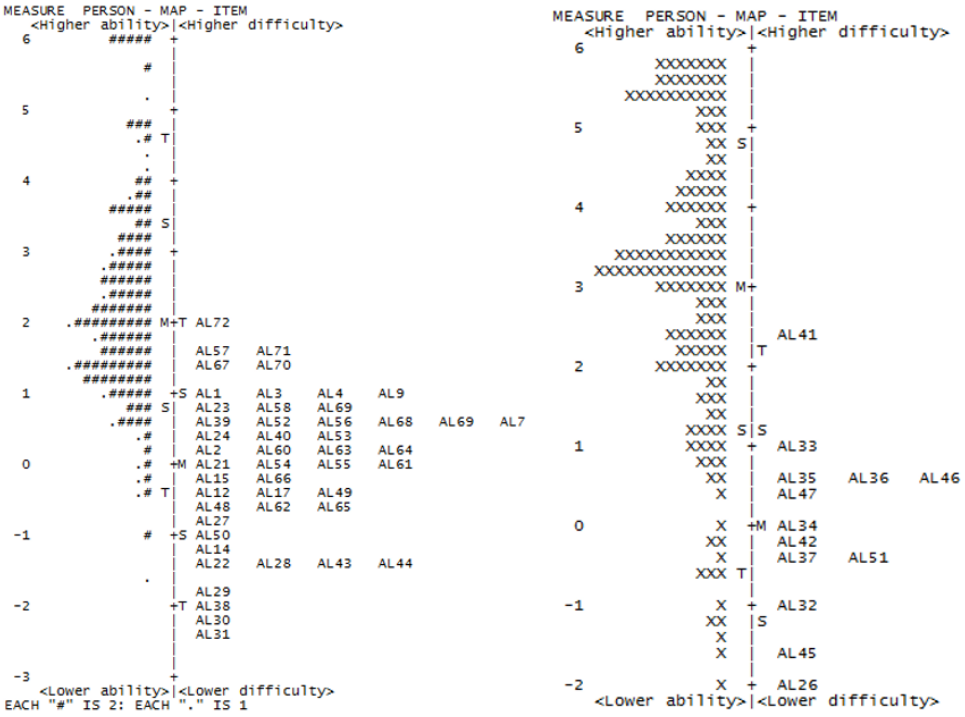

Figure 6.16 Person-item maps for a. AL–second iteration and a. Other near works
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Agreement analysis between AL–second group and AL–second iteration

The Bland and Altman analysis for the agreement between the second group of items (Other near works) and the second iteration (N = 212) was performed (Figure 6.17). The distribution was normal (Kolmogorov-Smirnov test, p = 0.074). The mean difference was low (-0.27 ± 1.46 logits) but statistically significant (Paired t test, p = 0.007). The limits of agreement were wide (upper limit of agreement: 2.60 ± 0.17; lower limit of agreement: -3.15 ± 0.17 logits). The Pearson Correlation coefficient was 0.62.

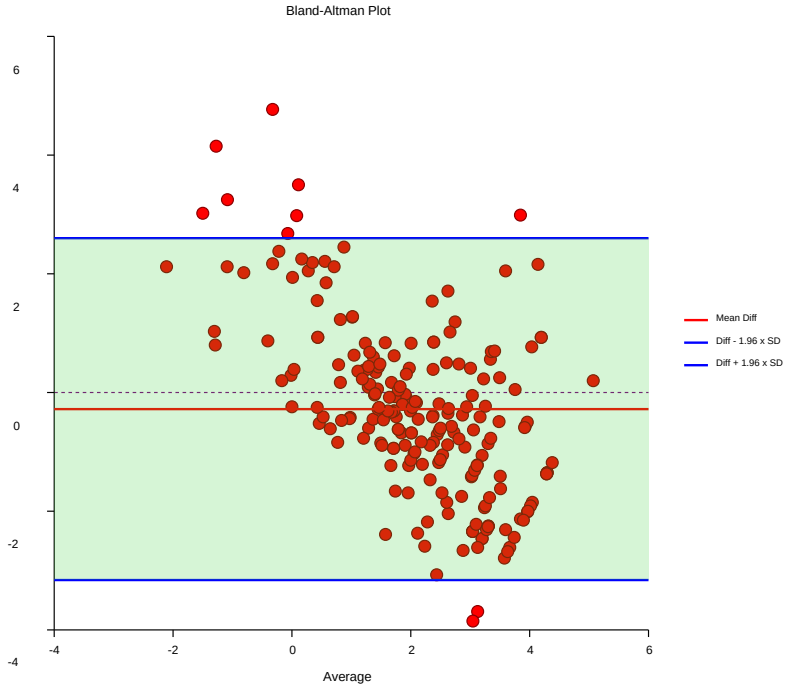

Figure 6.17 Bland and Altman plot for 'AL–second iteration' and 'Other near works'

The Bland and Altman plot shows a wide limit of agreement. This may partly be explained by the poorer targeting of the second group of items (Other near works; 3.04) compared to the second iteration (2.30) (Figure 6.15).The limits of agreement might have been even wider if the extreme responses had not been dropped (targeting for the second group of items would have been 4.74).

Third group: Far-distance works

Rasch analysis was done for 10 far-distance works items (AL1, AL2, AL3, AL4, AL21, AL24, AL39, AL60, AL61, and AL65). The PSI was low 1.86 to start with, which improved to 2.57 after dropping extreme responders. Almost one-third (n = 80) of the respondents had to be dropped. Targeting was poor both in terms of the difference between person and item means and the distribution of items and person in the person-item map (Figure 6.18). The range of measurement was narrow (Table 6.11).

There was a slight reduction in the eigen-value of the first contrast in the main scale after removing 10 'Far-distance works' items. However, there was a slight decrease in the PCA variance explained by measure, decrease in the PSI, and worsening in targeting). After removing these items, five items on 'Physical activities' loaded >0.40 (Table 6.10).

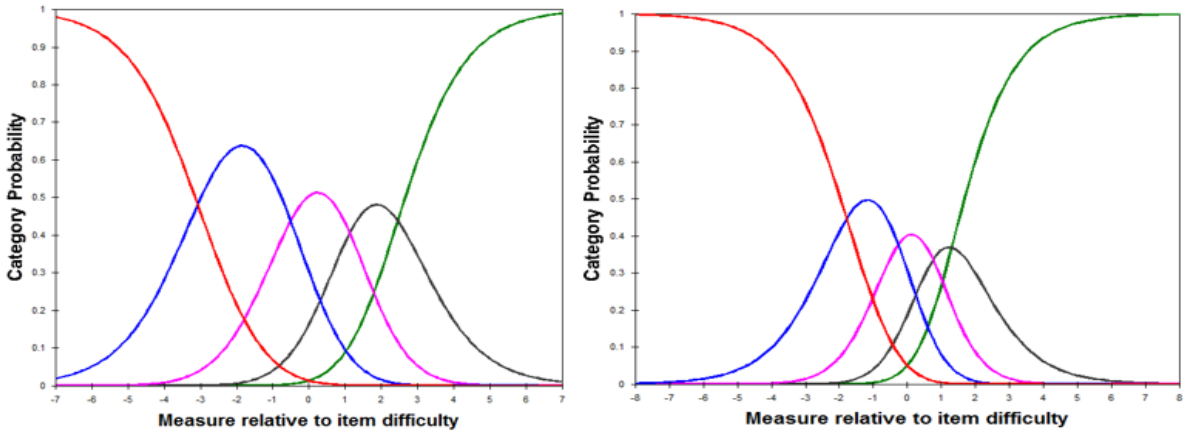

Figure 6.18 Category probability curves for a. Far-distance works and b. AL–third iteration
Note: red = 1. Unable to do because of my vision, blue = 2. A lot, pink = 3. Quite a bit, black = 4. A little, green = 5. None

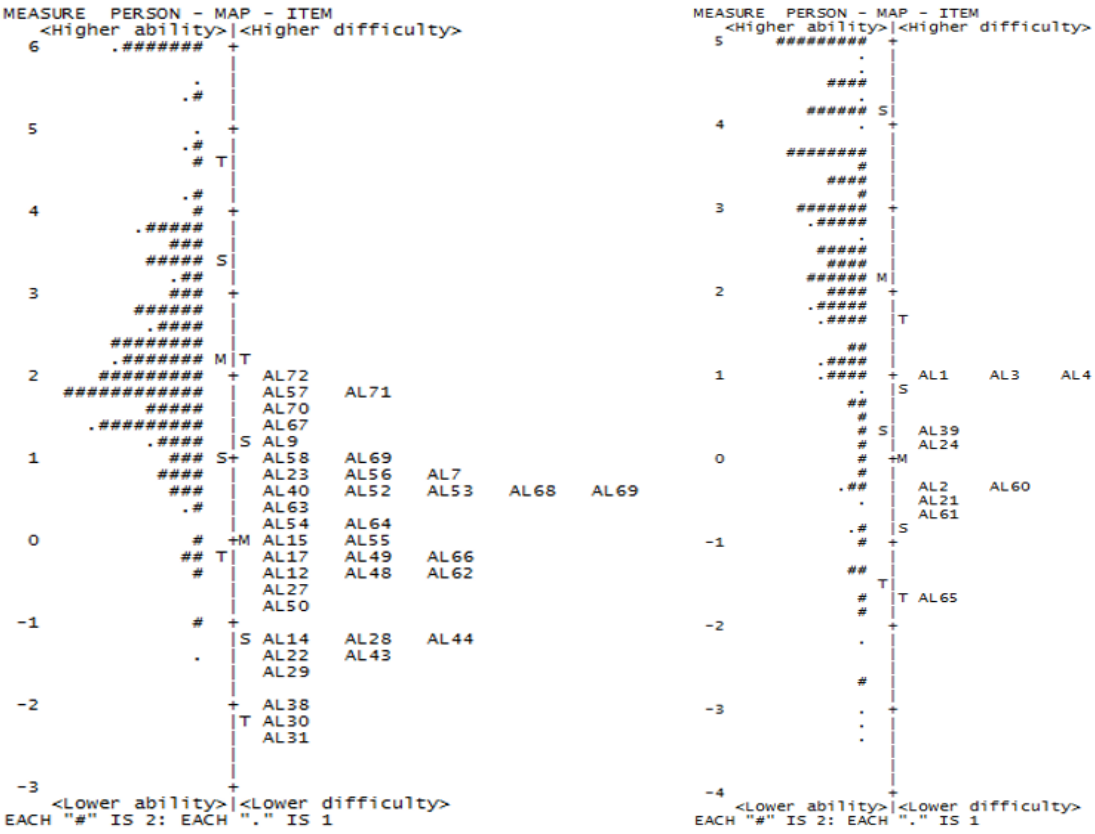

Figure 6.19 Person-item maps for a. Third iteration and b. Far-distance works
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Agreement analysis between 'Far-distance works' and 'AL–third iteration'

The figure below (Figure 6.20) shows the Bland and Altman plot for the agreement between the

third group of items and the third iteration (N = 153). The distribution was normal (Kolmogorov-Smirnov test = 0.2). The mean difference was -1.56 ± 1.53 logits (Paired t test, p < 0.001). The limits of agreement were wide (upper limit of agreement: 1.44 ± 0.21 logits; lower limit of agreement: -4.58 ± 0.21 logits). The Pearson Correlation coefficient was 0.58.

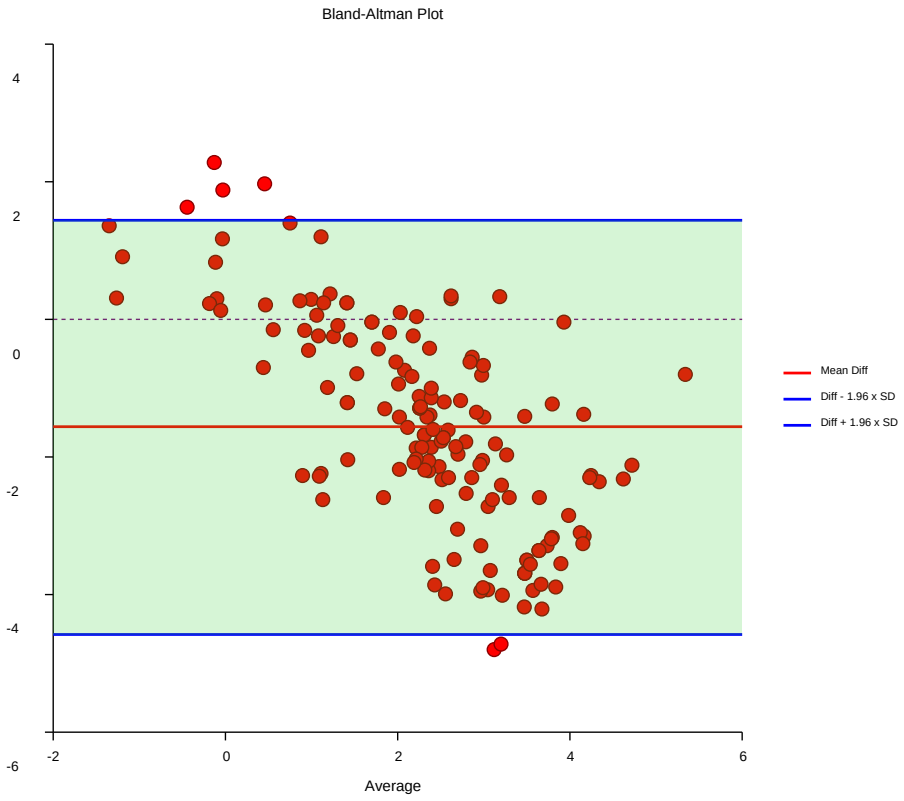

Figure 6.20 Bland and Altman plot between 'AL–third iteration' and 'Far-distance works'

The Bland and Altman plot shows a notable difference and wide limits of agreement. This may partly be explained by difference in targeting between third iteration (2.43 logits) and third group of items (2.24 logits) (Figure 6.19). For the 'Far-distance works', extreme responses were dropped. If the extreme responses had not been dropped, its targeting would have been 3.30 which might have altered the agreement values.

Fourth group: Physical activities

Ten items that require high physical activity were grouped together (AL48, AL49, AL50, AL52, AL53, AL54, AL56, AL57, AL58, AL69). Like the first, second and third groups of AL items, the PSI was originally low for this group of items (1.62). After dropping 27% (n = 78) respondents, PSI could be improved only to 1.83 (Table 6.11).

After removing these 10 items, only a little improvement occurred in the main Activity limitation

scale (slight increase in the PCA variance explained by measure, slight reduction in the eigen-value of the first contrast). However, there was a decrease in the PSI and a worsening on targeting. Since the eigen-value of the first contrast was less than 3.0, further splitting of items was not required. Three items on driving loaded >0.40 (Table 6.10).

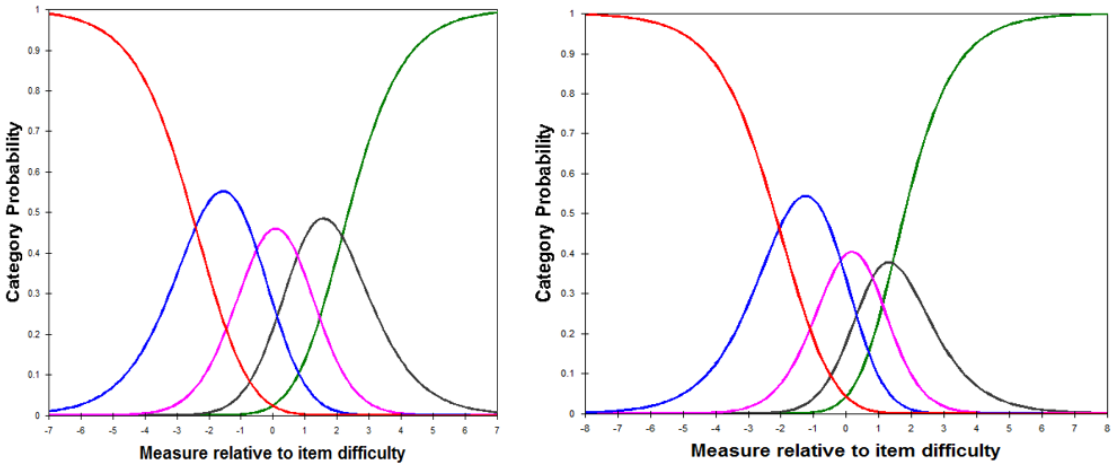

Figure 6.21 Category probability curves for a. Physical activities and b. AL–fourth iteration

Note: red = 1. Unable to do because of my vision, blue = 2. A lot, pink = 3. Quite a bit, black = 4. A little, green = 5. None

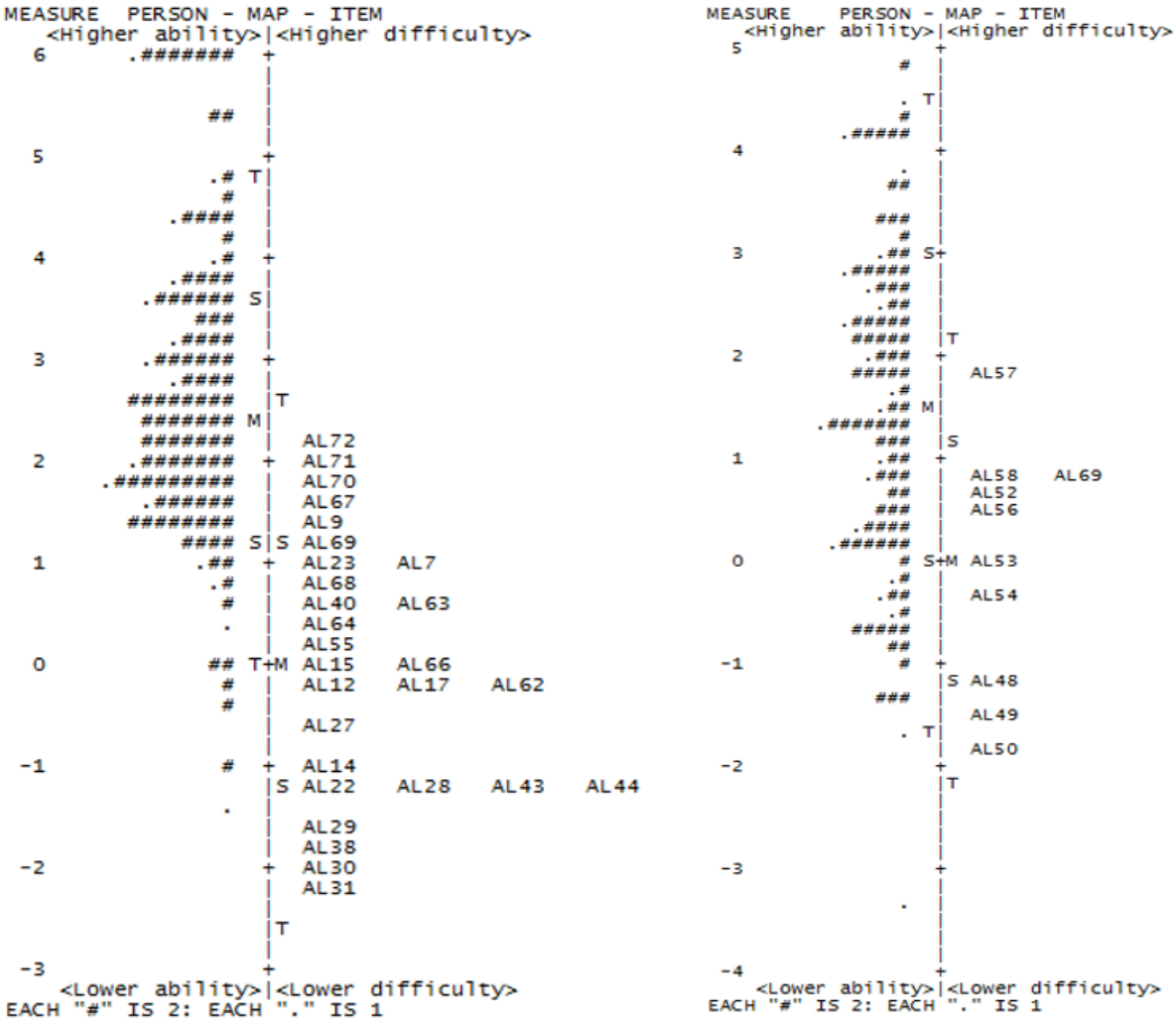

Figure 6.22 Person-item maps for a. AL – fourth iteration and b. Physical activities
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Agreement analysis between 'AL–fourth iteration' and 'Physical activities'

The Bland and Altman plot for the agreement between the fourth group of items and the fourth iteration (N = 208) was performed (Figure 6.23). The distribution was normal (Kolmogorov-Smirnov test, $p = 0.2$). The mean difference was low (0.79 ± 1.57 logits) but statistically significant (Paired t test, $p < 0.001$). The limits of agreement were wide (upper limit of agreement: 3.88 ± 0.19 logits; lower limit of agreement: -2.28 ± 0.19 logits). The Pearson correlation coefficient was 0.38.

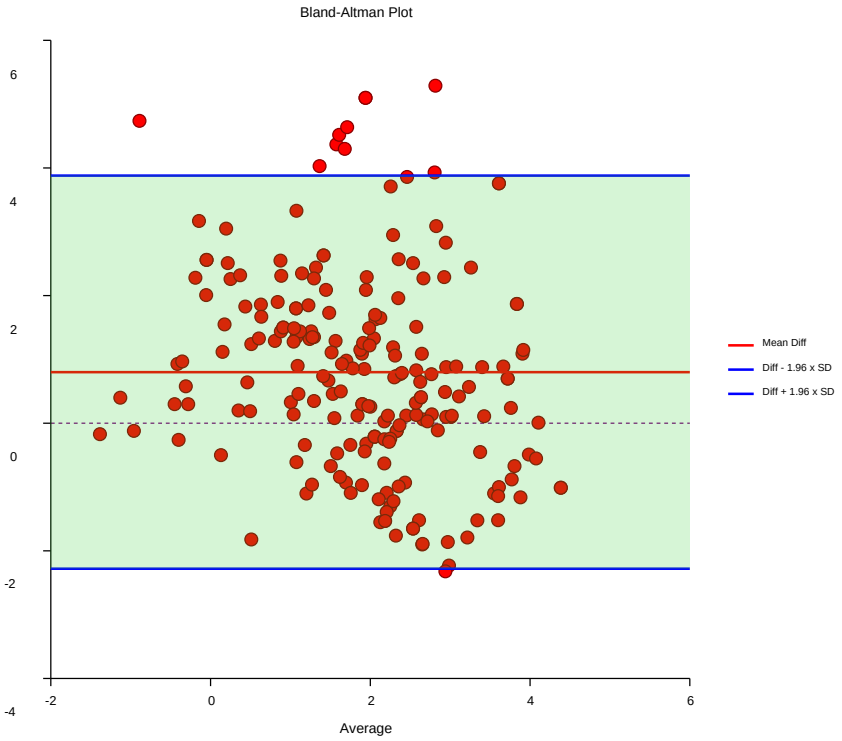

Figure 6.23 Bland and Altman plot for 'AL–fourth iteration' and 'Physical activities'

The Bland and Altman plot shows wide limits of agreement. This may be partly explained by difference in targeting between the fourth iteration (2.66) and the fourth group of items (1.48). For the 'Physical activities', extreme responses were dropped. If the extreme responses had not been dropped, its targeting would have been 2.51 which might have altered the agreement values.

Driving

Although driving was identified as a new domain in other ophthalmic item-bank modules[57], and perhaps in refractive error as well (as indicated by qualitative analysis of the Australian data (Chapter 4)[14], it fitted well to the overall Activity limitation domain in the current study. This is perhaps due to relatively less number of items (n = 6). Just for the curiosity, we did a separate analysis for driving. The driving items could form an independent scale. However, for this study, splitting driving items from the main Activity limitation scale was not required and not justified.

Decision making for the Activity limitation item bank

Although the four groups of items of Activity limitation domain had some satisfactory psychometric properties after dropping extreme responses, they had important limitations. High number of respondents had to be dropped in all groups. Overall, removing one group of items at a time offered only a little change in the main scale. In each iteration, the disattenuated correlation between first and second item-clusters was high suggesting the groups were essentially measuring

the same construct. In addition, after removing four groups of items, the resulting 28 item Activity limitation scale did not have a single conceptually meaningful construct. Conceptually, these subscales are part of activity limitations, and removing them from the main scale would minimize the face validity of the main scale (fourth iteration). Therefore, a single Activity limitation item bank was proposed.

The final Activity limitation item bank

On the PCA, eigen-value of the first contrast suggested that a cluster of more than six items might form a secondary dimension. However, there were multiple factors which suggested that all the items (and the subscales) in the Activity limitation domain were measuring the same construct. The variance explained in the first contrast was only 4.8% which is 3.65 times less than the variance explained by the items. Total variance explained by the measure was 49%. The disattenuated correlation between first and second item-clusters was very high (1.0). AL25 (Cooking) had poor fit statistics (infit MnSq 2.14; outfit MnSq: 3.05) that could not be improved to an acceptable level by adjusting for erratic responses. Therefore, AL25 was deleted. All other items had satisfactory fit statistics (Appendix I). Considering multiple parameters in combination, having a single 71-item Activity limitation item bank was justified.

The final Activity limitation item bank had excellent measurement precision and good fit statistics. However, targeting of person-ability and item-difficulty was outside an acceptable range (Table 6.10, Figure 6.11). The higher person measures in logits represented the lesser activity limitation (higher ability) due to refractive error. Whereas, the items with higher activity limitation due to refractive error had higher item measures. Items related to driving, active sports such as swimming, and activities with high distance visual resolution demand (e.g. reading things written on a black or white-board) were the most difficult items. Whereas, items for indoor works with less visual resolution demand, particularly near and intermediate works (e.g. identifying a tooth-brush, eating meals) were perceived as the easier items.

6.3.5 Mobility

The original Mobility (MB) domain had 14 items. The response categories for Mobility domain were same as for the Activity limitation domain. Each item started with an item root “How much difficulty do you have …?”, with a 5-point ‘difficulty’ rating scale and two other possible responses: ‘This task is not relevant to me / don’t do the task’ and ‘Refuse to answer’. The response options were coded from 1 to 5 with higher scores for higher ability levels. Alternatively, as the level of difficulty increased, score decreased (Table 6.12). Category structure statistics of the original Mobility domain are provided in Table 6.12.

Table 6.12 Category structure statistics for Mobility domain

Category	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. Unable to do because of my vision	13	0	4.10	2.88	None	(-4.92)*
2. A lot	129	3	1.40	1.40	-3.79	-2.19
3. Quite a bit	345	9	0.94	0.91	-0.55	0.42
4. A little	599	15	0.86	0.50	1.53	2.23
5. None	2,791	72	1.06	1.10	2.81	(4.08)*
Missing data#	253	6				

Note: Values in red font represent poor fit to the Rasch model. MnSq = Mean square; *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes. #Missing data = Missing data + This task is not relevant to me / don't do the task + Refuse to answer

The thresholds and the category measures were ordered with good spacing between adjacent thresholds. The frequency count for the category 1 was low suggesting only a few participants in the highest difficulty category. Whereas, 72% of the responses were for Category 5, which indicated that there was a ceiling effect, i.e. most of the participants had little mobility problems. This is also evident from the category probability curves (Figure 6.24) and poor targeting (Figure 6.24, Table 6.13).

The original Mobility scale had a low precision (PSI = 1.68). Therefore, 80 participants with extreme responses were dropped. MB4 (Walking around with reading spectacles) and MB2 (Walking in the rain) were misfitting items. MB4 was deleted as its fit statistics could not be fixed by person weighting. Also, this item was not applicable to most of the participants. After person-weighting, the final outfit MnSq for MB2 was 1.54. MB2 was retained as it is an important item for spectacle wearers. A separate Rasch analysis in spectacle wearers only was performed to confirm this.

Table 6.13 Rasch parameters of the Mobility domain iterations

Parameters	Model expectations	Original	**Iteration II (Final)** [Del MB4; PW: MB3, MB1, MB7]&
Disordered thresholds		No	**No**
No. of items (Ni) / No of persons (Np)	-	NI = 14 / Np = 295	**NI = 13 / Np = 212#**
PSI (person reliability)	>2.0 (>0.80)	1.68 (0.74)	**2.22 (0.83)**
ISI (item reliability)	>3.0 (>0.90)	7.11 (0.98)	**8.10 (0.98)**
PCA, variance by first factor	>50%	63.9%	**65.8%**
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	2.59 (6.7%) / r_d = 1	**2.46 (6.5%) / r_d = 1**
PCA, % raw variance explained by items	-	23.7%	**27%**

Item infit (MnSq)	<1.5	2 (MB4:2.5; MB2:1.8)	**0**
Item outfit (MnSq)	<1.5	2 (MB4:2.47; MB2:1.92)	**MB2 (1.54)**
Local item dependency (LID)	>0.3		**4/78 pairs; 4 LID items** (MB4, MB3, MB9, MB11)
Measurement range (logits)	-	3.06 to -1.18	**4.14 to -1.21**
Targeting, difference between person & item means	<1.0 logits	4.56	**4.71**
Items with PCA standardised residual loadings > 0.40		2 items: MB10, MB11 (MB13 and MB14 loaded close to 0.40	**2 items**: MB10, MB11 (MB13 and MB14 loaded close to 0.40)

Note: Values in red font represent poor fit to the Rasch model ISI = Item separation index, MB = Mobility, MnSq = Mean square, PCA = Principal component analysis, PSI = Person separation index. # 83 extreme responses were dropped/removed. &PW: person weighting was done such that persons with erratic responses (residuals ≥ |4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations

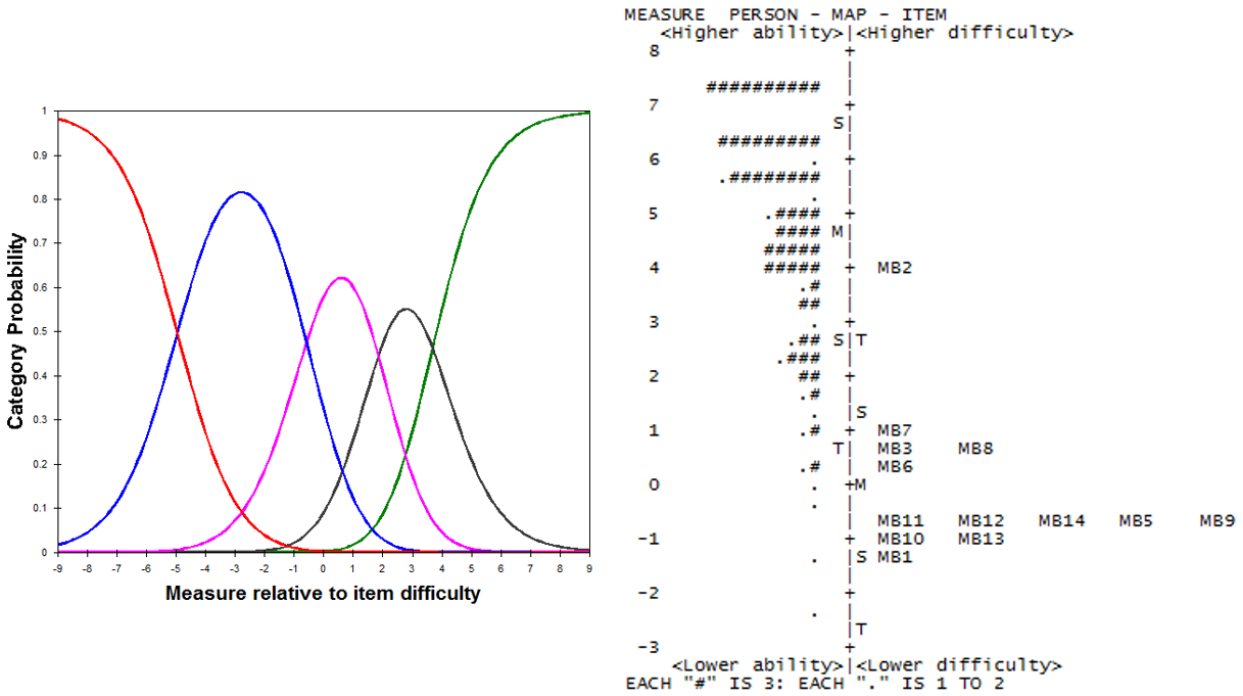

Figure 6.24 Mobility item bank: a. Category probability curves b. Person-item map
Note: Figure a: red = 1. Unable to do because of my vision, blue = 2. A lot, pink = 3. Quite a bit, black = 4. A little, green = 5. None; Figure b: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

The final Mobility item bank was a unidimensional scale. The PCA variance explained by the first factor was excellent. The eigen-value of the first contrast was within acceptable limit. The variance

explained by items was 4.2 times higher than the unexplained variance in the first contrast. Similarly, item fit statistics and measurement precision were satisfactory. The scale had a wide range of measurement (Table 6.13, Appendix I). However, targeting between item-difficulty and person-ability was poor (Figure 6.24). The higher person measures in logits represented the lesser difficulty in mobility (higher ability) due to refractive error. Whereas, the items with higher difficulty in mobility due to refractive error had higher item measures. Items related to walking in difficult conditions (e.g. walking in rain wearing spectacles, in dim light, in dawn or dusk) were perceived to be the most difficult items. Whereas, general walking (in normal condition) was perceived as the easiest item.

6.3.6 Emotional

The original Emotional domain had 32 items. Each item started with an item root "How often do you ...?" with 5 response categories. The response categories were coded from 1 to 5 with higher score implying lower emotional trait level/ frequency of emotion. Response polarity of the six positively worded items (pleasant emotions; EM7, EM9, EM10, EM13, EM16, and EM32) was changed to match the rest of the items, so that higher score always represented better emotional status. The category structure statistics of the original Emotional domain after changing the response polarity of the positively worded items are given in Table 6.14.

Table 6.14 Category structure of the original Emotional domain

Category	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. All of time	1,063	11	0.92	1.06	None	(-1.74)*
2. Most of the time	411	4	1.65	2.29	0.08	-0.71
3.Some of the time	731	8	1.05	1.70	-0.69	-0.07
4. A little of the time	1,521	16	0.98	0.76	0.13	0.65
5. None of the time	5,596	60	0.84	1.43	0.49	(1.95)*
Missing data#	54	1				

Note: Response polarity of the positively worded items was reversed to match the rest of the items. Values in red font represent poor fit to the Rasch model. MnSq = Mean square; *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes. #Missing data = Missing data + Refuse to answer

The original emotional scale had disordered category thresholds (Table 6.14, Figure 6.25.a). The fit statistics for the second response category "2. Most of the time" were poor. The category structure and use of the final Emotional domain are given in Table 6.15. The thresholds and category measures of the final scale were ordered and advanced monotonically. The spacing between the adjacent thresholds was excellent (Figure 6.25.b, Table 6.15). However, Similar to other domains, Emotional domain had a ceiling effect; most of the responses were for the extreme category "5. None of the time". On the other hand, frequency count for the category 1 was low indicating that only a few participants had the highest emotional impact due to refractive error.

However, the frequency count of this category was higher than the minimum number of responses required by Rasch model for producing stable threshold calibration (Table 6.15).[99]

Table 6.15 Category structure and use statistics for the final iteration of the Emotional domain

Category number	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. All the time	40	1	1.43	1.39	None	(-3.17)*
2. Most of the time	159	4	1.49	1.81	-1.91	-1.34
3.Some of the time	409	9	0.88	0.97	-0.51	0.03
4. A little of the time	1,042	23	0.93	0.70	0.62	1.35
5. None of the time	2,878	64	1.04	1.03	1.80	(3.09)*
Missing data#	3	0				

Note: Values in red font represent poor fit to the Rasch model. MnSq = Mean square; *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes. #Missing data = Missing data + Refuse to answer

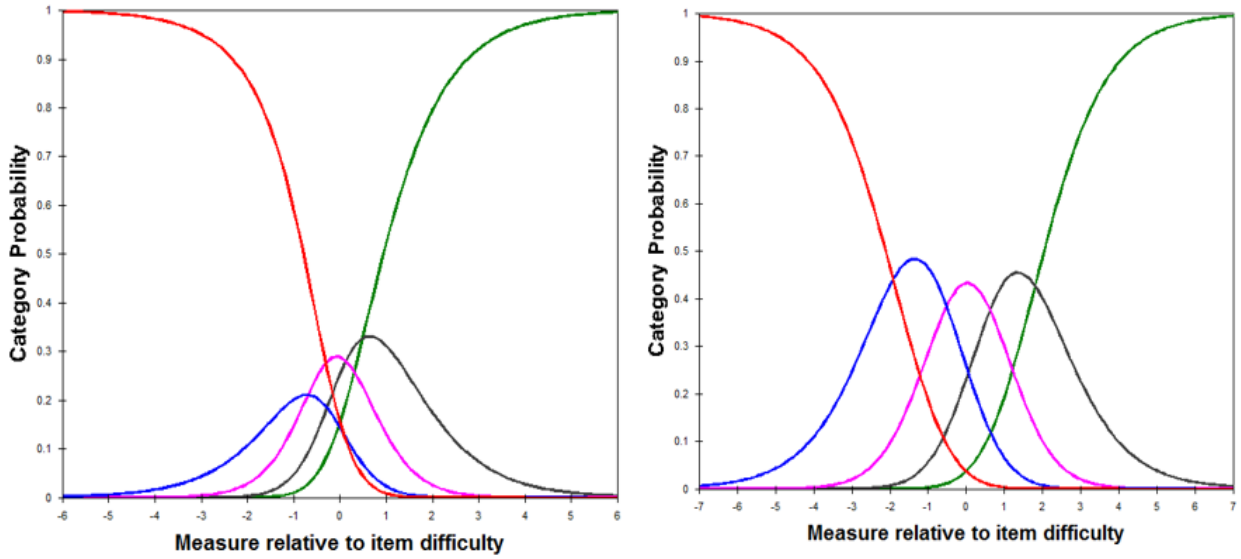

Figure 6.25 Category probability curves for Emotional domain: a. Original iteration b. Final iteration
Note: red = 1. All the time, blue = 2. Most of the time, pink = 3. Some of the time, black = 4. A little of the time, green = 5. None of the time

As the original Emotional domain had disordered thresholds, the first step in the Rasch analysis was to fix this. The scale was also multidimensional with high eigen-value of the first contrast. The PCA standardised residual loadings for six items (all positively worded items) were >0.40. The fit statistics for eight items were below satisfactory levels; six out of these eight items were the positively worded items (Table 6.16). Different behaviours of positive and negative emotional items has been reported elsewhere as well.[78] Therefore, all positively worded (n = 6) items (first contrast / secondary dimension) were removed, and a separate Rasch analysis was performed to test if these items were contributing to disordering of the thresholds. Whether these items could together form an independent scale was also evaluated.

The second dimension (first contrast) had disordered response categories. The PSI was low.

Measurement range was narrow (Table 6.16). Rasch iterations could not improve the response category functioning or PSI to acceptable levels.

Table 6.16 Rasch parameters of the Emotional domain iterations

Parameters	**Model expectations**	**Original**	**First contrast** (Second dimension): Positively worded items	**Final Emotional item bank (first dimension)** Deleted: EM19, EM3, EM11 (PW: EM8, EM5, EM1, EM2)[&]
Disordered thresholds	No	Yes	Yes	**No**
No. of items (Ni) / No of persons (Np)	-	Ni = 32 / Np = 293	Ni = 6 / Np = 293	**23; Np = 215**[#]
PSI (person reliability)	> 2.0 (> 0.80)	2.58 (0.87)	0.90 (0.45)	**2.39 (0.85)**
ISI (item reliability)	>3.0 (>0.90)	12.34 (0.99)	3.03 (0.90)	**5.44 (0.97)**
PCA, variance by first factor	>50%	72.9%	54.2%	**52.8%**
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, <5.0%	6.26 (5.3%) / r_d = 1	1.71 (13.1%) / r_d = 1	**2.78 (5.7%) / r_d = 1**
PCA, % raw variance explained by items	-	44.2%	32.3%	**16.9%**
Item infit (MnSq)	<1.5	0	EM10	**0**
Item outfit (MnSq)	<1.5	8 items (EM10, EM16, EM32, EM7, EM9, EM13, EM3, EM19)	EM 10	**0**
Local item dependency (LID)	>0.3			**14/253 pairs; 7 LID items** (EM2, EM6, EM14, EM22, EM28, EM29, EM30)
Measurement range (logits)	-	2.68 to -1.48	0.43 to -0.28	**1.20 to -1.33**
Targeting, difference between person & item means	<1.0 logits	1.38	1.58	**2.82**
Items with PCA standardised residual loadings > 0.40		6 items (all positively worded items)	EM10	**3 items** (EM22, EM21, EM23)

Note: Values in red font represent poor fit to the Rasch model. EM = Emotional, ISI = Item separation index, MnSq = Mean square, PCA = Principal component analysis, PSI = Person separation index [&]PW: person weighting was done such that persons with erratic responses (residuals ≥|4|) were weighted 0, so that they did not influence the fit statistics or measures of others persons or items. Person weighting does not affect dimensionality computations. [#] Extreme responses were dropped.

After removing these six positively worded items, the response category thresholds of the main

scale were ordered. Eigen-value of the first contrast decreased, suggesting unidimensionality (Table 6.16) However, the PSI was poor (1.66). The PSI improved to 2.11 after dropping extreme responders (n = 46, 15.7%). To fix the fit statistics, three items (EM3. Feel more conscious about your appearance, EM11. Feel older than you really are, and MB19. Feel regretful or guilty about your eye care in the past) had to be deleted as the person-weighting could not improve the fit statistics to an acceptable level. The erratic responses for items EM1, EM2, EM5, and EM8 were addressed by person-weighting. Among the deleted items, constructs measured by EM3 and EM11 may be captured by EM2.

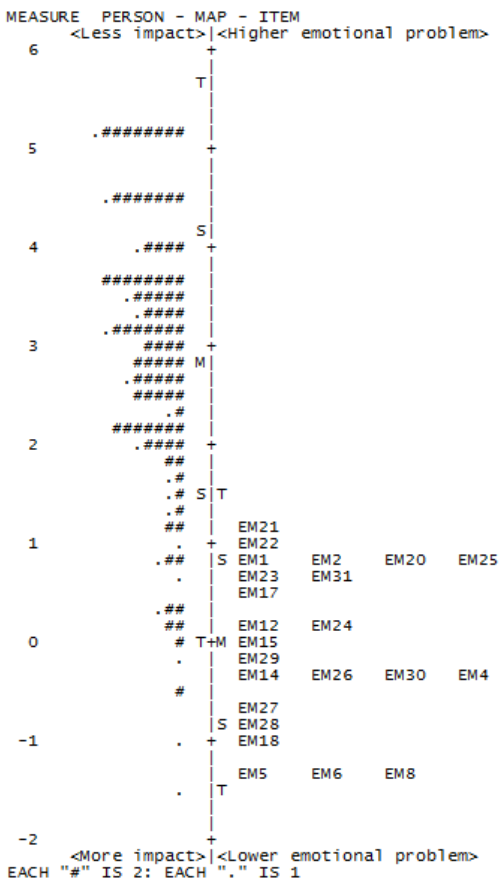

Figure 6.26 Person-item map for Emotional item bank
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Before removing the items in the first contrast from the main scale, item measure-correlation evaluation was performed. Table 6.17 shows the items in the first contrast with correlations between the residuals <-0.30 (i.e. negatively correlated items) with the items in the remaining scale. The table shows that although six positively worded items in the first contrast were deleted, there are items with opposite meaning in the remaining scale. Therefore, the final Emotional item bank may provide a comprehensive measurement of the emotional impact in refractive error.

Table 6.17 Inter-item residual correlation between the deleted item in the first contrast and other items

Item in the first contrast (Deleted)	Item in the main scale with residual correlations < -0.30
EM7	EM4, EM5, EM6, EM24, EM28
EM9	EM1, EM4, EM5, EM6, EM28, EM23, EM12, EM24, EM26, EM30, EM25
EM10	EM28, EM30
EM13	EM1, EM4, EM5, EM23, EM24, EM28
EM16	EM4, EM5, EM6, EM24
EM32	EM4, EM28, EM24, EM23

The Final 23-item Emotional item bank was essentially unidimensional scale with satisfactory measurement precision and fit statistics (Appendix I). However, it had a poor targeting (Figure 6.26). The higher person measure in logits represented the lower emotional impact due to refractive error. Whereas, the items with emotion with higher frequency had higher item measures. Items such as feeling like one is different from others, feeling embarrassed wearing glasses, and feeling irritated were considered as the more impactful (more frequent) emotions. These items were likely to be endorsed even by people with little emotional impact of refractive error. Whereas, the items for severe emotions such as 'feeling afraid, feeling humiliated' were perceived as the less impactful (less frequent) emotions likely to be endorsed by people with only high emotional impact from refractive error.

6.3.7 Social

The Social (SC) domain had 16 items. Each item started with an item root "How much of a problem do you have...?", with five response categories. The response options are coded from 1 to 5 with lower scores implying worse social impact. First, the response category functioning was assessed. Like other domains, the Social domain had a ceiling effect; 70% responses were for the extreme category "5. None". However, the category thresholds and category measures were ordered and advanced monotonically. The spacing between the adjacent thresholds was excellent (Table 6.18, Figure 6.27).

Table 6.18 Category structure and use statistics for the original Social domain

Category	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. Unable to do because of my vision	16	0	1.87	2.18	None	(-3.06)*
2. A lot	74	2	1.40	1.71	-1.72	-1.43
3. Quite a bit	311	7	0.97	1.04	-0.87	-0.13
4. A little	893	21	0.92	0.76	0.45	1.40
5. None	3,052	70	1.00	0.98	2.14	(3.36)*
Missing data#	326	7				

Note: MnSq = Mean square. *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes. #Missing data = Missing data + This task is not relevant to me / don't do the task + Refuse to answer

Table 6.19 Rasch parameters of the Social domain iterations

Parameters	Rasch model expectations	Original	Final: (PW: SC8, SC16)[&]
Disordered thresholds		No	**No**
No. of items (Ni) / No of persons (Np)	-	Ni = 16 / Np = 292	**Ni = 16 / Np = 209**[#]
PSI (person reliability)	>2.0 (>0.80)	1.46 (0.68)	**2.01 (0.80)**
ISI (item reliability)	>3.0 (>0.90)	5.04 (0.96)	**5.16 (0.96)**
PCA, variance by first factor	>50%	46.1%	**46.1%**
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	3.21 (10.8%) / r_d = 1	**3.21 (10.8%) / r_d = 1**
PCA, % raw variance explained by items	-	19.5%	**19.5%**
Item infit (MnSq)	<1.5	1 (SC8)	**0**
Item outfit (MnSq)	<1.5	1 (SC8)	**0**
Local item dependency (LID)	>0.3		**9 (7.5%) pairs; 5 LID items** (2, 3, 9, 12, 15)
Measurement range (logits)	-	1.54 to -0.83	**1.61 to -0.85**
Targeting, difference between person & item means	<1.0 logits	3.83	**2.84**
Items with PCA standardised residual loadings > 0.40		3 items (SC1-3)	**3 items** (SC1-3)

Note: Values in red font represent poor fit to the Rasch model. ISI = Item separation index, MnSq = Mean square, PCA = Principal component analysis, PSI = Person separation index, SC = Social; [#] 83 respondents with extreme responses were dropped/removed. [&]PW: person weighting was done such that persons with erratic responses (residuals ≥ |4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations.

The original Social scale had poor measurement precision (PSI, 1.46). Therefore, 83 (28.4%) respondents with extreme responses were dropped to obtain satisfactory measurement precision. On PCA, eigen-value of the first contrast (3.21) suggested that a cluster of more than three items might form a secondary dimension. This was slightly above the acceptable threshold (3.0). The PCA standardised residuals for three items (SC1, SC2, SC3) loaded >0.40. However, these three items did not form a separate valid scale. Separating these items reduced precision of the main scale to 1.68. Therefore, all the items were retained. Additional evidence to retain these items was the high disattenuated correlation between first and second item clusters on the PCA (Table 6.19).

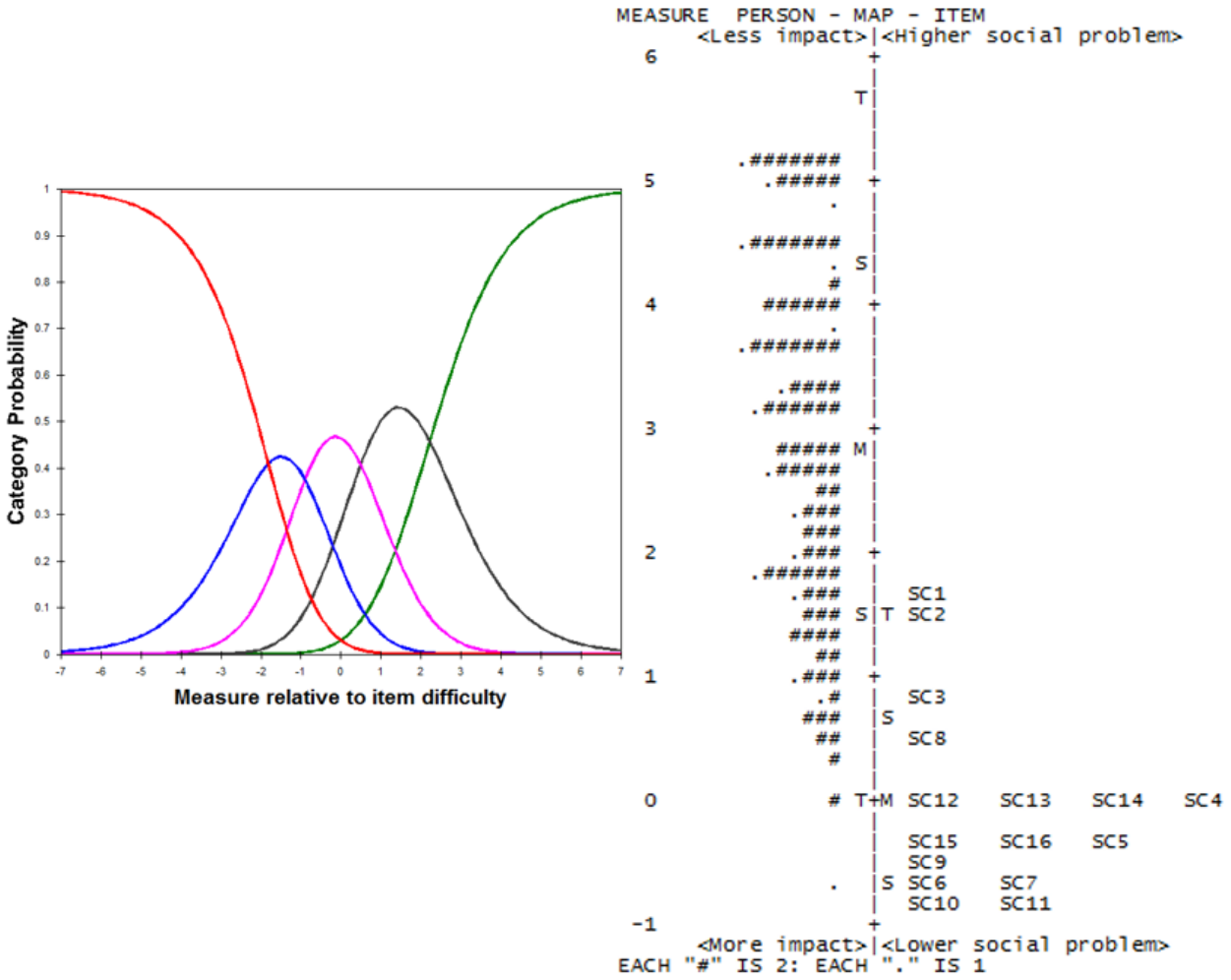

Figure 6.27 Final Social item-bank: a. Category probability curves and b. Person-item map
Note: In figure a, red = 1. Unable to do because of my vision, blue = 2. A lot, pink = 3. Quite a bit, black = 2. A lot, green = 5. None. In figure b, persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

All the items had satisfactory fit statistics after person-weighting the erratic responses for items SC8 and SC16 (Appendix I). However, targeting between persons and items was poor (Figure 6.27). The higher person measure in logits represented the lesser social problems due to refractive error. Whereas, the items with higher item measures represented items with more social problems. Items related to active social participation were perceived to be the most socially-problematic items (e.g. participating in social activities such as weddings, parties). Whereas, the items related to social roles (e.g. looking after children) were perceived as less-problematic items for people with refractive error.

6.3.8 Symptoms: a combined analysis

In the qualitative study, ocular-comfort and general symptoms (OS and GS), and visual symptoms (VS) emerged as separate themes (Chapter 4).[63] However, it is not clear in the literature if the symptoms should be measured in separate scales, or if they can be measured on a common scale.[36, 43, 185] In this study, the item-roots and response categories for VS (n = 23), OS (n = 14) and GS (n = 5) were the same. Therefore, a combined Rasch analysis was carried out for these domains by their attributes: Frequency, Severity and Bothersome.

6.3.8.1 Symptoms – frequency domain

For the frequency attribute of the symptoms, there were 42 items: 23 items for Visual symptoms – frequency (VSF), 14 items for Ocular-comfort symptoms – frequency (OSF) and 5 items for General symptoms – frequency (GSF). Each item started with an item root 'How often do you experience…?', with a 4-point 'Frequency' rating scale. The responses were coded from 1 to 4 with higher scores for better outcomes (i.e. less frequent symptoms). Alternatively, as the level of trait (symptoms – frequency) increased, the score decreased. Category structure statistics of the original Symptoms – frequency domain are given in (Table 6.20).

Table 6.20 Category structure statistics for the original Symptoms – frequency domain

Category number	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. Very often	243	2	1.20	1.61	None	(-2.33)*
2. Quite often	815	6	1.07	1.09	-0.93	-0.77
3. Occasionally	3,512	28	0.92	0.75	-0.40	0.64
4. Never	8,018	64	1.02	1.02	1.32	(2.54)*
Missing data	138	1				

Note: Values in red font represent poor fit to the Rasch model. MnSq = Mean square; *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes.

The thresholds and the category measures were ordered and advanced monotonically. Overall, the categories had good fit statistics (Table 6.20). However, the response category "Never" was utilized the most indicating a ceiling effect. Whereas, response categories 1 and 2 were utilized less. Nevertheless, the category frequencies for the first and the second categories were above the minimum number of responses required for threshold calibration (Table 6.20).[99]

A combined Rasch analysis was carried out for the VSF, OSF and GSF items. On dimensionality assessment, the eigen-value of the first contrast (4.32) suggested that a cluster of more than four items might form a secondary dimension (Table 6.21). The standardised residuals for six OSF items had loadings >0.40 on the PCA. The overall symptoms – frequency scale was then split into VSF and Comfort symptoms – frequency (CSF) scales, and separate Rasch analyses were carried out.

Table 6.21 Rasch parameters of the Symptoms – frequency domain iterations

Parameters	Model expectations	Combined frequency (VSF+OSF+GSF)	First dim: VSF (PW: VSF5, VSF14, VSF19)[&]	Second dim: CSF (OSF + GSF); (PW: OSF2)[&]
Disordered thresholds		No	**No**	**No**
No. of items (Ni)/ No of persons (Np)	-	Ni = 42/ Np = 303	**Ni = 23 / Np = 277**[#]	**Ni = 19 / Np = 298**
PSI (person reliability)	>2.0 (>0.80)	2.64 (0.87)	**2.01 (0.80)**	**2.11 (0.82)**
ISI (item reliability)	>3.0 (>0.90)	7.18 (0.98)	**6.70 (0.98)**	**7.98 (0.98)**
PCA, variance by first factor	>50%	36%	**40.4%**	**42.3%**
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	4.32 (6.6%) r_d = 0.88	**2.85 (7.4%)/ r_d = 1**	**2.67 (8.1%)/ r_d = 0.864**
PCA, % raw variance explained by items	-	18.3%	**17.7%**	**20.1%**
Item infit (MnSq)	<1.5	2 (VSF5, VSF14)	**0**	**0**
Item outfit (MnSq)	<1.5	1 (VSF5)	**0**	**0**
Local item dependency (LID)	>0.3		**6 (2.4%) pairs; 4 LID items** (VSF2, VSF8, VSF12, VSF17)	**4 (2.3%) pairs; 3 LID items** (OSF13, GSF2, GSF4)
Measurement range (logits)	-	1.47 to -3.24	**1.63 to -2.69**	**1.25 to -1.95**
Targeting, difference between person & item means	<1.0 logits	2.37	**2.61**	**2.34**
Items with PCA standardised residual loadings > 0.40		6 OSF items: OSF4, OSF7, OSF3, OSF9, OSF6, OSF14; (Loading for OSF13 was close to 0.40)	**3 items:** VSF1, VSF8, VSF2	**5 GSF items**

Note: Values in red font represent poor fit to the Rasch model. CSF = Comfort symptoms – frequency; GSF = General symptoms – frequency; ISI = Item separation index, MnSq = Mean square, OSF = Ocular-comfort symptoms – frequency; PCA = Principal component analysis; PSI = Person separation index, VSF = Visual symptoms – frequency; [#] Extreme responses were dropped/removed. [&]PW: person weighting was done such that persons with erratic responses (residuals >|4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations.

6.3.8.1.1 Visual symptoms – frequency

The psychometric properties of the original VSF scale were optimized. PSI of the original scale was low (1.74). Therefore, 25 participants with extreme responses were removed. The PSI improved to 1.91. After weighting extreme responses (residuals ≥ |4|) for VSF5, VSF14 and VSF19, the PSI further improved to an acceptable level. All items fit well after person-weighting. The final VSF item bank was essentially unidimensional, with satisfactory fit statistics and measurement precision. However, targeting (difference between mean person measures and mean item measures) was poor. Poor targeting can also be observed in Figure 6.29.

6.3.8.1.2 Comfort symptoms – frequency

A combined Rasch analysis with OSF and GSF items was carried out. All five GSF items loaded >0.40. However, they did not form a separate viable scale (low PSI) that could not be improved to acceptable standards. Since the unidimensionality parameters of the comfort scale were within Rasch model expectations, the GSF items were retained together with the OSF items. On the other hand, OSF items could form a valid scale independently, after deleting GSF items. However, since all the OSF items and GSF items together had satisfactory Rasch parameters, it was decided to have a single 'Comfort symptoms frequency' scale with OSF and GSF items.

The final CSF item bank was essentially unidimensional, and had satisfactory fit statistics and measurement precision. However, targeting (difference between mean person measures and mean item measures) was poor. Poor targeting can also be observed in (Figure 6.29).

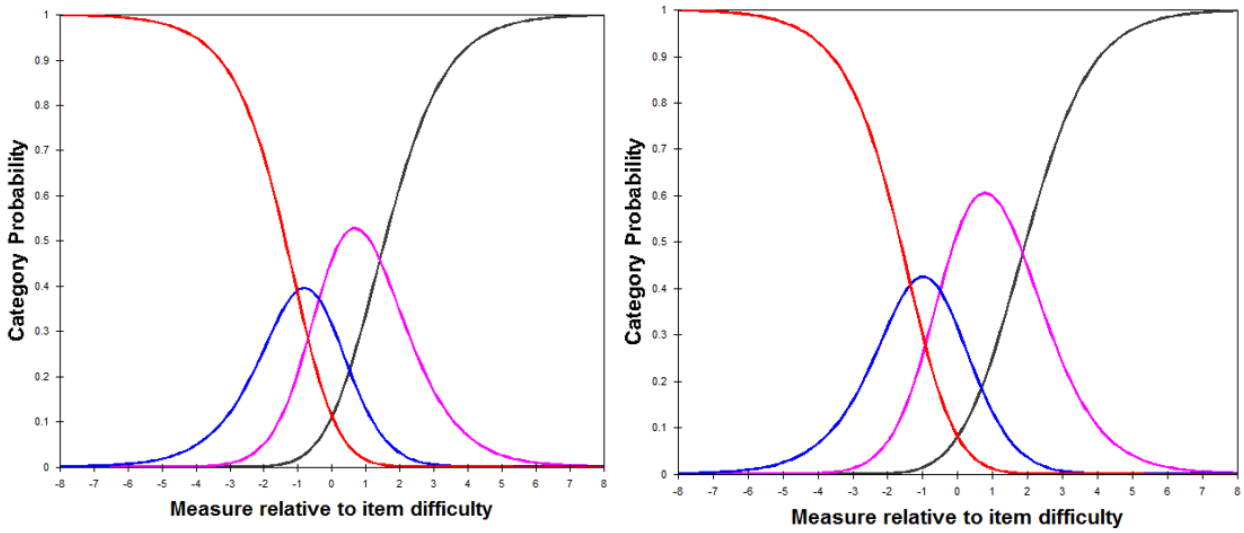

Figure 6.28 Category probability curves for: a. Visual symptoms – frequency b. Comfort symptoms – frequency
Note: red = 1. Very often, blue = 2. Quite often, pink =3. Occasionally, black = 4. Never

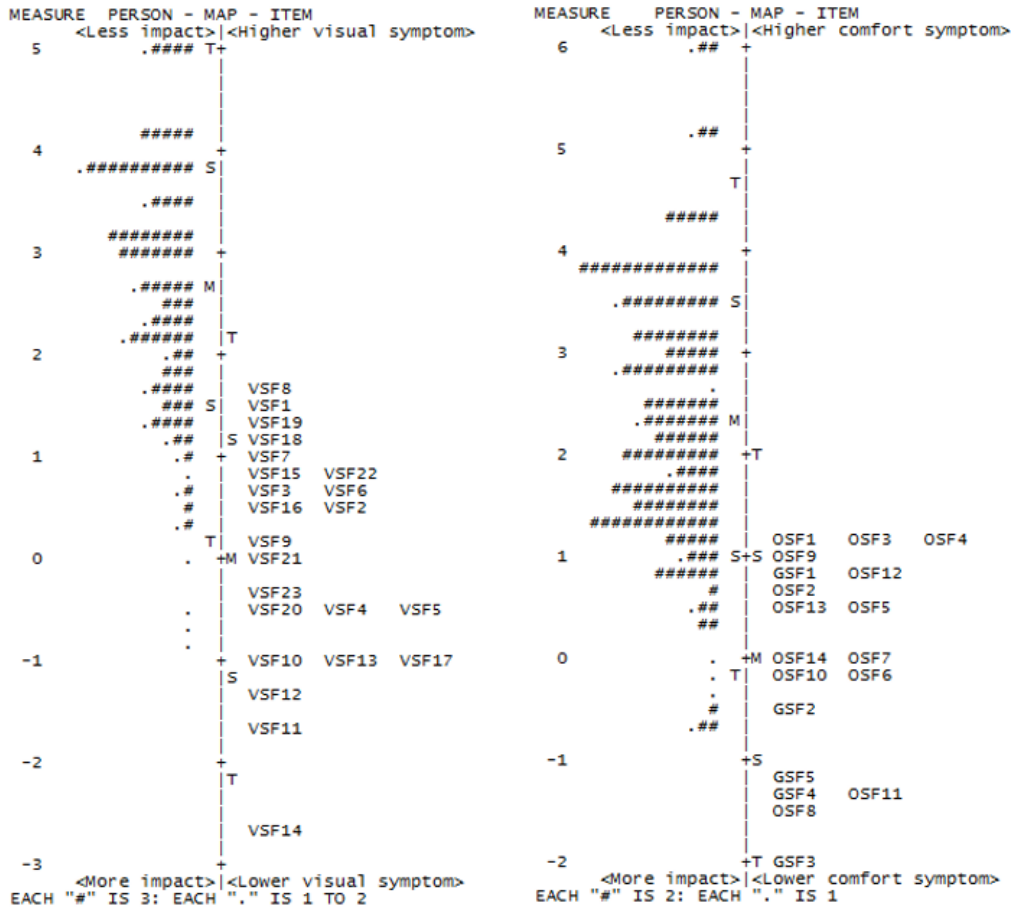

Figure 6.29 Person-item maps for: a. Visual symptoms frequency b. Comfort symptoms frequency
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Agreement between Visual symptoms – frequency and Comfort – frequency scales

The Bland and Altman analysis (Figure 6.30) was performed to evaluate the agreement between VSF and CSF (N = 273) item banks. Mean difference was low (0.28 logits) but statistically significant (Paired t test, $p < 0.001$). However, the limits of agreement were wide (upper limit of agreement: 2.48 ± 0.11 logits; lower limit of agreement: -1.93 ± 0.11 logits). The distribution was normal (Kolmogorov-Smirnov test, $p = 0.097$). The Pearson correlation coefficient was 0.58. Despite a low mean difference, it was decided to have separate scales based on other Rasch parameters (dimensionality: PCA variance explained by the measure, eigen-value of the first contrast, items with PCA standardised residuals loading >0.40) and wide limits of agreement on the Bland and Altman plot.

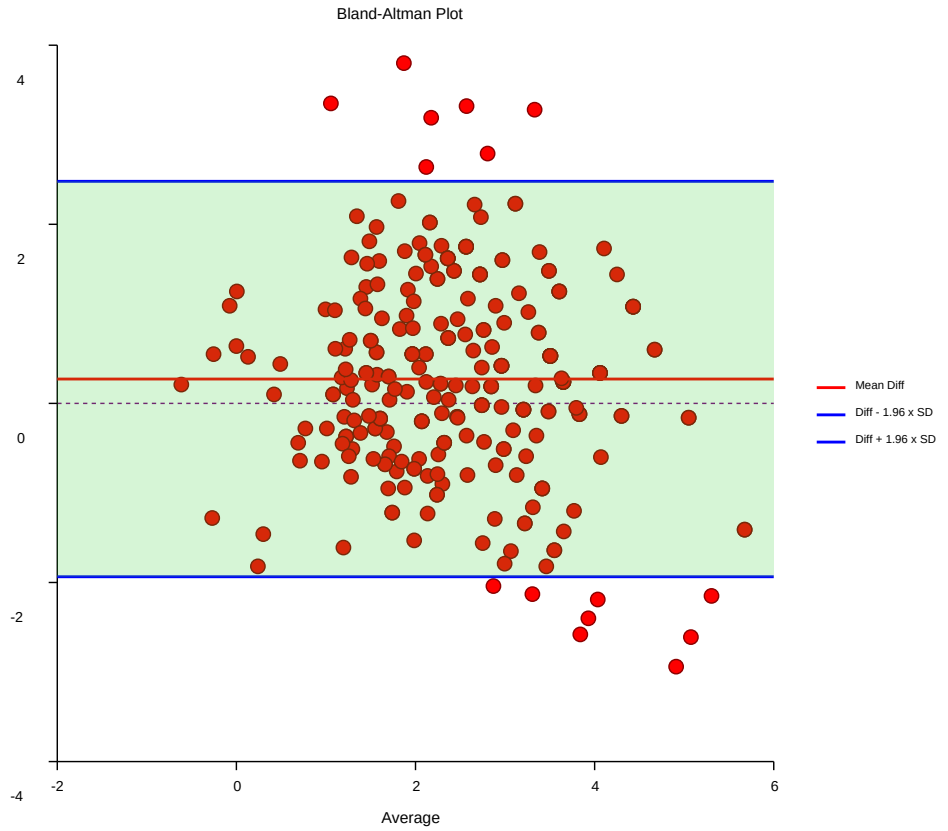

Figure 6.30 Visual symptoms – frequency vs Comfort symptoms – frequency

6.3.8.2 Symptoms – severity domain

Similar to Symptoms – frequency, a combined Rasch analysis for symptom-severity scale was performed. The original Symptoms – severity domain had 42 items: 23 items for visual symptoms – severity (VSS), 14 items for Ocular-comfort symptoms – severity (OSS) and 5 items for General symptoms – severity (GSS). Each item started with an item root 'How severe is/are the …', with a 4-point 'Severity' rating scale. The response options were coded from 1 to 4 with higher scores for better outcomes (i.e. less severe symptom). Alternatively, as the level of trait (symptom severity) increased, the score decreased. The category structure statistics of the original Symptoms – severity domain are given in (Table 6.22).

Table 6.22 Category structure statistics for the original Symptom – severity domain

Category	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. Severe	151	2	1.29	1.69	None	(-2.27)*
2. Moderate	399	6	1.08	1.05	-0.88	-0.71
3. Mild	1,452	21	0.95	0.74	-0.28	0.62
4. Not at all	4,834	71	1.01	1.00	1.16	(2.41)*
Missing data	41	1				

Note: Values in red font represent poor fit to the Rasch model. MnSq = Mean square;*As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes.

The thresholds and category measures were ordered and advanced monotonically. Overall, the categories had satisfactory fit statistics. However, the response category "Never" was utilized the most indicating a ceiling effect. Whereas, the response categories 1 and 2 were under-utilized. Nevertheless, the category frequency for the first and the second categories were higher than the minimum number of responses required for a stable threshold calibration(Table 6.22).[99]

The Rasch analysis indicated that the Symptom-severity scale was multidimensional, similar to the Symptoms – frequency scale. Multidimensionality was evident based on the eigen-value of first contrast (Table 6.23). The PCA standardised residuals for five OSS items had loadings >0.40, and other three OSS items had loadings close to 0.40. Therefore, the overall symptoms – severity scale was split into the VSS and the Comfort symptoms – severity (CSS) scales, and separate Rasch analyses were carried out.

Table 6.23 Rasch parameters of the Symptoms – severity domain iterations

Parameters	**Model expectations**	**Combined symptoms – severity** (VSS+OSS+GSS)	**VSS–Original**	**VSS - Final** (PW: VSS5, VSS14, VSS19)[&]	**CSS** (OSS+GSS)– Final (PW: OSS2)[&]
Disordered thresholds		No	No	**No**	**No**
No. of items/ No of persons (Np)	-	Ni = 42/ Np = 300	Ni = 23 / Np = 299	**Ni = 23 / Np = 270**[#]	**Ni = 19 / Np = 294**
PSI (person reliability)	>2.0 (>0.80)	2.49 (0.86)	1.72 (0.75)	**1.98 (0.80)**	**2.05 (0.81)**
ISI (item reliability)	>3.0 (>0.90)	6.90 (0.98)	6.55 (0.98)	**6.58 (0.98)**	**7.61 (0.98)**
PCA, variance by first factor	>50%	35.2	40.6	**40.6%**	**41.4%**
PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	4.34 (6.7%) r_d = 0.99	2.74 (7.1% / (r_d = 1)	**2.75 (7.1%)/ r_d = 1**	**2.56 (7.9%)** r_d **= 1**
PCA, % raw variance explained by items	-	18.2	**17.9%**	**17.9%**	**20%**
Item infit (MnSq)	<1.5	2 (VS5, VS14)	2 (VSS5, VSS14)	**1 (5: 1.56)**	**0**
Item outfit (MnSq)	<1.5	1 (VS 5)	1 (VSS19)	**0**	**0**
Local item dependency (LID)	>0.3			**2 (0.8%) pairs; 2 LID items** (VS8, VS3)	**3 (1.8%) pairs; 3 LID items** (GS2, OS13, GS5)
Measurement range (logits)	-	1.31 to -2.18	1.58 to -2.02	**1.63 to -2.63**	**1.16 to -1.68**
Targeting, difference between person & item means	<1.0 logits	2.16	2.71	**2.48**	**2.17**

Items with PCA standardised residual loadings > 0.40	5 items: OSS4, OSS3, OSS9, OSS6, OSS7 (Close to 0.40: OSS4, OSS1, OSS13)	3 items (VSS1, VSS8, VSS2)	**3 items** (VSS1, VSS8, VSS2)	**5 items** (GSS1 - GSS5)

Note: Values in red font represent poor fit to the Rasch model. CSS = Comfort symptoms – severity; GSS = General symptoms – severity; ISI = Item separation index; MnSq = Mean square; OSS = Ocular-comfort symptoms – severity; PCA = Principal component analysis; PSI = Person separation index; VSS = Visual symptoms – severity; # Extreme responses were dropped/removed. &PW: person weighting was done such that persons with erratic responses (residuals ≥ |4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations.

6.3.8.2.1 Visual symptoms – severity

The psychometric properties of the original VSS scale were optimized. PSI of the original scale was low (1.72). Therefore, 29 participants with extreme responses were dropped. The PSI improved to 1.95. After weighting extreme responses (residuals ≥ |4|) for VSS5, VSS14 and VSS19, the PSI further improved to 1.98. All items fit well after person-weighting. The final VSS item bank was essentially unidimensional, with satisfactory fit statistics and measurement precision. However, targeting (difference between mean person measures and mean item measures) was poor. Poor targeting can also be visually observed in the person-item map looking at the distribution of items and persons in Figure 6.32.

6.3.8.2.2 Comfort symptoms – severity

A combined Rasch analysis with OSS and GSS items was carried out. All five GSS items loaded >0.40. However, they did not form a separate valid scale. The PSI for the GSS domain was low (0.98) that increased to 1.31 after deleting GS4 and GS5, which was below the acceptable standard (2.0). Since the unidimensionality parameters of the CSS scale are within Rasch model expectations, the GSS items were retained together with the OSS items to form the CSS item bank. On the other hand, OSS items could form a valid scale after deleting the GSS items. However, since all the OSS items and GSS items combinedly had acceptable Rasch parameters, I decided to have a single CSS scale with OSS and GSS items.

The final CSS item bank was essentially unidimensional, and had satisfactory fit statistics and measurement precision. However, targeting (difference between mean person measures and mean item measures) was poor. Poor targeting can also be observed in Figure 6.32.

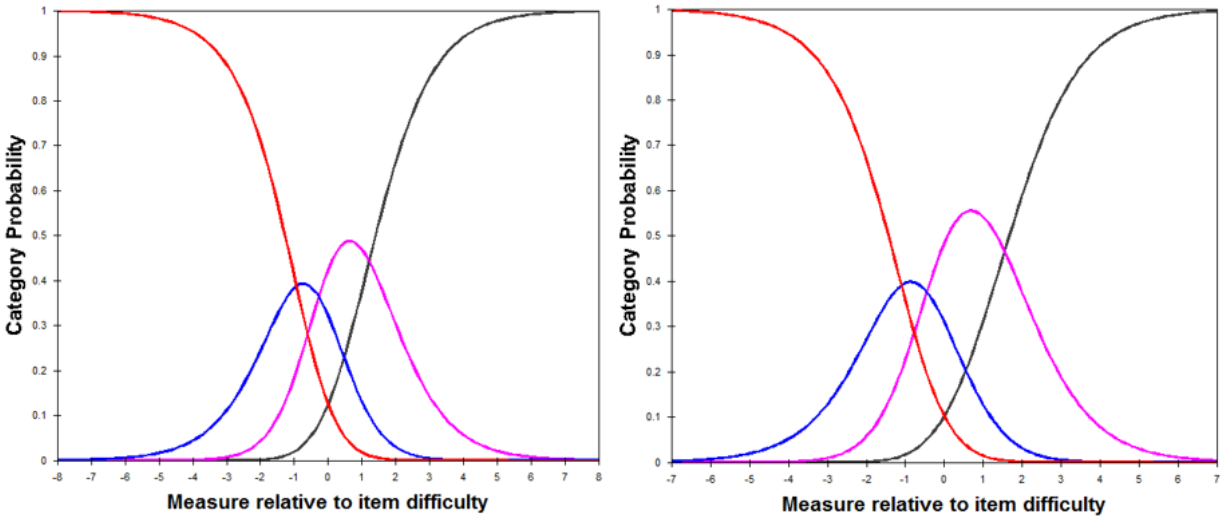

Figure 6.31 Category probability curves: a. Visual symptoms – severity b. Comfort symptoms – severity
Note: red = 1. Severe, blue = 2. Moderate, pink = 3. Mild, black = 4. Not at all

Figure 6.32 Person-item maps: a. Visual symptoms – severity b. Comfort symptoms – severity
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Agreement analysis between Visual symptoms – severity and Comfort symptoms – severity

The Bland and Altman analysis for the agreement between VSS and CSS (N = 267) was performed (Figure 6.33). The mean difference was low (0.36 logits) but statistically significant (Paired t test, $p < 0.001$). The limits of agreement were wide (upper limit of agreement: 2.68 ± 0.12 logits; lower limit of agreement: -1.95 ± 0.12 logits). The distribution was normal (Kolmogorov-Smirnov test, $p = 0.2$). The Pearson correlation coefficient was 0.55. Despite a low mean difference, it was decided to have separate scales based on other Rasch parameters (dimensionality: PCA variance explained by the measure, eigen-value of the first contrast, items with PCA standardised residual loading >0.4) and wide limits of agreement on the Bland and Altman plot.

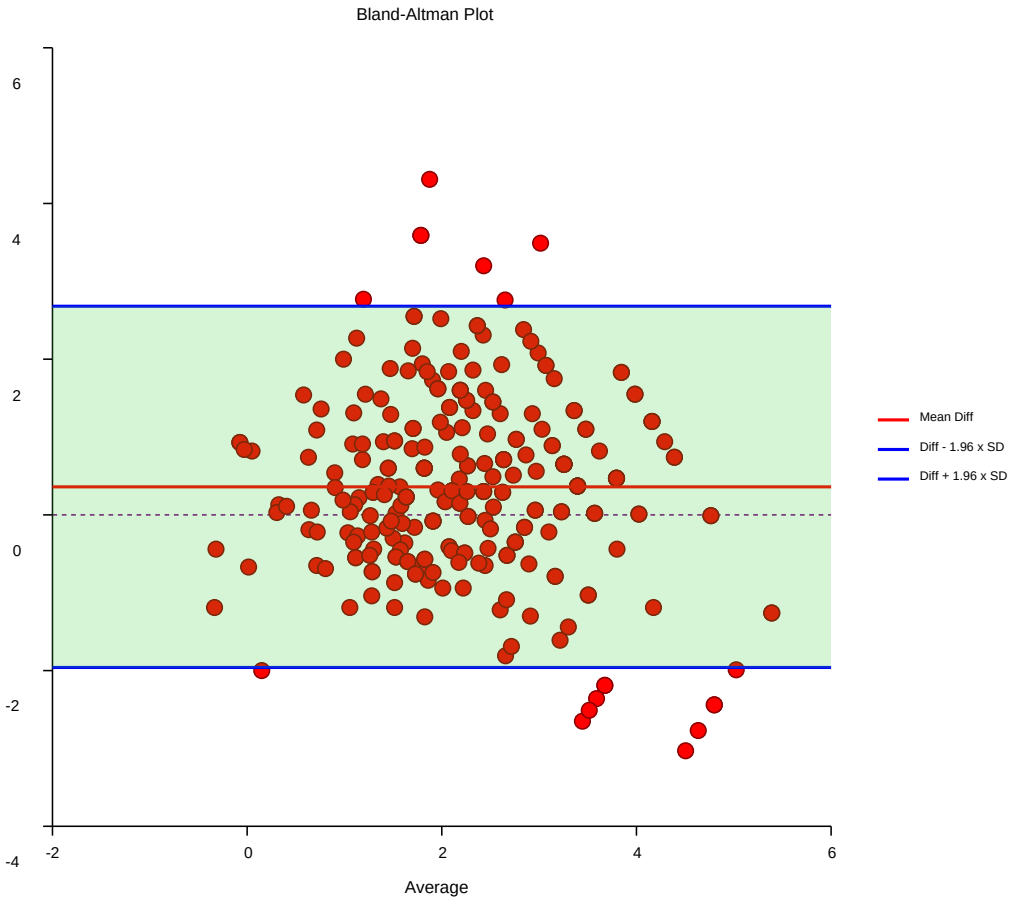

Figure 6.33 Visual symptoms – severity vs Comfort symptoms – severity

6.3.8.3 Symptoms – bothersome domain

Similar to Symptoms – frequency and symptoms – severity attributes, the bothersome attribute of the Symptoms item-pool consisted of 42 items: 23 items for visual symptoms bothersome (VSB), 14 items for Ocular-comfort symptoms bothersome (OSB) and 5 items for General symptoms – bothersome (GSB). Each item started with an item root 'How much of a problem is/are the…?', with a 4-point 'Bothersome' rating scale. The responses were coded from 1 to 4 with higher scores for better outcomes (i.e. less bothersome). Alternatively, as the level of trait (symptoms – bothersome) increased, the score decreased. The category structure statistics of the original Symptoms – bothersome domain are given in (Table 6.24).

Table 6.24 Category structure statistics for the original Symptoms – bothersome domain

Category	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. A lot	258	2	1.18	1.56	None	(-2.24)*
2. Quite a bit	811	7	1.09	1.13	-0.84	-0.71
3. A lot	3,173	26	0.91	0.73	-0.32	0.61
4. None	8,133	66	1.05	1.02	1.16	(2.41)*
Missing data	99	1				

Note, MnSq = Mean square; *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes.

The thresholds and category measures were ordered and advanced monotonically. The thresholds were well-spaced. Overall, the categories had good fit statistics (Table 6.24). However, the response category 'None' was utilized the most indicating a ceiling effect. Whereas, the first response category 'A lot' was under-utilized. Nevertheless, the frequency for the first category was higher than the minimum number of responses required for a stable threshold calibration(Table 6.24).[99]

During a combined Rasch analysis, multidimensionality was evident based on the eigen-value of first contrast (Table 6.25). The PCA standardised residuals for six OSB items had loadings >0.40, and three other OSB items had loadings >0.30. Therefore, the overall symptoms – severity scale was split into VSB and Comfort symptoms – bothersome (CSB) scales, and separate Rasch analyses were carried out.

Table 6.25 Rasch parameters of the Symptoms – Bothersome domain iterations

Parameters	**Model expectations**	**Original: Symptoms – bothersome**	**Visual symptoms – bothersome** (PW: VSB5, VSB19)[&]	**Comfort symptoms –bothersome** (PW: OSB2)[&]
Disordered thresholds		No	**No**	**No**
No. of items (Ni)/ No of persons (Np)	-	Ni = 42 / Np = 297	**Ni = 23 / Np = 260**[#]	**Ni = 19 / Np = 294**
PSI (person reliability)	>2.0 (>0.80)	2.55 (0.87)	**1.95 (0.79)**	**2.03 (0.80)**

ISI (item reliability)	>3.0 (>0.90)	6.76 (0.98)	**6.78 (0.98)**	**7.42 (0.98)**
PCA, variance by first factor	>50%	35.6%	**41.2%**	**42%**
PCA, eigen-value for the first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	4.32 (6.6%) r_d = 0.94	**2.83 (7.2%) / r_d = 1**	**2.64 (8.1%) / r_d = 0.89**
PCA, % raw variance explained by items	-	18.0	**17.8%**	**19.9%**
Item infit (MnSq)	<1.5	2 (VS5, VS14)	**0**	**0**
Item outfit (MnSq)	<1.5	1 (VS5)	**0**	**0**
Local item dependency (LID)	>0.3		**5 (2.0%) pairs; 3 LID items** (VSB2, VSB8, VSB17)	**5 (2.9%) pairs; 4 LID items** (OSB11, OSB13, GSB1, GSB4)
Measurement range (logits)	-	1.31 to -2.48	**1.60 to -2.56**	**1.15 to -1.69**
Targeting, difference between person & item means	<1.0 logits	2.29	**2.65**	**2.27**
Items with PCA standardised residual loadings > 0.40		6 items: OSB4, OSB3, OSB9, OSB7, OSB6, OSB14; (loadings >0.30: OSB1, OSB13, OSB11)	**2 items** (VSB1, VSB2)	**5 items** (GSB1-GSB5)

Note: Values in red font represent poor fit to the Rasch model. CSB = Comfort symptoms – bothersome; GSB = General symptoms – bothersome; ISI = Item separation index; MnSq = Mean square; OSB = Ocular-comfort symptoms – bothersome; PCA = Principal component analysis; PSI = Person separation index; VSB = Visual symptoms – bothersome; [#] 36 participants with extreme responses were dropped/removed. [&]PW: person weighting was done such that persons with erratic responses (residuals > |4|) were weighted 0, so that they did not influence the fit statistics or measures of other persons or items. Person weighting does not affect dimensionality computations.

6.3.8.3.1 Visual symptoms – bothersome

The psychometric properties of the original VSB scale were optimized. PSI of the original scale was low (1.65). Therefore, 36 participants with extreme responses were dropped. After dropping the extreme respondents and weighting the persons with erratic responses (residuals ≥ |4|) for items VSB5 and VSB19, the PSI improved to 1.95. The final VSB item bank was essentially unidimensional, with satisfactory fit statistics and measurement precision. However, targeting (difference between mean person measures and mean item measures) was poor (Table 6.24). Poor targeting can also be observed in Figure 6.35.

6.3.8.3.2 Comfort symptoms – bothersome

A combined Rasch analysis with OSB and GSB items was carried out. All five GSB items loaded >0.40. However, they did not form a separate valid scale. The PSI of the GSB domain was low that could not be improved to acceptable standards. On the other hand, OSB items could form an independent valid scale after deleting the GSB items. However, since all the OSB items and GSB

items together had acceptable Rasch parameters including unidimensionality, it was decided to have a single CSB item bank with OSB and GSB items. Initially, the item OSB2 was slightly misfitting (outfit MnSq = 1.55). After weighting the erratic responses as zero, all the CSB items had satisfactory fit statistics.

The final CSB item bank had satisfactory fit statistics and measurement precision, and was essentially unidimensional. However, targeting (difference between mean person measures and mean item measures) was poor (Table 6.25). Poor targeting can also be observed in Figure 6.35.

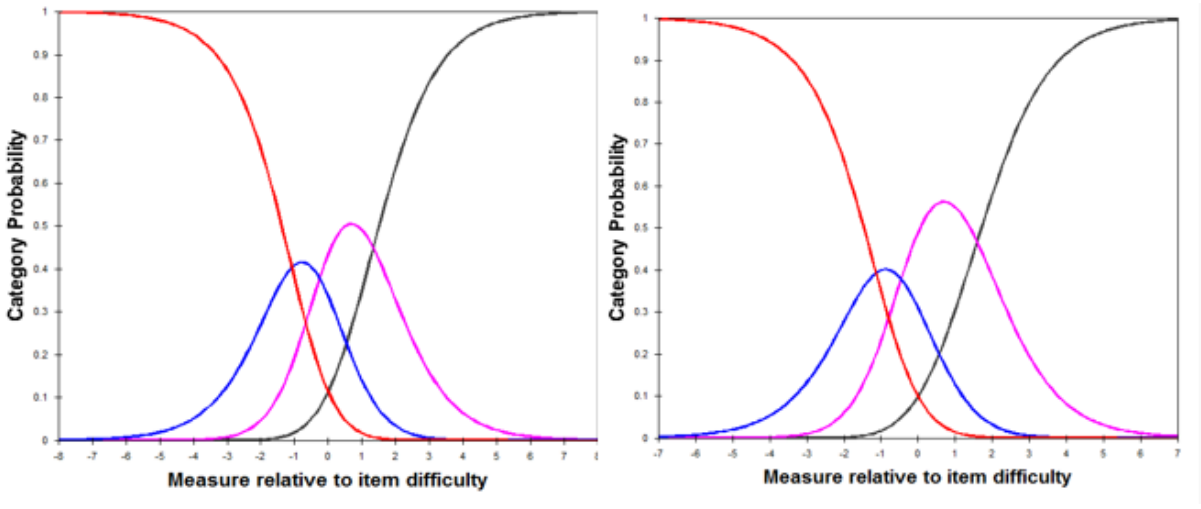

Figure 6.34 Category probability curves: a. Visual symptoms – bothersome b. Comfort symptoms – bothersome
Note: red = 1. A lot, blue = 2. Quite a bit, pink = 3. A little, black = 4. None

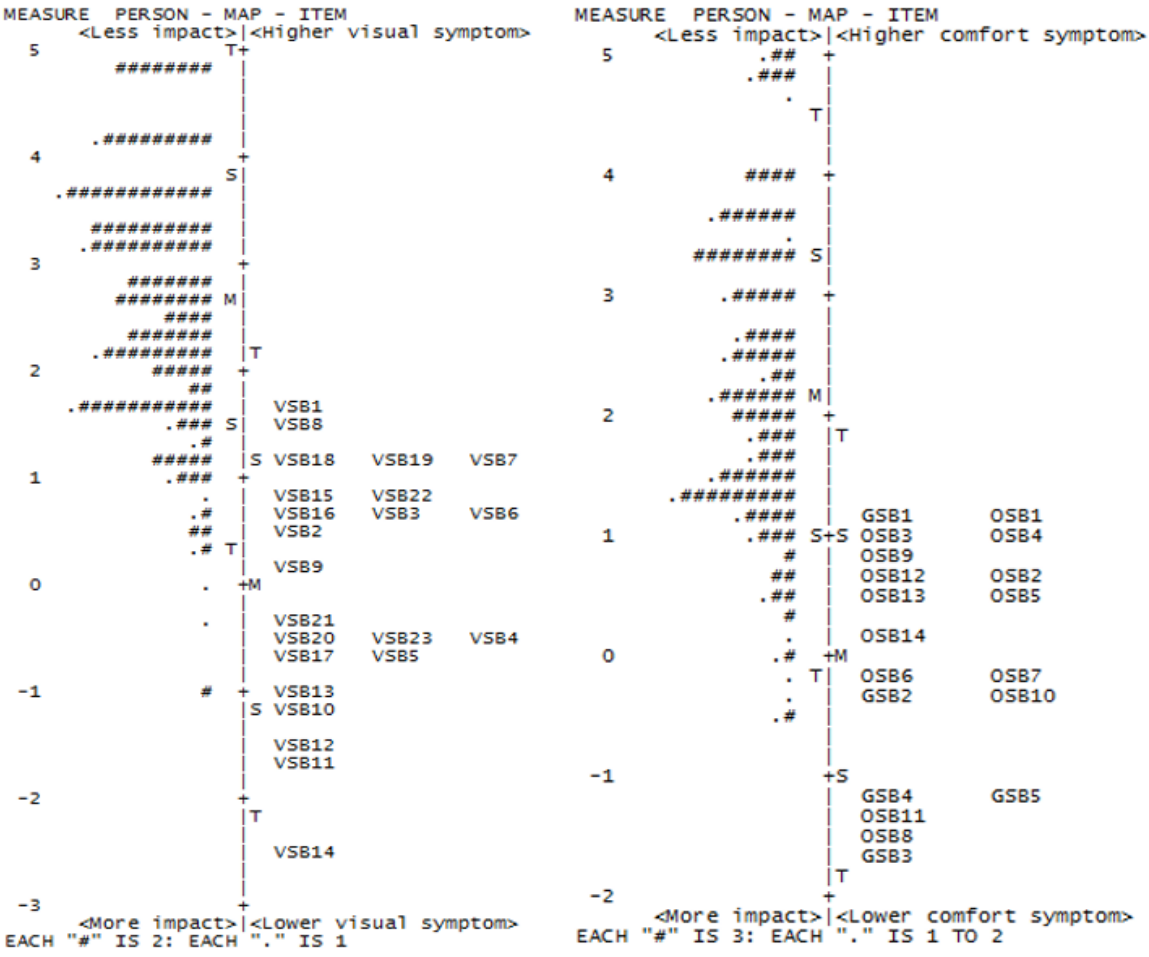

Figure 6.35 Person-item map: a. Visual symptoms – bothersome b. Comfort symptoms – bothersome
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

Agreement analysis between Visual symptoms – bothersome and Comfort symptoms – bothersome

The Bland and Altman analysis for the agreement between VSB and CSB (N = 259) was performed (Figure 6.36). The distribution was normal (Kolmogorov-Smirnov test, $p = 0.2$). The mean difference was low but statistically significant (0.40 logits; Paired t test, $p < 0.001$). The limits of agreement were wide (upper limit of agreement: 2.70 ± 0.13 logits; lower limit of agreement: -1.91 ± 0.13 logits). The Pearson correlation coefficient was 0.57. Despite a low mean difference, It was decided to have separate scales for VSB and CSB based on other Rasch parameters (dimensionality: PCA variance explained by the measure, eigen-value of the first contrast, items with PCA standardised residuals loading >0.40) and wide limits of agreement on the Bland and Altman plot.

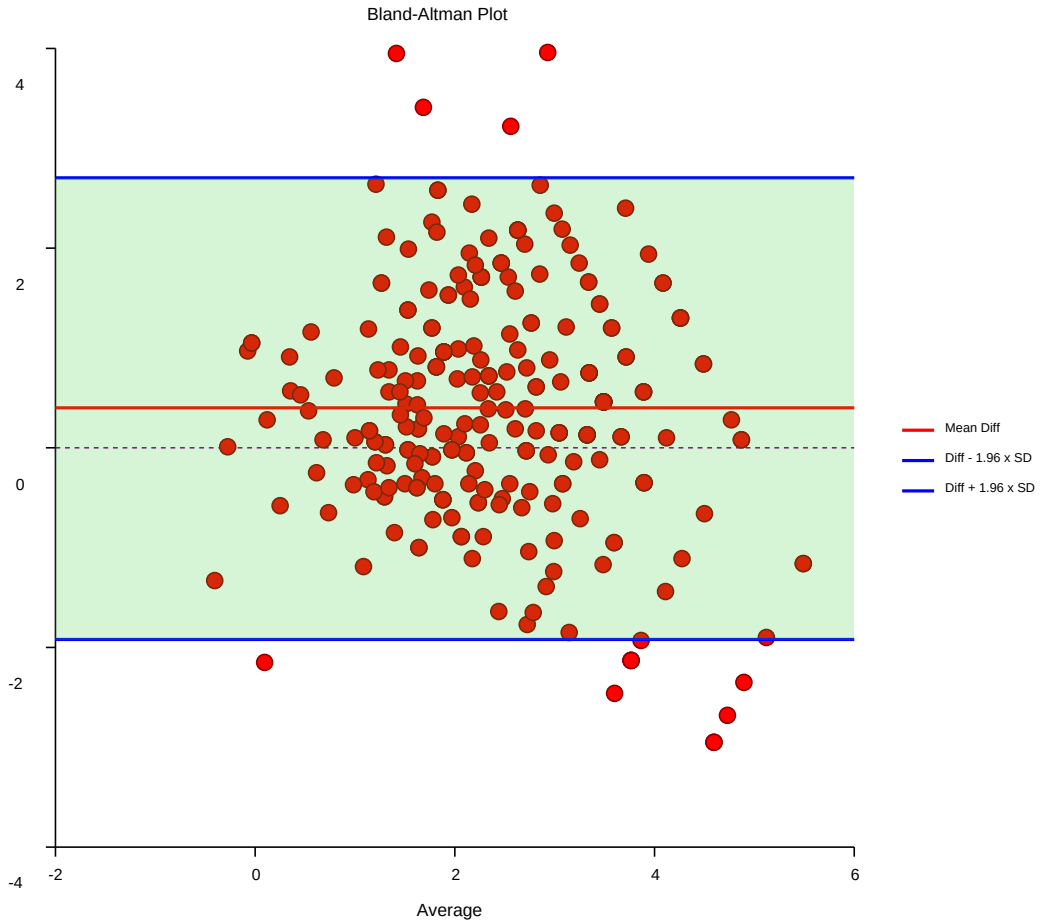

Figure 6.36 Visual symptoms – bothersome vs Comfort symptoms – bothersome

On the whole, the Visual symptoms subscales were unidimensional, and had good fit statistics and measurement precision. However, targeting between person-ability and item-difficulty was poor for each subscale. The higher person measures represented the lesser symptoms: lesser symptom frequency for the VSF, lesser symptom severity for the VSS, and lesser symptom bothersome for the VSB. Whereas, the higher item measures represented the higher symptoms: higher symptom frequency for the VSF, higher symptom severity for the VSS, and higher symptom bothersome for the VSB. In general, items related to visual acuity (e.g. blurred vision at distance) and lighting (e.g. light sensitivity, glare, poor vision at dim light) had the highest 'Visual symptoms' item measures. Whereas, the items not directly related to visual resolution or acuity (e.g. colour vision, distorted vision, double vision, flashes) were perceived as the visual symptoms with lesser item measures. This was similar for all (frequency, severity and bothersome) attributes of visual symptoms.

The comfort symptoms subscales were unidimensional, and had good fit statistics and good

measurement precision. However, targeting between person-ability and item-difficulty was poor for each subscale. The higher person measures represented the lesser symptoms: lesser symptom frequency for the CSF, lesser symptom severity for the CSS, and lesser symptom bothersome for the CSB. Whereas, the higher item measures represented the higher symptoms: higher symptom frequency for the CSF, higher symptom severity for the CSS, and higher symptom bothersome for the CSB. Symptoms such as discomfort, burning, dryness, and itchiness had higher 'comfort symptoms' item measures than other items. Whereas, general symptoms (e.g. nausea or vomiting) and ocular-comfort symptoms such as stinging in eyes and swelling of eyelids had lesser 'Comfort symptoms' item measures. This was similar for all (frequency, severity and bothersome) attributes of comfort symptoms.

6.3.9 Coping

The Coping domain (CP) had 14 items; eight items (CP3, CP4, CP5, CP7, CP8, CP9, CP10, CP11) for positive coping and six items (CP1, CP2, CP6, CP12, CP13, CP14) for negative coping. Polarity of the negative coping items were reversed to match the polarity of the positive coping items. Each item started with an item root 'Given that you know your eye condition, do you cope by….?'. Responses were coded from 1 to 5 with lower scores implying worse coping status, and an additional response category 'Refuse to answer' (Table 6.26).

Table 6.26 Category structure and use statistics for the original Coping domain

Category number	Category count	Category %	Infit MnSq	Outfit MnSq	Threshold calibration	Category measure
1. Not at all	185	5	1.43	2.06	None	(-2.30)*
2. A little bit	437	11	0.85	0.88	-1.01	-0.75
3. A moderate amount	463	11	0.96	1.22	0.22	0.08
4. A lot	797	20	1.06	0.99	0.25	0.83
5. Extremely	2,163	53	0.86	0.90	0.54	(2.04)*
Missing data#	43	1				

Note: Values in red font represent poor fit to the Rasch model. MnSq = Mean square; #Missing data = Missing data + Refuse to answer; *As the extremes are at infinity, estimated values in parenthesis correspond to 0.25 score points away from the extremes.

First, the response category functioning was assessed. The category thresholds and the category measures were ordered. However, gap between the third and the fourth thresholds was narrow (0.03 logits; Figure 6.37). Category 1 (Not at all) had poor outfit statistics. Slightly more than half of the responses were for Category 5 (Extremely) indicating that there is a ceiling effect i.e. most of the participants coped well with refractive error and its consequences (Table 6.26).

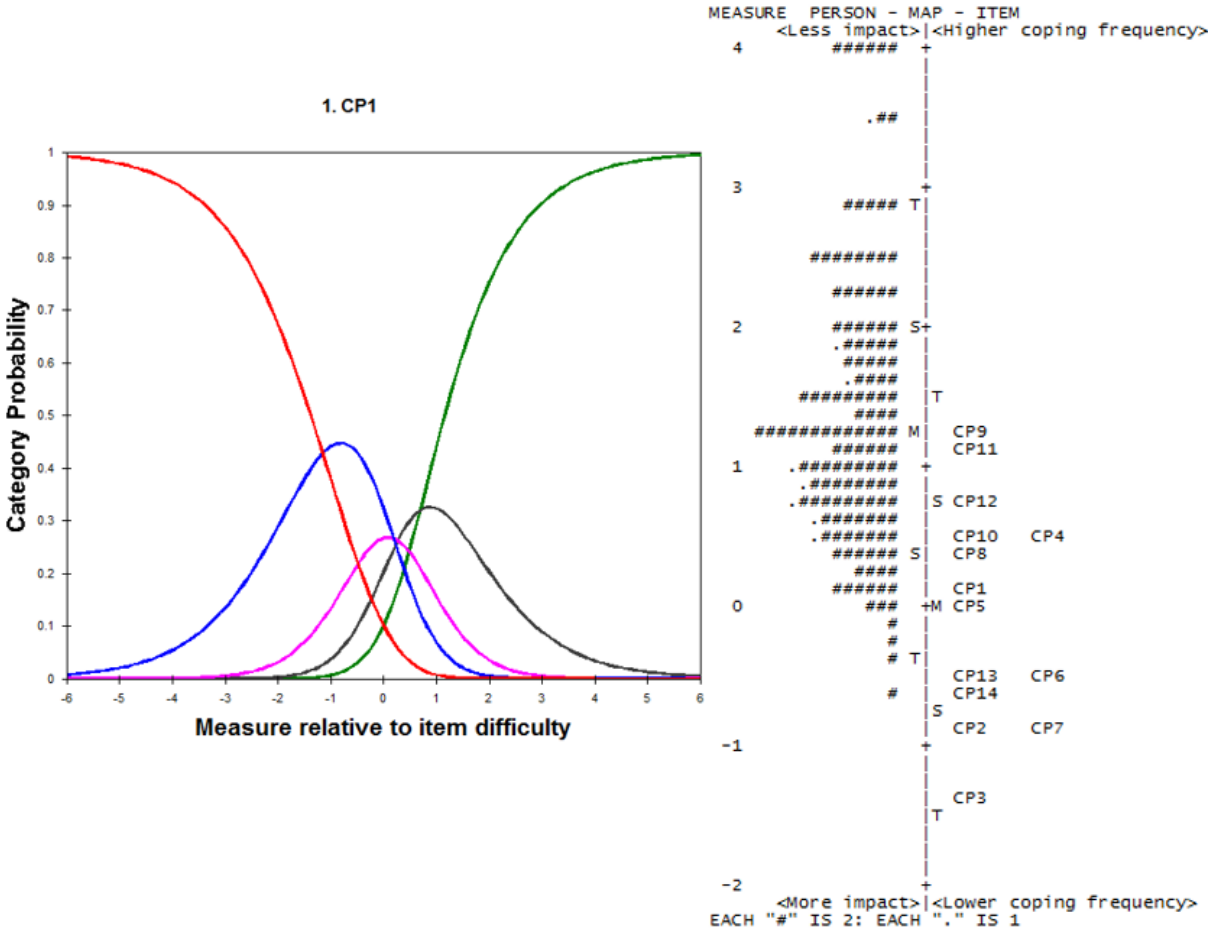

Figure 6.37 Coping: a. Category probability curves b. Person-item map
Note: In figure a, red = 1. Not at all, blue = 2. A little bit, pink = 3. A moderate amount, black = 4. A lot, green = 5. Extremely. In figure b, persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviations from the mean

The psychometric properties of the Coping domain were poor. The PSI was low (1.62) (Table 6.27). The PSI improved only to 1.65 after removing 12 participants with extreme responses. Deleting 13 misfitting persons also did not improve the PSI to an acceptable level; the PSI improved only to 1.76. Therefore, the psychometric properties of the Coping domain could not be improved to acceptable standards.

Table 6.27 Psychometric properties of the Coping domain

Parameters	Rasch model expectations	Original
Disordered thresholds		No
No. of items (Ni) / No of persons (Np)	-	Ni = 14 / Np = 292
Person separation index (person reliability)	> 2.0 (> 0.80)	1.62 (0.72)
Item separation index (item reliability)	> 3.0 (> 0.90)	9.01 (0.99)
PCA, variance by first factor	> 50%	50.6%

PCA, eigen-value for first contrast (% unexplained variance in first contrast) / Disattenuated correlation between first and second item clusters (r_d)	< 3.0, < 5.0%	3.03 (10.7%) / r_d = 1
PCA, % raw variance explained by items	-	28.9%
Item infit (MnSq)	< 1.5	0
Item outfit (MnSq)	< 1.5	CP6 (1.89)
Targeting, difference between person & item means	< 1.0 logits	1.37
Items with PCA standardised residual loadings > 0.40		2 items: CP9, CP11 (close to 0.40: CP10)

Note: Values in red font represent poor fit to the Rasch model. MnSq = Mean square, PCA = Principal component analysis.

6.3.10 Differential item functioning

The differential item functioning was assessed between refractive error subgroups by demographic characteristics (male vs female, rural vs urban), refractive error sub-types (myopia vs hyperopia, astigmatism vs spherical refractive error, presbyopia vs non-presbyopia), refractive correction types (uncorrected vs corrected refractive error, spectacle wearers vs non-spectacle wearers, contact lens wearers vs non-contact lens wearers, refractive surgery vs others) and other clinical groups (visual acuity better than 0.30 logMAR vs visual acuity worse than 0.30 logMAR; low vs high refractive error). When assessing the DIF functioning of the items across these 12 parameters, DIF was observed in 196 (4.46%) item observations. The DIF ranged from 2.47% observations for the Convenience item bank to 8.69% observations for the VSF item bank. The DIF contrast and the significance for each item with notable DIF is presented in Appendix J (due to large size of this table, it is kept as an appendix).

For the Convenience item bank, notable DIF was observed for 19 (2.47%) item observations (CV3, CV5, CV9, CV11, CV26, CV31, CV32, CV44, CV48, CV55, CV56, CV58, CV62). There was no notable DIF observed by gender, rural or urban, refractive error magnitude, and astigmatism or spherical refractive error (Appendix J)

For the Health concerns item bank, notable DIF was observed for HC32, HC33, HC36, HC38 (notable DIF observed in five (1.06%) item observations) (Appendix J) There was no notable DIF observed by gender, rural or urban, visual acuity category, refractive error magnitude, myopia or hyperopia, astigmatism, presbyopia, URE or CRE, and spectacle wear.

For the Economic item bank, notable DIF was observed for EC1, EC4, EC5 and EC7 (notable DIF observed in five (2.97%) item observations) (Appendix J). There was no notable DIF observed by gender, rural or urban, visual acuity category, refractive error magnitude, astigmatism, presbyopia,

URE or CRE, and contact lens wear.

For the Activity limitation item bank, notable DIF was observed for AL1, AL3, AL5, AL10, AL11, AL13, AL16, AL18-AL20, AL27, AL29, AL33, AL35, AL37, AL41, AL46, AL47, AL53, AL56, AL57, AL59-AL63,AL67, AL71 (notable DIF observed in 49 (5.75%) item observations) (Appendix J). There was no notable DIF observed by visual acuity category, refractive error magnitude, and astigmatism.

For the Mobility item bank, notable DIF was observed for MB2, MB3, MB7, MB9, and MB10 (notable DIF observed in six (3.84%) item observations) (Appendix J). There was no notable DIF observed by gender, myopia or hyperopia, presbyopia, URE or CRE, spectacle wear, refractive surgery, and surgical emmetropia.

For the Emotional item bank, notable DIF was observed for EM2, EM20, EM26, and EM27 (notable DIF observed in eight (2.89%) item observations) (Appendix J). There was no notable DIF observed by gender, rural or urban, myopia or hyperopia, astigmatism, presbyopia, URE or CRE, and contact lens wear.

For the Social item bank, notable DIF was observed for SC1, SC6, SC10, SC12, SC13, and SC14 (notable DIF observed in eight (4.16%) item observations) (Appendix J). There was no notable DIF observed by refractive error magnitude, myopia or hyperopia, astigmatism, URE or CRE, spectacle wear, and surgical emmetropia.

For the Visual symptoms – frequency item bank, notable DIF was observed for VSF4,VSF5,VSF6, VSF9, VSF11, VSF12, VSF14, VSF15, VSF17, VSF19, VSF20, VSF21, and VSF22 (notable DIF observed in 24 (8.69%) item observations) (Appendix J).There was no notable DIF observed by gender, rural or urban, and refractive error magnitude.

For the Comfort (OS+GS) symptoms – frequency item bank, notable DIF was observed for OSF2,OSF3, OSF4,OSF7, OSF8, OSF10, OSF11, OSF12, GSF1, GSF3, and GSF5 (notable DIF observed in 19 (8.33%) item observations) (Appendix J). There was no notable DIF observed by refractive error magnitude, astigmatism and contact lens wear.

For the Visual symptoms – severity item bank, notable DIF was observed for VSS4, VSS9, VSS11, VSS16, VSS19, VSS22 (notable DIF observed in 13 (4.71%) item observations) (Appendix J). There was no notable DIF observed by gender, rural or urban, refractive error magnitude and spectacle wear.

For the Comfort (OS+GS) symptoms – severity item bank, notable DIF was observed for OS2,

OSS5,OSS7, OSS8, GSS3, GSS5 (notable DIF observed in nine (3.94%) item observations) (Appendix J).There was no notable DIF observed by refractive error magnitude, myopia or hyperopia, URE or CRE, and history of refractive surgery.

For the Visual symptoms – bothersome item bank, notable DIF was observed for VSB4, VSB6, VSB7, VSB9, VSB10, VSB11, VSB15, VSB19, VSB22 (notable DIF observed in 20 (7.24%) item observations) (Appendix J).There was no notable DIF observed by gender and rural or urban.

For the Comfort (OS+GS) symptoms – bothersome item bank, notable DIF was observed for OSB2, OSB5,OSB6, OSB8, OSB14, GSB1, GSB3, GSB5 (notable DIF observed in 11 (4.82%) item observations) (Appendix J). There was no notable DIF observed by refractive error magnitude, myopia or hyperopia, history of refractive surgery, and surgical emmetropia.

6.4 Discussion

This chapter described the psychometric assessment of the 17 item-pools for measuring QoL in refractive error. A total of 392 items (308 unique items with items for three attributes (Frequency, Severity and Bothersome) for 42 symptoms) were interviewer-administered to 305 people across the diverse spectrum of refractive error, in regard to its clinical sub-types and demographic characteristics. A detailed psychometric assessment using Rasch analysis yielded 13 refractive error-specific item banks with a total of 366 items (Figure 6.38). General and Ocular-comfort symptoms were combined to form Comfort symptoms item banks for frequency, severity and bothersome attributes. The Rasch parameters investigated included response category functioning, dimensionality, measurement precision, targeting, fit statistics, and differential item functioning. The item measures, person measures and fit statistics yielded by Rasch analysis are sample-free population estimates.[106] When tested in equivalent samples of the same population (i.e. refractive error population), the estimates should ideally be the same.

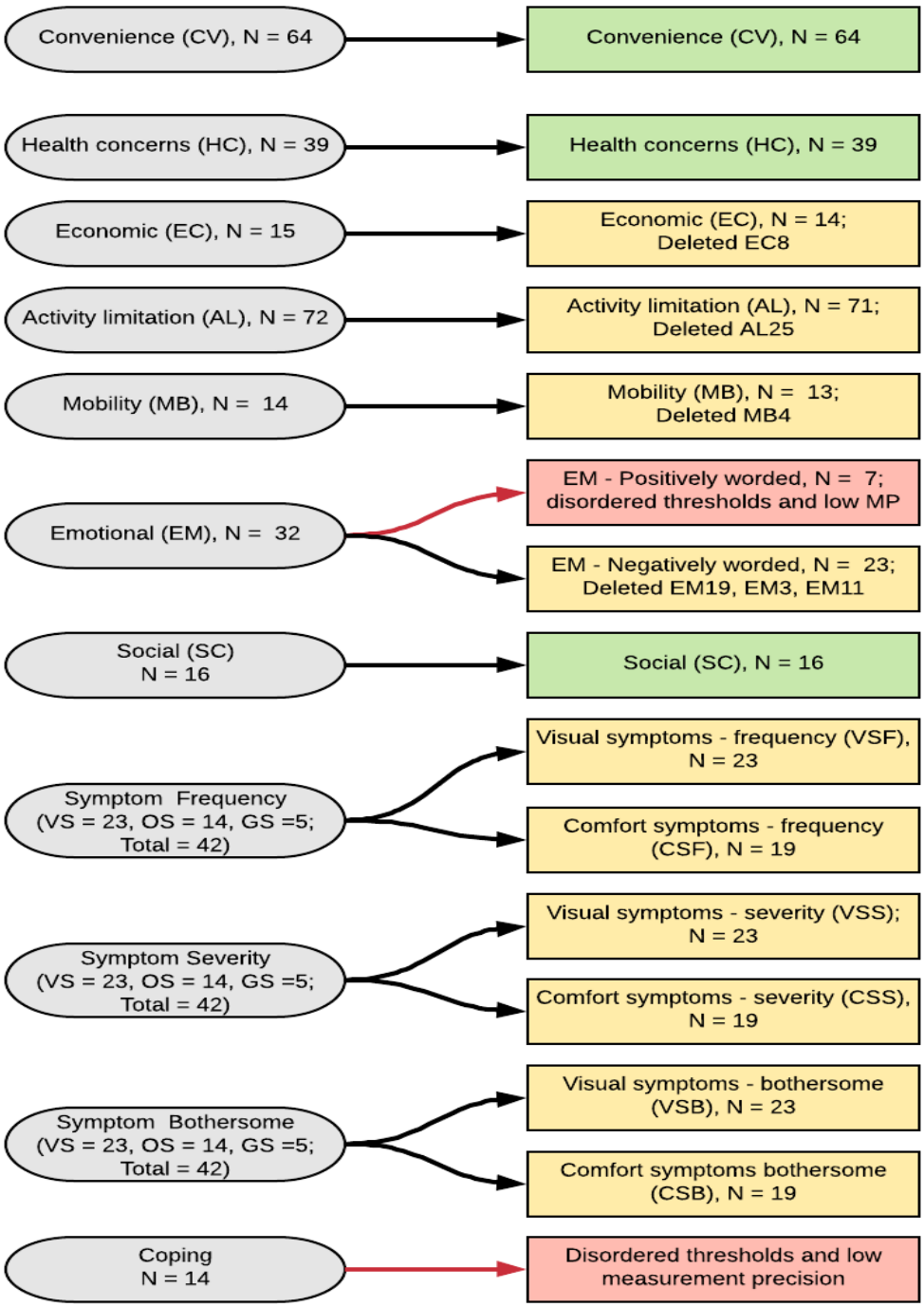

Figure 6.38 Construction of item-banks from the initial item-pools using Rasch analysis
Note: red = item pool that was not viable; Orange = item-bank constructed after significant amendments of the original item-pool, green = item-bank constructed after minor amendments of the original item-pool; MP = Measurement precision

The Coping domain had sub-optimal psychometric properties, and therefore was dropped at this stage. The poor psychometric properties of the Coping domain may be because of several reasons. Perhaps the content coverage was low to measure the construct indicating a need for

additional items. It is also possible that items in coping domain are not clearly bipolar (both ends meaningful distribution) items. Items should be interpretable across the continuum.[389] Or probably coping is not as important as other QoL domains for refractive error. Although refractive error is a chronic condition, it is a correctable condition unlike other conditions such as hereditary retinal conditions which are generally untreatable.[390] Although Coping was identified as a domain during qualitative analysis (Chapter 4), it may only have an indirect impact on QoL. Further work adding content or increasing the sample size may be required for the coping domain to make it a valid scale.

In general, the final refractive error item banks had good psychometric properties. All item banks had good measurement precision and fit statistics (Table 6.28). The response categories were ordered and advanced monotonically. The spacing between the categories was satisfactory most of the times. Measurement range for all item banks was satisfactory.

However, poor targeting was observed in all item banks except for the Convenience item bank. Distribution of the responses in the developmental study of the Refractive Status and Vision Profile questionnaire were also skewed towards response options for fewer problems.[37] Refractive error is a heterogeneous condition, and having a single well-targeted item bank across all sub-groups is challenging. Refractive error may have a large number of independent variables in many combinations. For example, contact lens variables include lens material, design, care system, wearing schedule, tear-film, and environmental factors, in several combinations. Many items in the item-banks may have a ceiling effect in the sample, however, those items may be important for people at the extreme end of the refractive error spectrum. For example, for the item ‘VSB9: How much of a problem is the blurred vision at near?’, 75% participants answered ‘None’. This may be an important item for a person with uncorrected presbyopia. Unlike short forms which can accommodate only a few items and therefore may demand deletion of the item with a ceiling effect, an item bank can cater for a large pool of items. In general, the poor targeting observed in this study may imply either the items were not difficult enough to many participants, or there were fewer participants with low ability levels, or both. Since the items were extracted from the extensive patient consultation and literature review, the latter is more likely. A large proportion of the study sample was in ‘more able’ spectrum. The participants with severe visual impairment were low in number.

However, targeting is a sample-dependent parameter[71] that may be improved in the third and fourth phases of this study after collecting more data. New items may also be added and calibrated with respect to the existing items of the item banks.[391] For example, if an Activity limitation item bank has items “Reading large print” and “Reading small print”, new item “Reading normal print

e.g. newspaper" may be added. New item may be added by intuition, or based on evidence from other IRT/Rasch-based PRO instruments, to fill the gap between difficulty levels.[74] The quality of data is also more likely to be better in next phases as there will be less respondent burden when implemented using the adaptive technology where only the most informative items will be administered tailoring to the individuals.

Targeting data provided information on which item banks were more challenging than others for this study sample. Targeting was satisfactory for Convenience domain. Whereas, Mobility item bank had the worst targeting. Mis-targeting values (Table 6.28) suggested that in general, the participants found that the Convenience item bank to be the most challenging item bank followed by Health concerns, comfort Symptoms and Activity limitation. Using Dutch ICF Activity Inventory, Latham *et al.* found that the mobility related goals were the most challenging goals for the people with retinitis pigmentosa.[105, 117] Whereas in this study, Mobility was the least challenging domain. This illustrates that the condition-specific PRO instruments may be required to capture the issues specific to eye conditions.

Within each item banks, the item measures or the relative location of items in the person-item maps indicated what QoL issues were more impactful to people with refractive error. For example, from Figure 6.2, it can be seen that 'CV11. Losing or misplacing glasses' was slightly more inconvenient issue than 'CV20. Glasses getting scratched'.

A possibility of secondary dimensions in Convenience, Activity limitation, Health concerns and Economic item banks was indicated by the PCA eigen-values of the first contrasts. The eigen-values were higher for these domains compared to domains with relatively lesser number of items (e.g. Mobility and Social). Activity limitation, Convenience and Health concerns are relatively larger item banks, and when there are a large number of items, issues of multidimensionality tend to magnify. It is inevitable that some items group together to form item-clusters.[57] However, these item banks are essentially unidimensional based on other parameters such as conceptual meaning, variance explained by the measure, ratio of explained variance by items to the explained variance by first contrast, Bland and Altman agreement and correlations, fit statistics and disattenuated correlation between the first and second item clusters. As discussed in the Section 2.3.1.2, an absolute unidimensionality is not possible in nature.[139] An individual status cannot be independent from the contextual and environmental conditions.[139] Even a simple measurement of length may be affected by room temperature. The aim was to achieve a productive measurement with essentially unidimensional item-banks.

The variance explained by the measure was less than 50% for Symptoms and Health concerns

domains. The eigen-values partly accounted for the unexplained variance. Low variance in symptoms domains was observed in the development of diabetic retinopathy-specific item banks as well.[57] Rasch model, unlike two or three-parameter IRT models, focuses on maximising the measurement properties of a scale rather than merely aiming to explain variance in the data (three parameter IRT models use other parameters than difficulty (discrimination and guessing) to partly explain the variance in the data).[70] Perhaps if analysed by two or three-parameters IRT models, the variance explained by the measures would have been in the acceptable range. The low variance could also be because of considerable noise in the measurement. Probably, these item banks may have indirect impact on QoL in addition to the direct impact. For example, symptoms may lead to activity limitations, mobility problems, health concerns and inconvenience. Similarly, health concerns may lead to emotional impact. Whatsoever, the low variance explained by Symptoms and Health concerns measures highlight the complexity of measuring these domains and the need to further explore what other factors could be responsible for the variance in the data.

The possibility of having subscales for the Activity limitation, Health concerns and Economic item banks was observed. A PRO measurement-scale may be essentially unidimensional with subscales. This increases the application of the items in these item banks either as a comprehensive measure, or as a more focused scale based on the purpose of measurement and intended population. For example, to assess the activity limitation in presbyopes, ‘reading and writing items at near’ may be used. However, overarching aim of this study was to construct item banks, not the short-forms, although short-forms may be easily constructed as by-products.[58]

Some items in each item banks had DIF in regard to some demographical or clinical parameters. Items with DIF have different probability of endorsement by respondents from different groups, although they have same ability. Unlike in short-forms, item banking and CAT system is a flexible PRO instrument where DIF can be addressed with group-specific calibrations for these items while developing algorithms for CAT. CAT can limit, or use different calibrations for certain sub-group.[102]

On the whole, refractive error item banks demonstrated promising psychometric properties for comprehensive and efficient measurement of quality-of-life in refractive error. A preliminary analysis on evaluation of QoL parameters in refractive error sub-groups is presented on the next chapter (Chapter 7).

Table 6.28 Psychometric properties of the final refractive error-specific item banks

Parameters*	Convenience	Health concerns	Economic	Activity limitation	Mobility	Emotional	Social
Disordered thresholds	No	No	No	No	No	No	No
No. of items (Ni) / No of persons (Np)	Ni = 64 / Np = 289	Ni = 39 / Np = 290	Ni = 14 / Np = 292	Ni = 71 / Np = 296	NI = 13 / Np = 212#	23; Np = 215#	Ni = 16 / Np = 209#
PSI (person reliability)	2.90 (0.89)	2.41(0.85)	2.12 (0.82)	3.09 (0.91)	2.22 (0.83)	2.39 (0.85)	2.01 (0.80)
ISI (item reliability)	5.05 (0.96)	6.15 (0.97)	6.47 (0.98)	7.30 (0.98	8.10 (0.98)	5.44 (0.97)	5.16 (0.96)
PCA, variance by first factor	48.8%	42.2%	60.6%	48.8%	65.8%	52.8%	46.1%
PCA, eigen-value for first contrast (% unexplained variance)/ Disattenuated correlation between first and second item-clusters (r_d)	6.3 (5%) / r_d = 0.90	4.64 (6.9%) / r_d = 0.89	4.02 (11.3%) / r_d = 1	6.59 (4.8%) / r_d = 1	2.46 (6.5%) / rd = 1	2.78 (5.7%) / r_d = 1	3.21 (10.8%) / r_d = 1
PCA, % raw variance explained by items	15.1 %	12.7%	13.3%	17.5%	27%	16.9%	19.5%
Item infit (MnSq) >1.5	0	0	0	0	0	0	0
Item outfit (MnSq) >1.5	0	0	0	0	MB2 (1.54)	0	0
Local item dependency (LID) [>0.3]	81 (4.0%) pairs; 38 LID items	42 (5.7%) pairs; 20 LID items	7 (7.7%) pairs; 5 LID items	125 (5.0%) pairs; 38 LID items	4 (5.1%) pairs; 4 LID items	14 (5.5%) pairs; 7 LID items	9 (7.5%) pairs; 5 LID items
Measurement range (logits)	1.23 to -1.13	0.85 to -1.35	1.81 to -1.30	2.14 to -2.25	4.14 to -1.21	1.20 to -1.33	1.61 to -0.85
Targeting, difference between person & item means (logits)	0.96	1.22	2.90	2.49	4.71	2.82	2.84
Items with PCA standardised residual loadings > 0.40	8 items (CV7, CV32-CV37, CV39)	6 items (HC21, HC23, HC19, HC17, HC22, HC24)	3 items: EC1, EC2, EC6	8 items [13, 11, 16, 5, 10, 19, 18, 20]	2 items (MB10, MB11)	3 items (EM21–EM23)	3 items (SC1-3)

Table 6.28…continued.

Parameters*	**Visual symptoms – frequency**	**Comfort symptoms – frequency**	**Visual symptoms – severity**	**Comfort symptoms – severity**	**Visual symptoms – bothersome**	**Comfort symptoms – bothersome**
Disordered thresholds	No	No	No	No	No	No
No. of items (Ni) / No of persons (Np)	Ni = 23 / Np = 277#	Ni = 19 / Np = 298	Ni = 23 / Np = 270#	Ni = 19 / Np = 294	Ni = 23 / Np = 260#	Ni = 19 / Np = 294
PSI (person reliability)	2.01 (0.80)	2.11 (0.82)	1.98 (0.80)	2.05 (0.81)	1.95 (0.79)	2.03 (0.80)
ISI (item reliability)	6.70 (0.98)	7.98 (0.98)	6.58 (0.98)	7.61 (0.98)	6.78 (0.98)	7.42 (0.98)
PCA, variance by first factor	40.4%	42.3%	40.6%	41.4%	41.2%	42%
PCA, eigen-value for first contrast (% unexplained variance)/ Disattenuated correlation between first and second item-clusters (r_d)	2.85 (7.4%)/ r_d = 1	2.67 (8.1%)/ r_d = 0.864	2.75 (7.1%)/ r_d = 1	2.56 (7.9%)/ r_d = 1	2.83 (7.2%)/ r_d = 1	2.64 (8.1%) / r_d = 0.89
PCA, % raw variance explained by items	17.7%	20.1%	17.9%	20%	17.8%	19.9%
Item infit (MnSq) >1.5	0	0	1 (5: 1.56)	0	0	0
Item outfit (MnSq) >1.5	0	0	0	0	0	0
Local item dependency (LID) [>0.3]	6 (2.4%) pairs; 4 LID items (2, 8, 12, 17)	4 (2.3%) pairs; 3 LID items	2 (0.8%) pairs; 2 LID items	3 (1.8%) pairs; 3 LID items	5 (2%) pairs; 3 LID items	5 (2.9%) pairs; 4 LID items
Measurement range (logits)	1.63 to -2.69	1.25 to -1.95	1.63 to -2.63	1.16 to -1.68	1.60 to -2.56	1.15 to -1.69
Targeting, difference between person & item means (logits)	2.61	2.34	2.48	2.17	2.65	2.27
Items with PCA standardised residual loadings > 0.40	3 items: VSF1, VSF8, VSF2	5 GSF items	3 items (VSS1, VSS8, VSS2)	5 GSS items	2 items (VSB1, VSB2)	5 GSB items

Note: Values in red font represent poor fit to the Rasch model. ISI = Item separation index, MnSq = Mean square, PCA = Principal component analysis, PSI = Person separation index; # Participants with extreme responses were dropped/removed. *Ideal values for each item bank: PSI >2.0 (reliability >0.80); ISI >3.0 (reliability > 0.90); PCA, variance by first factor >50%; PCA, eigen-value for first contrast (% unexplained variance) < 3.0, (< 5.0%); Targeting <1.0 logits.

Chapter 7. Phase II (Nepal): Evaluation of refractive error-specific quality-of-life using item banks

7.1 Introduction

A detailed psychometric assessment using Rasch analysis resulted in 13 refractive error-specific item banks consisting 366 items (Chapter 6). The primary purpose of the study described in this chapter was to assess the performance of the item banks for measuring refractive error-specific QoL parameters. The specific objectives were to evaluate the relationship between refractive error item banks, to test the performance of the item banks in a computer adaptive testing (CAT) system using CAT simulation, and to assess the impact of refractive error across QoL domains. The methods and results section are designed to answer the research questions: 'What is the association between refractive error item banks?', 'Can the item banks achieve high and moderate precision when evaluated by CAT simulation?' and 'What are the differences in QoL impact of refractive error by demographical and clinical characteristics?'. This chapter is also laid out in IMRAD (Introduction, Methods, Results and Discussion) structure.

7.2 Methods

7.2.1 Data collation and statistical analysis

Descriptive statistical analysis for this cross-sectional study was conducted in SPSS software, Version 23 (SPSS, Chicago, IL, USA). Rasch person measures obtained from WinSteps software, Version 3.92.1 (MSEA Press, Chicago, IL, USA) were exported to the SPSS software. Normality of the data was evaluated using histogram and Kolmogorov-Smirnov test. Parametric tests (e.g. mean, t-test) were conducted to analyse normally distributed data, and non-parametric tests (e.g. median, Mann-Whitney U test, Kruskal-Wallis test) were conducted to analyse non-normal distributions. The two-sided p value less than 0.05 was considered statistically significant.

For correlation analysis, Kaiser-Mayer-Olkin (KMO) measure of sampling adequacy for principal component analysis, and Barlett's test of sphericity to test equal variance in the correlation matrix, were performed. KMO measure close to one indicates adequate data for PCA analysis. Pearson correlation and Spearman's correlation were conducted to evaluate associations between continuous variables for normally and non-normally distributed data respectively. Correlations between 0.57 and 0.82 suggest moderate correlations.[32] However, as discussed in Chapter 2, two scales with a high correlation does not necessarily imply that the scales are in agreement.[109] Agreement analysis between the scales were conducted using NCSS software, version 55 (Kaysville, UT, USA). Bland and Altman agreement analysis enables evaluation for any systematic

difference between the measurement data.

7.2.1.1 Computer adaptive testing simulation

The CAT simulation was carried out using Firestar (Version 1.3.2)[392] and R (Version 3.1.3; the Foundation for Statistical Computing, Vienna, Austria) software. Initially, the Local item dependency (LID) was addressed. Items in a scale should not be locally dependent, i.e. a response to an item should not be influenced by a response to another item. First, the LID pair of items were identified for each item bank. Raw inter-item residual correlations ≥ 0.3 was considered significant.[57, 72, 384] One item from each pair was deleted temporarily (set aside) to obtain LID-free person measures. While temporarily deleting the LID items, a number of rules were applied. Careful attention was made to delete as few items as possible. An item with correlation ≥ 0.30 with maximum number of other items was deleted. Similarly, an item with higher clinical importance, wider content coverage, and better wording was considered for retaining. Then the LID-free person measures were obtained, and anchored to all the items in the item bank. The anchoring process avoided the influence of LID items on the final item calibration. Psychometric properties of the item banks after person-anchoring are given in Appendix K**.**

After person-anchoring, a CSV file with threshold values was prepared for the Firestar software (Figure 7.1).[392] These values were free from the influence of LID items. The Firestar software generated CAT simulation command to be run on the R software. CAT simulation was performed in 1,000 observations. Interim theta was estimated using *the Expected A Posteriori* (EAP) estimator. The item selection method used was the Maximum Posterior Weighted Info (MPWI). The IRT model 'Generalized partial credit model (GPCM)' was chosen as the rating scale model variant of Rasch analysis is considered as a special case of the GPCM where the slope for each item (item discrimination parameter) is set to be one.[392] The first item to administer was the item with average difficulty/latent trait (item location = 0 logits). The R-code was first generated for achieving high precision (Standard error of measurement (SEM): 0.387, corresponding to a reliability of 0.85). This was then repeated for moderate precision (SEM: 0.521, corresponding to reliability of 0.72). SEM indicates confidence in obtained score representing the true score. Aiming for a moderate precision may be a useful approach for group studies or for clinical practice. Whereas, high precision may be preferable for individual level studies or for research purposes.[57] The number of items to be administered for moderate and high precision, for each item bank were identified. Correlation between full item bank and the CAT simulation person measures were also calculated for both high and moderate precision (Table 7.2).

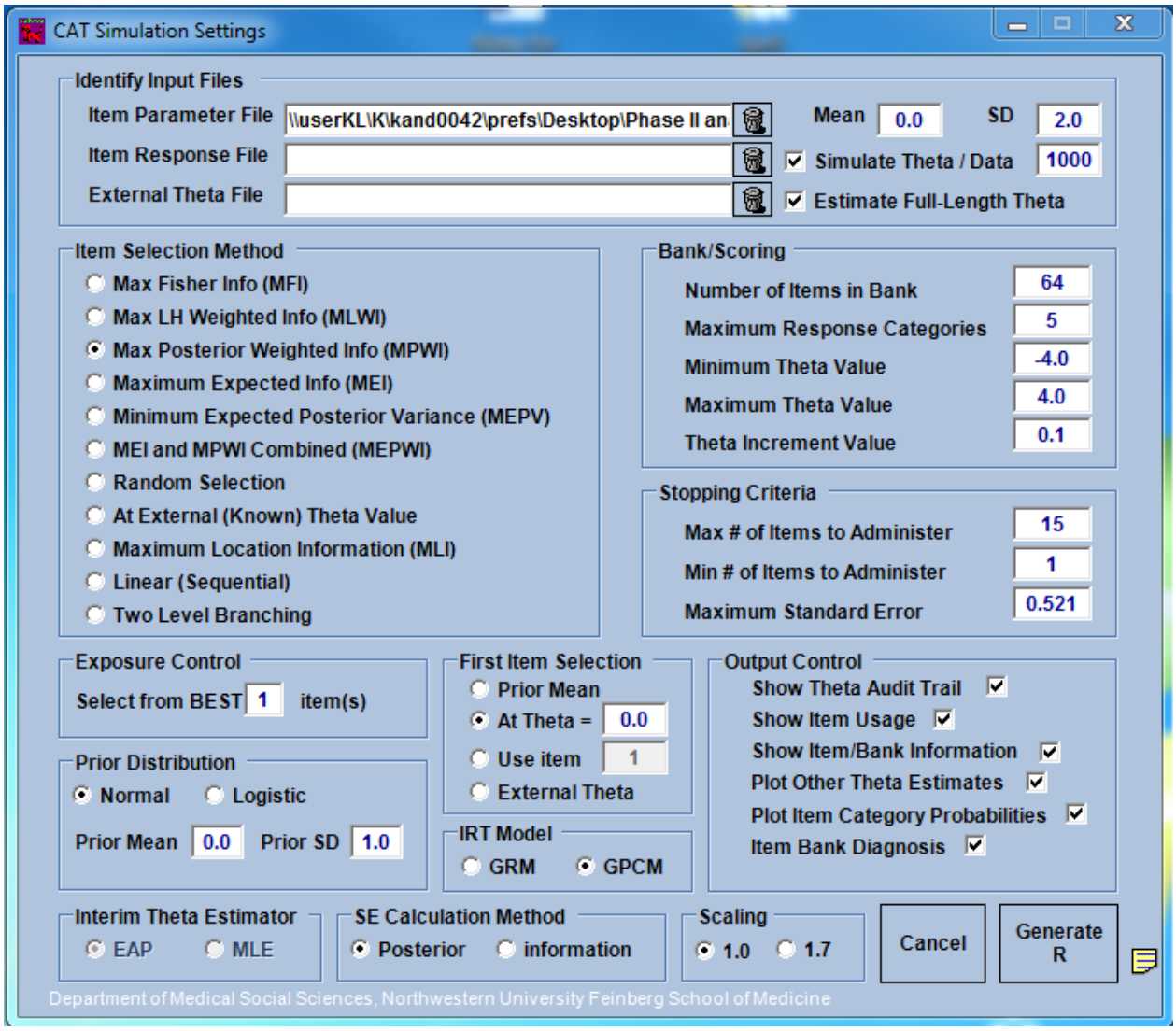

Figure 7.1 A screenshot showing settings for CAT simulation of the Convenience item bank in the Firestar software

The step-size (how far apart the two consecutive items administered are located in the scale) and the stopping criteria (rule based on the desired number of items administered or the desired level of precision achieved) are specified in the CAT-algorithm. The CAT system initiates the test by administering the first item with an average level of latent trait (e.g. average difficulty or average inconvenience; Figure 7.2). The next item to be administered is determined adaptively based on the response obtained to the preceding items and the specified step-size. Hence, the individually tailored items are administered (Figure 7.3). Adaptive administering of items continues until the stopping rule is satisfied.

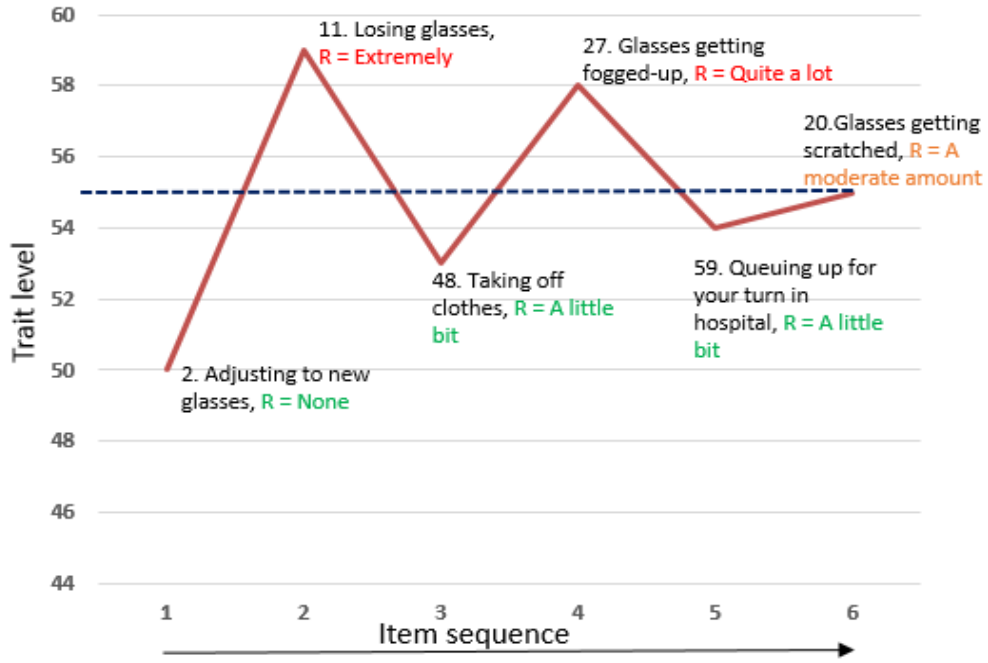

Figure 7.2 An example of CAT administration from the Convenience item bank
Note: CAT = Computer adaptive testing, R = response option

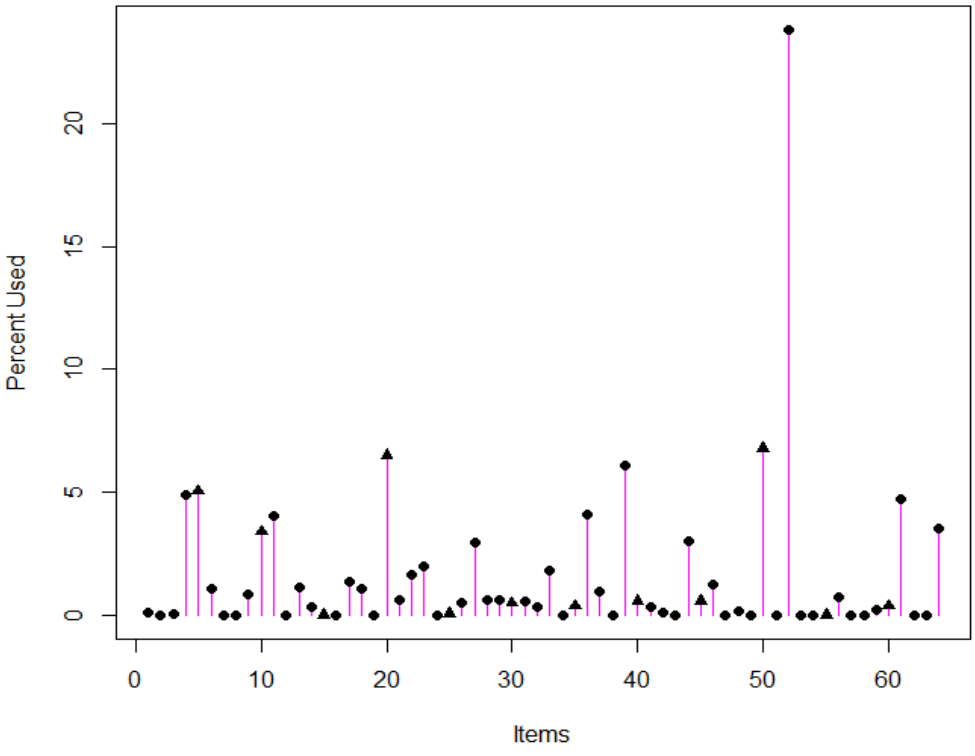

Figure 7.3 Item usage statistics for the Convenience item bank
Note: The standard error of measurement was set at 0.521. Item CV52 'How much trouble is it because of your contact lens falling off your eyes?' was used in all simulations as it was the starting item. Five other items were used more than 5% of the time. The remaining items were used less than 5% of the time.

7.2.1.2 Evaluation of QoL impact of refractive error

Median person measures in logits were compared across refractive error sub-groups. Mann-Whitney U test was employed to evaluate the statistical significance of the difference between two groups. The Kruskal-Wallis test was used to evaluate the statistical significance of the difference between multiple groups simultaneously. Spearman's correlation was used to evaluate strength and direction of the linear association between continuous variables (e.g. association between visual acuity and inconvenience).

7.3 Results

The demographic and clinical characteristics of the participants for this study were described in Section 6.3 (Table 6.2). The item banks were administered to 305 people with refractive error.

7.3.1 Correlation between item banks

Correlation between 13 refractive error item banks are presented in Table 7.1. Kaiser-Mayer-Olkin (KMO) Measure of Sampling Adequacy was 0.87. This verified the meaningfulness of PCA on the dataset. In addition, p value for the Barlett's test of sphericity was significant (< 0.001). This indicated presence of equal variances in the correlation matrix which is one of the requirements of applying a parametric test such as the Pearson correlation test. However, as some of the data distributions were not normally distributed, non-parametric Spearman's correlation was used to evaluate the relationships between the item banks.

There was a high correlation among frequency, severity and bothersome attributes of visual symptoms, and among frequency, severity and bothersome attributes of comfort symptoms. Therefore, the agreement analysis between the subscales was further carried out which is described in the next section. All other item banks had mild to moderate correlations between each other.

Table 7.1 Correlation (Spearman's ρ) between refractive error item banks

	CV	HC	EC	AL	MB	EM	SC	VSF	CSF	VSS	CSS	VSB	CSB
CV	1.000												
HC	0.708	1.000											
EC	0.570	0.502	1.000										
AL	0.569	0.490	0.517	1.000									
MB	0.462	0.421	0.506	0.754	1.000								
EM	0.575	0.557	0.565	0.436	0.367	1.000							
SC	0.448	0.549	0.486	0.396	0.481	0.555	1.000						
VSF	0.485	0.476	0.484	0.699	0.606	0.353	0.316	1.000					
CSF	0.383	0.526	0.416	0.511	0.457	0.455	0.367	0.566	1.000				
VSS	0.471	0.458	0.456	0.711	0.555	0.316	0.318	0.951	0.557	1.000			
CSS	0.384	0.529	0.400	0.503	0.414	0.407	0.340	0.539	0.968	0.544	1.000		
VSB	0.494	0.498	0.484	0.720	0.581	0.374	0.341	0.948	0.569	0.966	0.553	1.000	
CSB	0.380	0.528	0.406	0.524	0.443	0.435	0.369	0.537	0.948	0.544	0.971	0.567	1.000

Note: All the correlations were statistically significant (two-tailed p value < 0.05). High correlation coefficients >0.82 are in red fonts. Similarly, moderate correlations (0.57 to 0.82) are in blue fonts. AL = Activity limitation, CP = Coping, CSB = Comfort symptoms – bothersome, CSF = Comfort symptoms – frequency, CSS = Comfort symptoms – severity, CV = Convenience, EC = Economic, EM = Emotional, HC = Health concerns, MB = Mobility, SC = Social, VSB = Visual symptoms – bothersome, VSF = Visual symptoms – frequency, VSS = Visual symptoms – severity

7.3.1.1 Agreement analysis between symptoms subscales

Visual symptoms – frequency vs Visual symptoms – severity

The Bland and Altman analysis for the agreement between VSF and VSS (N = 270) was performed (Figure 7.4). The mean difference was low (0.11 logits; Paired t test, $p < 0.001$). The limits of agreement were narrow (upper limit of agreement: 0.78 ± 0.03; lower limit of agreement: -0.55 ± 0.03 logits).

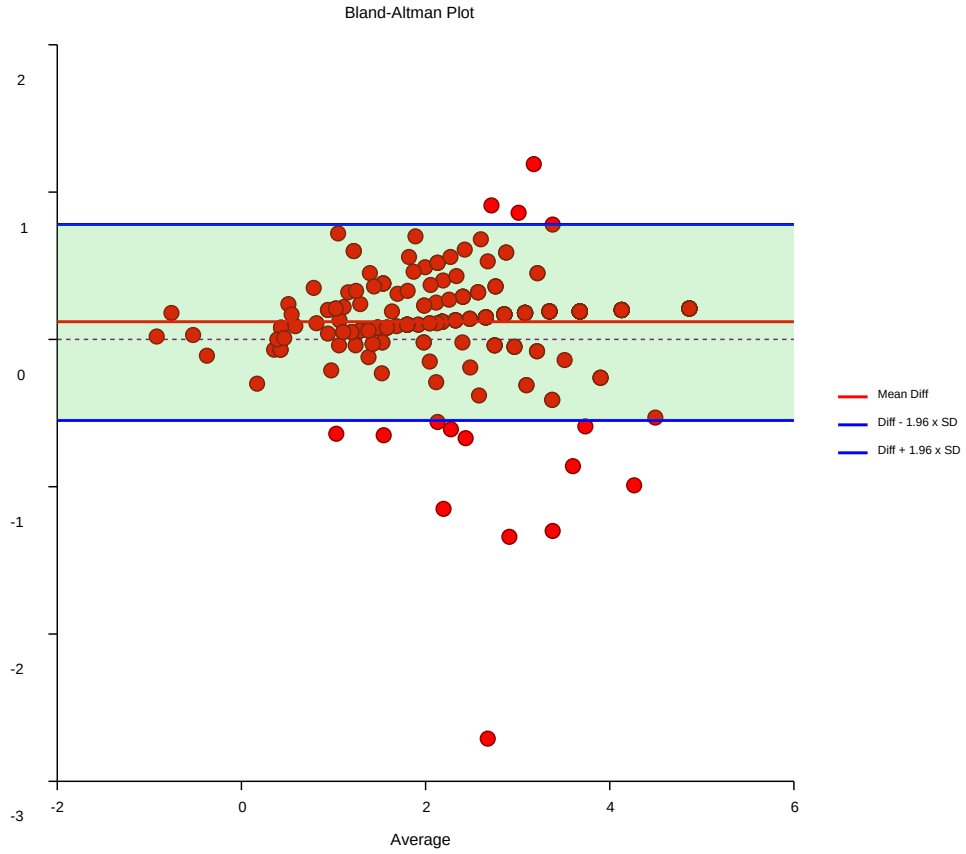

Figure 7.4 Visual symptoms – frequency vs Visual symptoms – severity

Visual symptoms – frequency vs Visual symptoms – bothersome

The Bland and Altman analysis for the agreement between VSF and VSB (N = 259) was performed (Figure 7.5). The mean difference was low (-0.03 logits) and was not statistically significant (Paired t test, $p = 0.14$). The limits of agreement were narrow (upper limit of agreement: 0.69 ± 0.04; lower limit of agreement: -0.57 ± 0.04 logits).

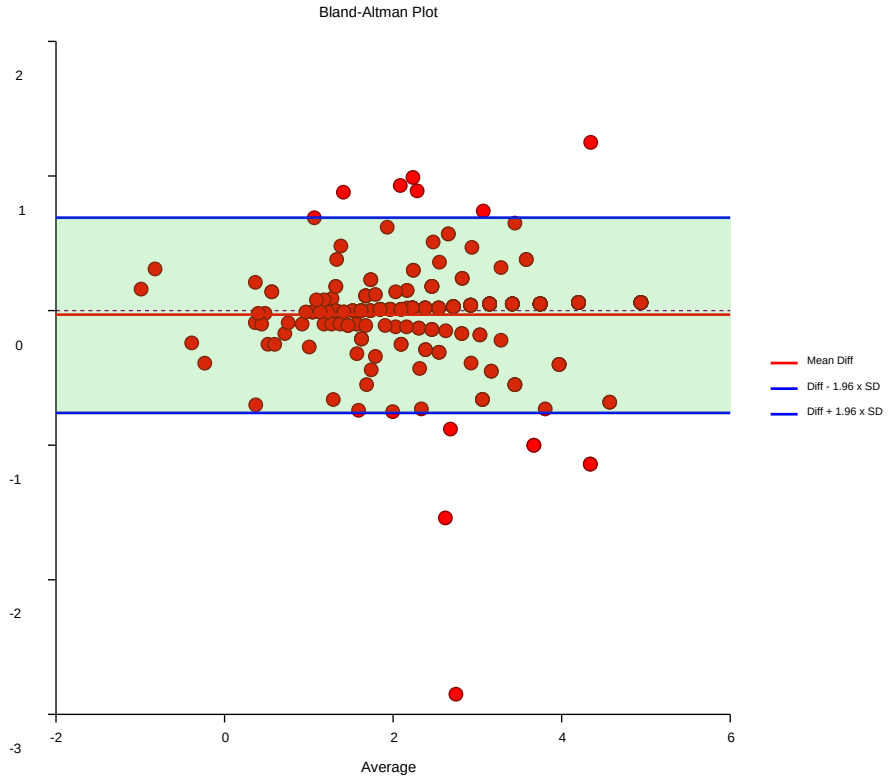

Figure 7.5 Visual symptoms – frequency vs Visual symptoms – bothersome

Visual symptoms – severity vs Visual symptoms – bothersome

The Bland and Altman analysis for the agreement between VSS and VSB (N = 258) was performed (Figure 7.6). The mean difference was low (-0.16 logits; Paired t-test, $p < 0.001$). The limits of agreement were narrow (upper limit of agreement: 0.41 ± 0.03; lower limit of agreement: -0.74 ± 0.03 logits).

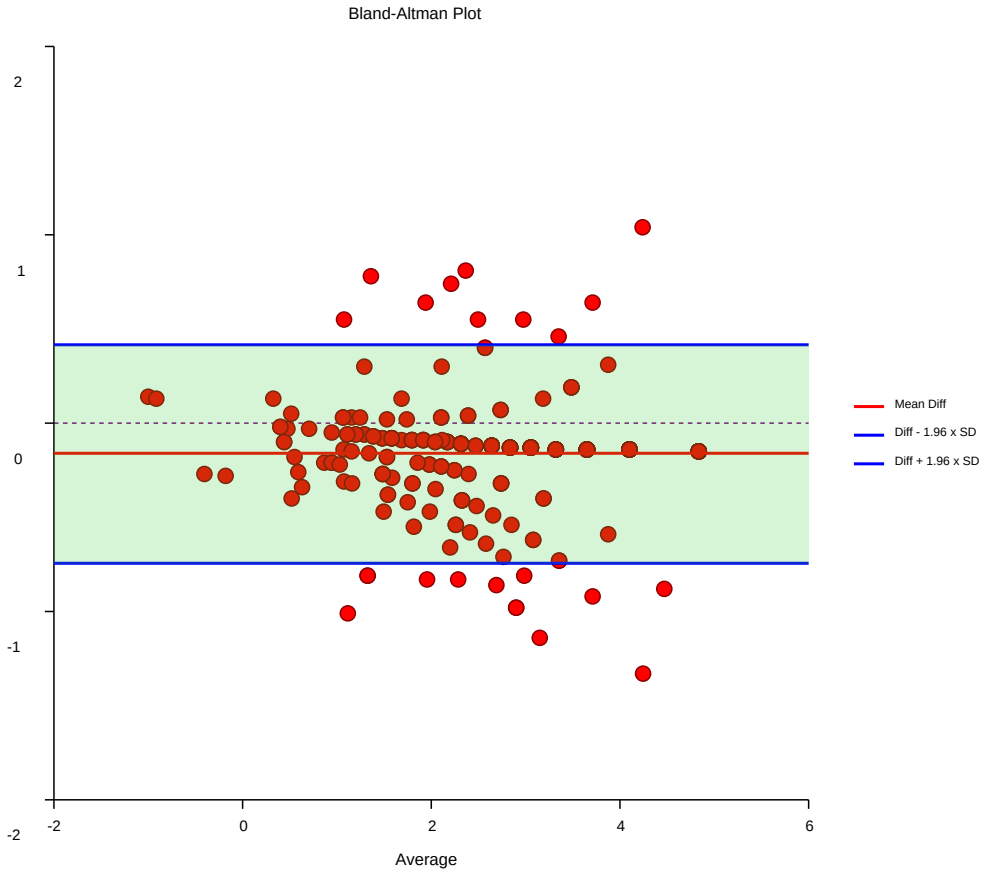

Figure 7.6 Visual symptoms – severity vs Visual symptoms – bothersome

Comfort symptoms – frequency vs Comfort symptoms – severity

The Bland and Altman analysis for the agreement between CSF and CSS (N = 294) was performed (Figure 7.7). Mean difference was low (0.19 logits; Paired t-test, $p < 0.001$). The limits of agreement were narrow (upper limit of agreement: 0.99 ± 0.04; lower limit of agreement: -0.61 ± 0.04 logits).

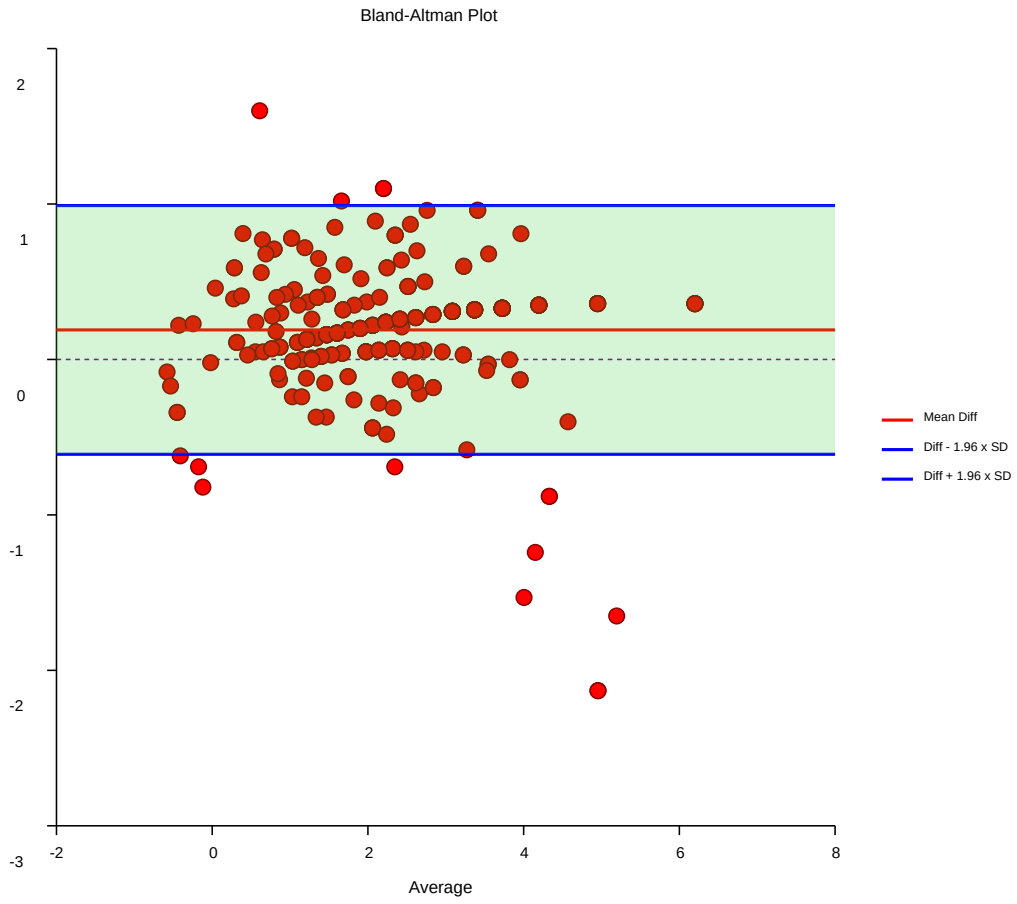

Figure 7.7 Comfort symptoms – frequency vs Comfort symptoms – severity

Comfort symptoms – frequency vs Comfort symptoms – bothersome

The Bland and Altman analysis for the agreement between the CSF and CSB (N = 294) item banks was performed (Figure 7.8). The mean difference was low (0.07 logits; Paired t-test, $p < 0.001$). The limits of agreement were narrow (upper limit of agreement: 0.98 ± 0.05; lower limit of agreement: -0.84 ± 0.05 logits).

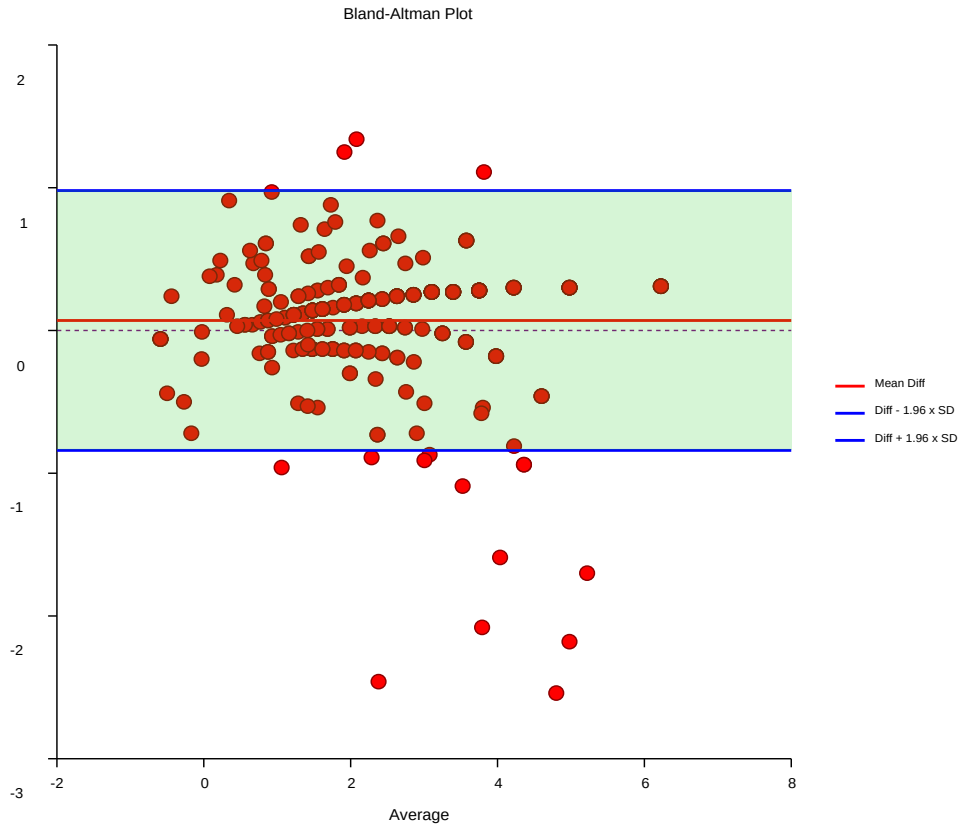

Figure 7.8 Comfort symptoms – frequency vs Comfort symptoms – bothersome

Comfort symptoms – severity vs Comfort symptoms – bothersome

The Bland and Altman analysis for the agreement between the CSS and CSB (N = 294) item banks was performed (Figure 7.9). The mean difference was low (-0.12 logits; Paired t-test, $p < 0.001$). The limits of agreement were narrow (upper limit of agreement: 0.54 ± 0.03; lower limit of agreement: -0.78 ± 0.03 logits).

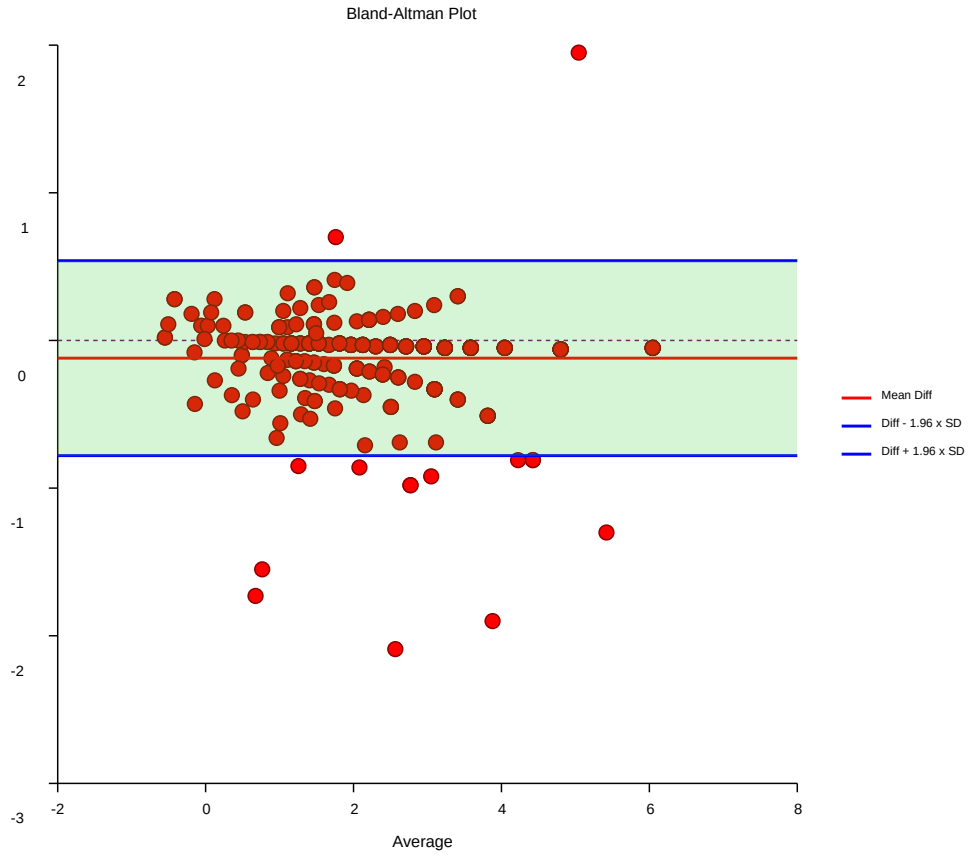

Figure 7.9 Comfort symptoms – severity vs Comfort symptoms – bothersome

In summary, there were high correlations and agreements between symptom subscales.

7.3.2 Computer adaptive testing simulation

The final item banks underwent CAT simulation. All item banks performed well to achieve moderate precision (SEM: 0.521). Similarly, all but Mobility item bank performed well to achieve high precision (SEM: 0.387). The average number of items to be administered for achieving high precision was 9.67 ± 1.55 (range: 7.21 for Health concerns to 12.91 from Mobility). Likewise, the average number of items to be administered for achieving moderate precision was 4.97 ± 1.08 (range: 3.64 for Health concerns to 8.00 for Mobility item bank). A total of 126 (34%) and 65 (17.5%) items were administered to achieve high and moderate precision, respectively, for all item banks.

The Activity limitation item bank had the maximum reduction in average number of items administered in CAT simulation. The full Activity limitation item bank had 71 items. The average number of items administered in CAT simulation were 7.23 and 3.94, for high and moderate precision, respectively.

The average correlation coefficients between CAT simulations and original version of the item banks were always very high, ranging from 0.98 to 0.99 for high precision, and from 0.96 to 0.99 for moderate precision.

Table 7.2 CAT simulation results for the Refractive error-specific item banks

Item banks	No. of items available for CAT	Average no. of items used by CAT		Correlation between CAT and item bank person measures		Mean SEM	
		SEM 0.387	SEM 0.521	SEM 0.387	SEM 0.521	SEM 0.387	SEM 0.521
CV	64	8.16	4.27	0.98	0.96	0.37	0.48
HC	39	7.21	3.64	0.98	0.96	0.39	0.49
EC	14	10.52	5.08	0.99	0.97	0.38	0.50
AL	71	7.23	3.94	0.98	0.96	0.37	0.49
MB	13	12.91	8.00	0.99	0.99	0.43[&]	0.50
EM	23	9.11	4.24	0.99	0.97	0.39	0.50
SC	16	10.21	4.45	0.99	0.97	0.38	0.50
VSF	23	9.47	5.22	0.99	0.96	0.39	0.49
VSS	23	9.50	4.66	0.99	0.97	0.39	0.50
VSB	23	9.85	5.15	0.99	0.97	0.38	0.49
CSF	19	11.02	5.53	0.99	0.97	0.39	0.50
CSS	19	10.17	5.17	0.99	0.97	0.39	0.50
CSB	19	10.41	5.36	0.99	0.97	0.39	0.50
Total	**366 (282[*])**	**125.77 (85.61[*])**	**64.71 (44.13[*])**				

Note: AL = Activity limitation, CAT = Computer adaptive testing, CP = Coping, CSB = Comfort symptoms – bothersome, CSF = Comfort symptoms – frequency, CSS = Comfort symptoms – severity, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, SC = Social, VSB = Visual symptoms – bothersome, VSF = Visual symptoms – frequency, VSS = Visual symptoms – severity; [*]The total value is obtained considering only one attribute (Bothersome) of the symptoms (VS and comfort) item banks. [&]High precision could not be achieved for the mobility item-bank.

7.3.3 Evaluation of impact of refractive error on quality-of-life

An evaluation of QoL parameters in refractive error sub-groups using the item-banks presented in Table 7.3. Below, I discuss the key findings with some likely explanations for the findings for each item bank.

Table 7.3 Evaluation of quality-of-life parameters between refractive error sub-groups

	CV	HC	EC	AL	MB	EM	SC	VSF	CSF	VSS	CSS	VSB	CSB
No of participants	289	290	292	296	212	215	209	277	298	270	294	260	294
Median (min to max)	0.91 (-1.49 to 6.89)	1.08 (-0.95 to 5.71)	2.54 (-3.52 to 7.01)	2.45 (-1.41 to 7.14)	4.74 (-2.77 to 7.49)	2.93 (-1.52 to 5.18)	2.88 (-0.62 to 5.24)	2.73 (-0.91 to 4.97)	2.17 (-0.72 to 6.38)	2.58 (-0.93 to 4.76)	1.95 (-0.54 to 6.02)	2.7 (-1.07 to 4.9)	2.14 (-0.56 to 6.07)
Gender													
Female	0.71	0.855	2.41	2.37	4.40	2.65	2.65	2.73	2.00	2.58	1.80	2.70	1.82
Male	1.09	1.27	2.60	2.54	5.15	3.09	3.10	2.55	2.54	2.41	2.195	2.53	2.415
MWU, p value	**0.016**	**<0.001**	0.254	0.837	0.544	**0.044**	**0.027**	0.443	**0.001**	0.448	**0.001**	0.587	**0.001**
Rural vs Urban													
Rural	0.40	0.88	1.27	1.895	3.85	2.21	2.34	2.10	1.62	2.12	1.52	2.37	1.75
Urban	1.03	1.120	2.98	2.70	5.15	3.09	3.10	2.73	2.35	2.58	2.11	2.70	2.14
MWU, p value	**0.016**	**0.045**	**0.001**	**0.001**	**0.002**	**<0.001**	0.068	**0.023**	**0.005**	**0.039**	**0.016**	**0.029**	**0.042**
Visual acuity classification: Better than 0.30 logMAR (6/12 Snellen equivalent) vs Worse than 0.30 (6/12 Snellen equivalent)													
Better than 6/12	0.94	1.09	2.50	2.495	5.15	3.09	3.10	2.73	2.17	2.58	1.95	2.70	2.14
Worse than 6/12	0.67	0.91	2.795	1.815	2.99	2.78	1.96	1.85	2.00	1.75	1.875	1.96	1.98
MWU, p value	0.442	0.320	0.798	**0.042**	**<0.001**	0.950	**0.031**	**0.009**	0.386	**0.029**	0.494	**0.047**	0.557
Refractive error category: Low (myopia or hyperopia), Moderate Low (myopia or hyperopia), High Low (myopia or hyperopia)													
Low	1.16	1.14	2.73	2.69	5.15	3.09	2.78	2.73	2.17	2.675	1.95	2.80	2.14
Moderate	0.895	0.975	2.895	2.24	4.74	3.09	3.10	2.55	1.92	2.26	1.65	2.53	1.82
High	0.025	0.70	1.105	1.68	3.39	2.31	2.64	1.97	2.35	2.25	1.95	1.96	2.14
KW, p value	**<0.001**	**0.015**	**0.004**	**<0.001**	**0.034**	0.187	0.480	0.083	0.590	0.123	0.540	0.087	0.704
Myopia vs Hyperopia (Spherical equivalent)													
Myopia	0.91	1.015	2.70	2.46	5.15	3.01	2.78	2.73	2.17	2.58	1.95	2.70	2.14
Hyperopia	0.82	1.09	2.12	1.81	4.11	2.93	3.14	2.24	1.69	2.12	1.52	2.295	1.54
MWU, p value	0.710	0.906	0.171	**<0.001**	0.095	0.674	0.550	**0.002**	0.137	**0.001**	0.170	**0.001**	0.132
'High + Moderate' vs 'Low' Spherical equivalent refractive error													
High+Moderate	0.625	0.90	2.025	2.08	4.74	2.93	3.10	2.55	2.17	2.26	1.95	2.37	1.98
Low	1.16	1.14	2.73	2.69	5.15	3.09	2.78	2.73	2.17	2.675	1.95	2.80	2.14
MWU, p value	**0.001**	**0.018**	0.131	**0.002**	0.208	0.283	0.931	0.073	0.566	**0.048**	0.597	0.079	0.645
Astigmatism													
Yes	0.82	0.98	2.35	1.725	4.11	3.09	2.88	1.97	2.00	1.87	1.80	1.96	1.98
No	0.99	1.13	2.54	2.58	5.15	2.93	2.86	2.73	2.35	2.58	2.11	2.70	2.14
MWU p value	0.099	0.307	0.800	**0.002**	**0.021**	0.803	0.686	**<0.001**	0.055	**0.001**	**0.047**	**0.001**	0.090
Presbyopia													
No	0.92	1.01	2.50	2.58	5.15	2.93	2.78	2.73	2.35	2.58	2.11	2.70	2.14
Yes	0.88	1.24	2.67	1.68	4.11	3.09	3.99	2.315	1.92	2.12	1.725	2.37	1.82
MWU, p value	0.978	0.130	0.730	**<0.001**	**0.034**	0.729	**0.031**	**0.042**	0.491	**0.014**	0.348	**0.025**	0.336
Corrected refractive error (CRE) vs Uncorrected refractive error (URE)													
CRE	0.875	1.07	2.58	2.36	4.945	3.09	3.10	2.73	2.17	2.58	1.95	2.70	2.06

URE	1.19	1.075	2.28	2.66	4.19	2.65	2.215	2.39	2.35	2.12	2.11	2.37	2.14
MWU, p value	0.101	0.745	0.753	0.825	0.272	0.481	**0.034**	0.089	0.573	0.140	0.804	0.248	0.989
Spectacles: 'Never + Not now' vs Yes (Current wearers)													
Never +Not now	1.59	1.51	3.955	3.73	4.04	4.46	3.34	3.17	3.24	2.99	3.07	3.39	3.385
Yes	0.84	1.00	2.35	2.255	4.74	2.93	2.86	2.55	2.085	2.26	1.95	2.53	1.98
MWU, p value	**0.002**	**0.037**	**0.008**	**<0.001**	0.831	0.161	0.680	**0.002**	**0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**
Contact lens: 'Never + Not now' vs Yes (Current wearers)													
Never + Not now	0.995	1.13	2.50	2.42	4.74	3.09	2.99	2.55	2.35	2.41	2.11	2.70	2.14
Yes	0.40	0.76	2.625	2.585	5.66	2.42	2.04	2.94	1.845	2.77	1.52	2.90	1.54
MWU, p value	**0.017**	**0.031**	0.629	0.448	0.078	**0.027**	0.061	0.512	**0.042**	0.857	**0.012**	0.729	**0.005**
History of refractive surgery													
No	0.90	1.04	2.58	2.35	4.74	2.93	2.88	2.55	2.17	2.41	1.95	2.70	2.06
Yes	1.52	1.39	2.06	4.205	7.49	4.46	3.41	2.94	3.12	2.88	3.56	3.39	3.61
MWU, p value	0.105	0.175	0.709	**<0.001**	0.349	0.336	0.686	**0.027**	**0.042**	**0.011**	**0.001**	**0.029**	**<0.001**
Surgical emmetropia													
No	0.895	1.02	2.58	2.35	4.74	2.93	2.86	2.60	2.17	2.41	1.95	2.70	2.14
Yes	1.795	1.495	2.275	4.40	*	3.86	4.27	2.94	2.75	2.99	3.385	3.72	3.61
MWU, p value	**0.078**	0.119	0.618	**<0.001**	**0.032**	0.556	0.569	**0.022**	**0.087**	**0.009**	**0.002**	**0.008**	**0.001**
Dominant correction status													
1. URE	1.19	1.13	2.28	2.66	3.945	2.65	2.12	2.39	2.35	2.12	2.11	2.37	2.32
2. Spectacles	0.87	1.065	2.50	2.245	4.74	3.09	3.10	2.64	2.17	2.41	1.95	2.615	1.98
3. Contact lens	0.40	0.69	3.20	2.70	6.015	1.77	2.32	3.44	2.35	2.99	1.95	3.39	1.98
4. Surgery	1.79	1.495	2.275	4.40	*	3.86	4.27	2.94	2.75	3.00	3.385	3.72	3.61
KW, p value	**0.028**	0.161	0.591	**<0.001**	**0.022**	0.296	0.096	**0.012**	0.399	**0.011**	**0.017**	**0.008**	**0.011**
1 vs 2 MWU p value	0.050	0.534	0.664	0.346	0.321	0.337	**0.025**	0.246	0.998	0.310	0.638	0.465	0.462
1 vs 3 MWU p value	**0.058**	0.119	0.293	0.267	0.056	0.359	0.815	**0.017**	0.875	**0.046**	0.698	**0.035**	0.491
1 vs 4 MWU p value	0.355	0.323	0.743	**0.000**	**0.051**	0.441	0.392	**0.007**	0.139	**0.006**	**0.009**	**0.007**	**0.011**
2 vs 3 MWU p value	0.141	0.134	0.219	**0.050**	**0.044**	0.095	0.218	0.053	0.907	0.079	0.838	0.043	0.804
2 vs 4 MWU p value	0.056	0.112	0.545	**0.000**	**0.030**	0.635	0.616	**0.026**	0.094	**0.010**	**0.002**	**0.007**	**0.001**
3 vs 4 MWU p value	0.126	0.067	0.693	**0.009**	0.064	0.245	0.566	0.950	0.145	0.641	**0.017**	0.359	**0.013**
Correlation (Spearman's correlation coefficient, ρ) with Visual acuity (Both eyes) in logMAR													
P	-0.213	-0.167	-0.165	-0.295	-0.401	-0.104	-0.205	-0.325	-0.068	-0.272	-0.049	-0.272	-0.038
p value	**0.000**	**0.005**	**0.005**	**0.000**	**0.000**	0.137	**0.003**	**0.000**	0.254	**0.000**	0.413	**0.000**	0.523
Correlation (Spearman's correlation coefficient, ρ) with refractive error magnitude (absolute spherical equivalent)													
P	-0.212	-0.157	-0.112	-0.129	-0.055	-0.114	-0.083	-0.042	0.004	-0.032	0.009	-0.046	-0.008
p value	**0.000**	**0.010**	0.066	**0.035**	0.429	0.105	0.245	0.507	0.953	0.621	0.878	0.479	0.899

Note: AL = Activity limitation, CP = Coping, CRE = Corrected refractive error, CSB = Comfort symptoms – bothersome, CSF = Comfort symptoms – frequency, CSS = Comfort symptoms – severity, CV = Convenience, EC = Economic, EM = Emotional, HC = Health concerns, KW = Kruskal-Wallis test, MB = Mobility, MWU = Mann-Whitney U test, SC = Social, URE = Uncorrected refractive error, VSB = Visual symptoms – bothersome, VSF = Visual symptoms – frequency, VSS = Visual symptoms – severity. p values in red font represent statistically significant differences ($p < 0.05$); * For mobility, All but two participants with refractive surgery had extreme responses (ceiling effect). Therefore, median was not calculated.

7.3.3.1 Convenience

The higher score (person measure) in logits represented a higher convenience level (lower inconvenience). The female participants had higher inconvenience than the male participants (Mann-Whitney U test, p = 0.016). Similarly, the participants from rural areas had higher inconvenience than the participants from urban areas (Mann-Whitney U test, p = 0.016).

The participants with high spherical equivalent refractive error had the highest inconvenience (median = 0.02 logits) followed by the participants with moderate refractive error (median = 0.90 logits) and low refractive error (median = 1.16 logits), respectively (Kruskal-Wallis test, p < 0.001). Similarly, the participants wearing contact lenses had the highest inconvenience (median = 0.40 logits) followed by the participants with spectacles (median = 0.87 logits), URE (median = 1.19 logits) and refractive surgery (median = 1.79 logits) (Kruskal-Wallis test, p = 0.028).

The differences in convenience levels between presbyopes and non-presbyopes, myopia and hyperopia, participants with astigmatism and without astigmatism, participants with visual acuity better than 0.30 logMAR and visual acuity worse than 0.30 logMAR were not statistically significant (Mann-Whitney U test, p = 0.978, 0.710, 0.099, 0.442 respectively). Similarly, there was only a mild negative correlation of convenience score with magnitude of refractive error (Spearman's ρ, -0.21; p < 0.001), and visual acuity in logMAR (Spearman's ρ, -0.21; p < 0.001).

Overall, these findings demonstrate good known-group validity of the Convenience item bank, and it can be used as an outcome measure of refractive error intervention.

7.3.3.2 Health concerns

The higher scores (person measure) in logits represented less health concerns. The female participants had higher health concerns than the male participants (Mann-Whitney U test, p < 0.001). Similarly, the participants from rural areas had higher concerns than the participants from urban areas (Mann-Whitney U test, p = 0.045).

The participants with high spherical equivalent refractive error had the highest health concerns (median = 0.70 logits) followed by the participants with moderate refractive error (median = 0.98 logits) and low refractive error (median = 1.14 logits), respectively (Kruskal-Wallis test, p = 0.015). Spectacle wearers had greater health concerns than non-spectacle wearers (Mann-Whitney U test, p = 0.037). Similarly, contact lens wearers had greater health concerns than non-contact lens wearers (Mann-Whitney U test, p = 0.031). On detailed pairwise comparisons by dominant refractive correction status (URE, spectacle wearers, contact lens wearers and refractive surgery), the contact lens wearers had the highest health concerns followed by spectacle wearers, URE

participants and the participants who underwent refractive surgery, respectively. However, the differences in health concerns between the pairs were not statistically significant (Mann-Whitney U test, $p > 0.05$ in all cases) (Table 7.3).

The differences in health concerns between the participants with or without visual acuity better than 0.30 logMAR, with myopia or hyperopia, with or without astigmatism, with or without presbyopia, and with or without a history of refractive surgery, were not statistically significant (Mann-Whitney U test, $p = 0.320$, 0.906, 0.307, 0.130, 0.175, respectively). Similarly, there was only a mild negative correlation of health concerns with magnitude of refractive error (Spearman's ρ, -0.16; $p = 0.010$), and visual acuity in logMAR (Spearman's ρ, -0.17 $p = 0.005$).

Overall, these findings demonstrate good known-group validity of the Health concerns item bank, and it can be used as an outcome measure of refractive error intervention.

7.3.3.3 Economic

The higher score (person measure) in logits represented less economic impact due to work or finance related issues. The participants from rural areas had higher economic concerns than the participants from the urban areas (Mann-Whitney U test, $p = 0.001$). Similarly, the spectacle wearers had higher economic concerns than the non-spectacle wearers (Mann-Whitney U test, $p = 0.008$). However, on detailed pairwise comparisons by dominant refractive correction status (URE, spectacle wearers, contact lens wearers and refractive surgery), the differences in economic impact scores between the pairs were not statistically significant (Mann-Whitney U test, $p > 0.05$ in all cases) (Table 7.3).

The differences in economic concerns between male and female, URE and CRE (participants with any type of refractive correction: spectacles, contact lens, or refractive surgery), presbyopes and non-presbyopes, visual acuity better or worse than 0.30 logMAR, myopia and hyperopia, low and high/moderate refractive error, and participants with astigmatism and participants without astigmatism, were not statistically significant (Mann-Whitney U test: $p = 0.254$, 0.753, 0.730, 0.798, 0.171, 0.131, 0.800 respectively). Similarly, the correlation between economic impact and the magnitude of refractive error was not statistically significant (Spearman's ρ, -0.11; $p = 0.066$). There was only a mild negative correlation between economic impact and visual acuity in logMAR (Spearman's ρ, -0.17 $p = 0.005$).

Overall, these findings demonstrate good known-group validity of the Economic item bank, and it can be used as an outcome measure of refractive error intervention.

7.3.3.4 Activity Limitation

The higher score (person measure) in logits represented less activity limitation (higher ability). The participants from rural areas had higher activity limitation than the participants from urban areas (Mann-Whitney U test, $p = 0.001$). Although the female participants had slightly higher activity limitation than the male participants, the difference was not statistically significant (Mann-Whitney U test, $p = 0.837$).

The presbyopes had greater activity limitation than the non-presbyopes (Mann-Whitney U test, $p < 0.001$). Similarly, the hyperopes had greater activity limitation than the myopes (Mann-Whitney U test, $p < 0.001$). The participants with high spherical equivalent refractive error had the maximum activity limitation (median = 1.68 logits) followed by the participants with moderate refractive error (median = 2.24 logits) and low refractive error (median = 2.69 logits), respectively (Kruskal-Wallis test, $p < 0.001$).

The spectacle wearers and the contact lens wearers had greater activity limitation than the non-spectacle wearers and the non-contact lens wearers, respectively (Mann-Whitney U test, $p < 0.001$ in both cases). Whereas, the participants who underwent refractive surgery had lesser activity limitation than the others (Mann-Whitney U test, $p < 0.001$). On a detailed pairwise comparisons by dominant refractive correction status (URE, spectacle wearers, contact lens wearers and refractive surgery), spectacle wearers had significantly higher activity limitation than contact lens wearers (Mann-Whitney U test, $p = 0.050$). Similarly, participants who had undergone refractive surgery had significantly less activity limitation than the URE participants, the spectacle wearers and the contact lens wearers (Mann-Whitney U test, $p < 0.001$, < 0.001 and $= 0.009$ respectively) (Table 7.3).

Interestingly, the difference between the Activity limitation scores for URE and CRE (participants with spectacles, contact lenses or refractive surgery put together) was not statistically significant (Mann-Whitney U test, $p = 0.825$). Similarly, there was only a mild negative correlation of activity limitation scores with visual acuity in logMAR (Spearman's ρ, -0.30 $p < 0.001$), and magnitude of refractive error (Spearman's ρ, -0.13; $p = 0.035$),

Overall, these findings demonstrate good known-group validity of the Activity limitation item bank, and it can be used as an outcome measure of refractive error intervention.

7.3.3.5 Mobility

The higher score (person measure) in logits represented less difficulty in mobility (higher ability). The participants from rural areas had higher mobility problems than the participants from urban

areas (Mann-Whitney U test, p = 0.002). Likewise, the participants with astigmatism had a greater mobility difficulty than the participants without astigmatism (Mann-Whitney U test, p = 0.021). The presbyopes had higher difficulty in mobility than the non-presbyopes (Mann-Whitney U test, p = 0.034). Likewise, the participants with habitual visual acuity better than 0.30 logMAR had less difficulty in mobility than the participants with visual acuity worse than 0.30 logMAR (Mann-Whitney U test, p = 0.042).The participants with high spherical equivalent refractive error had the highest mobility problem (median = 3.39 logits) followed by the participants with moderate refractive error (median = 4.74 logits) and low refractive error (median = 5.15 logits), respectively (Kruskal-Wallis test, p = 0.034).

On a pairwise comparisons by dominant refractive correction status, (URE, spectacle wearers, contact lens wearers and refractive surgery), the spectacle wearers had higher mobility problem than the contact lens wearers (Mann-Whitney U test, p = 0.044). Similarly, the spectacle wearers had significantly higher mobility problem than the refractive surgery participants (Mann-Whitney U test, p = 0.044). Whereas, the mobility scores between male and female, CRE and URE, spectacle wearers and non-spectacle wearers, contact lens wearers and non-contact lens wearers, myopia and hyperopia, were not statistically significant (Mann-Whitney U test, p = 0.544, 0.272, 0.831, 0.078, 0.095, respectively). Similarly, the correlation between mobility and the magnitude of refractive error was not statistically significant (Spearman's ρ, -0.06; p = 0.429). There was a mild negative correlation of mobility scores with visual acuity in logMAR (Spearman's ρ, -0.40 p < 0.001),

Overall, these findings demonstrate good known-group validity of the Mobility item bank, and it can be used as an outcome measure of refractive error intervention.

7.3.3.6 Emotional

The higher score (person measure) in logits represented a lower emotional impact. The female participants had higher emotional impact than the male participants (Mann-Whitney U test, p = 0.044). Similarly, the participants from rural areas had higher emotional impact than the participants from urban areas (Mann-Whitney U test, p < 0.001).

The contact lens wearers had the highest emotional impact due to refractive error (median = 1.77 logits), followed by the URE participants (median = 2.65 logits), spectacle wearers (median = 3.09 logits) and the participants with refractive surgery (median = 3.86 logits), respectively. However, the difference was not statistically significant (Kruskal-Wallis test, p = 0.296). Similarly, the emotional impact scores for CRE and URE, presbyopes and non presbyopes, myopia and hyperopia, visual acuity better or worse than 0.30 logMAR, were not statistically significant (Mann-

Whitney U test, 0.481, 0.729, 0.674, and 0.954, respectively). Likewise, differences in emotional impact scores among low, moderate or high spherical equivalent refractive error were not statistically significant (Kruskal-Wallis test, p = 0.187). Similarly, the correlation of emotional impact with magnitude of refractive error (Spearman's ρ, -0.11), and visual acuity in logMAR (Spearman's ρ, -0.10) were not statistically significant (p = 0.105 and 0.137 respectively).

Overall, these findings demonstrate good known-group validity of the Emotional item bank, and it can be used as an outcome measure of refractive error intervention.

7.3.3.7 Social

The higher scores (person measures) in logits represented less social problems. The female participants had higher social problem scores than the male participants (Mann-Whitney U test, p = 0.027). Similarly, the participants with URE had higher social problem than the participants with CRE (Mann-Whitney U test, p = 0.034). The participants with visual acuity worse than 0.30 logMAR had higher social problem than the participants with visual acuity better than 0.30 logMAR (Mann-Whitney U test, p = 0.031). Similarly, the participants with presbyopia had lower social problem than the participants without presbyopia (Mann-Whitney U test, p = 0.031). Similarly, there was a mild correlation between social problems and visual acuity in logMAR (Spearman's ρ, -0.21; p = 0.003). However, the correlation between social problems and the magnitude of refractive error was not statistically significant (Spearman's ρ, -0.083, p = 0.245).

The participants with URE had the highest social problem (median = 2.12 logits) followed by contact lens wearers (median = 2.32 logits), spectacle wearers (median = 3.10 logits) and the participants with refractive surgery (median = 4.27 logits), respectively. However, the difference was not statistically significant (Kruskal-Wallis test, p = 0.09)]. The differences between scores for low, moderate and high refractive error were also not statistically significant (Kruskal-Wallis test, p = 0.480). Likewise, differences in scores between participants from rural and urban areas, participants with and without astigmatism, myopia and hyperopia, were not statistically significant (Mann-Whitney U test: 0.068, 0.686, and 0.550 respectively).

Overall, these findings demonstrate good known-group validity of the Social item bank, and it can be used as an outcome measure of refractive error intervention.

7.3.3.8 Visual symptoms

The higher scores (person measures) represented less symptoms: less symptom–frequency for the VSF, less symptom–severity for the VSS, and lesser symptom–bothersome for the VSB. Symptom scores were similar for all demographic and clinical groups across Frequency, Severity

and Bothersome scales of Visual symptoms. Therefore, these three attributes are discussed together.

The participants from rural areas had higher visual symptoms than the participants from urban areas (Mann-Whitney U test: 0.023, 0.039 and 0.029 for VSF, VSS and VSB respectively). The participants with visual acuity better than 0.30 logMAR had less visual symptoms than the participants with visual acuity worse than 0.30 logMAR (Mann-Whitney U test: $p = 0.009$, 0.029 and 0.047 for VSF, VSS and VSB respectively). Likewise, the hyperopes had higher visual symptoms than the myopes (Mann-Whitney U test: $p = 0.002$, 0.001 and 0.001 for VSF, VSS and VSB respectively). Similarly, the participants with astigmatism had higher visual symptoms than the participants without astigmatism (Mann-Whitney U test: $p < 0.001$ for VSF, VSS and VSB). Likewise, the presbyopes had higher visual symptoms than the non-presbyopes (Mann-Whitney U test, $p = 0.042$, 0.014 and 0.025 for VSF, VSS and VSB respectively). Likewise, the participants with high refractive error had the highest visual symptoms, followed by the participants with moderate and low refractive error respectively. However, the differences were not statistically significant (Kruskal-Wallis test: $p = 0.083$, 0.123 and 0.087 for VSF, VSS and VSB respectively).

Spectacle wearers had higher visual symptoms than the others (Mann-Whitney U test: $p = 0.002$, < 0.001 and < 0.001 for VSF, VSS and VSB respectively). Whereas, the participants who had refractive surgery had lower visual symptoms than the others (Mann-Whitney U test: $p = 0.022$, 0.009 and 0.008 for VSF, VSS and VSB respectively). The participants with URE had the highest visual symptoms followed by the participants with spectacles, and contact lenses or refractive surgery, respectively (Kruskal-Wallis test: $p = 0.012$, 0.011 and 0.0008 for VSF, VSS and VSB respectively). The difference between visual symptoms between contact lens and refractive surgery was not statistically significant (Mann-Whitney U test, $p>0.05$ for VSF, VSS and VSB).

The differences in visual symptom scores between male and female, URE and CRE, contact lens wearers and non-contact lens wearers were not statistically significant (Mann-Whitney U test: $p > 0.05$ in all cases). Similarly, there was no statistically significant correlation between visual symptoms and magnitude of refractive error (Spearman's ρ; -0.04, -0.03 and -0.05 respectively; $p > 0.05$ for all cases) There were only mild negative correlations between visual acuity in logMAR and the visual symptoms scores (Spearman's ρ; -0.32, -0.27 and -0.27 for VSF, VSS and VSB respectively; $p < 0.001$ in all cases).

Overall, these findings demonstrate good known-group validity of the Visual symptoms item banks, and they can be used as outcome measures of refractive error intervention.

7.3.3.9 Comfort symptoms

The higher comfort symptom scores (person measures) represented less symptoms: lesser symptom–frequency for CSF, lesser symptom–severity for CSS and lesser symptom–bothersome for CSB. Symptom scores were similar for most of the demographic and clinical groups across Frequency, Severity and Bothersome scales of comfort symptoms. Therefore, these three attributes are discussed together.

The female participants had higher comfort symptoms than the male participants (Mann-Whitney U test: $p = 0.001$ for all (CSF, CSS and CSB) scales). Similarly, the participants from rural areas had higher comfort symptoms than the participants from the urban areas (Mann-Whitney U test: $p = 0.005$, 0.016 and 0.042 for CSF, CSS and CSB respectively).

Interestingly, the participants with history of refractive surgery had less comfort symptoms than the others (Mann-Whitney U test: $p = 0.042$, 0.001 and < 0.001 for CSF, CSS and CSB respectively). Whereas, the spectacle wearers had higher comfort symptoms than the non-spectacle wearers (Mann-Whitney U test: $p = 0.001$, < 0.001 and < 0.001 for CSF, CSS and CSB respectively). Similarly, the contact lens wearers had higher comfort symptoms than the non-contact lens wearers (Mann-Whitney U test: $p = 0.042$, 0.012 and 0.005 for CSF, CSS and CSB respectively). However, on detailed pairwise comparisons by dominant refractive correction status (URE, spectacle wearers, contact lens wearers and refractive surgery), the differences in CSF scores between the pairs were not statistically significant (Mann-Whitney U test, $p > 0.05$ in all cases) (Table 7.3). Similarly, the differences in CSF, CSS and CSB scores between spectacle wearers and contact lens wearers, between URE and spectacle wearers, and between URE and contact lens wearers were not statistically significant (Mann-Whitney U test, $p > 0.05$ in all cases) (Table 7.3).

The differences in comfort symptoms between URE and CRE, presbyopes and non-presbyopes, visual acuity worse or better than 0.30 logMAR, myopia and hyperopia, were not statistically significant (Mann-Whitney U test: $p > 0.05$ in all cases). Similarly, the differences in comfort symptoms among low, moderate and high spherical equivalent refractive error were not statistically significant (Kruskal-Wallis test, $p = 0.590$, 0.540 and 0.704 for CSF, CSS and CSB respectively).

Likewise, the correlation between refractive error magnitude and the comfort symptoms scores was not statistically significant (Spearman's ρ, $p > 0.05$ for CSF, CSS and CSB). Similarly, the correlation between visual acuity and the comfort symptoms scores were not statistically significant (Spearman's ρ, $p > 0.05$ for CSF, CSS and CSB).

Overall, these findings demonstrated good known-group validity of the Comfort symptoms item banks, and they can be used as an outcome measure of refractive error intervention.

7.4 Discussion

This chapter cross-sectionally evaluated the performance of the final refractive error-specific item banks that proved to have good psychometric properties. The CAT simulation demonstrated that the item banks may be able to measure QoL parameters comprehensively and efficiently using only a few items. Finally, the item banks provided valuable evidence on the impact of refractive error on QoL. These findings also provided evidence on known-group validity of the refractive error item banks, and indicated successful application of the item banks for measuring outcomes of refractive error interventions.

The correlations between item banks were mild to moderate for all item-banks except within item banks for measuring symptoms attributes. High correlations and agreements among the frequency, severity and bothersome subscales were observed for visual symptoms and comfort symptoms. This is logical as all three attributes are essentially the different ways of measuring the same latent constructs: visual symptoms or comfort symptoms. Although the frequency, severity and bothersome subscales could form independently valid measures (independent scales with similar psychometric properties), researchers may choose to measure only one subscale depending upon the concept of interest. There may be only a little added value in measuring all these attributes. On the other hand, McAlinden *et al.* had found poor agreements between the subscales of visual symptoms: frequency, severity and bothersome.[236] In this study, initial items for symptoms were framed to measure these three attributes based on this evidence and on the results of the qualitative studies (Chapter 4).[14, 63]

Measuring ophthalmic symptoms is complex as symptoms may not be strictly unidimensional.[393] In this doctoral study, the variance explained by the measure for the symptoms item-banks was less than 50%. Possible reasons and implications of this finding were discussed in Chapter 6, Section 6.4. In a recent study, McNeely *et al.* demonstrated that the same measure (Quality of Vision questionnaire) behaved differently when administered to the patients who received multifocal intraocular lenses one-month and twelve months post-operatively.[393] Therefore, more research is required to conclude on an appropriate way of measuring symptoms in refractive error and in other eye conditions.

The CAT simulation results indicated that refractive error item banks may provide efficient and precise measurement of QoL parameters when administered through the CAT system. As

discussed in previous sections, there may only be a little added value in measuring all the attributes of the symptoms (Visual symptoms and Comfort symptoms) scales. If we consider administering only the bothersome attributes of the symptoms item banks for instance, the total number of items to be administered were 85.61 (23%) and 44.13 (12%) for achieving high and moderate precision, respectively, for all item banks (Table 7.2). As each individual item bank forms an independent valid scale, selection of one or more item banks for use may be guided by the need or the researchers or clinicians. For instance, comfort symptoms item banks may be of higher interest in measuring refractive surgery outcomes.

High level of precision (SEM: 0.387) could not be achieved for Mobility item bank. This was probably because of the poor targeting. Persons outside the measurement range of the scale need more items to obtain an estimate. The Mobility item bank had 83 respondents with extreme responses. Extreme respondents are outside the operational range of the scale, and therefore take the full item set.[392] For successful implementation of the Mobility item bank achieving a high precision, further work is required to improve the targeting of this scale. Strategies to improve targeting of the item banks were discussed in the Section 6.4. Overall, the CAT simulation results provided an indication for the success of live-testing of the item banks and CAT system in Phase III.

The final 13 item banks were used as measures to determine impact of refractive error on QoL domains in refractive error sub-groups by demographical (gender, rural vs urban) and clinical (visual acuity, degree and type of refractive error, type of refractive correction) variables.

The differences in impact of refractive error was evaluated by demographical characteristics such as gender and location (rural vs urban) of the participants. The female participants had significantly higher inconvenience, health concerns, emotional impact, social problems and comfort symptoms than the male participants. Whereas, Brady *et al.* reported better QoL status in the female participants corrected with spectacles than their male counterparts, based on the VFQoL scores.[243] However, the VFQoL consists of items on activity limitation and symptoms only.[243] Satisfaction scores were also reported to be better in female participants than in the male participants.[243] In another study, Schein *et al.* reported higher glare problems in females.[37] On contrary, the female participants in this study had lower visual symptoms than the male participants, although the differences were not statistically significant.

Similarly, the participants from rural areas had higher inconvenience, health concerns, economic impact, activity limitation, mobility problems, emotional impact, visual symptoms and comfort symptoms. There could be many reasons for these differences. However, QoL impact of refractive

error in rural populations is an under-researched area. Thompson *et al.* reported that the participants from the rural areas were more likely to be unaware of their eye problem. Court *et al.* suggested that appropriate communication by the clinicians could reduce concerns and anxiety during examination.[299] In summary, this study findings highlight that the impact of refractive error may differ by demographical characteristics such as gender and socio-economic status.

Mild or non-statistically significant correlation between person-measures for all item banks with visual acuity and magnitude of refractive error were important findings that highlight the importance of measuring PROs in refractive error. The PRO measures in refractive error can provide additional information on measuring impact of refractive error. This also indicates that the PRO measures complement clinical measures but are not substitutes to traditional clinical measures. PRO assessment should be a part of comprehensive outcome assessment in refractive error.

On group-wise comparison, the participants with visual acuity worse than 0.30 logMAR (Snellen's equivalent: 6/18) had greater activity limitation, mobility problem, social impact, and visual symptoms, than the participants with visual acuity better than 0.30 logMAR. This is logical, and aligns with the literature which report that visual impairment adversely affects QoL.[394-396]

Similarly, the participants with high or moderate absolute spherical equivalent refractive error had higher inconvenience, health concerns, activity limitation, and visual symptoms. In regards to the magnitude of refractive error, Rose *et al.* reported poorer VF-14 and VQOL scores in high myopia compared to moderate and low myopia.[165] They reported that the participants with high myopia had higher concerns about cosmetic appearance especially with the thick lenses.[165] They found that the impact of high myopia was similar to that of Keratoconus.[165] Similarly, Pesudovs *et al.* found that the QIRC scores were higher (better QoL status) in low refractive error than for moderate refractive error in spectacle wearers. However, they reported that the differences were not significant for contact lens wearers and refractive surgery participants.[27] In this study, high and moderate refractive error had worse economic impact (median = 2.02 logits) than low refractive error (median = 2.73 logits). However, the difference was not statistically significant (Mann-Whitney U test, p = 0.131). In the study by Rose *et al.*, they found that the people with high myopia spent more money on spectacles than those with low or moderate myopia. They discussed the high cost for buying thinner and lighter (high index) spectacle lenses. However, all groups had similar expenditure on contact lenses.[165] In sum, people with higher magnitude of refractive of refractive error may have poorer QoL status.

Regarding the types of refractive error, the QoL impact of myopia is more widely explored than that of hyperopia in the literature. In this study, hyperopes had higher activity limitation and visual

symptoms than myopes. This is opposite to a report by Lamoureux *et al.* who found that uncorrected hyperopia did not affect visual functioning. Perhaps the reason for no significant impact in their study was that the hyperopes had a low mean refractive error magnitude.[397] The current study findings indicated that the impact of hyperopia on QoL is worse than that of myopia.

Likewise, the presbyopes in this study had higher activity limitation, mobility problems, social impact, and visual symptoms than the participants with no presbyopia. This is an important finding as uncorrected presbyopia is often neglected and not considered under the classification of visual impairment by the organizations such as the World Health Organization.[135] In a study conducted in a presbyopia population, Patel *et al.* reported more near vision problems in women than men.[54] On a separate analysis for presbyopes and non-presbyopes, the female participants (median = 0.86 logits) had greater activity limitation than the male participants (median = 2.07); Mann-Whitney U test, p = 0.014) in the presbyopic group of this study. Whereas, the difference in Activity limitation scores between male (median = 2.70) and female participants (median = 2.46) from non-presbyopes group was not statistically significant (Mann-Whitney U test, p = 0.873). Similarly, Patel *et al.* reported higher odds of reporting difficulty for near tasks by urban dwellers than the rural population.[54] On contrary, in our study, rural participants had higher activity limitation both for presbyopic groups and non presbyopic groups (Mann-Whitney U test, p = 0.05 and 0.022 respectively). Patel *et al.* argued that the difference between the town and village dwellers might have been because the town dwellers may have more near vision demands for some items.[54] However, this argument may not be valid as choice of items should not affect the latent trait measured.[96, 102] Perhaps the problem was with the psychometric property of their PRO instrument. In conclusion, the current study findings suggested that a presbyope from rural area was more likely to have worse QoL status than others.

Likewise, the participants with astigmatism had higher activity limitation, mobility problems, visual symptoms and comfort symptoms than the participants without astigmatism. In a study by Savage *et al.*, worse QoL status in presbyopes with myopic astigmatism was reported compared to presbyopes with spherical myopia.[224] Summing up the existing evidence and the current study findings, it is suggested that the people with astigmatism have poorer QoL status than the people with spherical refractive error.

Similarly, in terms of refractive correction status, the participants with URE had significantly higher social problems than the participants with corrected refractive error. The spectacle wearers had higher inconvenience, health concerns, economic impact, activity limitation, visual symptoms and comfort symptoms than the participants not wearing spectacles. Likewise, the participants wearing contact lenses had higher inconvenience, health concerns, emotional impact, social impact, and

comfort symptoms than the participants not wearing contact lenses. Whereas, the participants with refractive surgery had less activity limitation and less visual or comfort symptoms than those without refractive surgery. Most of the published literature is for exploring QoL implications of refractive surgery and contact lens; very little is on spectacles and URE. Moreover, a little research that exists for spectacle wear is mainly on children.[48, 49, 227] Using the NEI-VFQ, McClure *et al.* argued that correction of URE may yield larger gains in QoL than the interventions in diabetic retinopathy, and macular degeneration. They reported that the QoL gains might be similar to or larger than in cataract surgery. They argued that the gains in QoL in young-adults may be higher than in the elderly.[291] Elliott *et al.* also found no significant improvement in general physical functioning after refractive correction in an elderly population.[300] In another study, Sandhu *et al.* found that refractive correction could not achieve visual function to the level of emmetropes.[293] The current study findings suggested that while correction of refractive error may improve scores on most of the QoL domains, the QoL scores for other domains (e.g. Convenience) may decrease. The refractive correction may not always address the QoL issues of URE.

Symptoms are the most frequently explored QoL domains in contact lens wearers in the literature. A discordance between dry eye signs and symptoms has been widely reported in the literature.[266, 398, 399] Perhaps, measuring not just dry eye but the comfort symptoms holistically may prove to find an association with signs of dry eye. In this study, the contact lens wearers had worse comfort symptoms than the non-contact lens wearers. Discomfort and dryness are frequent symptoms in contact lens wearers.[47, 81] The reason for discomfort may be because of several reasons. Contact lenses reduce tear secretion, increase tear evaporation, cause inflammation or Meibomian gland dysfunction, and reduce corneal sensation.[267] The tear film over contact lenses is less stable compared to the tear film over the normal ocular surface.[260] Contact lens wear also increases blink rate.[260] Comfort after contact lens wear is one of the major concerns for people considering contact lens wear. This is also one of the determinant of the choice of rigid gas permeable or soft contact lens wear by patients or the clinicians.[264] Contact lens discomfort is also one of the reasons for people discontinuing contact lens wear.[47, 185, 264]

On comparing the groups of participants by their dominant refractive correction (URE, spectacles, contact lenses or refractive surgery), the refractive surgery participants had more favourable outcomes for most of the item-banks indicating better QoL status than other groups. Similar finding was identified in the qualitative studies (Chapter 4).[14, 63] This is in agreement with the findings reported in other studies in the literature.[19, 27, 82, 217, 229, 233] More specifically, the refractive surgery participants had statistically significant less activity limitation, inconvenience and visual symptoms than other groups in the current study. The findings from the Convenience item bank were in

agreement with the findings from the qualitative studies (Chapter 4) and the published studies which report that the inconvenience of wearing spectacles or contact lenses may be a major reason for seeking refractive surgery.[375, 400]

Similar to the current study, Waring *et al.* reported less symptoms after refractive surgery using the RSVP questionnaire. They reported 23% decrease in considerable difficulty in night-driving post-operatively.[226] The authors reported that only 3% patients reported increase in glare, halos, or starburst post-refractive surgery.[226] Whereas in contrast to the current study findings from Visual symptoms item banks, Queiros *et al.* reported worse clarity of vision and glare (consisting of items classified under visual symptoms in this study) in people who underwent refractive surgery for myopia correction compared with myopes wearing spectacles or contact lenses.[82] In the current study, there were no participants with refractive surgery complications except one with relapsed refractive error. This may be one of the reasons for low visual symptoms in people who underwent refractive surgery.

Similarly, the contact lens wearers had lesser activity limitation, mobility problems and visual symptoms than the spectacle wearers. Pesudovs *et al.* also reported higher QIRC scores (better QoL status) in contact lens wearers compared to the spectacle wearers.[27] Similarly, Schein *et al*. reported less activity limitation in contact lens wearers than the spectacle wearers.[37] On contrary to the current study findings, Kanonidou *et al.* reported better visual functioning (VF-14) scores from spectacle wear compared to contact lens wear. The contact lens wearers with mild to moderate myopia reported more problems especially for near works and driving.[287] There could be a number differences in visual symptoms in spectacle and contact lens wearers. Spectacle wear may reduce peripheral vision while contact lens may not affect peripheral vision as the latter sits on the cornea and moves with the eye.[163] Similarly, distorted vision may be more of a problem to spectacle wearers owing to pin-cushion, barrel or mixed distortion effects.[401] Whereas, contact lens wearers may experience more occasional blurring of vision due to unstable tear-film over the contact lenses.[383 47, 253] The reason for the difference in visual symptoms scores between spectacle and contact lens wearers in this study is not clear.

Despite some evidence, the importance of measuring emotional impact of refractive error is often overlooked in optometry practice.[299] Yokoi *et al.* reported greater than 20% incidence for depression and anxiety in high myopia.[161] Day *et al.* reported that contact lens wear resulted into greater self-esteem than that from spectacle wear.[162] Discomfort during clinical procedure (e.g. while inserting contact lenses), poor clinician-patient communication, financial cost, and poor attention could lead to anxiety.[299] Good communication may lead to patient motivation and satisfaction.[299] Morse *et al.* found that the patients with depressive symptoms were less likely to be

satisfied after refractive surgery.[187] Having the emotional item bank is particularly important as without using a PRO instrument, it would be difficult, if not impossible, for an ophthalmic personnel to identify anxiety and depression disorders resulting from refractive error.[161]

One of the limitations of this study could be the sampling strategy. Although the study sample may represent a clinical refractive error population in Nepal, it may not represent the distribution of refractive error in the community. Several people in Nepal receive refraction services from eye camps.[327, 328] They may have different characteristics than the clinical sample. Similarly, refractive surgery participants would be rarely found in the community. Nevertheless, the goal was not to find the prevalence of QoL issues in the population. The primary objective of the Phase II study was to calibrate items in the item-banks that are applicable to as diverse refractive error population as possible. This goal has been achieved (Chapter 6). The second type of selection bias was that the participants who volunteered might have better or worse QoL status than others. However, this bias was likely to be random.

The sample consisted of participants from a wide range of refractive error in terms of types, correction types and demographic characteristics. However, the number of participants in some sub-groups (e.g. refractive surgery) were less than the number of participants in other groups (e.g. spectacle wearers). This might have limited in the power for some group-wise comparisons. This could explain absence of statistically significant differences in some observations (Table 7.3). Additionally, there is no 'clear blue water' between several groups compared. For example, people in the higher end of the 'Low refractive' group may be similar to the people in the lower end of the 'Moderate or high refractive error group'. All the contact lens wearers also used spectacles. All participants who had undergone refractive surgery had used spectacles in the past.

While assessing the relationship between variables, roles of potential confounding factors were not explored owing to small sample sizes for some sub-groups. As refractive error-specific QoL is a complex construct, it could be influenced by a number of demographical, cultural, clinical and personality related factors. For example, people with the same prescription for glasses may have different QoL issues (Figure 7.10). For a more focused study to compare refractive error outcomes by sub-groups, different design and different sampling strategy (e.g. randomization, matching or restriction) and statistical methods (e.g. multivariate analysis) might be more appropriate.[402] Adjusting for the potential confounders may establish more assertive relationships between the variables. For example, equal number of participants wearing spectacles, contact lenses and refractive surgery with matching (e.g. matching for age, visual acuity) may be more appropriate for determining the QoL differences between these groups. However, that approach could also have limitation that study population would not be representative of a clinical population. Matching

number of participants with refractive surgery or contact lenses with spectacle wearers might have caused low proportional participation of rural participants as all the participants who had refractive surgery or contact lenses in this study were from urban areas. In addition, it should be noted that all contact lens users also used spectacles. This is a common scenario that contact lens wearers use spectacles as well at least for some level of frequency. The current study findings are useful to understand comprehensive impact of refractive error on QoL, and to derive hypotheses for future studies. More data may be required to validate these hypotheses.

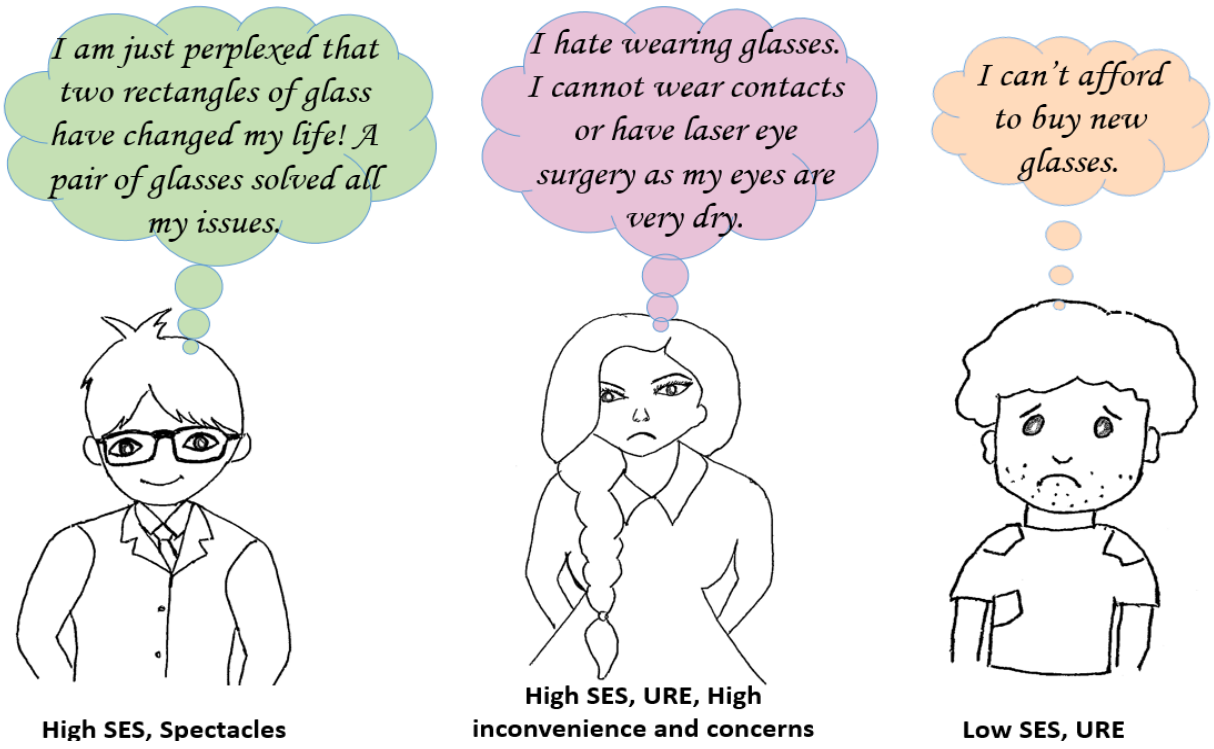

Figure 7.10 People with same spectacle-prescription (-2.50D) but different QoL issues
Note: QoL = Quality-of-life, SES = Socio-economic status, URE = Uncorrected refractive error

As discussed above, a caution should be taken while interpreting the results as role of potential confounders were not assessed. There may be a number of possible reasons for the underlying difference (or no difference) between the groups. For example, rural participants had higher mobility problems possibly due to bad roads in rural areas, participants with contact lenses and refractive surgery who had less mobility problems were from urban areas, or due to combination of these issues.[63] Likewise, all the participants who had undergone laser refractive surgery (the participants with the least inconvenience) were from urban areas, which may be one of the reasons for less inconvenience in the participants from the urban areas than the participants from the rural areas.

Several findings in this study challenge the current school of thought regarding refractive correction impacts. For example, although economic issues are widely considered to be the primary cause of URE being uncorrected[8], in this study, difference in economic impact between URE and CRE was not statistically significant, nevertheless URE did have higher economic impact. Perhaps, inconvenience and other issues may be more influential reasons for refractive error remaining uncorrected in adults. This finding is similar to the qualitative study findings (Chapter 4).[63] This finding may indicate a need to make changes in approach to combating avoidable blindness and visual impairment due to URE. Another interesting finding was that the presbyopes had higher visual symptoms than non-presbyopes. One reason for this could be that many presbyopes use spectacles irregularly. Again, convenience related issues may play important role for this finding. Similarly, in this study, participants with refractive surgery had less comfort symptoms than others. This is an interesting finding as there is a common notion that with increase in dryness related symptoms, refractive surgery worsens ocular-comfort symptoms. Perhaps this finding is due to the fact that this item bank consists of many items other than dryness related symptoms, such as headache and eye pain. The fact that all refractive surgery participants except one did not have any complications from refractive surgery may also partly account for this finding.

This study provided an overview of the QoL impact of refractive error. Overall, the final 13 refractive error item banks demonstrated promising evidence on the applicability of the refractive error item banks to comprehensively and scientifically evaluate QoL parameters. A comprehensive evaluation of QoL parameters across diverse groups of refractive error was performed. Findings of this study in many instances are not directly comparable with the literature that largely evaluates QoL parameters between specific populations (e.g. within types of refractive surgery techniques[189, 201, 208-210, 213, 214, 220, 232, 234, 237], contact lens modalities[204, 205, 211, 215], spectacles[243], presbyopic correction[45, 237], correction in myopia[242]). This is logical as they employ short questionnaires that cannot evaluate the comprehensive QoL across entire adult refractive error population that is highly heterogeneous. Small sample sizes in the refractive surgery and contact lens groups precluded meaningful intra-group comparisons in refractive surgery (e.g. comparison between LASIK and SMILE) or in contact lenses (e.g. between occasional wearers and frequent wearers) that could explain intra-group variations. For example, Nichols *et al.* reported that myopes seeking LASIK had greater activity limitations and worse appearance than the myopes not seeking refractive surgery.[203] Whether the item banks can differentiate between specific interventions such as two types of refractive surgery or two types of contact lenses has not been evaluated yet. However, since the content of the item banks is broad that includes content of most of the existing PRO instruments in refractive error, the item banks are likely to differentiate between the specific interventions as well. The broad findings of this study provided an overview and comparison of the

impact of refractive error across broad inclusive groups that may be particularly useful to the refraction service providers (clinicians, managers, NGOs), researchers and policy makers in diverse settings. The findings also provide impetus for researchers to derive hypotheses and conduct more-specific studies to explore within-group differences in QoL impact of refractive error. The intra-group comparisons will be possible after a large data is collected in next phases of this study.

The application of item banking described in this chapter is a new approach of measuring QoL impact in refractive error. Several findings are of immediate clinical relevance applicable to general ophthalmic practice. This work may contribute to improved refractive error care to the billions of people affected by refractive error and presbyopia. Accurate QoL measurement is the fundamental step towards improving QoL. The item banking and CAT technology is an exciting opportunity for all eye care professionals involved in refractive error care (including refractive surgery and contact lenses) to understand, measure, monitor and improve refractive error-specific QoL. In the next chapter, the broad implications of the findings presented in this chapter, and the recommendations for future research are discussed.

Chapter 8. Overall discussion and conclusions

This doctoral thesis comprises Phase I and Phase II of the multi-phase prospective study for the development of item banks to measure refractive error-specific QoL. Phase I has been completed in Australia and Nepal which resulted in 17 item-pools with 443 items in Australia and 17 item-pools with 392 items in Nepal (Chapter 3, 4, 5). Phase II data collection in Australia is ongoing (refer to Appendix L for the general characteristics of the participants recruited until July 2018, and the reason for not including the analysis in this thesis). Phase II has been completed in Nepal (Chapters 6 and 7). The psychometric assessment of the Phase II data in Nepal resulted into 13 refractive error-specific item banks with 366 items. The final item banks underwent CAT simulation, and were used to evaluate QoL domains across various sub-groups of refractive error. In this chapter I broadly discuss the findings, describe strengths and limitations of the doctoral study and suggest implications and future directions.

Numerous PRO instruments have been used to quantify QoL implications of refractive error. The studies claim that the impact of refractive error and its corrections on QoL parameters is profound. However, understanding the extent of the impact is limited due to a dearth of scientific and comprehensive PRO instruments, and lack of published qualitative studies. The findings from existing PRO instruments were not easily comparable. The limitations of the existing paper-based PRO instruments may be addressed by implementing third generation PRO instrument: item banking with the CAT system.[23] The item banks developed in this study are the foundation for the new generation of PRO instruments in refractive error for precise and comprehensive measurement of QoL parameters across all refractive error groups.

In chapters 2 and 3, I described the theoretical context and background for this study and the available evidence on refractive error-specific QoL, with a focus on the PRO instruments used in refractive error. ‘Refractive error’ and ‘Patient-reported outcomes’ are both recently recognised as important public health areas.

Refractive error is the most common cause of visual impairment globally.[5, 6] Billions of people live with refractive error and presbyopia.[5-8] The burden of refractive error and presbyopia is the highest in low-resource settings.[6, 9] The prevalence of refractive error, particularly myopia and presbyopia, is increasing rapidly, mainly due to change in lifestyle and ageing.[7, 120] Although, spectacles are the most popular ways of correcting refractive error, the popularity of contact lenses and refractive surgery is increasing.[128, 150-1528] Similar to URE, refractive correction methods could have QoL implications. The impact of refractive error and its correction on QoL can be quantitatively measured using PRO instruments.

Patient-reported outcome research is a relatively new and rapidly evolving field. The global shift in focus from 'Clinician driven health care' to 'Patient driven health care' has further increased the importance of the PRO measurement for clinical practice, research and policy setting.[18, 403] PRO instruments have a number of uses in refractive error care. The advantages of PRO instruments have been discussed in detail in Chapter 3. The PRO instruments are essential to quantify the impact of refractive error on people's QoL. The measurement of PROs should be a part of comprehensive outcome assessment in refractive error correction, along with other objective measures, such as visual acuity and contrast sensitivity.[46] PRO instruments are useful in identifying concerns related to refractive error or its correction methods. Similarly, they are useful in comparing effectiveness of different types of refractive corrections from patients' perspectives.[211]

However, there are several challenges in implementing PROs in refractive error. Respondent and clinician burden is one of the major challenges. Similarly, findings from different published studies are not easily comparable due to the heterogeneity in the studies and the use of poor-quality PRO instruments. The standards for PRO instrument development, application, frequency of PRO data collection, data security methods, and PRO data analysis methods are not uniform across the studies. For example, although the FDA[25, 138] recommends extensive consultation with patients to ensure the instrument is relevant to the intended population, most of the PRO instruments were developed with minimum or no patient consultation.[1, 12, 34, 39-41, 43, 44, 49, 54, 162] Another challenge in the PRO application is the expertise required. PRO instruments developed with modern psychometric methods have been proven to be of superior quality, as the traditional methods are based on the erroneous assumptions of summary scoring.[23, 77] However, the expertise required for understanding, implementing and analysing modern psychometric methods, such as Rasch analysis, is limited. Likewise, another challenge is that the existing PRO instruments are paper-based questionnaires that do not enable real-time measurement of PROs. This limits the applicability of PRO data in routine clinics. Most of the challenges may be addressed by carefully implementing item banks administered through the CAT system.

Measuring refractive error-specific QoL has further challenges. Drawing conclusions based on PROs is often difficult. For example, some people are satisfied with monovision while others may not be able to adapt to this correction method.[404] Similarly, while many people wear spectacles with no issues at all, some participants in the qualitative study indicated they were severely impacted by refractive error. A female participant ineligible for refractive surgery due to having thin corneas was devastated. Generalizing the QoL impacts for two persons, even when both wear spectacles for a similar prescription, is challenging. While PRO data may help us in benchmarking and policy making, individual experience, expectation and priorities need to be carefully assessed. This is

similar to other areas of health and disability (e.g. the Global burden of disease study). Some express that they would rather be dead than live with a disability, while others may consider disability as a part of their life. Having refractive error in itself may not be a disability, but factors such as environmental or availability of correction options may make refractive error a disability. Therefore, cautious interpretation of PRO data at population level and individual level as per the objectives may be required.

The CTT and IRT are the two commonly used psychometric methods in development and analysis of PRO instruments. CTT is a traditional method which uses summary scoring. Summary scoring is done by simple addition of ordinal values representing response categories. It assumes that the response categories are equidistant from one another on the measurement scale and the items have the same worth. Item-response theory proves that neither assumption is valid.[23, 77] Rasch analysis employed in this study is a model based on IRT.

Rasch analysis is a probabilistic theory which estimates person and item parameters and aligns them in a common logit scale. It converts ordinal level data into interval level data by logarithmic transformation. Rasch analysis is based on sound measurement principles. It is applied to construct new PRO instruments, or to assess and/or optimize the PRO instruments constructed by using CTT. However, it cannot convert poorly developed PRO instruments into valid ones.[73, 405] Rasch analysis provides better insights about a PRO instrument by providing information on parameters such as response category functioning, dimensionality, fit statistics, measurement precision and targeting. These parameters are also known as the Rasch diagnostic parameters, as they can be used to identify short-comings of the PRO instruments.

In the second section of Chapter 3, systematic analysis of existing evidence on refractive error-specific QoL was presented. A multitude of PRO instruments were used to evaluate QoL in refractive error. Selection of a PRO instrument for assessing refractive correction outcomes is not straight forward. The literature review chapter (Chapter 3) guides the selection of appropriate PRO instruments based on the quality and concept being measured from the plethora of existing paper-based questionnaires. The QIRC[28], the QOV[33] and the CLIQ[46] were identified as the superior quality PRO instruments. These superior quality PRO instruments were developed using Rasch analysis. However, even these highest quality PRO instruments had limitations. No existing PRO instrument could comprehensively assess each QoL domain in adults in all sub-groups of refractive error. Nevertheless, the superior quality PRO instruments performed satisfactorily as outcome measures, which signifies the importance of measuring PROs in refractive error.

PRO research in refractive error in low- and middle-income country settings was limited.[12, 243, 283]

Even the PRO instruments developed for low-income country settings had the content derived from the PRO instruments originally constructed for high-income country settings. [12, 243, 283] Similarly, PRO research in URE was limited.[12, 54] Content of the PRO instruments for URE were also derived from the PRO instruments originally constructed for refractive correction population or non-refractive populations.[12, 54]

From the extensive literature review, a need for a psychometrically robust and comprehensive PRO instrument in refractive error was identified. The existing PRO instruments were paper-based, and had a fixed set of items administered to people irrespective of their ability levels. Therefore, they either measured low range of trait difficulty, or had low precision if they covered wide range of difficulty levels. They consisted of limited number of items and thus may be poorly targeted to new refractive error populations. Each aimed in measuring QoL (or a QoL domain) in only a subgroup of refractive error such as presbyopic or non-presbyopic, uncorrected or corrected refractive error, and refractive surgery, contact lenses or spectacles. They were not comprehensive enough to measure QoL. Such issues might be addressed by implementing item-banking administered through a CAT system.[23] An item bank has a large number of items, and therefore may cater for issues relevant to all refractive error sub-groups. Application of item banking and CAT system is theoretically possible, and needs to be proven empirically.

Chapter 4 qualitatively investigated the impact of refractive error on QoL in Australia and Nepal. During the literature review, a published qualitative study exploring impact of refractive error on QoL in adults could not be identified. Qualitative study through in-depth interviews or focus group discussion is one of the most important step in identifying content of a PRO instrument.[25] Qualitative methods ensure patient relevant intended concepts are included in the PRO instrument for a refractive error population. This is important because clinicians' and patients' perspectives often mismatch. Clinicians often see only the tip of the iceberg and miss out most of the QoL issues of patients (Figure 8.1). To minimize this disparity, qualitative patient consultation before developing an instrument is required. Furthermore, relevance of content of the PRO instrument may change with time, and therefore require reviewing them qualitatively over time.

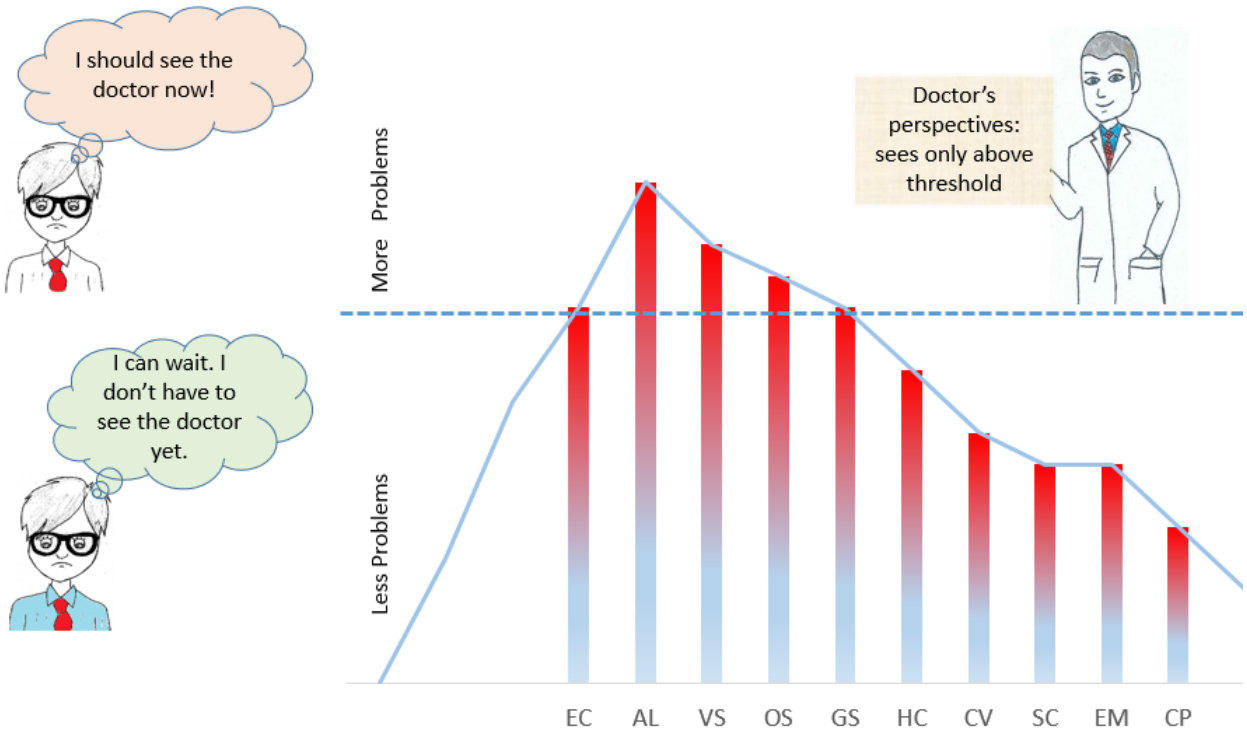

Figure 8.1 Tip of the ice-berg: clinicians usually miss out many quality-of-life issues
Note: AL = Activity limitation, CP = Coping, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, OS = Ocular-comfort symptoms, SC = Social, VS = Visual symptoms

Qualitative research often complements quantitative research and has several advantages. Qualitative studies are flexible, and do not have to depend upon statistical or clinical significances. They make voice of every participant hearable. Qualitative research helps us understand why many people discontinue using spectacles or contact lenses although these devices can prevent from visual disability by restoring vision to normal or near-normal level. Health concerns, inconvenience, emotional, and social issues may be some of the reasons to explain this. Qualitative research allows us to explore impact of refractive error on QoL seeing through the lens of the patients. This is crucial as the ultimate goal of refraction services is to improve people's QoL, not just improving visual acuity or other clinical measures.

In the first qualitative study conducted in Australia[14], 48 participants with refractive correction were interviewed. I found that refractive correction did not address all the QoL issues of adults with refractive error. The participants with refractive correction reported a plethora of QoL issues including issues related to health concerns, inconveniences, emotional and social impact. In fact, refractive correction added some QoL issues. People wearing spectacles were concerned about their cosmetic appearance with spectacles. Likewise, participants wearing spectacles reported activity limitations for swimming and playing outdoor sports. Many participants reported

inconveniences handling spectacles or contact lenses. Similarly, participants wearing contact lenses or those who underwent refractive surgery reported concerns about short- and long-term complications, and reported more ocular-comfort symptoms.

The second qualitative study was conducted in Nepal[63] to address the limitations of the first qualitative study, particularly because the Australian study did not have participants with URE. In addition, I wanted to explore the refractive error-specific QoL issues in a low-income country setting. 101 participants with refractive error, including 47 participants with URE, were interviewed in Nepal.

Interestingly, many of the QoL issues in uncorrected and corrected refractive error groups were similar although mechanism and extent might vary. For example, participants with URE had difficulty playing sports due to having poor vision. Whereas, the participants wearing spectacles had difficulty playing sports due to fogging up of spectacle lenses or spectacles constantly slipping down the nose.

Activity limitations, visual symptoms and economic impact were more frequently reported by URE. Whereas, most of the inconveniences were reported by spectacles and contact lens wearers. Health concerns were more often reported by the people wearing contact lenses or those who considered having refractive surgery. Many spectacle wearers reported that they use contact lenses for social occasions only to address social impact of wearing spectacles.

Findings from both the studies highlighted that the QoL impact of refractive error was multidimensional.[14, 63] Interesting similarities and differences in QoL issues in refractive sub-groups were observed in both the studies. Most of the symptoms identified in both the settings were similar. Overall, the findings emphasized tailoring refractive error services to individual, environmental, socio-economic and cultural characteristics. The qualitative studies were instrumental in identifying content for the refractive error-specific item banks that was described in detail in Chapter 5.

The Chapter 5 described the multi-phase content identification process of the item banks. Item refinement process and cognitive interviews resulted into two item pools for Australia and Nepal, with 443 and 392 items respectively (337 and 308 unique items respectively). The items were extracted from the existing literature (existing questionnaires and grey literature), the QIRC development item-pool, and the qualitative studies conducted in Australia and in Nepal (described in Chapter 4) The decision on selection of items and domains were made with expert panel consensus using systematic criteria.

Chapter 6 described the psychometric assessment of the Item-pool (Nepal). 13 final item banks with 366 items were constructed using Rasch analysis. The original Coping domain had sub-optimal psychometric properties that could not be repaired using Rasch analysis, and therefore was dropped at this stage. Similarly, general symptoms and ocular-comfort symptoms were combined to form comfort symptoms for all (frequency, severity and bothersome) attributes.

In general, the final item banks (n = 13) had satisfactory psychometric properties. The response categories were ordered, and the thresholds advanced monotonically in all item banks. Measurement precision and item fit statistics were satisfactory. Likewise, measurement range was mostly satisfactory for all item banks. However, most of the item banks suffered from poor targeting. Targeting is a sample dependent parameter which may be improved in Phase III and Phase IV by collecting more data from people with more QoL issues or with more visual impairment.[71] New items may also be added to the item banks and calibrated with reference to the existing items. Similarly, some items in each item banks had differential item functioning by some demographical or clinical characteristics. This may also be addressed by group-wise calibrations for those items in the CAT algorithms.

There is no universally accepted method of establishing unidimensionality.[106] In fact, an absolute unidimensionality is not possible.[406] In this study, essential unidimensionality (acceptable for the data) was established by considering multiple indicators of dimensionality (PCA variance explained by the measure, eigen-value of the first contrast, disattenuated correlation between first contrast and second cluster of items, ratio between variance explained by the items to variance explained by the first contrast, and above all – meaningfulness of the construct (conceptual meaning of the items), in combination. Based on the eigen-value of the first contrast, Convenience, Activity limitation, Health concerns, and Economic scales had indications of having secondary dimensions. Since item banks contain a large number of items with a wide range of ability levels, the assumption of unidimensionality may be violated to some extent. For strict unidimensional measures, high number of narrow measures may need to be developed, which is against the ethos of the item banking. Nevertheless, the refractive error-specific item banks were essentially unidimensional. On the whole, refractive error-specific item banks demonstrated promising psychometric properties for comprehensive and scientific measurement of refractive error-specific QoL.

Chapter 7 described an evaluation on performance of the item banks. The Convenience, Health concerns, Economic, Emotional and Social item banks had only mild correlations with other item banks. Whereas, Activity limitation, Mobility and Symptoms item banks had moderate correlation with one or more item banks. Correlation and agreement between symptom subscales (frequency,

severity or bothersome attributes) of visual and comfort symptoms was high. Therefore, there may be little added value in measuring all three attributes for symptom domains. Either frequency, severity or bothersome attribute of symptoms may be selected based on the purpose of measurement. Nevertheless, the frequency, severity and bothersome subscales of visual symptoms and comfort symptoms could form independent valid scales.

CAT simulation revealed that the average number of items to be administered from each item bank for achieving high and moderate precision were 9.67 ± 1.55 and 4.97 ± 1.08, respectively. High correlations (> 0.96) between the CAT simulations with the full item-banks indicated an efficient and successful application of the real CAT system in the next phases.

Chapter 7 also described the comprehensive evaluation of QoL impact in various refractive error sub-groups by demographics and clinical characteristics. The broad analysis on QoL impact of refractive error and corrections may be important and immediately useful for researchers, policy makers, clinicians and refraction service providers such as NGOs. Weak or non-statistically significant correlation between item bank scores with visual acuity and magnitude of refractive error demonstrated additional value of measuring PROs in refractive error. Similar to qualitative studies (Chapter 4), findings from this chapter also highlighted that refractive correction may not always address all QoL issues of URE. In general, refractive surgery participants had more favourable QoL status than spectacle wearers and contact lens wearers. The findings also demonstrated good known-group validity of the item banks by differentiating clinically significant groups. As the bivariate analysis was done, the role of confounders was not explored. Therefore, caution should be taken while interpreting the findings. The findings may be particularly useful for hypotheses derivation for future QoL studies in refractive error.

8.1.1 Strengths of the doctoral study

This doctoral study is a milestone towards accurately measuring QoL implication of refractive error and presbyopia that affect billions of people worldwide. The impetus behind this study was the understanding that measuring PROs in refractive error is important, and measuring them correctly is even more important. It is now indisputable that robust instruments may complement clinical measures in measuring impact and outcomes of refractive error or correction, as the clinical measures may not represent day-to-day issues of people. This is one of the reasons why PROs are nowadays increasingly gaining attention. Item banking administered through CAT system can address the limitations of the existing PRO instruments.

Each stage of this doctoral study in the development of refractive error item banks had several strengths. The systematic reviews conducted in Phase I identified all the existing PRO instruments

in refractive error. The need for a comprehensive and scientifically robust PRO instrument in refractive error was identified. The Quality assessment of the existing PRO instruments will guide the selection of appropriate PRO instrument in refractive error until the item banks and CAT system are readily available. Similarly, the two qualitative studies conducted in Phase I were probably the first two qualitative studies (published[14, 63]) to evaluate the comprehensive impact of refractive error on QoL of adults. The first qualitative study conducted in high-resource setting (Australia) qualitatively explored the QoL issues in refractive correction. The second qualitative study conducted in a low-income country setting (Nepal) qualitatively explored the QoL issues in people with refractive error, with and without correction. Both the studies identified a myriad of ways how refractive error may impact on people's QoL. Since refractive error and presbyopia affect billions of people worldwide, the findings may have high public health impact, and may be useful to improve refraction services globally.

The second phase of this study established 13 refractive error-specific item banks. Use of Rasch analysis for item-calibrations is one of the major strengths of this study. As discussed extensively in Chapter 2, Rasch analysis is based on a sound measurement philosophy. Several quality control mechanisms in Rasch analysis have ensured that the item banks are valid and functional for measuring refractive error-specific QoL parameters.

This doctoral study is particularly important as the CAT system can only perform well if content of the item banks is derived well. Standard protocol for developing a PRO instrument, including in-depth patient consultation, systematic review of literature, content extraction and refinement, and robust psychometric assessment, were carried out to develop the item-banks. The final item banks were used to comprehensively evaluate refractive error-specific QoL across various refractive error-sub groups. The psychometric assessment, CAT simulation and validation of the final item banks indicated successful application of item banking administered through the CAT system in the next phases. However, this must be proven empirically. Since a large amount of data has been collected from both high- and low-income country settings, the final item banks may be applicable to all (low or high) resource settings.

Ultimately, the item-banks will be administered through the validated CAT systems, which will offer many advantages over currently existing paper- and pencil-based PRO instruments such as efficiently administering only the best few items matching item-difficulty with person-ability, and enabling real time measurement of QoL domains.[57] CAT systems have been developed for many other generic or disease-specific health domains, such as pain, activity limitation, mental health. [57, 391, 407] The findings of this doctoral study indicate successful application of item banking administered through the CAT system.

8.1.2 Limitations of the doctoral study

This study had some limitations. As discussed in Chapter 1, children were not included in this study. The measurement of QoL in children is more complex, and often the QoL issues of children and adults are not easily comparable. A separate similar exercise has to be carried out to construct refractive error-specific item banks for children in the future.

Phase I qualitative study in Australia did not have participants with URE. This is despite the fact that URE is one of the most common causes of visual impairment also in the low resource settings of high-income countries such as Australia.[14, 296, 382] This limitation was one of the impetus of conducting a second qualitative study in Nepal.

Poor targeting for most of the item-banks, high eigen-values for Activity limitation, Convenience, Health concerns, and Economic item banks, and notable differential item-functioning were some of the limitations on psychometric properties of the final item-banks. However, targeting is a sample-dependent parameter, and can be improved in next phases of the study.[71] Similarly, the DIF can be addressed by using groups-specific calibrations (separate coding for groups with DIF items) while developing the CAT algorithms. Overall, all item banks had satisfactory psychometric properties.

The sampling strategy employed for Phase II had limitations, particularly on evaluating QoL parameters across refractive error sub-groups. The number of participants in some groups (e.g. refractive surgery, contact lenses) were less than in other groups (e.g. spectacles). This precluded from conducting a multivariate analysis. However, the primary purpose of this phase was to develop and evaluate the performance of the refractive error item banks rather than to compare outcomes by various sub-groups. The participants from diverse refractive error sub-groups were recruited in order to make the item-calibrations as generalizable and widely-applicable as possible to the entire spectrum of refractive error. Although the sample perhaps closely represents a clinical population, this study was not free from selection bias. The participants who volunteered might have had better or worse QoL status than the others.[157, 408] However, this bias was likely to be random.

It is also important to note that although an item bank consists of a large number of items, it is only a small subset of possible items to measure a latent trait. We might have missed out some QoL issues important to people with refractive error. For example, as we did not have participants with unilateral refractive error, their specific issues might have been missed. Similarly, some items may become outdated with time. Therefore, generalisation may be an issue, like any other PRO instruments. However, an item bank is a flexible PRO instrument; new content can be added and calibrated with respect to the existing items.[57] In addition, as the trait levels can be estimated from

any subsets of items in a continuum, we could still measure impact of refractive error in unilateral refractive error.[74, 102] With participants from a diverse demographical and clinical spectrum of refractive error, it can be hoped that the items will be relevant to people with refractive error in diverse settings. In addition, few items that are directly related to pathophysiology of refractive error (e.g. symptoms) may be common in all settings as found in the qualitative studies (Chapter 4).[14, 63] However, whether the item calibrations will remain the same (within standard errors) for any populations is yet to be proven. After completing the data collection and analysis in Australia, more insights regarding this will be obtained.

8.1.3 Future directions

Results of Phase I and Phase II presented in this thesis justify the continuation of the research strategy. Item banks have been developed and calibrated for Nepal. CAT simulation tests have been conducted. A similar exercise will be carried out with the Australian data, and the comparison will be made. Although two separate sets of item-pools have been developed for Australia and Nepal, the possibility of combining these item pools into common item banks will be explored by using techniques such as common item linking and item-anchoring after the data collection in Australia is completed, post-PhD.[112, 409-411]

Linking item banks (Nepal and Australia) can be done either by concurrent calibration, or by separate calibration and linking (i.e. mapping the item banks) methods.[112, 409-411]The DIF assessment can be done if some common items perform differently in two settings. A separate Rasch analysis with responses pooled together for the common items in Item-pool (Australia) and Item-pool (Nepal) may allow us to investigate the possibility of having a single PRO instrument sensitive to both high-income country and low- and middle-income country settings, or in high or low resource settings. Thus, number and content of the item banks will be finalized after collecting the Phase II data for Item-pool (Australia). Finally, algorithms will be developed to program the item bank calibrations into a CAT system.[412] The algorithms will include rules for item selection, scoring and termination of the test.[412, 413]

In Phase III and Phase IV, the CAT systems will be evaluated in real data. In Phase III, the item banks will be administered to people with refractive error and people without any eye conditions using the CAT system for validation. The responses will be directly entered in the CAT -application in an iPad or through a web-based application. Different types of validity and reliability assessments (construct validity, discriminant validity, convergent validity, known-group validity, criterion validity and test-retest reliability) will be made. The convergent validity of the CAT system with the existing superior quality PRO instruments (the QIRC[28] and the QoV[33]) will also be tested.

The test-retest reliability of the CAT system will also be investigated by re-collecting data from a subset of participants at one-month interval.[30] Similarly, in Phase IV, sensitivity and responsiveness of the validated CAT system will be evaluated. Using a normative data, thresholds for low, moderate and severe impact of refractive error on QoL parameters will be established.[30] In the long run, strategies will be implemented to make it available to the researchers and clinicians.

In the CAT system, first the item with average latent trait level (e.g. item with average difficulty level from Activity limitation domain) is administered (Figure 7.3). The next item to administer depends upon the response to the first item (e.g. if the first item administered from the Activity limitation domain was answered as 'Not difficult', an item with higher difficulty level will be administered next). The step size is specified in the algorithm.[74] Only the relevant items are administered to the persons according to their position on the latent trait continuum.[57] Different subsets of items may be administered based on the trait level at the time of measurement. Precise measurement can be achieved with relatively fewer items.

Although different sets of items are administered to different groups of people, the results can be compared as the items share common calibrations. After the CAT is administered to a large number of people, the data can be pooled together to re-calibrate the item banks. Any changes in time can be addressed, and as the data quality is higher (as opposed to while administering the whole item pools in Phase II), more stable calibrations may be made. Continuous qualitative studies may be required to ensure that the content is relevant and is of high quality. New content may be added and calibrated with respect to the existing item calibrations as required.[391]

There is no doubt about the usefulness of incorporating patients' perspectives in routine clinical practice through the use of PRO instruments. A number of uses of PRO instruments, such as enhance clinical decision making (e.g. Which group of spectacles or contact lenses wearers should be targeted to refractive surgery?') along with the primary purpose of incorporating patient-perspectives in refractive error care, were discussed in detail in Chapter 3. However, PROs are not routinely collected in refractive error care due to the short-comings of the existing paper- and pencil-based questionnaires. Development of the item banks is the beginning for bringing routine collection of PROs in clinics into reality. Unlike paper-based questionnaires, item banks administered through CAT system can provide real-time efficient measurement which enables consideration of acute patient needs in clinical practice. From real time measurement, patients can be immediately advised based on their scores. CAT data can be added to the patient's electronic records. It also reduces history taking time during consultation. In addition, CAT system can be a useful tool to monitor change in PROs over time.

However, there are several challenges in implementing item banking with CAT system. Data privacy and security is a concern. Interdisciplinary efforts are required for successful implementation of CAT in research and clinical practice. We should work with researchers, clinicians, administrators (e.g. hospital administration for incorporating CAT data into electronic health recording system) and programmers. Storage of large amount of data maintaining confidentiality is crucial. Item banking is a long and resource intensive process. Cost and technology required for implementing item banking and CAT system, particularly in low-resource areas, may be another challenge. However, with a rapid advancement in technology which is driving the cost down, this could in fact be an opportunity rather than a barrier.

Although the usefulness of item banking and CAT system have a sound science, demonstrated to some extent by the findings, success of the CAT system in real-life for refractive error is yet to be observed. This is complex, as in existing PRO instruments, due to the heterogeneity of refractive error. A common item bank with items across all sub-groups may decrease sensitivity of the scale as many participants may endorse 'Not applicable' option for the issues not relevant to them. For example, many items related to handling spectacles and contact lenses will be endorsed as 'Not applicable' by people with URE or pre-presbyopic surgical emmetropes. This limitation could be addressed by coding the items by sub-groups while developing the CAT system so that the group-specific non-relevant items are not administered to individuals.[391, 407] Another useful feature of item-banking is that usually there are more than one item for similar trait level; if 'Not applicable' option is endorsed, another item with similar item measure may be administered.[106]

In summary, the findings from this doctoral study demonstrated promising features of the refractive error-specific item banks. The final instruments, once CAT is available, will provide researchers, refraction service providers (e.g. clinicians, non-governmental organisations) and policy planners with high quality, psychometrically robust methods to assess the impact of refractive error on QoL from patients' perspective. QoL is the most important outcome in refractive error like in any health care intervention. Accurate PRO measurement is the foundation for assessing, monitoring, evaluating and improving QoL. This doctoral study therefore may contribute to enhance the refraction services to the billions of people with refractive error and presbyopia worldwide. However, usefulness of the item banks administered through a CAT system in measuring real-life PRO data in refractive error is yet to be observed. This study may also be a reference document for the development of PRO instruments in other areas of health.

References

1. Lee J, Lee J, Park K, Cho W, Kim JY, Kang HY. Assessing the value of laser in situ keratomileusis by patient-reported outcomes using quality-of-life assessment. *J Refract Surg*. 2005;21(1):59-71.
2. Dandona R, Dandona L. Refractive error blindness. *Bull World Health Organ*. 2001;79:237-43.
3. Naidoo KS, Wallace DB, Holden BA, Minto H, Faal HB, Dube P. The challenge of uncorrected refractive error: driving the agenda of the Durban Declaration on refractive error and service development. *Clin Exp Optom*. 2010;93(3):131-6.
4. Flaxman SR, Bourne RR, Resnikoff S, Ackland P, Braithwaite T, Cicinelli MV*, et al.* Global causes of blindness and distance vision impairment 1990–2020: a systematic review and meta-analysis. *Lancet Glob Health*. 2017;5(12):e1221-34.
5. Bourne RRA, Stevens GA, White RA, Smith JL, Flaxman SR, Price H*, et al.* Causes of vision loss worldwide, 1990–2010: a systematic analysis. *Lancet Glob Health*. 2013;1(6):e339-49.
6. Naidoo KS, Leasher J, Bourne RR, Flaxman SR, Jonas JB, Keeffe J*, et al.* Global vision impairment and blindness due to uncorrected refractive error, 1990–2010. *Optom Vis Sci*. 2016;93(3):227-34.
7. Bourne RRA, Flaxman SR, Braithwaite T, Cicinelli MV, Das A, Jonas JB*, et al.* Magnitude, temporal trends, and projections of the global prevalence of blindness and distance and near vision impairment: a systematic review and meta-analysis. *Lancet Glob Health*. 2017.
8. Naidoo KS, Jaggernath J. Uncorrected refractive errors. *Indian J Ophthalmol*. 2012;60(5):432-7.
9. Lou L, Yao C, Jin Y, Perez V, Ye J. Global patterns in health burden of uncorrected refractive error. *Invest Ophthalmol Vis Sci*. 2016;57(14):6271-7.
10. World Health Organization. International statistical classification of diseases and related health problems, tenth revision (ICD-10). Geneva: World Health Organization, 2016. [Accessed on 04 June 2018]. Available from: http://apps.who.int/classifications/icd10/browse/2016/en#/H49-H52.
11. Sakimoto T, Rosenblatt MI, Azar DT. Laser eye surgery for refractive errors. *Lancet*. 2006;367(9520):1432-47.
12. Brady CJ, Keay L, Villanti A, Ali FS, Gandhi M, Massof RW*, et al.* Validation of a Visual Function and Quality of Life instrument in an urban Indian population with uncorrected refractive error using Rasch analysis. *Ophthalmic Epidemiol*. 2010;17(5):282-91.
13. Thompson S, Naidoo K, Gonzalez-Alvarez C, Harris G, Chinanayi F, Loughman J. Barriers to use of refractive services in Mozambique. *Optom Vis Sci*. 2015;92(1):59.
14. Kandel H, Khadka J, Goggin M, Pesudovs K. Impact of refractive error on quality-of-life: a qualitative study. *Clin Exp Ophthalmol*. 2017;45(7):677-88.
15. Kandel H, Khadka J, Lundström M, Goggin M, Pesudovs K. Questionnaires for measuring refractive surgery outcomes. *J Refract Surg*. 2017;33(6):416-24.
16. Kandel H, Khadka J, Goggin M, Pesudovs K. Patient-reported outcomes for assessment of quality-of-life in refractive error: a systematic review. *Optom Vis Sci*. 2017;94(12):1102-19.
17. McDonnell PJ, Lee P, Spritzer K, Lindblad AS, Hays RD. Associations of presbyopia with vision-targeted health-related quality-of-life. *Arch Ophthalmol*. 2003;121(11):1577-81.
18. Khadka J, McAlinden C, Pesudovs K. Quality assessment of ophthalmic questionnaires: review and recommendations. *Optom Vis Sci*. 2013;90(8):720-44.
19. Meidani A, Tzavara C, Dimitrakaki C, Pesudovs K, Tountas Y. Femtosecond laser-assisted LASIK improves quality-of-life. *J Refract Surg*. 2012;28(5):319-26.
20. Pesudovs K, Hazel C, Doran R, Elliott DB. The usefulness of Vistech and FACT contrast sensitivity charts for cataract and refractive surgery outcomes research. *Br J Ophthalmol*. 2004;88(1):11-6.
21. Vestergaard AH, Grauslund J, Ivarsen AR, Hjortdal JØ. Efficacy, safety, predictability, contrast sensitivity, and aberrations after femtosecond laser lenticule extraction. *J Cataract Refract Surg*. 2014;40(3):403-11.
22. Pesudovs K. Patient-centred measurement in ophthalmology – a paradigm shift. *BMC Ophthalmol*. 2006;6(1):1-4.
23. Pesudovs K. Item banking: a generational change in patient-reported outcome measurement. *Optom Vis Sci*. 2010;87(4):285-93.
24. Denniston A, Kyte D, Calvert M, Burr J. An introduction to patient-reported outcome measures in ophthalmic research. *Eye*. 2014;28(6):637-45.
25. US Department of Health for Drug Human Services FDA Centre for Drug Evaluation and Research, US Department of Health and Human Services FDA Center for Biologics Evaluation and Research, US Department of Health and Human Services FDA Center for Devices and Radiological Health. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: draft guidance. *Health Qual Life Outcomes*. 2006;4:79.

References: 256

26. Pesudovs K, Burr JM, Harley C, Elliott DB. The development, assessment, and selection of questionnaires. *Optom Vis Sci*. 2007;84(8):663-74.
27. Pesudovs K, Garamendi E, Elliott D. A quality-of-life comparison of people wearing spectacles or contact lenses or having undergone refractive surgery. *J Refract Surg*. 2006;22(1):19-27.
28. Pesudovs K, Garamendi E, Elliott DB. The Quality of Life Impact of Refractive Correction (QIRC) questionnaire: development and validation. *Optom Vis Sci*. 2004;81(10):769-77.
29. Khadka J, McAlinden C, Craig JE, Fenwick EK, Lamoureux EL, Pesudovs K. Identifying content for the glaucoma-specific item bank to measure quality-of-life parameters. *J Glaucoma*. 2015;24(1):12-9.
30. Khadka J, Fenwick E, Lamoureux EL, Pesudovs K. Methods to develop the Eye-tem Bank to measure ophthalmic quality-of-life. *Optom Vis Sci*. 2016;93(12):1485-94.
31. Fenwick EK, Pesudovs K, Khadka J, Rees G, Wong TY, Lamoureux EL. Evaluation of item candidates for a diabetic retinopathy quality-of-life item bank. *Qual Life Res*. 2013;22(7):1851-8.
32. Khadka J, Fenwick EK, Lamoureux EL, Pesudovs K. Item banking enables stand-alone measurement of driving ability. *Optom Vis Sci*. 2016;93(12):1502-12.
33. McAlinden C, Pesudovs K, Moore JE. The development of an instrument to measure quality of vision: the Quality of Vision (QoV) questionnaire. *Invest Ophthalmol Vis Sci*. 2010;51(11):5537-45.
34. Buckhurst PJ, Wolffsohn JS, Gupta N, Naroo SA, Davies LN, Shah S. Development of a questionnaire to assess the relative subjective benefits of presbyopia correction. *J Cataract Refract Surg*. 2012;38(1):74-9.
35. Berry S, Mangione CM, Lindblad AS, McDonnell PJ, Investigators N-RFG. Development of the National Eye Institute Refractive error correction Quality of Life questionnaire: focus groups. *Ophthalmology*. 2003;110(12):2285-91.
36. Hays RD, Mangione CM, Ellwein L, Lindblad AS, Spritzer KL, McDonnell PJ*, et al.* Psychometric properties of the National Eye Institute - Refractive error Quality of Life instrument. *Ophthalmology*. 2003;110(12):2292-301.
37. Schein OD. The measurement of patient-reported outcomes of refractive surgery: the Refractive Status and Vision Profile. *Trans Am Ophthalmol Soc*. 2000;98:439-69.
38. Vitale S, Schein OD, Meinert CL, Steinberg EP. The Refractive Status and Vision Profile: a questionnaire to measure vision-related quality-of-life in persons with refractive error. *Ophthalmology*. 2000;107(8):1529-39.
39. Brunette I, Gresset J, Boivin JF, Pop M, Thompson P, Lafond GP*, et al.* Functional outcome and satisfaction after photorefractive keratectomy. Part 2: survey of 690 patients. *Ophthalmology*. 2000;107(9):1790-6.
40. Brunette I, Gresset J, Boivin J-F, Boisjoly H, Makni H. Functional outcome and satisfaction after photorefractive keratectomy. Part 1: Development and validation of a survey questionnaire. *Ophthalmology*. 2000;107(9):1783-9.
41. Bourque LB, Cosand BB, Drews C, Waring GO, Lynn M, Cartwright C. Reported satisfaction, fluctuation of vision, and glare among patients one year after surgery in the Prospective Evaluation of Radial Keratotomy (PERK) study. *Arch Ophthalmol*. 1986;104(3):356-63.
42. Fraenkel G, Comaish l F, Lawless MA, Kelly MR, Dunn SM, Byth K*, et al.* Development of a questionnaire to assess subjective vision score in myopes seeking refractive surgery. *J Refract Surg*. 2004;20(1):10-9.
43. Erickson DB, Stapleton F, Erickson P, du Toit R, Giannakopoulos E, Holden B. Development and validation of a multidimensional quality-of-life scale for myopia. *Optom Vis Sci*. 2004;81(2):70-81.
44. Sukhawarn R, Wiratchai N, Tatsanavivat P, Pitiyanuwat S, Kanato M, Srivannaboon S*, et al.* Development of a Refractive Error Quality-of-life scale for Thai adults (the REQ-Thai). *J Med Assoc Thai*. 2011;94(8):978-84.
45. Berdeaux G, Meunier J, Arnould B, Viala-Danten M. Measuring benefits and patients' satisfaction when glasses are not needed after cataract and presbyopia surgery: scoring and psychometric validation of the Freedom from Glasses Value Scale (FGVS©). *BMC Ophthalmol*. 2010;10:15.
46. Pesudovs K, Garamendi E, Elliott D. The Contact Lens Impact on Quality of Life (CLIQ) Questionnaire: development and validation. *Invest Ophthalmol Vis Sci*. 2006;47(7):2789-96.
47. Begley CG, Caffery B, Nichols KK, Chalmers R. Responses of contact lens wearers to a dry eye survey. *Optom Vis Sci*. 2000;77(1):40-6.
48. Walline JJ, Jones LA, Chitkara M, Coffey B, Jackson JM, Manny RE*, et al.* The Adolescent and Child Health Initiative to Encourage Vision Empowerment (ACHIEVE) study design and baseline data. *Optom Vis Sci*. 2006;83(1):37-45.

49. Crescioni M, Messer DH, Warholak TL, Miller JM, Twelker JD, Harvey EM. Rasch analysis of the Student Refractive Error and Eyeglass Questionnaire. *Optom Vis Sci*. 2014;91(6):624-33.
50. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL*, et al.* The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res*. 2010;19(4):539-49.
51. Kandel H, Khadka J, Shrestha M, Kaiti R, Dhungana P, Poudel R*, et al.* Living experiences of people with refractive error – a qualitative study from Nepal. *Invest Ophthalmol Vis Sci*. 2017;58(8):3420.
52. Begley CG, Chalmers RL, Mitchell GL, Nichols KK, Caffery B, Simpson T*, et al.* Characterization of ocular surface symptoms from optometric practices in North America. *Cornea*. 2001;20(6):610-8.
53. Levy P, Elies D, Dithmer O, Gil-Campos I, Benmedjahed K, Berdeaux G*, et al.* Development of a new subjective questionnaire: the Freedom from Glasses Value Scale (FGVS). *J Refract Surg*. 2010;26(6):438-46.
54. Patel I, Munoz B, Burke AG, Kayongoya A, McHiwa W, Schwarzwalder AW*, et al.* Impact of presbyopia on quality-of-life in a rural African setting. *Ophthalmology*. 2006;113(5):728-34.
55. Hays RD, Tarver ME, Spritzer KL, Reise S, Hilmantel G, Hofmeister EM*, et al.* Assessment of the psychometric properties of a questionnaire assessing Patient-Reported Outcomes With Laser In Situ Keratomileusis (PROWL). *JAMA Ophthalmol*. 2017;135(1):3-12.
56. Morlock R, Wirth RJ, Tally SR, Garufis C, Heichel CW. Patient-Reported Spectacle Independence Questionnaire (PRSIQ): development and validation. *Am J Ophthalmol*. 2017.
57. Fenwick EK, Khadka J, Pesudovs K, Rees G, Wong TY, Lamoureux EL. Diabetic retinopathy and macular edema quality-of-life item banks: development and initial evaluation using computerized adaptive testing. *Invest Ophthalmol Vis Sci*. 2017;58(14):6379-87.
58. Cella D, Gershon R, Lai J-S, Choi S. The future of outcomes measurement: item banking, tailored short-forms, and computerized adaptive assessment. *Qual Life Res*. 2007;16(1):133-41.
59. Paz SH, Spritzer KL, Reise SP, Hays RD. Differential item functioning of the patient-reported outcomes information system (PROMIS®) pain interference item bank by language (Spanish versus English). *Qual Life Res*. 2017;26(6):1451-62.
60. Gruber-Baldini AL, Velozo C, Romero S, Shulman LM. Validation of the PROMIS® measures of self-efficacy for managing chronic conditions. *Qual Life Res*. 2017;26(7):1915-24.
61. Gershon R, Rothrock N, Hanrahan R, Bass M, Cella D. The use of PROMIS and assessment center to deliver patient-reported outcome measures in clinical research. *J Appl Meas*. 2010;11:304-14.
62. DeWalt DA, Rothrock N, Yount S, Stone AA, Group PC. Evaluation of item candidates: the PROMIS qualitative item review. *Med Care*. 2007;45(5 Suppl 1):S12-21.
63. Kandel H, Khadka J, Shrestha M, Sharma S, Neupane Kandel S, Dhungana P*, et al.* Uncorrected and corrected refractive error experiences of Nepalese adults: a qualitative study. *Ophthalmic Epidemiol*. 2018;25(2):147-61.
64. Human Development Report 2014 Team. Human Development Report 2014: sustaining human progress-reducing vulnerabilities and building resilience. New York: 2014. [Accessed on 27 March 2017]. Available from: http://hdr.undp.org/sites/default/files/hdr14-summary-en.pdf.
65. Thompson P. Thesis and dissertation writing. In: Paltridge B, Starfield S, editors. The handbook of English for specific purposes. West Sussex, UK: Wiley-Blackwell; 2013, p 283-99.
66. Paltridge B. Thesis and dissertation writing: an examination of published advice and actual practice. *English for Specific Purposes*. 2002;21(2):125-43.
67. Massof RW, Rubin GS. Visual function assessment questionnaires. *Surv Ophthalmol*. 2001;45(6):531-48.
68. Massof R. The measurement of vision disability. *Optom Vis Sci*. 2002;79(516-52).
69. Gothwal VK, Wright TA, Lamoureux EL, Pesudovs K. Multiplicative rating scales do not enable measurement of vision-related quality of life. *Clin Exp Optom*. 2011;94(1):52-62.
70. Bond T, Fox CM. A synthetic review. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 296-324.
71. McAlinden C, Skiadaresi E, Moore J, Pesudovs K. Subscale assessment of the NEI-RQL-42 questionnaire with Rasch analysis. *Invest Ophthalmol Vis Sci.* 2011;52(8):5685-94.
72. Petrillo J, Cano SJ, McLeod LD, Coon CD. Using classical test theory, item response theory, and Rasch measurement theory to evaluate patient-reported outcome measures: a comparison of worked examples. *Value Health*. 2015;18(1):25-34.
73. Lamoureux E, Pesudovs K. Vision-specific quality-of-life research: a need to improve the quality. *Am J Ophthalmol*. 2011;151(2):195.

74. Hays RD, Morales LS, Reise SP. Item response theory and health outcomes measurement in the 21st century. *Med Care*. 2000;38(9 Suppl):II28-II42.
75. Bond T, Fox CM. Invariance: a crucial property of scientific measurement. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 83-111.
76. Bond T, Fox CM. Rasch model requirements: model fit and unidimensionality. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 265-95.
77. Kandel H, Khadka J, Pesudovs K. Intensive blood-pressure treatment and patient-reported outcomes. *N Engl J Med*. 2017;377(21):2096-7.
78. Zanon C, Hutz CS, Yoo HH, Hambleton RK. An application of item response theory to psychological test development. *Psicologia: Reflexão e Crítica*. 2016;29(1):18.
79. Bond T, Fox CM. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015.
80. Kuo T-C, Sheng Y. A comparison of estimation methods for a multi-unidimensional Graded Response IRT Model. *Front Psychol*. 2016;7.
81. Michel M, Sickenberger W, Pult H. The effectiveness of questionnaires in the determination of contact lens induced dry eye. *Ophthalmic Physiol Opt*. 2009;29(5):479-86.
82. Queirós A, Villa-Collar C, Gutiérrez AR, Jorge J, González-Méijome JM. Quality-of-life of myopic subjects with different methods of visual correction using the NEI RQL-42 questionnaire. *Eye Contact Lens*. 2012;38(2):116-21.
83. Linacre JM. Rasch Model estimation: further topics. *J Appl Meas*. 2004;5(1):95-110.
84. Rasch G. Probabilistic models for some intelligence and attainment tests. Copenhagen: Danmarks Paedagogiske Institut1960.
85. Bond T, Fox CM. Basic principles of the Rasch model. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 36-59.
86. Bond T, Fox CM. Why measurement is fundamental. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 1-18.
87. Grimby G, Tennant A, Tesio L. The use of raw scores from ordinal scales: time to end malpractice? *J Rehabil Med*. 2012;44(2):97-8.
88. Tesio L, Simone A, Bernardinello M. Rehabilitation and outcome measurement: where is Rasch analysis-going? *Europa medicophysica*. 2007;43(3):417-26.
89. Gothwal VK, Bharani S, Kekunnaya R, Chhablani P, Sachdeva V, Pehere NK*, et al.* Measuring health-related quality-of life in Strabismus: a modification of the Adult Strabismus-20 (AS-20) questionnaire using Rasch analysis. *PLoS One*. 2015;10(5):e0127064.
90. Gothwal VK, Wright TA, Elliott DB, Pesudovs K. The Refractive Status and Vision Profile: Rasch analysis of subscale validity. *J Refract Surg*. 2010;26(11):912-5.
91. Bond T, Fox CM. Measurement using Likert scales. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 112-39.
92. Bond T, Fox CM. Measuring facets beyond ability and difficulty. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 166-86.
93. Latham K, Baranian M, Timmis M, Pardhan S. Emotional health of people with visual impairment caused by Retinitis Pigmentosa. *PLoS One*. 2015;10(12):e0145866.
94. Andrich D. Controversy and the Rasch model: a characteristic of incompatible paradigms? *Medical care*. 2004:I7-I16.
95. Fenwick EK, Man RE, Rees G, Keeffe J, Wong TY, Lamoureux EL. Reducing respondent burden: validation of the brief Impact of Vision Impairment questionnaire. *Qual Life Res*. 2017;26(2):479-88.
96. Massof RW, Ahmadian L, Grover LL, Deremeik JT, Goldstein JE, Rainey C*, et al.* The Activity Inventory: an adaptive visual function questionnaire. *Optom Vis Sci*. 2007;84(8):763-74.
97. Bond T, Fox CM. The Partial Credit Rasch model. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 140-65.
98. Andrich D. A rating formulation for ordered response categories. *Psychometrika*. 1978;43(4):561-73.

99. Bond T, Fox CM. Rasch modeling applied: Rating scale design. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 245-64.
100. Yan Z, Stone G, Betltyukova S. Making measures, setting standards, and Rasch regression. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 187-225.
101. Pesudovs K. Influence of refractive surgery complications on quality-of-life. In: Alio JL, Azar DT, editors. Management of complications in refractive surgery. 2nd ed. Germany: Springer; 2018, p 9-13.
102. Teresi JA, Ramirez M, Jones RN, Choi S, Crane PK. Modifying measures based on differential item functioning (DIF) impact analyses. *J Aging Health*. 2012;24(6):1044-76.
103. Khadka J, Gothwal VK, McAlinden C, Lamoureux EL, Pesudovs K. The importance of rating scales in measuring patient-reported outcomes. *Health Qual Life Outcomes*. 2012;10(1):1.
104. Khadka J, McAlinden C, Gothwal VK, Lamoureux EL, Pesudovs K. The importance of rating scale design in the measurement of patient-reported outcomes using questionnaires or item banks. *Invest Ophthalmol Vis Sci*. 2012;53(7):4042-54.
105. Latham K, Baranian M, Timmis MA, Fisher A, Pardhan S. Relative difficulties of daily living tasks with Retinitis Pigmentosa. *Optom Vis Sci*. 2017;94(3):317-28.
106. Velozo CA, Seel RT, Magasi S, Heinemann AW, Romero S. Improving measurement methods in rehabilitation: core concepts and recommendations for scale development. *Arch Phys Med Rehabil*. 2012;93(8):S154-S63.
107. Bjorner JB, Bech P. Modern psychometric approaches to analysis of scales for health-related quality-of-life. In: Awad AG, Voruganti L, editors. Beyond assessment of quality-of-life in Schizophrenia. Switzerland: Springer; 2016, p 103-20.
108. Pesudovs K, Wright TA, Gothwal VK. Visual disability assessment: valid measurement of activity limitation and mobility in cataract patients. *Br J Ophthalmol*. 2010;94(6):777-81.
109. McAlinden C, Khadka J, Pesudovs K. Statistical methods for conducting agreement (comparison of clinical tests) and precision (repeatability or reproducibility) studies in optometry and ophthalmology. *Ophthalmic Physiol Opt*. 2011;31(4):330-8.
110. Bland JM, Altman DG. Comparing methods of measurement: why plotting difference against standard method is misleading. *Lancet*. 1995;346(8982):1085-7.
111. Bland JM, Altman D. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet*. 1986;327(8476):307-10.
112. Boone WJ. Rasch analysis for instrument development: why, when, and how? *CBE Life Sci Educ*. 2016;15(4).
113. Linacre J. Winsteps® (Version 3.92.0) Rasch measurement computer program User's Guide. Beaverton, Oregon: Winsteps.com: 2016. [Accessed on 01 January 2016]. Available from: http://www.winsteps.com/.
114. Boone WJ, Staver JR, Yale MS. Rasch analysis in the human sciences: Springer; 2013.
115. Boone WJ, Staver JR, Yale MS. Fit. In: Boone WJ, Staver JR, Yale MS, editors. Rasch analysis in the human sciences. New York / London: Springer Dordrecht Heidelberg; 2013, p 159-90.
116. Khadka J, Ryan B, Margrain TH, Woodhouse JM. Development of the 25-item Cardiff Visual Ability Questionnaire for Children (CVAQC). *Br J Ophthalmol*. 2010;94(6):730-5.
117. Latham K, Baranian M, Timmis MA, Pardhan S. Difficulties with goals of the dutch ICF Activity Inventory: perceptions of those with Retinitis Pigmentosa and of those who support them. *Invest Ophthalmol Vis Sci*. 2015;56(4):2381-91.
118. Bond T, Fox CM. The Rasch model applied across the human science. In: Bond T, Fox CM, editors. Applying the Rasch model: fundamental measurement in the human sciences. 3rd ed. New York: Routledge; 2015, p 226-44.
119. Fricke TR, Tahhan N, Resnikoff S, Papas E, Burnett A, Ho SM*, et al.* Global prevalence of presbyopia and vision impairment from uncorrected presbyopia: systematic review, meta-analysis, and modelling. *Ophthalmology*. 2018.
120. Holden BA, Fricke TR, Wilson DA, Jong M, Naidoo KS, Sankaridurg P*, et al.* Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. *Ophthalmology*. 2016;123(5):1036-42.
121. Anjou MD, Boudville AI, Taylor HR. Correcting Indigenous Australians' refractive error and presbyopia. *Clin Exp Ophthalmol*. 2013;41(4):320-8.
122. Taylor HR, Keeffe JE, Vu H, Wang JJ, Rochtchina E, Pezzullo ML*, et al.* Vision loss in Australia. *Med J Aust*. 2005;182(11):565-8.

123. Schneider J, Leeder SR, Gopinath B, Wang JJ, Mitchell P. Frequency, course, and impact of correctable visual impairment (uncorrected refractive error). *Surv Ophthalmol*. 2010;55(6):539-60.
124. Smith T, Frick K, Holden B, Fricke T, Naidoo K. Potential lost productivity resulting from the global burden of uncorrected refractive error. *Bull World Health Organ*. 2009;87(6):431-7.
125. Fricke T, Holden B, Wilson D, Schlenther G, Naidoo K, Resnikoff S*, et al.* Global cost of correcting vision impairment from uncorrected refractive error. *Bull World Health Organ*. 2012;90(10):728-38.
126. Reddy PA, Congdon N, MacKenzie G, Gogate P, Wen Q, Jan C*, et al.* Effect of providing near glasses on productivity among rural Indian tea workers with presbyopia (PROSPER): a randomised trial. *Lancet Glob Health*. 2018.
127. Morgan IG, Ohno-Matsui K, Saw S-M. Myopia. *Lancet*. 2012;379(9827):1739-48.
128. American Academy of Ophthalmology Refractive Management/Intervention Panel. Preferred practice pattern guidelines. Refractive errors and refractive surgery. San Francisco, CA: American Academy of Ophthalmology, 2013. [Accessed on 01 June 2018]. Available from: www.aao.org/ppp.
129. Katz J, Tielsch JM, Sommer A. Prevalence and risk factors for refractive errors in an adult inner city population. *Invest Ophthalmol Vis Sci*. 1997;38(2):334-40.
130. Wojciechowski R, Congdon N, Bowie H, Munoz B, Gilbert D, West S. Familial aggregation of hyperopia in an elderly population of siblings in Salisbury, Maryland. *Ophthalmology*. 2005;112(1):78-83.
131. Webber AL, Wood J. Amblyopia: prevalence, natural history, functional effects and treatment. *Clin Exp Optom*. 2005;88(6):365-75.
132. Kumaran SE, Khadka J, Baker R, Pesudovs K. Patient-reported outcome measures in amblyopia and strabismus: a systematic review. *Clin Exp Ophthalmol*. 2017.
133. Marr JE, Halliwell-Ewen J, Fisher B, Soler L, Ainsworth J. Associations of high myopia in childhood. *Eye*. 2001;15(1):70-4.
134. Marr J, Harvey R, Ainsworth J. Associations of high hypermetropia in childhood. *Eye*. 2003;17(3).
135. Pascolini D, Mariotti SP. Global estimates of visual impairment: 2010. *Br J Ophthalmol*. 2012;96(5):614-8.
136. Durr NJ, Dave SR, Lage E, Marcos S, Thorn F, Lim D. From unseen to seen: tackling the global burden of uncorrected refractive errors. *Annu Rev Biomed Eng*. 2014;16:131-53.
137. Amos JF, editor. Diagnosis and management in vision care. Oxford, UK: Butterworth-Heinemann; 1987.
138. US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH). Guidance for Industry - patient-reported outcome measures: use in medical product devemopment to support labeling claims. Maryland, USA: Food and Drug Administration, 2009. [Accessed on 04 June 2018]. Available from: https://www.fda.gov/downloads/drugs/guidances/ucm193282.pdf.
139. Tesio L. Quality-of-life measurement: one size fits all. Rehabilitation medicine makes no exception. *J Med Person*. 2009;7(1):5-9.
140. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality-of-life. *Ann Intern Med*. 1993;118(8):622-9.
141. Wirth R, Edwards MC, Henderson M, Henderson T, Olivares G, Houts CR. Development of the Contact Lens User Experience: CLUE Scales. *Optom Vis Sci*. 2016;93(8):801.
142. Tahhan N. Utility and uncorrected refractive error [PhD Thesis]. Sydney, Australia: University of New South Wales; 2013.
143. Gothwal VK, Bagga DK, Rao HL, Bharani S, Sumalini R, Garudadri CS*, et al.* Is utility-based quality of life in adults affected by glaucoma? *Invest Ophthalmol Vis Sci*. 2014;55(3):1361-9.
144. Fenwick E, Pesudovs K, Rees G, Dirani M, Kawasaki R, Wong T*, et al.* The impact of diabetic retinopathy: understanding the patient's perspective. *Br J Ophthalmol*. 2010:bjo. 2010.191312.
145. Reinstein DZ, Carp GI, Pradhan KR, Engelfried C, Archer TJ, Heintz J*, et al.* Role of laser refractive surgery in cross-subsidization of nonprofit humanitarian eyecare and the burden of uncorrected refractive error in Nepal: pilot project. *J Cataract Refract Surg*. 2018:doi: 10.1016/j.jcrs.2018.05.023.
146. Morgan PB, Efron N. Demographics of UK contact lens prescribing. *Cont Lens Anterior Eye*. 2008;31(1):50-1.
147. Morgan PB, Efron N. A decade of contact lens prescribing trends in the United Kingdom (1996–2005). *Cont Lens Anterior Eye*. 2006;29(2):59-68.
148. Hashemi H, Yekta A, Nojomi M, Mohazzab-Torabi S, Behnia B, Khabazkhoob M. Excimer laser refractive surgery rate in Iran: 2010–2014. *J Curr Ophthalmol*. 2017.

149. Ahn JH, Kim DH, Shyn KH. Investigation of the changes in refractive surgery trends in Korea. *Korean J Ophthalmol*. 2018;32(1):8-15.
150. Stapleton F, Keay L, Jalbert I, Cole N. The epidemiology of contact lens related infiltrates. *Optom Vis Sci*. 2007;84(4):257-72.
151. Key JE. Development of contact lenses and their worldwide use. *Eye Contact Lens*. 2007;33(6, Part 2 of 2):343-5.
152. Seet B, Wong TY, Tan DT, Saw SM, Balakrishnan V, Lee LK*, et al.* Myopia in Singapore: taking a public health approach. *Br J Ophthalmol*. 2001;85(5):521-6.
153. Naidoo K, Govender P, Holden B. The uncorrected refractive error challenge. *Community Eye Health*. 2014;27(88):74.
154. Li L, Lam J, Lu Y, Ye Y, Lam DS, Gao Y*, et al.* Attitudes of students, parents, and teachers toward glasses use in rural China. *Archives of ophthalmology*. 2010;128(6):759-65.
155. Holden BA, Fricke TR, Ho SM, Wong R, Schlenther G, Cronjé S*, et al.* Global vision impairment due to uncorrected presbyopia. *Arch Ophthalmol*. 2008;126(12):1731-9.
156. Nowinski CJ, Miller DM, Cella D. Evolution of patient-reported outcomes and their role in multiple sclerosis clinical trials. *Neurotherapeutics*. 2017;14(4):934-44.
157. Ahern S, Ruseckaite R, Ackerman IN. Collecting patient-reported outcome measures. *Intern Med J*. 2017;47(12):1454-7.
158. Lamoureux EL, Pallant JF, Pesudovs K, Rees G, Hassell JB, Keeffe JE. The impact of vision impairment questionnaire: an assessment of its domain structure using confirmatory factor analysis and rasch analysis. *Invest Ophthalmol Vis Sci*. 2007;48(3):1001-6.
159. Amtmann D, Cook KF, Jensen MP, Chen W-H, Choi S, Revicki D*, et al.* Development of a PROMIS item bank to measure pain interference. *Pain*. 2010;150(1):173-82.
160. Owsley C, McGwin G, Jr., Scilley K, Meek GC, Seker D, Dyer A. Effect of refractive error correction on health-related quality-of-life and depression in older nursing home residents. *Arch Ophthalmol*. 2007;125(11):1471-7.
161. Yokoi T, Moriyama M, Hayashi K, Shimada N, Tomita M, Yamamoto N*, et al.* Predictive factors for comorbid psychiatric disorders and their impact on vision-related quality-of-life in patients with high myopia. *Int Ophthalmol*. 2014;34(2):171-83.
162. Day H, Jutai J. Measuring the Psychosocial Impact of Assistive Devices: the PIADS. *Can J Rehabil*. 1996;9(2):159-68.
163. Walline JJ, Bailey MD, Zadnik K. Vision-specific quality-of-life and modes of refractive error correction. *Optom Vis Sci*. 2000;77(12):648-52.
164. Hom MM. Use of cyclosporine 0.05% ophthalmic emulsion for contact lens–intolerant patients. *Eye Contact Lens*. 2006;32(2):109-11.
165. Rose K, Harper R, Tromans C, Waterman C, Goldberg D, Haggerty C*, et al.* Quality-of-life in myopia. *Br J Ophthalmol*. 2000;84(9):1031-4.
166. Chen CY, Keeffe JE, Garoufalis P, Islam FMA, Dirani M, Couper TA*, et al.* Vision-related quality-of-life comparison for emmetropes, myopes after refractive surgery, and myopes wearing spectacles or contact lenses. *J Refract Surg*. 2007;23(8):752-9.
167. Wu AW, Kharrazi H, Boulware LE, Snyder CF. Measure once, cut twice - adding patient-reported outcome measures to the electronic health record for comparative effectiveness research. *J Clin Epidemiol*. 2013;66(8):S12-S20.
168. Eydelman M, Hilmantel G, Tarver ME, Hofmeister EM, May J, Hammel K*, et al.* Symptoms and satisfaction of patients in the Patient-Reported Outcomes With Laser In Situ Keratomileusis (PROWL) studies. *JAMA Ophthalmol*. 2017;135(1):13-22.
169. Sugar A, Hood CT, Mian SI. Patient-reported outcomes following LASIK: quality-of-life in the PROWL studies. *JAMA*. 2017;317(2):204-5.
170. Bennett AV, Jensen RE, Basch E. Electronic patient-reported outcome systems in oncology clinical practice. *CA Cancer J Clin*. 2012;62(5):337-47.
171. Gwaltney CJ, Shields AL, Shiffman S. Equivalence of electronic and paper-and-pencil administration of patient-reported outcome measures: a meta-analytic review. *Value Health*. 2008;11(2):322-33.
172. Zargaran E, Schuurman N, Nicol AJ, Matzopoulos R, Cinnamon J, Taulu T*, et al.* The electronic Trauma Health Record: design and usability of a novel tablet-based tool for trauma care and injury surveillance in low resource settings. *J Am Coll Surg*. 2014;218(1):41-50.
173. Lawson D. PROMIS: a new tool for the clinician scientist. *J Can Chiropr Assoc*. 2011;55:16-9.

174. Lai JS, Cella D, Choi S, Junghaenel DU, Christodoulou C, Gershon R*, et al.* How item banks and their application can influence measurement practice in rehabilitation medicine: a PROMIS Fatigue item bank example. *Arch Phys Med Rehabil*. 2011;92(10 Suppl):S20-7.
175. Fries JF, Krishnan E, Rose M, Lingala B, Bruce B. Improved responsiveness and reduced sample size requirements of PROMIS physical function scales with item response theory. *Arthritis Res Ther*. 2011;13(5):R147.
176. Hahn EA, Devellis RF, Bode RK, Garcia SF, Castel LD, Eisen SV*, et al.* Measuring social health in the patient-reported outcomes measurement information system (PROMIS): item bank development and testing. *Qual Life Res*. 2010;19(7):1035-44.
177. Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S*, et al.* The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. *J Clin Epidemiol*. 2010;63(11):1179-94.
178. Rotenstein LS, Huckman RS, Wagle NW. Making patients and doctors happier - the potential of patient-reported outcomes. *N Engl J Med*. 2017;377(14):1309-12.
179. Porter ME, Larsson S, Lee TH. Standardizing patient outcomes measurement. *N Engl J Med*. 2016;374(6):504-6.
180. Pakhomov S, Jacobsen SJ, Chute CG, Roger VL. Agreement between patient-reported symptoms and their documentation in the medical record. *Am J Manag Care*. 2008;14(8):530.
181. Atkinson TM, Li Y, Coffey CW, Sit L, Shaw M, Lavene D*, et al.* Reliability of adverse symptom event reporting by clinicians. *Qual Life Res*. 2012;21(7):1159-64.
182. Basch E, Iasonos A, McDonough T, Barz A, Culkin A, Kris MG*, et al.* Patient versus clinician symptom reporting using the National Cancer Institute Common Terminology Criteria for Adverse Events: results of a questionnaire-based study. *Lancet Oncol*. 2006;7(11):903-9.
183. Basch E. Patient-reported outcomes - harnessing patients' voices to improve clinical care. *N Engl J Med*. 2017;376(2):105-8.
184. Tabrett DR, Latham K. Factors influencing self-reported vision-related activity limitation in the visually impaired. *Invest Ophthalmol Vis Sci*. 2011;52(8):5293-302.
185. Pult H, Murphy PJ, Purslow C. A novel method to predict the dry eye symptoms in new contact lens wearers. *Optom Vis Sci*. 2009;86(9):e1042-50.
186. Baumhauer JF. Patient-reported outcomes - are they living up to their potential? *N Engl J Med*. 2017;377(1):6-8.
187. Morse JS, Schallhorn SC, Hettinger K, Tanzer D. Role of depressive symptoms in patient satisfaction with visual quality after laser in situ keratomileusis. *J Cataract Refract Surg*. 2009;35(2):341-6.
188. Schein OD, Vitale S, Cassard SD, Steinberg EP. Patient outcomes of refractive surgery: the Refractive Status and Vision Profile. *J Cataract Refract Surg*. 2001;27(5):665-73.
189. Blaylock JF, Si Z, Aitchison S, Prescott C. Visual function and change in quality-of-life after bilateral refractive lens exchange with the ReSTOR multifocal intraocular lens. *J Refract Surg*. 2008;24(3):265-73.
190. Gothwal VK, Pesudovs K, Wright TA, McMonnies CW. McMonnies questionnaire: enhancing screening for dry eye syndromes with Rasch analysis. *Invest Ophthalmol Vis Sci*. 2010;51(3):1401-7.
191. Nirmalan PK, John RK, Gothwal VK, Baskaran S, Vijayalakshmi P, Rahmathullah L. The impact of visual impairment on functional vision of children in rural South India: the Kariapatti Pediatric Eye Evaluation Project. *Invest Ophthalmol Vis Sci*. 2004;45(10):3442-5.
192. Baumeister H, Abberger B, Haschke A, Boecker M, Bengel J, Wirtz M. Development and calibration of an item bank for the assessment of activities of daily living in cardiovascular patients using Rasch analysis. *Health Qual Life Outcomes*. 2013;11(1):133.
193. Rudnicka AR, Owen CG. An introduction to systematic reviews and meta-analyses in health care. *Ophthalmic Physiol Opt*. 2012;32(3):174-83.
194. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J*, et al.* Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol*. 2007;60(1):34-42.
195. de Boer MR, Moll AC, de Vet HC, Terwee CB, Volker-Dieben HJ, van Rens GH. Psychometric properties of vision-related quality-of-life questionnaires: a systematic review. *Ophthalmic Physiol Opt*. 2004;24(4):257-73.
196. Vandenbroeck S, De Geest S, Zeyen T, Stalmans I, Dobbels F. Patient-reported outcomes (PROs) in glaucoma: a systematic review. *Eye* 2011;25(5):555-77.

197. Lundstrom M, Pesudovs K. Questionnaires for measuring cataract surgery outcomes. *J Cataract Refract Surg*. 2011;37(5):945-59.
198. Toker E, Onal S, Eraslan M, Eyriparmak M. The Turkish version of the National Eye Institute - Refractive error Quality of Life instrument: translation, validity and reliability. *Qual Life Res*. 2008;17(10):1269-76.
199. Labiris G, Gkika MG, Giarmoukakis A, Sideroudi H, Kyratzoglou K, Kozobolis VP. Psychometric properties of the Greek NEI-RQL-42. *Eur J Ophthalmol*. 2011;22(3):466-76.
200. Nichols JJ, Mitchell GL, Saracino M, Zadnik K. Reliability and validity of refractive error-specific quality-of-life instruments. *Arch Ophthalmol*. 2003;121(9):1289-96.
201. Kobashi H, Kamiya K, Igarashi A, Matsumura K, Komatsu M, Shimizu K. Long-term quality-of-life after posterior chamber phakic intraocular lens implantation and after wavefront-guided laser in situ keratomileusis for myopia. *J Cataract Refract Surg*. 2014;40(12):2019-24.
202. Berntsen DA, Mitchell GL, Barr JT. The effect of overnight contact lens corneal reshaping on refractive error-specific quality-of-life. *Optom Vis Sci*. 2006;83(6):354-9.
203. Nichols JJ, Twa MD, Mitchell GL. Sensitivity of the National Eye Institute Refractive error Quality of Life instrument to refractive surgery outcomes. *J Cataract Refract Surg*. 2005;31(12):2313-8.
204. Lipson MJ, Musch DC. Synergeyes versus soft toric lenses: vision-related quality-of-life. *Optom Vis Sci*. 2007;84(7):593-7.
205. Lipson MJ, Sugar A, Musch DC. Overnight corneal reshaping versus soft daily wear: a visual quality-of-life study (interim results). *Eye Contact Lens*. 2004;30(4):214-7.
206. Lipson MJ, Sugar A, Musch DC. Overnight corneal reshaping versus soft disposable contact lenses: vision-related quality-of-life differences from a randomized clinical trial. *Optom Vis Sci*. 2005;82(10):886-91.
207. McDonnell PJ, Mangione C, Lee P, Lindblad AS, Spritzer KL, Berry S*, et al.* Responsiveness of the National Eye Institute Refractive Error Quality of Life instrument to surgical correction of refractive error. *Ophthalmology*. 2003;110(12):2302-9.
208. Mencucci R, Giordano C, Favuzza E, Gicquel J-J, Spadea L, Menchini U. Astigmatism correction with toric intraocular lenses: wavefront aberrometry and quality-of-life. *Br J Ophthalmol*. 2013;97(5):578-82.
209. Nehls SM, Ghoghawala SY, Hwang FS, Azari AA. Patient satisfaction and clinical outcomes with laser refractive surgery performed by surgeons in training. *J Cataract Refract Surg*. 2014;40(7):1131-8.
210. Pérez-Cambrodí RJ, Blanes-Mompó FJ, García-Lázaro S, Piñero DP, Cerviño A, Brautaset R. Visual and optical performance and quality-of-life after implantation of posterior chamber phakic intraocular lens. *Graefes Arch Clin Exp Ophthalmol*. 2013;251(1):331-40.
211. Richdale K, Mitchell GL, Zadnik K. Comparison of multifocal and monovision soft contact lens corrections in patients with low-astigmatic presbyopia. *Optom Vis Sci*. 2006;83(5):266-73.
212. Ritchey ER, Barr JT, Mitchell GL. The Comparison of Overnight Lens Modalities (COLM) study. *Eye Contact Lens*. 2005;31(2):70-5.
213. Schmidt GW, Yoon M, McGwin G, Lee PP, McLeod SD. Evaluation of the relationship between ablation diameter, pupil size, and visual function with vision-specific quality-of-life measures after laser in situ keratomileusis. *Arch Ophthalmol*. 2007;125(8):1037-42.
214. Visser N, Beckers HJ, Bauer NJ, Gast ST, Zijlmans BL, Berenschot TT*, et al.* Toric vs aspherical control intraocular lenses in patients with cataract and corneal astigmatism: a randomized clinical trial. *JAMA Ophthalmol*. 2014;132(12):1462-8.
215. Willen CM, McGwin G, Liu B, Owsley C, Rosenstiel C. Efficacy of cyclosporine 0.05% ophthalmic emulsion in contact lens wearers with dry eyes. *Eye Contact Lens*. 2008;34(1):43-5.
216. Lin HT, Chen WR, Ding ZF, Chen W, Wu CR. Clinical evaluation of two multifocal intraocular lens implantation patterns. *Int J Ophthalmol*. 2012;5(1):76-83.
217. Shams N, Mobaraki H, Kamali M, Jafarzadehpour E. Comparison of quality-of-life between myopic patients with spectacles and contact lenses, and patients who have undergone refractive surgery. *J Curr Ophthalmol*. 2015;27(1-2):32-6.
218. Blaylock JF, Si Z, Vickers C. Visual and refractive status at different focal distances after implantation of the ReSTOR multifocal intraocular lens. *J Cataract Refract Surg*. 2006;32(9):1464-73.
219. Iijima A, Shimizu K, Yamagishi M, Kobashi H, Igarashi A, Kamiya K. Assessment of subjective intraocular forward scattering and quality of vision after posterior chamber phakic intraocular lens with a central hole (Hole ICL) implantation. *Acta ophthalmol*. 2016;94(8):e716-20.

220. Pepose JS, Qazi MA, Davies J, Doane JF, Loden JC, Sivalingham V*, et al.* Visual performance of patients with bilateral vs combination crystalens, ReZoom, and ReSTOR - intraocular lens implants. *Am J Ophthalmol*. 2007;144(3):347-57.
221. Kadkhoda A, Ahani IA, Montazeri A. The Refractive Status and Vision Profile (RSVP): translation into Persian, reliability and validity. *Ophthalmic Epidemiol*. 2006;13(6):385-92.
222. Garamendi E, Pesudovs K, Stevens M, Elliott D. The Refractive Status and Vision Profile: evaluation of psychometric properties and comparison of Rasch and summated Likert-scaling. *Vision Res*. 2006;46(8-9):1375-83.
223. Nichols J, Mitchell G, Zadnik K. The performance of the refractive status and vision profile survey in a contact lens clinical trial. *Ophthalmology*. 2001;108(6):1160-6.
224. Savage H, Rothstein M, Davuluri G, El Ghormli L, Zaetta DM. Myopic astigmatism and presbyopia trial. *Am J Ophthalmol*. 2003;135(5):628-32.
225. Lane S, Waycaster C. Correction of high myopia with a phakic intraocular lens: interim analysis of clinical and patient-reported outcomes. *J Cataract Refract Surg*. 2011;37(8):1426-33.
226. Waring G, Dougherty PJ, Chayet A, Fischer J, Fant B, Stevens G*, et al.* Topographically guided LASIK for myopia using the Nidek CXII customized aspheric treatment zone (CATz). *Trans Am Ophthalmol Soc*. 2007;105:240-6.
227. Esteso P, Castanon A, Toledo S, Rito MA, Ervin A, Wojciechowski R*, et al.* Correction of moderate myopia is associated with improvement in self-reported visual functioning among Mexican school-aged children. *Invest Ophthalmol Vis Sci*. 2007;48(11):4949-54.
228. Garamendi E, Pesudovs K, Elliott DB. Changes in quality-of-life after laser in situ keratomileusis for myopia. *J Cataract Refract Surg*. 2005;31(8):1537-43.
229. Ieong A, Hau SC, Rubin GS, Allan BD. Quality-of-life in high myopia before and after Implantable Collamer Lens implantation. *Ophthalmology*. 2010;117(12):2295-300.
230. McAlinden C, Moore JE. Multifocal intraocular lens with a surface-embedded near section: short-term clinical outcomes. *J Cataract Refract Surg*. 2011;37(3):441-5.
231. Plowright AJ, Maldonado-Codina C, Howarth GF, Kern J, Morgan PB. Daily disposable contact lenses versus spectacles in teenagers. *Optom Vis Sci*. 2015;92(1):44-52.
232. Ang M, Ho H, Fenwick E, Lamoureux E, Htoon HM, Koh J*, et al.* Vision-related quality-of-life and visual outcomes after small-incision lenticule extraction and laser in situ keratomileusis. *J Cataract Refract Surg*. 2015;41(10):2136-44.
233. Ieong A, Rubin GS, Allan BD. Quality-of-life in high myopia: Implantable Collamer Lens implantation versus contact lens wear. *Ophthalmology*. 2009;116(2):275-80.
234. Maurino V, Allan BD, Rubin GS, Bunce C, Xing W, Findl O. Quality of vision after bilateral multifocal intraocular lens implantation: a randomized trial - At LISA 809M versus AcrySof ReSTOR SN6AD1. *Ophthalmology*. 2015;122(4):700-10.
235. McAlinden C, Skiadaresi E, Pesudovs K, Moore JE. Quality of vision after myopic and hyperopic laser-assisted subepithelial keratectomy. *J Cataract Refract Surg*. 2011;37(6):1097-100.
236. McAlinden C, Skiadaresi E, Gatinel D, Cabot F, Huang J, Pesudovs K. The Quality of Vision questionnaire: subscale interchangeability. *Optom Vis Sci*. 2013;90(8):760-4.
237. Luger MH, McAlinden C, Buckhurst PJ, Wolffsohn JS, Verma S, Arba Mosquera S. Presbyopic LASIK using hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. *Am J Ophthalmol*. 2015;160(3):493-505.
238. Tahzib NG, Bootsma SJ, Eggink FA, Nabar VA, Nuijts RM. Functional outcomes and patient satisfaction after laser in situ keratomileusis for correction of myopia. *J Cataract Refract Surg*. 2005;31(10):1943-51.
239. Tahzib NG, Bootsma SJ, Eggink FA, Nuijts RM. Functional outcome and patient satisfaction after Artisan phakic intraocular lens implantation for the correction of myopia. *Am J Ophthalmol*. 2006;142(1):31-9.
240. Steinberg EP, Tielsch JM, Schein OD, Javitt JC, Sharkey P, Cassard SD*, et al.* The VF-14: an index of functional impairment in patients with cataract. *Arch Ophthalmol*. 1994;112(5):630-8.
241. Lazon de la Jara L, Erickson D, Erickson P, Stapleton F. Pre-operative quality-of-life and psychological factors that influence patient decision making in LASIK. *Eye*. 2010;24(2):270-5.
242. Lazon de la Jara L, Erickson D, Erickson P, Stapleton F. Visual and non-visual factors associated with patient satisfaction and quality-of-life in LASIK. *Eye*. 2011;25(9):1194-201.
243. Brady CJ, Villanti AC, Gandhi M, Friedman DS, Keay L. Visual function after correction of distance refractive error with ready-made and custom spectacles: a randomized clinical trial. *Ophthalmology*. 2012;119(10):2014-20.

244. Fletcher AE, Ellwein LB, Selvaraj S, Vijaykumar V, Rahmathullah R, Thulasiraj R. Measurements of vision function and quality-of-life in patients with cataracts in southern India: report of instrument development. *Arch Ophthalmol*. 1997;115(6):767-74.
245. Sivardeen A, Laughton D, Wolffsohn JS. Randomized crossover trial of silicone hydrogel presbyopic contact censes. *Optom Vis Sci*. 2016;93(2):141-9.
246. Gupta N, Wolffsohn JS, Naroo SA, Davies LN, Gibson GA, Shah S. Development of a near activity visual questionnaire to assess accommodating intraocular lenses. *Cont Lens Anterior Eye*. 2007;30(2):134-43.
247. Lu Q, Congdon N, He X, Murthy G, Yang A, He W. Quality-of-life and near vision impairment due to functional presbyopia among rural Chinese adults. *Invest Ophthalmol Vis Sci*. 2011;52:4118-23.
248. Mangione CM, Lee PP, Pitts J, Gutierrez P, Berry S, Hays RD. Psychometric properties of the National Eye Institute visual function questionnaire (NEI-VFQ). *Arch Ophthalmol*. 1998;116(11):1496-504.
249. Walline JJ, Gaume A, Jones LA, Rah MJ, Manny RE, Berntsen DA*, et al.* Benefits of contact lens wear for children and teens. *Eye Contact Lens*. 2007;33(6 Pt 1):317-21.
250. Li L, Moody K, Tan D, Yew KC, Ming PY, Long QB. Contact lenses in pediatrics study in Singapore. . *Eye Contact Lens*. 2009;35(4):188-95.
251. Rah MJ, Walline JJ, Jones-Jordan LA, Sinnott LT, Jackson JM, Manny RE*, et al.* Vision specific quality-of-life of pediatric contact lens wearers. *Optom Vis Sci*. 2010;87(8):560-6.
252. Santodomingo-Rubido J, Villa-Collar C, Gilmartin B, Gutierrez-Ortega R. Myopia control with orthokeratology contact lenses in Spain: a comparison of vision-related quality-of-life measures between orthokeratology contact lenses and single-vision spectacles. *Eye Contact Lens*. 2013;39(2):153-7.
253. Nichols JJ, Mitchell GL, Nichols KK, Chalmers R, Begley C. The performance of the contact lens dry eye questionnaire as a screening survey for contact lens-related dry eye. *Cornea*. 2002;21(5):469-75.
254. Nichols JJ, Mitchell GL, Curbow B. Relation between mood and self-reported dry eye in contact lens wearers. *Cornea*. 2006;25(8):937-42.
255. Berry M, Pult H, Purslow C, Murphy PJ. Mucins and ocular signs in symptomatic and asymptomatic contact lens wear. *Optom Vis Sci*. 2008;85(10):e930-8.
256. Chalmers R, Long B, Dillehay S, Begley C. Improving contact-lens related dryness symptoms with silicone hydrogel lenses. *Optom Vis Sci*. 2008;85(8):778-84.
257. Geldis JR, Nichols JJ. The impact of punctal occlusion on soft contact lens wearing comfort and the tear film. . *Eye Contact Lens*. 2008;34(5):261-5.
258. Pult H, Purslow C, Berry M, Murphy PJ. Clinical tests for successful contact lens wear: relationship and predictive potential. *Optom Vis Sci*. 2008;85(10):e924-9.
259. Greiner KL, Walline JJ. Dry eye in pediatric contact lens wearers. *Eye Contact Lens*. 2010;36(6):352-5.
260. Jansen ME, Begley CG, Himebaugh NH, Port NL. Effect of contact lens wear and a near task on tear film break-up. *Optom Vis Sci*. 2010;87(5):350-7.
261. Martin R, Sanchez I, de la Rosa C, de Juan V, Rodriguez G, de Paz I*, et al.* Differences in the daily symptoms associated with the silicone hydrogel contact lens wear. *Eye Contact Lens*. 2010;36(1):49-53.
262. Chalmers RL, Begley CG, Moody K, Hickson-Curran SB. Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) and opinion of contact lens performance. *Optom Vis Sci*. 2012;89(10):1435-42.
263. Young G, Chalmers R, Napier L, Kern J, Hunt C, Dumbleton K. Soft contact lens-related dryness with and without clinical signs. *Optom Vis Sci*. 2012;29(8):1125-32.
264. Carracedo GPD, Martin-Gil A, Peixoto-de-Matos SC, Abejon-Gil P, Macedo-de-Araújo R, González-Méijome JM. Symptoms and signs in rigid gas permeable lens wearers during adaptation period. *Eye Contact Lens*. 2016;42(2):108-14.
265. Tuisku IS, Lindbohm N, Wilson SE, Tervo TM. Dry eye and corneal sensitivity after high myopic LASIK. *J Refract Surg*. 2007;23(4):338-42.
266. Guillon M, Maissa C. Dry eye symptomatology of soft contact lens wearers and nonwearers. *Optom Vis Sci*. 2005;82(9):829-34.
267. Chen SP, Massaro-Giordano G, Pistilli M, Schreiber CA, Bunya VY. Tear osmolarity and dry eye symptoms in women using oral contraception and contact lenses. *Cornea*. 2013;32(4):423-8.
268. Tao A, Cai C, Shen M, Wang J, Chen Z, Xu S*, et al.* Tear menisci after overnight contact lens wear. *Optom Vis Sci*. 2011;88(12):1433-8.

References: 266

269. Wang B, Naidu RK, Chu R, Dai J, Qu X, Zhou H. Dry eye disease following refractive surgery: a 12-month follow-up of SMILE versus FS-LASIK in high myopia. *Am J Ophthalmol*. 2015;2015:132417.
270. Berry M, Purslow C, Murphy PJ, Pult H. Contact lens materials, mucin fragmentation and relation to symptoms. *Cornea*. 2012;31(7):770-6.
271. Jalbert I, Rejab S. Increased numbers of demodex in contact lens wearers. *Optom Vis Sci*. 2015;92(6):671-8.
272. Yang S, Tai Y, Sheedy JE, Kinoshita B, Lampa M, Kern JR. Comparative effect of lens care solutions on blink rate, ocular discomfort and visual performance. *Ophthalmic Physiol Opt*. 2012;32(5):412-20.
273. Ghoreishi M, Aidenloo NS, Peyman A, Peyman M, Haghdoustoskoey M. Does hinge position affect dry eye after laser in situ keratomileusis? *Ophthalmologica*. 2005;219(5):276-80.
274. Mian SI, Shtein RM, Nelson A, Musch DC. Effect of hinge position on corneal sensation and dry eye after laser in situ keratomileusis using a femtosecond laser. *J Cataract Refract Surg*. 2007;33(7):1190-4.
275. Huang JC, Sun CC, Chang CK, Ma DH, Lin YF. Effect of hinge position on corneal sensation and dry eye parameters after femtosecond laser-assisted LASIK. *J Refract Surg*. 2012;28(9):625-31.
276. Hassan Z, Szalai E, Berta A, Modis L, Jr., Nemeth G. Assessment of tear osmolarity and other dry eye parameters in post-LASIK eyes. *Cornea*. 2013;32(7):e142-5.
277. Lee JC, Chiu GB, Bach D, Bababeygy SR, Irvine J, Heur M. Functional and visual improvement with prosthetic replacement of the ocular surface ecosystem scleral lenses for irregular corneas. *Cornea*. 2013;32(12):1540-3.
278. Sun CC, Chang CK, Ma DH, Lin YF, Chen KJ, Sun MH*, et al.* Dry eye after LASIK with a femtosecond laser or a mechanical microkeratome. *Optom Vis Sci*. 2013;90(10):1048-56.
279. Maychuk DY, Dry Eye Prevalence Study G. Prevalence and severity of dry eye in candidates for laser in situ keratomileusis for myopia in Russia. *J Cataract Refract Surg*. 2016;42(3):427-34.
280. Albietz JM, Lenton LM, mcLennan SG. Effect of laser in situ keratomileusis for hyperopia on tear film and ocular surface. *J Refract Surg*. 2002;18(2):113-23.
281. Farahi A, Hashemi H, Mehravaran S, Tavakolizadeh S, Khabazkhoob M. Tear function evaluation in candidates of corneal laser refractive surgery for myopia. *Eye Contact Lens*. 2014;40(2):91-4.
282. Evans KS, North RV, Purslow C. Tear ferning in contact lens wearers. *Ophthalmic Physiol Opt*. 2009;29(2):199-204.
283. Bhargava RMS, Kumar PMD. Oral omega-3 fatty acid treatment for dry eye in contact lens wearers. *Cornea*. 2015;34(4):413-20.
284. Wang Q, Zhao G, Wang Q, Jia W. Visual quality after AcrySof IQ ReSTOR intraocular lens implantation in eyes with high myopia. *Eur J Ophthalmol*. 2012;22(2):168-74.
285. Marques FF, Sato RM, Chiacchio BB, Marques DM, Barreiro J, Caetano RL. Evaluation of visual performance and patient satisfaction with pseudophakic monovision technique. *Arq Bras Oftalmol*. 2009;72(2):164-8.
286. Gierek-Ciaciura S, Cwalina L, Bednarski L, Mrukwa-Kominek E. A comparative clinical study of the visual results between three types of multifocal lenses. *Graefes Arch Clin Exp Ophthalmol*. 2010;248(1):133-40.
287. Kanonidou E, Chatziralli IP, Konidaris V, Kanonidou C, Papazisis L. A comparative study of visual function of young myopic adults wearing contact lenses vs. spectacles. *Cont Lens Anterior Eye*. 2012;35(5):196-8.
288. Vingolo EM, Carnevale C, Fragiotta S, Rigoni E, Iacobelli L. Visual outcomes and contrast sensitivity after bilateral implantation of multifocal intraocular lenses with +2.5 or +3.0 Diopter addition: 12-month follow-Up. *Semin Ophthalmol*. 2016;31:1-6.
289. Freitas C, Oliveiros BM, Marques E, Leite EB. Effect of photorefractive keratectomy on visual functioning and quality-of-life. *J Refract Surg*. 1995;11(Suppl):s327-34.
290. Coleman AL, Yu F, Keeler E, Mangione CM. Treatment of uncorrected refractive error improves vision-specific quality-of-life. *J Am Geriatr Soc*. 2006;54(6):883-90.
291. McClure TM, Choi D, Wooten K, Nield C, Becker TM, Mansberger SL. The impact of eyeglasses on vision-related quality-of-life in American Indian/Alaska natives. *Am J Ophthalmol*. 2011;151(1):175-82.e2.
292. Ryan A, Hartnett C, Lanigan B, O'Keefe M. Foldable iris-fixated intraocular lens implantation in children. *Acta Ophthalmol*. 2012;90(6):e458-62.
293. Sandhu RK, Munoz BE, Swenor BK, West SK. Refractive error and visual function difficulty in a Latino population. *Ophthalmology*. 2012;119(9):1731-6.

294. Ziaei H, Katibeh M, Sabbaghi M, Yaseri M, Eskandari A. Vision related quality-of-life in myopia; photorefractive keratectomy versus nonsurgical optical correction. *J Ophthalmic Vis Res*. 2012;7(3):219-24.
295. Gundersen KG, Potvin R. Comparison of visual outcomes after implantation of diffractive trifocal toric intraocular lens and a diffractive apodized bifocal toric intraocular lens. *Clin Ophthalmol*. 2016;10:455-61.
296. Rahi J, Peckham C, Cumberland P. Visual impairment due to undiagnosed refractive error in working age adults in Britain. *Br J Ophthalmol*. 2008;92(9):1190-4.
297. Day HY, Jutai J, Woolrich W, Strong G. The stability of impact of assistive devices. *Disabil Rehabil* 2001;23(9):400-4.
298. Jutai J, Day H, Woolrich W, Strong G. The predictability of retention and discontinuation of contact lenses. *Optometry*. 2003;74(5):299-308.
299. Court H, Greenland K, Margrain TH. Evaluating patient anxiety levels during contact lens fitting. *Optom Vis Sci*. 2008;85(7):574-80.
300. Elliott AF, McGwin G, Jr, Owsley C. Vision-enhancing interventions in nursing home residents and their short-term effect on physical and cognitive function. *J Am Geriatr Soc*. 2009;57(2):202-8.
301. Takashima T, Yokoyama T, Futagami S, Ohno-Matsui K, Tanaka H, Tokoro T*, et al.* The quality-of-life in patients with pathologic myopia. *Jpn J Ophthalmol*. 2001;45(1):84-92.
302. Toczolowski J, Oles P, Zagórski Z, Szymona KU, Baltaziak L, Rymgayllo-Jankowska B. The sense of self-concept change in patients after radial keratotomy. *J Refract Surg*. 2001;17(2):134-7.
303. Kidd B, Stark C, McGhee CN. Screening for psychiatric distress and low self-esteem in patients presenting for excimer laser surgery for myopia. *J Refract Surg*. 1997;13(1):40-4.
304. Vetrugno M, Maino A, Cardia L. Prospective randomized comparison of simultaneous and sequential bilateral photorefractive keratectomy for the correction of myopia. *Ophthalmic Surg Lasers Imaging*. 2000;31(5):400-10.
305. Vetrugno M, Maino A, Quaranta GM, Cardia L. A randomized, double-masked, clinical study of the efficacy of four nonsteroidal anti-inflammatory drugs in pain control after excimer laser photorefractive keratectomy. *Clin Ther*. 2000;22(6):719-31.
306. Garcia R, Horovitz RN, Torricelli AA, Mukai A, Bechara SJ. Improved evaluation of postoperative pain after photorefractive keratectomy. *Cornea*. 2016;35(2):205-9.
307. Frangouli A, Shah S, Chatterjee A, Morgan PB, Kinsey J. Efficacy of topical nonsteroidal drops as pain relief after excimer laser photorefractive keratectomy. *J Refract Surg*. 1998;14(2 Suppl):s207-8.
308. Pesudovs K, Garamendi E, Keeves JP, Elliott DB. The Activities of Daily Vision Scale for cataract surgery outcomes: re-evaluating validity with Rasch analysis. *Invest Ophthalmol Vis Sci*. 2003;44(7):2892-9.
309. Alio J. Refractive surgery today: is there innovation or stagnation? *Eye Vis (Lond)*. 2014;1(1):4.
310. Unick GJ, Shumway M, Hargreaves W. Are we ready for computerized adaptive testing? *Psychiatr Serv*. 2008;59(4):369-.
311. Eiser C. Children's quality-of-life measures. *Arch Dis Child*. 1997;77(4):350-4.
312. Foster PJ, Jiang Y. Epidemiology of myopia. *Eye* 2014;28(2):202-8.
313. Lohr KN, Zebrack BJ. Using patient-reported outcomes in clinical practice: challenges and opportunities. *Qual Life Res*. 2008;18(1):99-107.
314. Black N. Patient reported outcome measures could help transform healthcare. *BMJ (Clin Res ed)*. 2013;346:f167.
315. Murthy G, Gupta SK. Qualitative research in ophthalmic sciences. *Indian J Ophthalmol*. 1999;47(4):257.
316. Malterud K. The art and science of clinical knowledge: evidence beyond measures and numbers. *Lancet*. 2001;358(9279):397-400.
317. Malterud K. Qualitative research: standards, challenges, and guidelines. *Lancet*. 2001;358(9280):483-8.
318. Nyman SR, Dibb B, Victor CR, Gosney MA. Emotional well-being and adjustment to vision loss in later life: a meta-synthesis of qualitative studies. *Disabil Rehabil*. 2012;34(12):971-81.
319. Fereday J, Muir-Cochrane E. Demonstrating rigor using thematic analysis: a hybrid approach of inductive and deductive coding and theme development. *Int J Qual Methods*. 2006;5(1):80-92.
320. Ryan GW, Bernard HR. Techniques to identify themes. *Field Methods*. 2003;15(1):85-109.
321. Parrott W. Inventory of Emotions. Philadelphia, USA: Psychology Press; 2001.

322. Sturrock BA, Xie J, Holloway EE, Lamoureux EL, Keeffe JE, Fenwick EK*, et al.* The influence of coping on vision-related quality-of-life in patients with low vision: a prospective longitudinal study. *Invest Ophthalmol Vis Sci*. 2015;56(4):2416-22.
323. Fenwick EK, Pesudovs K, Khadka J, Dirani M, Rees G, Wong T*, et al.* The impact of diabetic retinopathy on quality-of-life: qualitative findings from an item bank development project. *Qual Life Res*. 2012;21(10):1771-82.
324. Green J, Siddall H, Murdoch I. Learning to live with glaucoma: a qualitative study of diagnosis and the impact of sight loss. *Soc Sci Med* 2002;55(2):257-67.
325. McCloud C, Khadka J, Gilhotra JS, Pesudovs K. Divergence in the lived experience of people with macular degeneration. *Optom Vis Sci*. 2014;91(8):966-74.
326. McCloud C, Lake S. Understanding the patient's lived experience of neovascular age-related macular degeneration: a qualitative study. *Eye* 2015;29(12):1561-9.
327. Kandel H, Murthy G, Bascaran C. Human resources for refraction services in central Nepal. *Clin Exp Optom*. 2015;98(4):335-41.
328. Kandel H. Situational analysis of refraction services in the central Nepal [MSc Thesis]. London, UK: London School of Hygiene and Tropical Medicine, University of London; 2013.
329. Ntodie M, Danquah L, Kandel H, Abokyi S. Toward eliminating blindness due to uncorrected refractive errors: assessment of refractive services in the northern and central regions of Ghana. *Clin Exp Optom*. 2014;97(6):511-5.
330. Thakur AK, Joshi P, Kandel H, Bhatta S. Profile of low vision clinics in eastern region of Nepal: a retrospective study. *Br J Vis Impair*. 2011;29(3):215-26.
331. Khadka J, Ryan B, Margrain TH, Woodhouse JM, Davies N. Listening to voices of children with a visual impairment: a focus group study. *Br J Vis Impair*. 2012;30(3):182-96.
332. Shakya KM, Rupakheti M, Aryal K, Peltier RE. Respiratory effects of high levels of particulate exposure in a cohort of traffic police in Kathmandu, Nepal. *Int J Occup Environ Med*. 2016;58(6):e218-e25.
333. Pärssinen O, Kirjonen J, Saari K. Wearing of spectacles and occurrence of ocular symptoms in close work in different occupations. *Scand J Soc Med* 1987;15(2):99-103.
334. Guisasola L, Tresserras R, Rius A, Purtí E. Visual correction and occupational social class. *Optom Vis Sci*. 2014;91(4):464-71.
335. Gyawali R, Nestha Mohamed F, Bist J, Kandel H, Marasini S, Khadka J. Compliance and hygiene behaviour among soft contact lens wearers in the Maldives. *Clin Exp Optom*. 2014;97(1):43-7.
336. Shickle D, Griffin M, Evans R, Brown B, Haseeb A, Knight S*, et al.* Why don't younger adults in England go to have their eyes examined? *Ophthalmic Physiol Opt*. 2014;34(1):30-7.
337. Holden BA. Uncorrected refractive error: the major and most easily avoidable cause of vision loss. *Community Eye Health*. 2007;20(63):37-9.
338. Shickle D, Griffin M. Why don't older adults in England go to have their eyes examined? *Ophthalmic Physiol Opt*. 2014;34(1):38-45.
339. Pokharel A, Kandel H, Shrestha P. Pervasive blindness and ocular morbidity in the Chepang people of Nepal. *Nepal J Ophthalmol*. 2016;8(2):189-91.
340. Gordon GE, Chronicle EP, Rolan P. Why do we still not know whether refractive error causes headaches? Towards a framework for evidence based practice. *Ophthalmic Physiol Opt*. 2001;21(1):45-50.
341. Pokharel A, Kandel H, Shrestha R. Harrowing blindness and ocular morbidity in a Himalayan village. *Nepal J Epidemiol*. 2016;6(2):582-3.
342. Maxwell JA. Using numbers in qualitative research. *Qual Inq*. 2010;16(6):475-82.
343. Kandel H, Khadka J, Goggin M, Pesudovs K. An item bank to measure impact of refractive error on quality-of-life. Association for Research in Vision and Ophthalmology - Asia (ARVO - Asia); February 8, 2017; Brisbane, Australia 2017.
344. Pesudovs K, Khadka J, Prem Senthil M, Kandel H, Kumaran SE, Fenwick E*, et al.* The Eye-tem Bank project: an update on development and validation. *Invest Ophthalmol Vis Sci*. 2017;58(8):1359.
345. Foreman J, Dirani M, Taylor H. Refractive error, through the lens of the patient. *Clin Exp Ophthalmol*. 2017;45(7):673.
346. Kandel H, Khadka J, Goggin M, Pesudovs K. Continuing professional development. *Clin Exp Ophthalmol*. 2017;45(7):755-7.
347. Kandel H, Khadka J, Goggin M, Pesudovs K. Continuing professional development. *Clin Exp Ophthalmol*. 2017;45(8):843-5.

348. Kandel H. Thinking beyond a pair of glasses [Internet] 2018. [cited 03 March 2018]. Available from: https://iapb.standardlist.org/thinking-beyond-pair-glasses/.
349. Patrick DL, Burke LB, Gwaltney CJ, Leidy NK, Martin ML, Molsen E*, et al.* Content validity - establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force report: part 2 - assessing respondent understanding. *Value Health*. 2011;14(8):978-88.
350. Rothman M, Burke L, Erickson P, Leidy NK, Patrick DL, Petrie CD. Use of existing patient-reported outcome (PRO) instruments and their modification: the ISPOR Good Research Practices for evaluating and documenting content validity for the use of existing instruments and their modification PRO Task Force report. *Value Health*. 2009;12(8):1075-83.
351. Brod M, Tesler LE, Christensen TL. Qualitative research and content validity: developing best practices based on science and experience. *Qual Life Res*. 2009;18(9):1263-78.
352. Prem Senthil M. Development and validation of technologically advanced patient-reported outcome measures for retinal diseases [PhD Thesis]. Adelaide, Australia: Flinders University; 2018.
353. Wilson IB, Cleary PD. Linking clinical variables with health-related quality-of-life: a conceptual model of patient outcomes. *JAMA*. 1995;273(1):59-65.
354. McDougall J, Wright V, Rosenbaum P. The ICF model of functioning and disability: incorporating quality-of-life and human development. *Dev Neurorehabil*. 2010;13(3):204-11.
355. Bruce B, Fries JF, Ambrosini D, Lingala B, Gandek B, Rose M*, et al.* Better assessment of physical function: item improvement is neglected but essential. *Arthritis Res Ther*. 2009;11(6):R191.
356. Perez JL, Mosher ZA, Watson SL, Sheppard ED, Brabston EW, McGwin G*, et al.* Readability of orthopaedic patient-reported outcome measures: is there a fundamental failure to communicate? *Clin Orthop Relat Res*. 2017;475(8):1936-47.
357. Stockmeyer NO. Using Microsoft Word's readability program. *Michigan Bar Journal*. 2009;88:46-7.
358. Bode RK, Lai JS, Cella D, Heinemann AW. Issues in the development of an item bank. *Arch Phys Med Rehabil*. 2003;84(4 Suppl 2):S52-60.
359. Khadka J, Pesudovs K, McAlinden C, Vogel M, Kernt M, Hirneiss C. Reengineering the Glaucoma Quality of Life-15 questionnaire with Rasch analysis. *Invest Ophthalmol Vis Sci*. 2011;52(9):6971-7.
360. Wild D, Grove A, Mona Martin M, Eremenco S, McElroy S. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) Measures: report of the ISPOR task force for translation and cultural adaptation. *Value Health*. 2005;8(2):94-104.
361. Bierly JR, Lim ES, Litteral G, Anderson CW. A quantitative and qualitative assessment of the Solitaire bifocal contact cens. *CLAO Journal*. 1995;21(1):20-3.
362. Bucci Jr FA, Myers PJ, Evans RE, Tanner JB, Moody KJ, Lopatynsky MO. Clinical and overnight corneal swell comparison of the 1-Day Acuvue lens versus the Medalist, Surevue, Biomedics, and Acuvue lenses. *Eye Contact Lens*. 1997;23(2):103-12.
363. Cheung SW, Cho P. Subjective and objective assessments of the effect of orthokeratology: a cross-sectional study. *Curr Eye Res*. 2004;28(2):121-7.
364. Dias L, Manny RE, Hyman L, Fern K, COMET Group. The relationship between self-esteem of myopic children and ocular and demographic characteristics. *Optom Vis Sci*. 2002;79(11):688-96.
365. Diec J, Lazon de la Jara P, Willcox M, Holden BA. The clinical performance of lenses disposed of daily can vary considerably. *Eye Contact Lens*. 2012;38(5):313-8.
366. Dumbleton K, Keir N, Moezzi A, Feng Y, Jones L, Fonn D. Objective and subjective responses in patients refitted to daily-wear silicone hydrogel contact lenses. *Optom Vis Sci*. 2006;83(10):758-68.
367. Dumbleton KA, Woods CA, Jones LW, Fonn D. Comfort and adaptation to silicone hydrogel lenses for daily wear. *Eye Contact Lens*. 2008;34(4):215-23.
368. Fortuin MF, Schilperoort J, Evans BJW, Edgar DF, Manon HMT, Kiers H. Randomised controlled study comparing comfort-related outcomes between two rigid gas permeable (RGP) lenses with different sessile drop contact angles. *Ophthalmic Physiol Opt*. 2011;31(2):190-9.
369. Hamberg-Nystrom H, Tengroth B, Fagerholm P, Epstein D, van der Kwast EM. Patient satisfaction following photorefractive keratectomy for myopia. *J Refract Surg*. 1995;11(3 (Suppl)):S335-6.
370. Ichijima H, Karino S, Sakata H, Cavanagh HD. Improvement of subjective symptoms and eye complications when changing from 2-week frequent replacement to daily disposable contact lenses in a subscriber membership system. *Eye Contact Lens*. 2015;0:1-6.
371. Jones-Jordan LA, Walline JJ, Mutti DO, Rah MJ, Nichols KK, Nichols JJ*, et al.* Gas permeable and soft contact lens wear in children. *Optom Vis Sci.* 2010;87(6):414-20.

372. Lee J, Lee HK, Kim CY, Hong YJ, Choe CM, You TW*, et al.* Purified high-dose anthocyanoside oligomer administration improves nocturnal vision and clinical symptoms in myopia subjects. *Br J Nutr*. 2005;93(6):895-9.
373. Levinger E, Trivizki O, Pokroy R, Levartovsky S, Sholohov G, Levinger S. Monovision surgery in myopic presbyopes: visual function and satisfaction. *Optom Vis Sci*. 2013;90(10):1092-7.
374. Lin MC, Yuen J, Graham AD. Contact lens care solutions: a pilot study of ethnic differences in clinical signs and symptoms. *Eye Contact Lens*. 2014;40(4):191-9.
375. McGhee C, Orr D, Kidd B, Stark C, Bryce IG, Anastas CN. Psychological aspects of excimer laser surgery for myopia: reasons for seeking treatment and patient satisfaction. *Br J Ophthalmol*. 1996;80(10):874-9.
376. Pasquali TA, Smadja D, Savetsky MJ, Reggiani Mello GH, Alkhawaldeh F, Krueger RR. Long-term follow-up after laser vision correction in physicians: quality-of-life and patient satisfaction. *J Cataract Refract Surg*. 2014;40(3):395-402.
377. Sakuma K, Toshida H, Honda R, Tanaka K, Fukazawa A, Takahashi K*, et al.* Effects of topical application of Ibudilast for seasonal allergic conjunctivitis in patients wearing soft contact lenses *Eye Contact Lens*. 2009;35(5):251-4.
378. Schrecker J, Feith A, Langenbucher A. Comparison of additional pseudophakic multifocal lenses and multifocal intraocular lens in the capsular bag. *Br J Ophthalmol*. 2014;98(7):915-9.
379. Spyridon M, Hickson-Curran S, Hunt C, Young G. Eye sensitivity in soft contact lens wearers. *Optom Vis Sci*. 2012;89(12):1682-90.
380. Yu J, Chen H, Wang F. Patient satisfaction and visual symptoms after wavefront-guided and wavefront-optimized LASIK with the WaveLight platform. *J Refract Surg*. 2008;24(5):477-86.
381. Zalentein WN, Tervo TMT, Holopainen JM. Seven-year follow-up of LASIK for myopia. *J Refract Surg*. 2009;25(3):312-8.
382. Taylor HR, Xie J, Fox S, Dunn RA, Arnold A-L, Keeffe JE. The prevalence and causes of vision loss in Indigenous Australians: the National Indigenous Eye Health Survey. *Med J Aust*. 2010;192(6):312-8.
383. Kandel H, Khadka J, Fenwick E, Sharma S, Sharma B, Kafle K*, et al.* Constructing item banks for measuring quality of life in refractive error. *Optom Vis Sci*. 2018;95(7):575-87.
384. Linacre J. Winsteps - Rasch measurement computer program. Version 3.92.1. Chiago: Winsteps.com; 2016.
385. Abberger B, Haschke A, Wirtz M, Kroehne U, Bengel J, Baumeister H. Development and evaluation of a computer adaptive test to assess anxiety in cardiovascular rehabilitation patients. *Arch Phys Med Rehabil*. 2013;94(12):2433-9.
386. Pelton T. Where are the limits to the Rasch advantage. International Objective Measurement Workshop, New Orleans 2002.
387. Gothwal VK, Wright TA, Lamoureux EL, Lundstrom M, Pesudovs K. Catquest questionnaire: re-validation in an Australian cataract population. *Clin Exp Ophthalmol*. 2009;37(8):785-94.
388. Wang JH. Using real-data simulations to compare computer adaptive testing and static short-form administrations of an upper extremity item bank [PhD Thesis]. ProQuest: Michigan, USA: University of Florida; 2009.
389. Reise S, Rodriguez A. Item response theory and the measurement of psychiatric constructs: some empirical and conceptual issues and challenges. *Psychological medicine*. 2016;46(10):2025-39.
390. Prem Senthil M, Khadka J, De Roach J, Lamey T, McLaren T, Campbell I*, et al.* Developing an item bank to measure the coping strategies of people with hereditary retinal diseases. *Graefes Arch Clin Exp Ophthalmol*. 2018.
391. Haley SM, Ni P, Jette AM, Tao W, Moed R, Meyers D*, et al.* Replenishing a computerized adaptive test of patient-reported daily activity functioning. *Qual Life Res*. 2009;18(4):461-71.
392. Choi SW. Firestar: computerized adaptive testing simulation program for polytomous item response theory models. *Appl Psychol Meas*. 2009;33(8):644-5.
393. McNeely RN, Moutari S, Arba-Mosquera S, Verma S, Moore JE. An alternative application of Rasch analysis to assess data from ophthalmic patient-reported outcome instruments. *PLoS One*. 2018;13(6):e0197503.
394. Langelaan M, de Boer MR, van Nispen RM, Wouters B, Moll AC, van Rens GH. Impact of visual impairment on quality-of-life: a comparison with quality-of-life in the general population and with other chronic conditions. *Ophthalmic Epidemiol*. 2007;14(3):119-26.

395. Brown RL, Barrett AE. Visual impairment and quality-of-life among older adults: an examination of explanations for the relationship. *Journals of Gerontology Series B: Psychological Sciences and Social Sciences*. 2011;66(3):364-73.
396. Khorrami-Nejad M, Sarabandi A, Akbari M-R, Askarizadeh F. The impact of visual impairment on quality-of-life. *Med Hypothesis Discov Innov Ophthalmol*. 2016;5(3):96.
397. Lamoureux EL, Saw S-M, Thumboo J, Wee HL, Aung T, Mitchell P*, et al.* The impact of corrected and uncorrected refractive error on visual functioning: the Singapore Malay Eye Study. *Invest Ophthalmol Vis Sci*. 2009;50(6):2614-20.
398. Nichols KK, Nichols JJ, Mitchell GL. The lack of association between signs and symptoms in patients with dry eye disease. *Cornea*. 2004;23(8):762-70.
399. Nichols KK, Mitchell GL, Zadnik K. The repeatability of clinical measurements of dry eye. *Cornea*. 2004;23(3):272-85.
400. Khan-Lim D, Craig JP, McGhee CN. Defining the content of patient questionnaires: reasons for seeking laser in situ keratomileusis for myopia. *J Cataract Refract Surg*. 2002;28(5):788-94.
401. Ojanen H. Automatic correction of lens distortion by using digital image processing. Rutgers University, Dept. of Mathematics technical report, 1999. [Accessed on 18 June 2018]. Available from: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.28.8132&rep=rep1&type=pdf.
402. Pourhoseingholi MA, Baghestani AR, Vahedi M. How to control confounding effects by statistical analysis. *Gastroenterology and Hepatology from bed to bench*. 2012;5(2):79.
403. Swan M. Emerging patient-driven health care models: an examination of health social networks, consumer personalized medicine and quantified self-tracking. *Int J Environ Res Public Health*. 2009;6(2):492-525.
404. Erickson DB, Erickson P. Psychological factors and sex differences in acceptance of monovision. *Perceptual and motor skills*. 2000;91(3):s1113-9.
405. Gothwal VK, Bagga DK, Bharani S, Sumalini R, Reddy SP. The patient health questionnaire-9: validation among patients with glaucoma. *PLoS One*. 2014;9(7):e101295.
406. Reeve BB, Hays RD, Bjorner JB, Cook KF, Crane PK, Teresi JA*, et al.* Psychometric evaluation and calibration of health-related quality-of-life item banks: plans for the Patient-Reported Outcomes Measurement Information System (PROMIS). *Med Care*. 2007;45(5):S22-31.
407. Devine J, Fliege H, Kocalevent R, Mierke A, Klapp BF, Rose M. Evaluation of computerized adaptive tests (CATs) for longitudinal monitoring of depression, anxiety, and stress reactions. *J Affect Disord*. 2016;190:846-53.
408. Gomes M, Gutacker N, Bojke C, Street A. Addressing missing data in patient-reported outcome measures (PROMS): implications for the use of PROMS for comparing provider performance. *Health economics*. 2016;25(5):515-28.
409. Hanson BA, Béguin AA. Obtaining a common scale for item response theory item parameters using separate versus concurrent estimation in the common-item equating design. *Appl Psychol Meas*. 2002;26(1):3-24.
410. Vale CD. Linking item parameters onto a common scale. *Appl Psychol Meas*. 1986;10(4):333-44.
411. Kim S-H, Cohen AS. A comparison of linking and concurrent calibration under item response theory. *Appl Psychol Meas*. 1998;22(2):131-43.
412. Scalise K, Allen DD. Use of open-source software for adaptive measurement: Concerto as an R-based computer adaptive development and delivery platform. *Br J Math Stat Psychol*. 2015;68(3):478-96.
413. Thompson NA, Weiss DJ. A framework for the development of computerized adaptive tests. *Practical Assessment, Research & Evaluation*. 2011;16.
414. Schiffman RM, Christianson MD, Jacobsen G, Hirsch JD, Reis BL. Reliability and validity of the ocular surface disease index. *Arch Ophthalmol*. 2000;118(5):615-21.
415. Mangione CM, Lee PP, Gutierrez PR, Spritzer K, Berry S, Hays RD. Development of the 25-list-item National Eye Institute Visual Function Questionnaire. *Arch Ophthalmol*. 2001;119(7):1050-8.
416. McMonnies C, Ho A, Wakefield D. Optimum dry eye classification using questionnaire responses. In: Sullivan DA, Dartt DA, Meneray MA, editors. Lacrimal Gland, Tear Film, and Dry Eye Syndromes. New York: Springer; 1998, p 835-38.
417. Johnson ME, Murphy PJ. Measurement of ocular surface irritation on a linear interval scale with the Ocular Comfort Index. *Invest Ophthalmol Vis Sci*. 2007;48(10):4451-8.
418. Du Toit R, Situ P, Simpson T, Fonn D. The effects of six months of contact lens wear on the tear film, ocular surfaces, and symptoms of presbyopes. *Optom Vis Sci*. 2001;78(6):455-62.

419. Nichols KK, Begley CG, Caffery B, Jones LA. Symptoms of ocular irritation in patients diagnosed with dry eye. *Optom Vis Sci*. 1999;76(12):838-44.
420. Schaumberg DA, Gulati A, Mathers WD, Clinch T, Lemp MA, Nelson JD*, et al.* Development and validation of a short global dry eye symptom index. *Ocul Surf*. 2007;5(1):50-7.
421. Schein OD, Muno B, Tielsch JM, Bandeen-Roche K, West S. Prevalence of dry eye among the elderly. *Am J Ophthalmol*. 1997;124(6):723-8.
422. Uusitalo RJ, Brans T, Pessi T, Tarkkanen A. Evaluating cataract surgery gains by assessing patients' quality-of-life using the VF-7. *J Cataract Refract Surg*. 1999;25(7):989-94.
423. Mangione CM, Phillips RS, Seddon JM, Lawrence MG, Cook EF, Dailey R*, et al.* Development of the'Activities of Daily Vision Scale': a measure of visual functional status. *Med Care*. 1992:1111-26.
424. Frost N, Sparrow J, Durant J, Donovan J, Peters T, Brookes S. Development of a questionnaire for measurement of vision-related quality-of-life. *Ophthalmic Epidemiol*. 1998;5(4):185-210.
425. Scilley K, Owsley C. Vision-specific health-related quality-of-life: content areas for nursing home residents. *Qual Life Res*. 2002;11(5):449-62.
426. Spielberger CD, Jacobs G, Russell S, Crane RS. Assessment of anger: the state-trait anger scale. In: Spielberger CD, Butcher JN, editors. Advances in Personality Assessment. Vol. 2. New York and London: Routledge, Taylor & Fancis Group; 1983, p 159-87.
427. Fazio AF. A concurrent validational study of the NCHS General Well-Being Schedule. Hyattsville, MD: National Center for Health Statistics 1977.
428. Gough HG. The adjective check list as a personality assessment research technique. *Psychol Rep*. 1960;6:107-22.
429. Goldberg DP, Hillier VF. A scaled version of the General Health Questionnaire. *Psychol Med*. 1979;9(01):139-45.
430. Abell N, Jones BL, Hudson WW, editors. Revalidation of the index of self-esteem. Soc Work Res Abstr; 1984: Oxford University Press. 20(3)11-6.
431. Retzlaff PD, King RE, McGlohn SE, Callister JD. The development of the Armstrong Laboratory Aviation Personality Survey (ALAPS). DTIC Document, 1996. [Accessed on 01 June 2018]. Available from: http://www.dtic.mil/docs/citations/ADA314576.
432. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica*. 1983;67(6):361-70.
433. Lachman ME, Howland J, Tennstedt S, Jette A, Assmann S, Peterson EW. Fear of falling and activity restriction: the survey of activities and fear of falling in the elderly (SAFE). *J Gerontol B Psychol Sci Soc Sci*. 1998;53(1):43-50.
434. Kilpatrick FP, Cantril H. Self-anchoring scaling: a measure of individuals' unique reality worlds. *J Individ Psychol*. 1960;16(2):158.
435. Harter S. Self-Perception Profile for Children: revision of the perceived competence scale for children: Universidad de Denver; 1985.
436. Derogatis L. Symptom Checklist-90-Revised: administration, scoring and procedures manual. 3rd ed: Minneapolis, MN: National Computer Systems, Inc.; 1994.
437. Melzack R. The McGill Pain Questionnaire: major properties and scoring methods. *Pain*. 1975;1(3):277-99.
438. Cleeland C, Ryan K. Pain assessment: global use of the Brief Pain Inventory. *Ann Acad Med Singapore*. 1994;23(2):129-38.
439. Ware Jr JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36): I. Conceptual framework and item selection. *Med Care*. 1992:473-83.

Appendix A. Ethics approval and approved documents

Appendix A.01 SAC-HREC ethics approval and approved documents

Note: This doctoral study is the part of refractive error module of the 'Eye-tem' bank project. The Eye-tem bank project has an ethics approval from the Southern Adelaide Clinical Human Research Ethics committee (SAC-HREC), which is renewed every year. The ethics amendments were approved to add the author as a 'Professional Research Personnel (PRP), Research Higher Degree Student', to add Tilganga Institute of Ophthalmology, Nepal; University School of Medical Sciences, Dhulikhel Hospital, Nepal; and Ashford Advanced Eye care centre, Australia as the research centres, and to add the relevant refractive error-specific participant information sheets, consent forms, background questionnaires (for collecting clinical and demographic information), questionnaires, translations, to conduct Phase I and Phase II in Australia and Nepal. The enclosed approval certificates/documents indicate that the ethics approval was obtained for the period from 20 Jan 2015 to 20 Jan 2019. These certificates also indicate which documents (e.g. patient information sheets) were approved by the SAC-HREC. In addition to the approval certificates, the documents approved by the SAC-HREC are also enclosed.

Ethics approvals were also obtained from TIO and KUSMS to conduct Phase I and Phase II of refractive error in Nepal.

Appendix A.02 Ethics Approval Letter from Tilganga Institute of Ophthalmology

Appendix A.03 Ethics Approval Letter from Dhulikhel Hospital

Appendix A.04 Phase I (Australia), Participant information sheet

Appendix A.5 Phase I (Australia), Consent to participate in research

Appendix A.02 Phase II (Australia), Participant information sheet

Appendix A.06 Phase II (Australia), Consent to participate in research

Appendix A.07 Phase I (Nepal), Participant information sheet

Appendix A.08 Phase I (Nepal), Consent to participate in research

Appendix A.09 Phase II (Nepal), Participant information sheet

Appendix A.10 Phase II (Nepal), Consent to participate in research

Appendix A.11 Phase I and II, Refractive error flyers

Appendix A.12 Background questionnaire

Note: The background questionnaire consists of the questions for demographic and general clinical characteristics. The background questionnaire for phase II are presented with the Phase II item-pools (questionnaires): Appendices G and H.

Southern Adelaide Clinical Human Research Ethics Committee

Government of South Australia
Southern Adelaide Health Service

15 June 2015

Dear Professor Pesudovs

This is a formal correspondence from the Southern Adelaide Clinical Human Research Ethics Committee. Whilst this official title of the committee has changed the committee is still properly constituted under AHEC requirements with the registration number EC00188. This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." This department only uses email correspondence for all documents unless prior arrangements have been made with the manager. No hard copy correspondence will be issued.

Application Number: 469.11

Title: A system of measurement of vision-specific quality of life using item banking and computer adaptive testing (Eye-tem bank)

Chief Investigator: Professor Konrad Pesudovs

The Issue: The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) has approved the project amendment, and your project may now incorporate these amendments into your research. The approval extends to the following documents/changes:

- Cover letter
- SAC HREC Project Amendment Application form dated 03 June 2015
- SAC HREC General Research Application form v9 dated June 2015 (tracked)

This amendment approval does not alter the current SAC HREC approval period for the study: 20 January 2016

Please read the terms and conditions of ethical approval below, as researchers have a significant responsibility to comply with reporting requirements and the other stated conditions.

For example, the implications of not providing annual reports and requesting an extension for research prior to approval expiring could lead to the suspension of the research, and has further serious consequences.

Please retain a copy of this approval for your records.

Flinders Medical Centre

The Flats G5 – Rooms 3 and 4

Flinders Drive, Bedford Park SA 5042

T: 08 8204 6453

E:Research.ethics @health.sa.gov.au

TERMS AND CONDITIONS OF ETHICAL APPROVAL
Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions.

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below.

Researchers have a significant responsibility to comply with the *National Statement 5.5.* in providing the SAC HREC with the required information and reporting as detailed below:

1. **Compliance** with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
2. To **immediately report to SAC HREC** anything that may change the ethical or scientific integrity of the project.
3. **If University personnel are involved in this project,** the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
4. **It is the policy of the SAC HREC not to provide signed hardcopy or signed electronic approval letters**, as our office is moving to electronic documentation. The SAC HREC office provides an unsigned electronic PDF version of the study approval letter to the Chief Investigator/Study Manager via email. These email approvals are generated via the email address research.ethics@health.sa.gov.au which can be linked back to the SAC HREC.
5. **Report Significant Adverse events (SAE's)** as per SAE requirements available at our website.
6. **Submit an annual report on each anniversary of the date of final approval** and in the correct template from the SAC HREC website.
7. **Confidentiality** of research participants MUST be maintained at all times.
8. A copy of the **signed consent form** must be given to the participant unless the project is an audit.
9. Any **reports or publications derived from the research** should be submitted to the Committee at the completion of the project.
10. All requests for **access to medical records** at any SALHN site must be accompanied by this approval email.
11. To **regularly review the SAC HREC website** and comply with all submission requirements, as they change from time to time.
12. The researchers agree to use **electronic format** for all correspondence with this department.
13. Researchers are reminded that **all advertisements/flyers** need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contract should be coordinated through the FMC media unit.

Yours sincerely

Anna Pantelidis
Administration Officer, SAC HREC

On behalf of

Professor David Gordon
Chair, SAC HREC

Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Amendment to ethics application approved

You are reminded that this letter constitutes ethical approval only for this amendment. If you are waiting on Site Specific Assessment (SSA) authorisation for your study, you must not commence this research project at any public Health site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

06 September 2016

Professor Konrad Pesudovs
Optometry and Vision Science
Flinders Medical Centre
BEDFORD PARK SA 5042

Dear Professor Pesudovs

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this amendment which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research.*

Application Number: OFR # 469.11

Title: A system of measurement of vision-specific quality of life using item banking and computer adaptive testing (Eye-tem bank)

Chief Investigator: Professor Konrad Pesudovs

Approval date: 06 September 2016

This amendment approval does not alter the current SAC HREC approval period for the study: 20 January 2016 to 20 January 2017

The below documents have been reviewed and approved:

- Cover Letter dated July 2016
- Project Amendment Application form dated 17 June 2016
- General Research Application form v12 dated July 2016
- Tilganga Institute of Ophthalmology Ethics Approval Letter dated 20 April 2016
- Data Collection Approval – Dhulikhel Hospital dated 08 March 2016
- Phase I Participant Information Sheet – Refractive Error v2 dated July 2016
- Phase I Consent to Participate in Research v2 dated July 2016
- Phase II Participant Information Sheet – Refractive Error v2 dated July 2016
- Phase II Consent to Participate in Research v2 dated July 2016
- Translation of Information Sheets and Consent form dated 04 April 2016
- Phase II Refractive Error Flyer
- Group Email to Students and Staff at Flinders University v1 dated July 2016
- Response to Ethics Committee v1 dated July 2016

TERMS AND CONDITIONS OF ETHICAL APPROVAL
As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval covers the ethics component of the application. Please submit a copy of the approved amendment to the local RGO for acknowledgement
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
4. To immediately report to SAC HREC anything that may change the ethical or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.
13. Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

Yours sincerely

A/Professor Bernadette Richards
Chair, SAC HREC

Extension request to ethics approval approved

11 January 2017

Dear Professor Konrad Pesudovs

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this extension which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research*

Application number: OFR # 469.11

Study title: A system for measurement of vision-specific quality of life using item banking and computer adaptive testing

Chief Investigator: Professor Konrad Pesudovs

Ethics approval period: 20 January 2017 to 20 January 2018

The below document/s have been reviewed and approved:

- SAC HREC Extension Request and Annual Review form dated 06 January 2017

TERMS AND CONDITIONS OF ETHICAL APPROVAL
As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
2. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
3. To immediately report to SAC HREC anything that may change the ethical or scientific integrity of the project.
4. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
5. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
6. Confidentiality of research participants MUST be maintained at all times.
7. A copy of the signed consent form must be given to the participant unless the project is an audit.
8. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
9. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
10. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
11. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.

Dani Eley
Administration Officer, Office for Research

On behalf of

Petrina Kasperski
Ethics Officer (QA), Office for Research

Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Amendment: Ethics Approval

15 March 2018

Associate Professor Ecosse Lamoureux
Department of Ophthalmology
University of Melbourne
Locked Bag 8
East Melbourne VIC 8002

Dear Associate Professor Lamoureux

OFR Number: 469.11
Project title: A system for measurement of vision-specific quality of life using item banking and computer adaptive testing (Eye-tem Bank)
Chief Investigator: Associate Professor Ecosse Lamoureux

Ethics and Governance Approval Period: 20 January 2018 - 20 January 2019

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) has reviewed and provided ethics approval for this amendment which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

This amendment approval does not alter the current SAC HREC approval period.

Public health sites approved under this Ethics amendment application:
- Flinders Medical Centre
- Royal Adelaide Hospital
- the Queen Elizabeth Hospital

The below documents have been reviewed and approved by the SAC HREC:
- Project amendment form - staff changes - dated 02 February 2018
- General research application form v15 dated 05 March 2018

Terms and Conditions Of Ethics Approval:
It is essential that researchers adhere to the conditions below and with the *National Statement Chapter 5.5.*

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval covers the ethics component of the application. Please submit a copy of the approved amendment to the local RGO for acknowledgement
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).

4. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.
13. Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

For any queries about this matter, please contact the Executive Officer on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au.

Yours sincerely

[redacted]

A/Professor Bernadette Richards
Chair, SAC HREC

Nepal Eye Program

Tilganga Institute of Ophthalmology

Tilganga, Bagmati Bridge, P.O.Box 561, Kathmandu, Nepal Tel: 4493684, 4493775, Fax: 977-1-4474937, Email: tio@tilganga.org, Web: www.tilganga.org

Nepal Eye Program
Tilganga Institute of Ophthalmology
Institutional Review Committee
(TIO-IRC)
Kathamandu, Nepal
2005

20 April 2016

Mr. Himal Kandel
Principal Investigator,
PhD Student,
NH&MRC Centre for Clinical Eye Research, Discipline of Optometry and Vision Science,
Flinders University

Subject: Approval of proposed research

Dear Mr. Kandel,

I would like to inform you that the research titled on "**Development and Validation of Technologically Advanced Patient-Reported Outcome measure for Refractive Error**" was reviewed and approved by the Institutional Review Committee of Tilganga Institute of Ophthalmology (IRC-TIO) dated on 30/03/2016.

We would also like to remind you that if there are any further modifications in the approved proposal, you should be notified to IRC-TIO. Similarly, you have mandatory to submit regulator progress report. The final report must be submitted to the IRC -TIO at the **end of the project**.

I would like to wish you success in the forthcoming research.

Sincerely,

[redacted]

Mohan Krishna Shrestha, MPH
Member Secretary,
IRC-TIO

KATHMANDU UNIVERSITY
SCHOOL OF MEDICAL SCIENCES

Date: August19, 2016

To,

Dr. Bhagavat Prasad Nepal
Professor
Department of Ophthalmology
Kathmandu University School of Medical Sciences
Dhulikhel, Nepal

To,

Dr. Konrad Pesudovs
Professor
Foundation Chair of Optometry and Vision Science,
Flinders University
Adelaide, Australia

Dear Dr. Pesudovs & Dr. Nepal

The Institutional Review Committee of Kathmandu University School of Medical Sciences/Dhulikhel Hospital (IRC-KUSMS) reviewed and discussed your application to conduct study entitled **"Development and validation of technologically advanced patient-reported outcome measure for refractive error"** on 10th July 2016.

The Committee has approved the protocol.

Your protocol approval number is: **103/16**

The IRC-KUSMS expects to be informed about the progress of the study, any changes in the protocol and patient information/informed consent. A copy of the final report should be submitted to IRC-KUSMS.

With best regards,

[redacted]

Dr. Dipak Shrestha
Member Secretary, IRC-KUSMS

Dhulikhel, Kavre GPO Box 11008 Kathmandu, Nepal Phone: 00977 11 490497 Fax: 00977 11 490707 Email: kusms@ku.edu.np www.dhulikhelhospital.org Collaborative Program of Kathmandu University and Dhulikhel Hospital

Government of South Australia
SA Health

Flinders UNIVERSITY

PARTICIPANT INFORMATION SHEET
[Refractive Error]

Title of the project:
Questionnaire Study: A system for measurement of refractive error-specific quality of life using item banking and computer adaptive testing (Eye-tem Bank):

Phase I- Item identification

Name of organizations:
This is a collaborative study carried out between Flinders University as a lead organization and the five centres: the Flinders Vision, SA; the Queen Elizabeth Hospital, SA; the Royal Adelaide Hospital, SA, the Royal Victorian Eye and Ear Hospital, VIC, and the Ashford Advanced Eye Care, SA.). In Nepal, the collaborating centres are the Tilganga Institute of Ophthalmology, and the Dhulikhel Hospital, Kathmandu University.

This is a research project, and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way.

You are invited to take part in **Phase I** of a research study conducted by the Discipline of Optometry at Flinders University. This study aims to develop and refine banks of items (questions) that will be used for the assessment of quality of life in patients with refractive error and its correction. The item bank will assist eye doctors and researchers to gain a better understanding of the impact of refractive error and its correction on each patient and determine the appropriate course for treatment.

If you choose to participate, you may be invited to attend a focus group discussion or one-on-one interview (face-to-face or telephone), in which you will be asked to talk about how your eye problem is affecting you and your life. The focus group/ face-to-face interviews will take place in one of six settings (Flinders University/Flinders Medical Centre, Adelaide or Bedford Park, SA, the Queen Elizabeth Hospital, Woodville West, SA, the Royal Adelaide Hospital, Adelaide, SA, and theAshford Advanced Eye Care, SA, wherever is most convenient for you. Similarly, in Nepal, the focus groups or interviews will take place in the collaborating centres: Tilganga Institute of Ophthalmology, and Dhulikhel Hospital, Kathmandu University. A facilitator will be present to guide the discussion/interviews, which will last around 1 hour. If you instead prefer a telephone interview, one of our staff will contact you at your preferred time and will guide the telephone interview. The focus group discussion and interviews will be audio-recorded, but your identity and what you say will remain confidential. Apart from attending a group discussion group / interview you will not be asked to attend any special visits. You will receive a flat rate of $20 to assist with transport and parking costs. Refreshments will also be provided during the focus group/ face-to-face interviews.
You will need to fill out the demographic form and sign the consent (attached) before participating in the study, this should only take few minutes. If you agree to participate, we will acquire measurements of your vision and diagnosis from your clinical file. If you do not consent, we will not access your clinical file.

There are no direct benefits to you from being associated with this study. However, your input may help eye doctors and researchers in being better able to assess how these eye problems affect quality of life in future patients.

Your involvement in this study will not affect your treatment in any way. Your participation in the study is entirely voluntary and you have the right to withdraw at any time. If you decide not to participate in this study or if you withdraw, you may do this freely without prejudice to any treatment.

If you suffer injury as a result of participation in this research or study, compensation might be paid without litigation. However, such compensation is not automatic and you may have to take legal action to determine whether you should be paid.

All records containing personal information will remain confidential and no information that could lead to your identification will be released. Records will be kept in a securely locked filing cabinet and in a password protected computer located in room S171, Sturt West, Flinders University. The audio recording of the focus groups and interviews will be transcribed for analytic purposes only. Data will be deleted and destroyed 5 years after the study is completed. We expect that once the study is completed, the results will be published in a scientific journal. All patient responses will be de-identified and then collated, so that your identity and any personal information will remain completely confidential.

Please note, if you do not want to be identified by name during the focus group session, you can use a different name. In order to respect the privacy of other participants, we request that you do not share what has been discussed in the focus group or divulge the identity of fellow participants to anybody outside the group.

Should you require further details about the project, either before, during or after the study, you may contact the research personnel (PhD **Student) Mr Himal Kandel, Mobile No: +61 450 899 575; (Australia), +977 9841706580 (Nepal); E-mail:** himal.kandel@flinders.edu.au (Discipline of Optometry, Flinders University).

This study has been reviewed by the Southern Adelaide Clinical Human Research Ethics Committee. If you wish to discuss the study with someone not directly involved, in particular with relation to policies and your rights as a participant, or should you wish to make a confidential complaint, you may contact the executive officer on 8204 6543 or email SALHNofficeforresearch@sa.gov.au.

Thank you for your time and support!

Government of South Australia
SA Health

Flinders UNIVERSITY

SOUTHERN ADELAIDE CLINICAL HUMAN RESEARCH ETHICS COMMITTEE / FLINDERS UNIVERSITY

CONSENT TO PARTICIPATION IN RESEARCH

I, ... request and give consent
(first or given names) *(last name)*

to my involvement in the research project: Questionnaire Study – Phase I

A system for measurement of refractive error-specific quality of life using item banking and computer adaptive testing (Eye-tem Bank)
Phase I: Item identification

I acknowledge the nature, purpose and contemplated effects of the research project, especially as far as they affect me, have been fully explained to my satisfaction by…**Himal**..... **Kandel**
(first or given names) *(last name)*
and my consent is given voluntarily.

I acknowledge that the detail(s) of the following has/have been explained to me, including indications of risks, any discomfort involved, and the frequency with which they will be performed.

I will be involved in a focus group / one one-on-one interviews to talk about how my refractive error and its correction are affecting me and my life

I have understood and am satisfied with the explanations that I have been given.
I have been provided with a written information sheet.

I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.
I understand that my medical records may be accessed to confirm my diagnosis.
I declare that I am over the age of 18 years.

I also consent to extracting my clinical details (measurements of vision and diagnosis) from my clinical file for this research *(please tick)* Yes ☐ No ☐

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action to determine whether I should be paid.

Signature of Research Participant : ..... Date: .....

I, **Himal Kandel** ..... have described to .....
the research project and nature and effects of procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature: ..... Date: .....
Status in the project: **PhD Student**

Government of South Australia
SA Health

Flinders UNIVERSITY

PARTICIPANT INFORMATION SHEET
[Refractive Error]

Title of the project:
Questionnaire Study: A system for measurement of refractive error-specific quality of life using item banking and computer adaptive testing (Eye-tem Bank):

Phase II- Developing the item bank

Name of organizations:
This is a collaborative study carried out between Flinders University as a lead organization and the five centres: the Flinders Vision, SA; the Queen Elizabeth Hospital, SA; the Royal Adelaide Hospital, SA, the Royal Victorian Eye and Ear Hospital, VIC, and the Ashford Advanced Eye Care, SA.). In Nepal, the collaborating centres are the Tilganga Institute of Ophthalmology, and the Dhulikhel Hospital, Kathmandu University.

This is a research project, and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way.

You are invited to take part in **Phase II** of a research study conducted by the Discipline of Optometry at Flinders University. This study aims to develop and refine banks of items (questions) that will be used for the assessment of quality of life in patients with refractive error and its correction. The item bank will assist eye doctors and researchers to gain a better understanding of the impact of refractive error and its correction on each patient and determine the appropriate course for treatment.

If you choose to participate, you will be asked a set of questions about how your eye problem and its treatment are affecting you and your life. The questions may be self-administered (in paper or online), interviewer-administered (face-to-face or telephone). Filling out a complete questionnaire may take about an hour. Your answers will be recorded on a password protected computer but your identity and your answers will remain forever confidential. You will not receive any payment for participation in this study apart from $20 compensation for travel and parking costs. Apart from attending the interview, you will not be asked to attend any further visits. If you choose a telephone interview, one of our staff will contact you at a convenient time.

You will need to fill out the demographic form and sign the consent (attached) before participating in the study - this should only take few minutes to complete. If you decide to participate, we will acquire measurements of your vision and diagnosis from your clinical file. If you do not consent, we will not access your clinical files.

There are no direct benefits to you from being associated with this study. However, the information obtained from your interview will help us refine our item banks. Therefore, your input may help eye doctors and researchers in being better able to assess how these refractive error and its correction affect quality of life in future patients.

Your involvement in this study will not affect your treatment in any way. Your participation in the study is entirely voluntary and you have the right to withdraw at any time. If you decide not to participate in this study or if you withdraw, you may do this freely without prejudice to any treatment.

If you suffer injury as a result of participation in this research or study, compensation might be paid without litigation. However, such compensation is not automatic and you may have to take legal action to determine whether you should be paid.

All records containing personal information will remain confidential and no information that could lead to your identification will be released. Records will be kept in a securely locked filing cabinet and in a password protected computer located in room S171, Sturt West, Flinders University. Data will be deleted and destroyed five years after the study is completed. We expect that once the study is completed, the results will be published in a scientific journal. However, all your answers will be de-identified and then collated so that your identity and any personal information will remain completely confidential.

Should you require further details about the project, either before, during or after the study, you may contact the research personnel **(PhD Student) Mr Himal Kandel, Mobile No: +61 450 899 575; (Australia), +977 9841706580 (Nepal); E-mail:** himal.kandel@flinders.edu.au (Discipline of Optometry, Flinders University).

This study has been reviewed by the Southern Adelaide Clinical Human Research Ethics Committee. If you wish to discuss the study with someone not directly involved, in particular in relation to policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the executive officer on 8204 6543 or email SALHNofficeforresearch@sa.gov.au.

Thank you for your time and support!

Government of South Australia
SA Health

Flinders UNIVERSITY

SOUTHERN ADELAIDE CLINICAL HUMAN RESEARCH ETHICS COMMITTEE / FLINDERS UNIVERSITY

CONSENT TO PARTICIPATION IN RESEARCH

I, ... request and give consent
(first or given names) *(last name)*

to my involvement in the research project: Questionnaire Study – Phase II

A system for measurement of refractive error-specific quality of life using item banking and computer adaptive testing (Eye-tem Bank)
Phase II: Developing the Item bank

I acknowledge the nature, purpose and contemplated effects of the research project, especially as far as they affect me, have been fully explained to my satisfaction by…**Himal**…… **Kandel**
(first or given names) *(last name)*
and my consent is given voluntarily.

I acknowledge that the detail(s) of the following has/have been explained to me, including indications of risks, any discomfort involved, and the frequency with which they will be performed.

I will be involved in a survey which requires me to answer a set of questions about how my refractive error and its correction are affecting me and my life

I have understood and am satisfied with the explanations that I have been given.
I have been provided with a written information sheet.

I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.
I understand that my medical records may be accessed to confirm my diagnosis.
I declare that I am over the age of 18 years.

I also consent to extracting my clinical details (measurements of vision and diagnosis) from my clinical file for this research *(please tick)* Yes ☐ No ☐

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action to determine whether I should be paid.

Signature of Research Participant : ..... Date: .....

I, **Himal Kandel** ..... have described to .....
the research project and nature and effects of procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature: ..... Date: .....
Status in the project: **PhD Student**

Government of South Australia
SA Health

Flinders UNIVERSITY

सहभागिको लागि जानकारी पत्र

रिफ्र्याक्टिभ एरर् (Refractive Error)

परियोजनाको शीर्षक : रिफ्र्याक्टिभ एरर (Refractive error – चस्मा वा कन्ट्याक्ट लेन्स लगाउन पर्ने अवस्था) ले जीवनमा पार्ने प्रभावहरुको मापन गर्ने प्रणाली

चरण १- रिफ्र्याक्टिभ एरर्ले जीवनमा पार्ने प्रभावहरुको मापन गर्ने प्रश्नहरुको पहिचान (Item Identification)

संस्थाका नामहरु:

यो परियोजना विभिन्न संस्थाहरुको सहकार्यमा भइरहेको छ जसमा फिलिन्डर्स विश्वविद्यालय प्रमुख संस्था हो। अन्य संस्थाहरुमा दक्षिण अस्टेलियाका क्विनएलिजावेथ अस्पताल, रोयल एडिलेड अस्पताल र आश्फोर्ड एड्भान्सड आई केयर तथा भिक्टोरियाको रोयल भिक्टोरीयन आँखा तथा कान अस्पताल रहेका छन् । साथै नेपालका तिलगंगा आँखा अस्पताल र धुलिखेल सामुदायिक अस्पताल रहेका छन् ।

यो एउटा अनुसन्धान परियोजना हो र तपाई यसमा संलग्न हुन सक्नु हुन्छ । यदि तपाई भाग लिन चाहनु हुन्न भने, तपाईको उपचार कुनै प्रकारले पनि प्रभावित हुने छैन ।

फिलिन्डर्स विश्वविद्यालयको दृष्टि विज्ञान विभागदारा संचालन गर्न लागिएको यो अनुसन्धानको पहिलो चरणमा भाग लिनलाई तपाईलाई हार्दिक आमन्त्रण गर्दछौं ।

यो अध्ययन रिफ्र्याक्टिभ एरर्ले मानिसको जीवनमा कसरी असर पार्छ भन्ने कुरा पत्ता लगाउनका लागि गरिदै छ । यो सोधकार्यबाट प्राप्त जानकारी जीवनको गुणस्तरको मापन गर्ने धेरै प्रश्नहरुको संगालो (आइटम बैंक-Item Bank)विकास गर्न प्रयोग गरिनेछ । यो आइटम बैंकले चिकित्सक तथा खोजकर्तालाई आँखाको समस्याले विरामीलाई पार्ने असर मुल्याङ्कन गर्न र सोको उपयूक्त उपचार विधि निर्धारण गर्न मद्दत गर्नेछ ।

यदि तपाई यो अध्ययनमा सहभागी हुन चाहनुहुन्छ भने तपाईलाई ध्यान समुह छलफल (Focus Group Discussion) वा अन्तर्वार्ताको (प्रत्यक्षवा टेलिफोन) लागि आग्रह गरिने छ जसमा रिफ्र्याक्टिभ एरर्ले कसरी तपाईलाई र तपाईको जीवनलाई असर गरिरहेको छ भन्ने बारे सोधिने छ । सो ध्यान समुह छलफल वा अन्तर्वाता माथि उल्लेखित स्थानमध्य तपाईको अनुकुलता अनुसार कुनै एक स्थानमा गरिने छ जुन १ देखि २ घण्टा सम्म हुनेछ । छलफललाई एउटै दिशातर्फ लानको लागि एक जना सहजकर्ता उपस्थित हुनेछ । यदि तपाई टेलिफोन अन्तर्वार्ता रुचाउनु हुन्छ भने हाम्रो एक जना शोधकर्ताले तपाईको अनुकुल समयमा अन्तर्वार्ताको लागि सम्पर्क गर्नेछ । तपाईले बोलेका कुराहरुलाई टेप रेकर्ड गरिनेछ तर तपाईको पहिचानलाई गोप्य राखिनेछ । छलफल वा अन्तर्वार्ता बाहेक अन्य कुनै पनि वेला तपाईको उपस्थितिको लागि सोधिने छैन । केन्द्र आएको खण्डमा तपाईलाई यातायात खर्च स्वरुप रु १०० प्रदान गरिनेछ । सो छलफल वा अन्तर्वार्तामा जलपान आयोजना गरिनेछ ।

यो अध्ययनमा सहभागिता जनाउनु अघि तपाईले जनसाङ्ख्यिकी फाराम (demographic form) भर्नु पर्दछ । यो फाराम भर्न केहि मिनेट मात्र लाग्छ । तपाई सहभागी हुन सहमत भएमातपाईको अनुमतिमा हामीले तपाईको चिकित्सकीय फाइलबाट दृष्टि र निदानको माप प्राप्त गर्नेछौं ।

यो अध्ययनबाट तपाईलाई प्रत्यक्ष लाभ नहुन सक्छ । तर तपाईको सहयोगले आँखाका चिकित्सक तथा अनुसन्धानकर्ताहरुलाई भविष्यका विरामीहरुमा रिफ्र्याक्टिभ एरर्ले जीवनको गुणस्तरलाई कसरी असर गर्छ भन्ने कुरा आंकलन गर्न मद्दत गर्दछ ।

यो अध्ययनमा तपाईको सहभागिताको कारण तपाईको उपचार कुनै पनि तरिकाले प्रभावित हुने छैन । तपाईको सहभागिता पूर्ण रुपले स्वइच्छिक हुनेछ र तपाई कुनै पनि समयमा आफ्नो सहभागिता फिर्ता लिन सक्नु हुनेछ। यसले तपाईको उपचारमा कुनै पनि प्रकारको पूर्वाग्रह हुने छैन ।

अध्ययनका क्रममा तपाईलाई चोटपटक लागेमा यसको क्षतिपूर्ति मुद्दा विना भुक्तानी गर्न सकिनेछ । यो क्षतिपूर्ति स्वचालित नभएको हुदा तपाईले कानुनी सल्लाह लिन सक्नुहुनेछ ।

व्यक्तिगत विवरण रहेका सबै रेकर्ड गोप्य रहने छन् र तपाईको पहिचान खुल्ने किसिमको कुनै पनि जानकारी बाहिर निकालिने छैन । रेकर्डहरु फिलिन्डर्स विश्वविद्यालयको स्टर्ट पश्चिम भवनको कोठा एस १७१ मा बन्द दराजमा तथा पासवर्ड सुरक्षित कम्प्यटरमा सुरक्षित राखिने छ । ध्यान समुह र अन्तर्वार्ताको अडियो रेकर्डिङ विश्लेषणात्मक उद्देश्यका लागि लिखित गरिनेछ । यो अध्ययन पुरा भएको ५ वर्षमा रेकर्डहरु नष्ट गरिनेछ । अध्ययन पुरा भएपछि वैज्ञानिक पत्रिकामा परिणामहरु प्रकाशित गरिने कुरा हामी आशा गर्दछौं । व्यक्तिगत जानकारीहरु गोप्य राख्नको लागि विरामीको प्रतिक्रियाहरुबाट पहिचान हटाइने छ।

यदितपाई ध्यान समुह सत्रमा आफ्नो नाम खुलाउन नचाहनु भएमा तपाई फरक नाम प्रयोग गर्न सक्नुहुनेछ । अन्य सहभागिहरुको गोपनियता कायम गर्नको लागि ध्यान समुहमा छलफल गरिएका कुराहरु अन्य कुनै ठाउँमा छलफल नगरिदिनहुन अनुरोध गर्दछौं ।

यदितपाईलाई यो अध्ययनको बारेमाकेहीजानकारी चाहिएमातपाईले यो अध्ययन सुरु हुनु भन्दापहिले, अध्ययनअवधिमावाअध्ययनपश्चात् कुनै पनि बेलापि.एच.डी विद्यार्थी हिमाल कँडेललाई टेलिफोन मार्फत सम्पर्क गर्न सक्नुहुनेछ । (टे.नं. +६१४५०८९९५७५ (अष्टेलिया),+९७७९८४१७०६५८० (नेपाल) दृष्टि विज्ञान विभाग, फिलिन्डर्स विश्वविद्यालय) ।

यो अध्ययन दक्षिणी एडिलेड क्लिनिकल मानब अनुसन्धान नीति शास्त्र समिति दारा समिक्षा गरिएको छ । यदितपाई अध्ययन सम्बन्धि नीति नियम वा सहभागिको अधिकारको बारेमा यो अध्ययनमा प्रत्यक्ष संलग्नन भएको व्यक्तिसँग छलफल वा उजुरी गर्न चाहनुहुन्छ भने कार्यकारी अधिकृतलाई फोन गरि अथवा इमेल मार्फत सम्पर्क गर्न सक्नुहुनेछ । फो.नं. +६१८२०४४५०७, इमेल
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अनुसन्धानमा सहभागिताको लागि मन्जुरिनामा

म,..... ले रिफ्र्याक्टिभ एरर् (Refractive error – चस्मा वा कन्ट्याक्ट लेन्स लगाउनु पर्ने अवस्था) ले जीवनमा पार्ने प्रभावहरुको मापन गर्ने प्रणाली अध्ययनको **चरण १ (रिफ्र्याक्टिभ एरर्ले जीवनमा पार्ने प्रभावहरुको मापन गर्ने प्रश्नहरुको पहिचान - Item Identification)]** मा आफ्नो सहभागिताको लागि मन्जुरिनामा दिन्छु ।

मलाई यो अनुसन्धानको प्रकृति, उद्देश्य र यसका असरहरुको बारेमा..... द्वारा पूर्ण रुपमा व्याख्या गरिएको छ र मैले स्वइच्छाले मन्जुरीनामा दिन्छु ।

यो अध्ययन सँग सम्बन्धि विवरणहरु रामो संग व्याख्या गरिएको कुरा म स्वीकार्छु । मलाई यस अध्ययनमा हुन सक्ने जोखिमहरु, असुविधाहरु र चाहिने समयको बारेमा पनि रामो संग व्याख्या गरिएको कुरा स्विकार्छु । मलाई लिखित जानकारी पत्र प्रदान गरिएको छ । मलाई गरिएको व्याख्या मैले बुझें र म यसमा सन्तुष्ट छु ।

यो अनुसन्धानमा मेरो संलग्नताले मलाई प्रत्यक्ष लाभ नहुन सक्ने र मैले आफ्नो अधिकार वा सोधकर्ताको जिम्मेवारीलाई प्रभाव नहुने गरि कुनै पनि अवस्थामा मेरो सहमति फिर्ता लिन सक्ने कुरा मलाई ज्ञान छ ।

मेरो उमेर १८ वर्ष भन्दा माथि छ भनेर म ठोकुवा गर्छु ।

निदान पुष्टि गर्नको लागी मेरो चिकित्सा रेकर्ड हेर्न सकिने छ भन्ने कुरा मलाई जानकारी छ । म मेरो चिकित्सकीय फाइलबाट आवश्यक विवरण (दृष्टि र निदान) झिक्न अनुमति दिन्छु ।

यो अनुसन्धानको क्रममा मलाई चोटपटक लागेमा, क्षतीपुर्तीको लागि मैले कानुनी कारवाही गर्न सक्ने कुरा मलाई रामो संग जानकारी गराइएको छ ।

अनुसन्धान सहभागीको दस्तखत..... मिति.....

म ..... ले ..... लाई यो अनुसन्धान, यसको प्रकृति र असरहरुका बारेमा रामो संग व्याख्या गरेको छु । मेरो विचारमा उँहाले दिइएको विवरण रामो सँग बुझ्नुहुन्छ र उँहाले स्वइच्छाले मन्जुरीनामा दिनु भएको हो ।

दस्तखत..... मिति.....

पद.....

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सहभागिको लागि जानकारी पत्र
रिफ्र्याक्टिभ एरर् (Refractive Error)

परियोजनाको शीर्षक : रिफ्र्याक्टिभ एरर् (Refractive error चस्मा वा कन्ट्याक्ट लेन्स लगाउनु पर्ने अवस्था) ले जीवनमा पार्ने प्रभावहरुको मापन गर्ने प्रणाली

चरण २ जीवनको गुणस्तर मापन गर्ने धेरै प्रश्नहरुको संगालो निर्माण (आइटम बैंक निर्माण – Developing the Item Bank)

संस्थाका नामहरु:

यो परियोजना विभिन्न संस्थाहरुको सहकार्यमा भइरहेको छ जसमा फिलिन्डर्स विश्वविद्यालय प्रमुख संस्था हो। अन्य संस्थाहरुमा दक्षिण अस्ट्रेलियाका क्विन एलिजावेथ अस्पताल, रोयल एडिलेड अस्पताल र आश्फोर्ड एड्भान्सड आई केयर तथा भिक्टोरियाको रोयल भिक्टोरीयन आँखा तथा कान अस्पताल रहेका छन् । साथै नेपालका तिलगंगा आँखा अस्पताल र धुलिखेल सामुदायिक अस्पताल रहेका छन् ।

यो एउटा अनुसन्धान परियोजना हो र तपाई यसमा संलग्न हुन सक्नुहुन्छ । यदि तपाई भाग लिन चाहनुहुन्न भने, तपाईको उपचार कुनै प्रकारले पनि प्रभावित हुने छैन ।

फिलिन्डर्स विश्वविद्यालयको दृष्टि विज्ञान विभागदारा संचालन गर्न लागिएको यो अनुसन्धानको दोस्रो चरणमा भाग लिनलाई तपाईलाई हार्दिक आमन्त्रण गर्दछौं ।

यो अध्ययन रिफ्र्याक्टिभ एरर्ले मानिसको जीवनमा कसरी असर पार्छ भन्ने कुरा पत्ता लगाउनका लागि गरिदै छ । यो सोधकार्यबाट प्राप्त जानकारी जीवनको गुणस्तरको मापन गर्ने धेरै प्रश्नहरुको संगालो (आइटम बैंक - Item Bank) विकास गर्न प्रयोग गरिनेछ । यो आइटम बैंकले चिकित्सक तथा खोजकर्तालाई आँखाको समस्याले विरामीलाई पार्ने असर मुल्याङ्कन गर्न र सोको उपयूक्त उपचार विधि निर्धारण गर्न मद्दत गर्नेछ ।

इदि तपाई यो अध्ययनमा सहभागी हुन चाहनुहुन्छ भने तपाईलाई अन्तर्वार्ताको (प्रत्यक्ष वा टेलिफोन) लागि आग्रहगरिने छ जसमा रिफ्र्याक्टिभ एरर्ले कसरी तपाईलाई र तपाईको जीवनलाई असर गरिरहेको छ भन्ने बारे प्रश्नहरु सोधिने छ । सो अन्तर्वाता माथि उल्लेखित स्थानमध्य कुनै एक स्थानमा गरिने छ जुन १ देखि २ घण्टा सम्म हुनेछ । तपाईको जवाफलाई रेकर्ड गरिनेछ तर तपाईको पहिचानलाई गोप्य राखिनेछ । अन्तर्वार्ता बाहेक अन्यकुनै पनि वेलातपाईको उपस्थितीको लागि सोधिने छैन । केन्द्र आएको खण्डमा तपाईलाई यातायात खर्च स्वरुप रु १०० प्रदान गरिनेछ ।

यो अध्ययनमा सहभागिता जनाउनु अघि तपाईले जनसाङ्ख्यकी फाराम (demographic form) भर्नु पर्दछ । यो फाराम भर्न केहि मिनेट मात्र लाग्छ । तपाई सहभागी हुन सहमत भएमा तपाईको अनुमतिमा हामीले तपाईको चिकित्सकीय फाइलबाट दृष्टि र निदानको माप प्राप्त गर्नेछौं ।

यो अध्ययनबाट तपाईलाई प्रत्यक्ष लाभ नहुन सक्छ। तर तपाईको सहयोगले आँखाका चिकित्सक तथा अनुसन्धानकर्ताहरुलाई भविष्यका विरामीहरुमा आंखाको समस्याले जीवनको गुणस्तरलाई कसरी असर गर्छ भन्ने कुरा आंकलन गर्न मद्दत गर्दछ।

यो अध्ययनमा तपाईको सहभागिताको कारण तपाईको उपचार कुनै पनि तरिकाले प्रभावित हुने छैन। तपाईको सहभागिता पूर्ण रुपले स्वइच्छिक हुनेछ र तपाई कुनै पनि समयमा आफ्नो सहभागिता फिर्ता लिनसक्नु हुनेछ। यसले तपाईको उपचारमा कुनै पनि प्रकारको पूर्वाग्रह हुने छैन।

अध्ययनका क्रममा तपाईलाई चोटपटक लागेमा यसको क्षतिपूर्ति मुद्दा विना भुक्तानी गर्न सकिनेछ। यो क्षतिपूर्ति स्वचालित नभएको हुदा तपाईले कानुनी सल्लाह लिन सक्नुहुनेछ।

व्यक्तिगत विवरण रहेका सबै रेकर्ड गोप्य रहने छन् र तपाईको पहिचान खुल्ने किसिमको कुनै पनि जानकारी बाहिर निकालिने छैन। रेकर्डहरु फिलिन्डर्स विश्वविद्यालयको स्टर्ट पश्चिम भवनको कोठा एस १७१ मा बन्द दराजमा तथा पासवर्ड सुरक्षित कम्प्यटरमा सुरक्षित राखिने छ। ध्यान समुह र अन्तर्वार्ताको अडियो रेकर्डिङ विश्लेषणात्मक उद्देश्यका लागि लिखित गरिनेछ। यो अध्ययन पुरा भएको ५ वर्षमा रेकर्डहरु नष्ट गरिनेछ। अध्ययन पुरा भएपछि वैज्ञानिक पत्रिकामा परिणामहरु प्रकाशित गरिने कुरा हामी आशा गर्दछौं। व्यक्तिगत जानकारीहरु गोप्य राख्नको लागि विरामीको प्रतिक्रियाहरुबाट पहिचान हटाइने छ।

यदि तपाई ध्यान समुह सत्रमा आफ्नो नाम खुलाउन नचाहनु भएमा तपाई फरक नाम प्रयोग गर्न सक्नुहुनेछ। अन्य सहभागिहरुको गोपनियता कायम गर्नको लागि ध्यान समुहमा छलफल गरिएका कुराहरु अन्य कुनै ठाउँमा छलफल नगरिदिन हुन अनुरोध गर्दछौं।

यदि तपाईलाई यो अध्ययनको बारेमा केही जानकारी चाहिएमा तपाईले यो अध्ययन सुरु हुनु भन्दा पहिले, अध्ययन अवधिमा वा अध्ययन पश्चात् कुनै पनि बेला पि.एच.डी विद्यार्थी हिमाल कँडेललाई टेलिफोन मार्फत सम्पर्क गर्न सक्नुहुनेछ। (टे.नं. +६१४५०८९९५७५ (अष्टेलिया), +९७७९८४१७०६५८० (नेपाल) दृष्टि विज्ञान विभाग, फिलिन्डर्स विश्वविद्यालय)।

यो अध्ययन दक्षिणी एडिलेड क्लिनिकल मानब अनुसन्धान नीति शास्त्र समिति दारा समिक्षा गरिएको छ। यदि तपाई अध्ययन सम्बन्धि नीति नियम वा सहभागिको अधिकारको बारेमा यो अध्ययनमा प्रत्यक्ष संलग्न नभएको व्यक्तिसँग छलफल वा उजुरी गर्न चाहनुहुन्छ भने कार्यकारी अधिकृतलाई फोन गरि अथवा इमेल मार्फत सम्पर्क गर्न सक्नुहुनेछ। फो.नं. +६१८२०४४५०७, इमेल
research.ethics@health.sa.gov.au

Government of South Australia
SA Health

Flinders UNIVERSITY

SOUTHERN ADELAIDE CLINICAL HUMAN RESEARCH ETHICS COMMITTEE / FLINDERS UNIVERSITY

अनुसन्धानमा सहभागिताको लागि मन्जुरिनामा

म,..... ले रिफ्र्याक्टिभ एरर् (Refractive error – चस्मा वा कन्ट्याक्ट लेन्स लगाउनु पर्ने अवस्था) ले जीवनमा पार्ने प्रभावहरुको मापन गर्ने प्रणाली अध्ययनको **चरण २ (आइटम बैंक निर्माण : Developing the Item bank**) मा आफ्नो सहभागिताको लागि मन्जुरिनामा दिन्छु ।

मलाई यो अनुसन्धानको प्रकृति, उद्देश्य र यसका असरहरुको बारेमा..... द्वारा पूर्ण रुपमा व्याख्या गरिएको छ र मैले स्वइच्छाले मन्जुरीनामा दिन्छु ।

म एक अन्तर्वार्तामा सहभागी हुनेछु जसमा मैले रिफ्र्याक्टिभ एरर् र यसको उपचारले मेरो जीवनमा पर्ने प्रभावको बारेमा प्रश्नको जवाफ दिनु पर्नेछ ।

यो अध्ययन सँग सम्बन्धि विवरणहरु रामो संग व्याख्या गरिएको कुरा म स्वीकार्छु । मलाई यस अध्ययनमा हुन सक्ने जोखिमहरु, असुविधाहरु र चाहिने समयको बारेमापनि रामो संग व्याख्या गरिएको कुरा स्विकार्छु ।मलाई लिखित जानकारी पत्र प्रदान गरिएको छ। मलाई गरिएको व्याख्या मैले बुझें र म यसमा सन्तुष्ट छु ।

यो अनुसन्धानमा मेरो संलग्नताले मलाई प्रत्यक्ष लाभ नहुन सक्ने र मैले आफ्नो अधिकार वा सोधकर्ताको जिम्मेवारीलाई प्रभाव नहुने गरि कुनै पनि अवस्थामा मेरो सहमति फिर्ता लिन सक्ने कुरा मलाई ज्ञान छ ।

मेरो उमेर १८ वर्ष भन्दामाथि छ भनेर म ठोकुवा गर्छु ।

निदान पुष्टि गर्नको लागी मेरो चिकित्सा रेकर्ड हेर्न सकिने छ भन्ने कुरा मलाई जानकारी छ । म मेरो चिकित्सकीय फाइलबाट आवश्यक विवरण (दृष्टि र निदान) झिक्न अनुमति दिन्छु ।

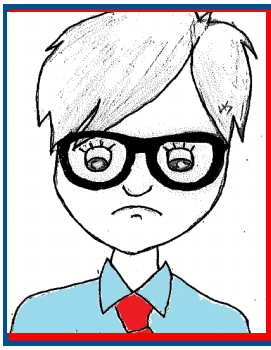
यो अनुसन्धानको क्रममा मलाई चोटपटक लागेमा, क्षतीपुर्तीको लागि मैले कानुनी कारवाही गर्न सक्ने कुरा मलाई रामो संग जानकारी गराइएको छ ।

अनुसन्धान सहभागीको दस्तखत..... मिति.....

म ..... ले ..... ,लाई यो अनुसन्धान, यसको प्रकृति र असरहरुका बारेमा रामो संग व्याख्या गरेको छु । मेरो विचारमा उँहाले दिइएको विवरण रामो सँग बुझ्नुहुन्छ र उँहाले स्वइच्छाले मन्जुरीनामा दिनु भएको हो ।

दस्तखत..... मिति.....

पद.....



Do you wear glasses or contact lens? Or, have you had a refractive surgery?

Questionnaire Study - Phase I

Participants needed for Interviews

People who wear prescription glasses or contact lens, or who have had a refractive surgery, are required to participate in a face-to-face or a telephone interview.
This study is being conducted to explore how having refractive error affects peoples' lives.

Who are we looking for?

We are looking for men and women above the age of 18 years old who need glasses or contact lenses, or those who have had Laser refractive surgery, but otherwise have healthy eyes.

What does the study involve?

Participants will need to attend a one-on-one interview (face-to-face or telephone). You will be asked to talk about how having Refractive error or its correction is affecting you and your life.

How long will it take?

The interview may last for about 30—40 minutes.

Is any remuneration available?

You will not receive any payment for participation in this study apart from $20 compensation for travel and parking costs.

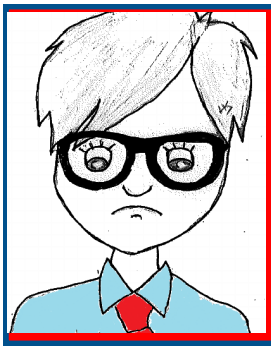
How do you participate?

If you would like to take part in this study or need further information, please contact:

Himal Kandel
PhD Candidate
Discipline of Optometry, Flinders University
Mobile No: 0450899575 or email: himal.kandel@flinders.edu.au

This study has been reviewed by the Southern Adelaide Clinical Human Research Ethics Committee. If you wish to discuss the study with someone not directly involved, in particular in relation to policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the Executive Officer on 8204 6543 or email SALHNofficeforresearch@sa.gov.au

Questionnaire Study—Phase II
Contact: Himal Kandel
Mobile No: 0450899575 or
himal.kandel@flinders.edu.au



Do you wear glasses or contact lens? Or, have you had a refractive surgery?

Questionnaire Study - Phase II

Participants needed for a survey

People who wear prescription glasses or contact lens, or who have had a refractive surgery, are required to participate in a survey.
This study is being conducted to explore how having refractive error affects peoples' lives.

Who are we looking for?

We are looking for men and women above the age of 18 years old who need glasses or contact lenses, or those who have had Laser refractive surgery, but otherwise have healthy eyes.

What does the study involve?

You will be asked to fill out a **questionnaire (online or in paper)**. Questions are about how refractive error or its correction is affecting you and your life.

How long will it take?

Filling out the complete questionnaire takes about 45 –60 minutes.

Is any remuneration available?

You will not receive any payment for participation in this study apart from $20 compensation for travel and parking costs.

How do you participate?

If you would like to take part in this study or need further information, please contact:

Himal Kandel
PhD Candidate
Discipline of Optometry, Flinders University
Mobile No: 0450899575 or email: himal.kandel@flinders.edu.au

This study has been reviewed by the Southern Adelaide Clinical Human Research Ethics Committee. If you wish to discuss the study with someone not directly involved, in particular in relation to policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the Executive Officer on 8204 6543 or email SALHNofficeforresearch@sa.gov.au

Questionnaire Study—Phase II
Contact: Himal Kandel
Mobile No: 0450899575 or
himal.kandel@flinders.edu.au

Discipline of Optometry
Flinders University
South Australia

Background Questionnaire

DEMOGRAPHIC DETAILS - *please print or circle options*			
Title *(please circle):*	Mr / Ms / Mrs / Miss / Dr		Date:
Surname:			
First & Second Names:			
Address:			
			Postcode:
Telephone Number:	Home:	Work:	Mobile:
Date of Birth:			Sex*:* Male / Female
Eye Diagnosis:			
Age at diagnosis:	years / or Year of diagnosis:		
Other eye disease/s:			
Other medical conditions or diagnoses			
Do you wear glasses? If Yes, how often do you wear your Glasses? *(please circle):*	Yes / No 1. All of the time 2. Most of the time 3. Rarely 4. Never 5.For reading only		
Do you wear contact lenses? If Yes, how often do you wear your contact lenses? *(please circle):*	Yes / No 1. All of the time 2. Most of the time 3. Rarely 4. Never 5.For reading only		

DEMOGRAPHIC QUESTIONNAIRE - *please print or circle options* **(This information will be used to compare participants' demographic characteristics with people in the Australian population using the National Health Survey (ABS) data.)**		
1.	In general, how would you **describe your overall health**? *(please circle):*	1. Excellent / 2. Very good / 3. Good / 4. Fair / 5. Poor
2.	What is your **country of birth**? *(please circle):*	1. Australia / 2. Other (specify):

3.	Are you of **Aboriginal or Torres trait Islander** origin? *(please circle):*	1. No / 2. Aboriginal / 3. Torres Strait Islander / 4. Both
4.	Do you speak a **language other than English**, at home? *(please circle):*	1. No, English only 2. Yes (specify):
5.	What is the **highest year of school completed**? *(please circle):*	1. Year twelve or equivalent / 2. Year eleven / 3. Year ten / 4. Year nine / 5. Year eight or lower / 6. Never attended school / 7. Other (specify):
6.	What is the **highest level of post-school education** you have achieved? *(please circle):*	1. Higher degree or postgraduate diploma / 2. Bachelor degree / 3. Undergraduate diploma or associate diploma / 4. Vocational qualification, i.e. TAFE or trade certificate / 5. No post-school qualification / 6. Other qualification (specify):
7.	What is your **marital status**? *(please circle):(Note: **'Married'** indicates registered marriage only)*	1. Married / 2. De Facto / 3. Widowed / 4. Divorced / 5. Separated but not divorced / 6. Never married
8.	What is your **gross weekly household income**? *(please circle):*	1. Less than $200, including no income and negative income / 2. $200 to $399 / 3. $400 to $599 / 4. $600 to $799 / 5. $800 to $999 / 6. $1,000 to $1,499 / 7. $1,500 to $1,999 / 8. $2,000 to $2,499 / 9. $2,500 or more than / 10. Don't know

Thank you for completing this demographic questionnaire.
All information provided will remain confidential and will be used only for the purposes of this study.

OFFICE USE ONLY
Participant ID:

Habitual visual acuity: RE: LE: BE

Prescription for glasses - RE :

LE:

Near add:

Remarks:

Appendix B. Search syntaxes for MEDLINE, PubMed, Scopus, Web of Science and Cochrane databases

***Note**: This appendix has been published as Appendix 1 of article 1 (Kandel et al. Optom Vis Sci. 2017;94(12):1102-19).[16]*

Concepts:

1. Condition: Refractive error and its sub-types

2. Management: Refractive error correction types (spectacles, contact lenses, refractive surgery)

3. Instrument, techniques and outcomes

Search date: 22 June 2016

Medline (549):

Database(s): **Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)** 1946 to Present
Search Strategy:

#	Searches	Results
1	refractive errors/ or astigmatism/ or hyperopia/ or myopia/ or presbyopia/	26653
2	(refractive error* or astigmati* or hyperopi* or hypermetropi* or myopi* or presbyopi* or short sighted* or near sighted* or long sighted* or far sighted*).tw,kw.	29916
3	1 or 2	37681
4	Eyeglasses/	6934
5	(eyeglasses or spectacles or glasses).tw,kw.	12231
6	contact lenses/ or contact lenses, hydrophilic/ or contact lenses, extended-wear/	11561
7	(contact lens* or orthokeratology or silicone hydrogel or iotrafilcon or rigid-gas permeable or disposable len*).tw,kw.	13173
8	corneal surgery, laser/ or keratectomy, subepithelial, laser-assisted/ or keratomileusis, laser in situ/ or photorefractive keratectomy/ or keratotomy, radial/ or lens implantation, intraocular/	17274
9	(Refractive surg* or lasik or lasek or epi-lasik or epi lasik or prk or rk or iol or implant* or inlay* or intacs or intracorneal ring segment* or icr or artiflex or keratotomy or epikeratoplasty or thermokeratoplasty or Keratectomy or keratomileusis or keratotomy or laser*).tw,kw.	548582
10	lenses, intraocular/ or phakic intraocular lenses/	13442
11	(Lens* adj3 (exchange* or replace* or extract* or intra-ocular or intra ocular or intraocular or foldable)).tw,kw.	15827
12	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	584137
13	Self Report/	15142
14	(questionnaire* or patient reported outcome* or pro or pros or rasch analys* or self report*).tw,kw.	598722
15	13 or 14	602525
16	3 and 12 and 15	611
17	limit 16 to english language	549

Translation for other databases:

PubMed (52):

((("refractive error*"[tiab] OR astigmati*[tiab] OR hyperopi*[tiab] OR hypermetropi*[tiab] OR myopi*[tiab] OR presbyopi*[tiab] OR "short sighted*"[tiab] OR "near sighted*"[tiab] OR "long sighted*"[tiab] OR "far sighted*"[tiab]) AND (eyeglasses[tiab] OR spectacles[tiab] OR glasses[tiab] OR "contact lens*"[tiab] OR orthokeratology[tiab] OR "silicone hydrogel"[tiab] OR iotrafilcon[tiab] OR "rigid-gas permeable"[tiab] OR "disposable len*"[tiab] OR "Refractive surg*"[tiab] OR lasik[tiab] OR lasek[tiab] OR "epi-lasik"[tiab] OR "epi lasik"[tiab] OR prk[tiab] OR rk[tiab] OR iol[tiab] OR implant*[tiab] OR inlay*[tiab] OR intacs[tiab] OR "intracorneal ring segment*"[tiab] OR icr[tiab] OR artiflex[tiab] OR keratotomy[tiab] OR epikeratoplasty[tiab] OR thermokeratoplasty[tiab] OR Keratectomy[tiab] OR keratomileusis[tiab] OR keratotomy[tiab] OR laser*[tiab] OR (Lens*[tiab] AND (exchange*[tiab] OR replace*[tiab] OR extract*[tiab] OR "intra-ocular"[tiab] OR "intra ocular"[tiab] OR intraocular[tiab] OR foldable[tiab])) AND (questionnaire*[tiab] OR "patient reported outcome*"[tiab] OR pro[tiab] OR pros[tiab] OR "rasch analys*"[tiab] OR "self report*"[tiab])) **NOT medline[sb])**

Scopus (780):

(TITLE-ABS-KEY ("refractive error*" OR astigmati* OR hyperopi* OR hypermetropi* OR myopi* OR presbyopi* OR "short sighted*" OR "near sighted*" OR "long sighted*" OR "far sighted*")) AND ((TITLE-ABS-KEY (eyeglasses OR spectacles OR glasses OR "contact lens*" OR orthokeratology OR "silicone hydrogel" OR iotrafilcon OR "rigid-gas permeable" OR "disposable len*" OR "Refractive surg*" OR lasik OR lasek OR "epi-lasik" OR "epi lasik" OR prk OR rk OR iol) OR TITLE-ABS-KEY (implant* OR inlay* OR intacs OR "intracorneal ring segment*" OR icr OR artiflex OR keratotomy OR epikeratoplasty OR thermokeratoplasty OR keratectomy OR keratomileusis OR keratotomy OR laser*) OR TITLE-ABS-KEY (lens* W/3 (exchange* OR replace* OR extract* OR "intra-ocular" OR "intra ocular" OR intraocular OR foldable)))) AND (TITLE-ABS-KEY (questionnaire* OR "patient reported outcome*" OR pro OR pros OR "rasch analys*" OR "self report*"))

Web of Science (452):

("refractive error*" OR astigmati* OR hyperopi* OR hypermetropi* OR myopi* OR presbyopi* OR "short sighted*" OR "near sighted*" OR "long sighted*" OR "far sighted*") ANDTOPIC: (eyeglasses OR spectacles OR glasses OR "contact lens*" OR orthokeratology OR "silicone hydrogel" OR iotrafilcon OR "rigid-gas permeable" OR "disposable len*" OR "Refractive surg*" OR lasik OR lasek OR "epi-lasik" OR "epi lasik" OR prk OR rk OR iol OR implant* OR inlay* OR intacs OR "intracorneal ring segment*" OR icr OR artiflex OR keratotomy OR epikeratoplasty OR thermokeratoplasty OR Keratectomy OR keratomileusis OR keratotomy OR laser* OR (Lens* NEAR/3 (exchange* OR replace* OR extract* OR "intra-ocular" OR "intra ocular" OR intraocular OR foldable))) ANDTOPIC: (questionnaire* OR "patient reported outcome*" OR pro OR pros OR "rasch analys*" OR "self report*")

Cochrane (221):

(("refractive error*" OR astigmati* OR hyperopi* OR hypermetropi* OR myopi* OR presbyopi* OR "short sighted*" OR "near sighted*" OR "long sighted*" OR "far sighted*") AND (eyeglasses OR spectacles OR glasses OR "contact lens*" OR orthokeratology OR "silicone hydrogel" OR iotrafilcon OR "rigid-gas permeable" OR "disposable len*" OR "Refractive surg*" OR lasik OR lasek OR "epi-lasik" OR "epi lasik" OR prk OR rk OR iol OR implant* OR inlay* OR intacs OR "intracorneal ring segment*" OR icr OR artiflex OR keratotomy OR epikeratoplasty OR thermokeratoplasty OR Keratectomy OR keratomileusis OR keratotomy OR laser* OR (Lens* NEAR/3 (exchange* OR replace* OR extract* OR "intra-ocular" OR "intra ocular" OR intraocular OR foldable))) AND (questionnaire* OR "patient-reported outcome*" OR pro OR pros OR "rasch analys*" OR "self report*"))

Appendix C. Description of the patient-reported outcome instruments used in refractive error

***Note**: This table has been published as the Appendix 3 of article 1 (Kandel et al. Optom Vis Sci. 2017;94(12):1102-19).[16]*

SN	Name of the PRO instrument / Author (Year) / Developed using Classical test theory (CTT) or Item response theory (IRT)	Concept/s measured / Study population (Country; Refractive error or correction)	No of domains (total items) / Types of domains (no of Items)	Item wordings (examples)	Response categories wordings (examples)
A.	**Refractive error-specific patient-reported outcome (PRO) instruments**				
1	National Eye Institute Refractive Quality of Life (NEI-RQL) / Berry[35] and Hays[36] (2003) / CTT	Quality-of-life / USA; All types of refractive error including Presbyopia; Spectacles, Contact lenses, Refractive surgery	13 Subscales (42) / Clarity of vision(4), Expectations (2), Near vision (4), Far vision (5), Diurnal fluctuations (2), Activity limitations (4), Glare (2), Symptoms (7), Dependence on correction (4), Worry (2), Suboptimal correction (2), Appearance (3), Satisfaction with correction (1)	- At this time, how clear is your vision using the correction you normally use, including glasses, contact lenses, a magnifier, surgery, or nothing at all? - If you had perfect vision without glasses, contact lenses, or any other type of vision correction, how different would your life be? - How much difficulty do you have reading ordinary print in newspapers? - How often are you bothered by changes in the clarity of your vision over the course of the day? - Are there daily activities that you would like to do, but don't do because of your vision or the type of vision correction you have? - How much does dryness in your eyes bother you?	- Perfectly clear, Pretty clear, Somewhat clear, Not clear at all; - No difference, Small difference for the better, Large difference for the better, I have this already - No difficulty at all, A little difficulty, Moderate difficulty, A lot of difficulty, Never try to do these activities because of vision, Never do these activities because of other reasons - Never, Rarely, Occasionally, Sometimes, All of the time - Yes, many; Yes, a few; No - Don't have dryness; Not at all; Very little; Moderately; Quite a lot; A lot [16 types of response categories]

2.1	Refractive Status and Vision Profile (RSVP-42) / Schein[37] and Vitale[38] (2000) / CTT	Quality-of-life / USA; Myopia, Hyperopia; Spectacles, Contact lenses, Refractive surgery	8 subscales (42) / Concerns (6), Driving (3), Expectations(2), Physical/social functioning (11), Symptoms(5), Optical problems(5), Glare(3), Problems with corrective lenses (7)	- I worry about my vision (check only 1): - During the past month, how much difficulties have you had with each activity, using these types of corrections? - During the past month, how bothered have you been by each of the following things, using these types of corrections? - During the past month, how bothered have you been with each of the following?	- Never (1), Rarely (2), Sometimes (3), Often (4), Always (5) - Not applicable (0), No difficulty at all (1), A little difficulty (2), Moderate difficulty (3), Severe difficulty (4), So much difficulty that I did not do the activity with this type of correction (5), Never did the activity for other reasons (not related to vision) (6); - Not applicable (0), No trouble at all (1), Moderate trouble (2), Al little trouble (3), Severe trouble (4), So much trouble that I did not do the activity with this type of correction (5) [4 types of response categories]
2.2	Refractive Status and Vision Profile (RSVP-20) / Garamendi (2005)[222] / CTT	Quality-of-life / UK; Myopia: [Refractive surgery clinic and general optometric practice]	NR	Same as above	Same as above
3	Quality of Life Impact of Refractive Correction (QIRC)/ Pesudovs (2004)[28] / IRT	Quality-of-life / UK; All types of refractive error except presbyopia; Spectacles, Contact lenses, Refractive surgery	6 domains (20) / Activity limitation, Health concerns, Well-being, Convenience, Symptoms, Economic issues	- How much difficulty do you have driving in glare conditions? - How much trouble is with your spectacles or contact lenses when you wear them when using a gym/ doing keep-fit classes/ circuit training etc.? - How concerned are you about having to increasingly rely on your spectacles or contact lenses since you started to wear them? - During the last month, how much of the time have you felt able to do the things you want to do?	- None at all; A little bit; A moderate amount; A lot; So much that I can't do this activity - None, A little bit, A moderate amount, Quite a lot, Extreme - Not at all, A little bit, A moderate amount, Quite a lot, Extremely - Never, Occasionally, Fairly often, Very often, Always [4 types of response categories]
4	Quality Of Vision (QoV-30)/ McAlinden (2010)[33] / IRT	Visual symptoms / UK; Spectacles and Contact lenses, Refractive surgery	3 Subscales for 10 symptoms (30) / Frequency (10), Severity (10), Bothersome (10)	- How often do you experience glare? - How severe is the glare? - How bothersome is the glare?	- Never (0), Occasionally (1), Quite often (2), Very often (3) - Not at all (0), Mild (1), Moderate (2), Severe (3): - Not at all (0), A little (1), Quite (2), Very (3) [Three types of response categories for frequency, severity and bothersome]

5	Canadian Refractive Surgery Research Group Quality of Vision Questionnaire (QVQ) / Brunette (2000)[39, 40] / CTT	Activity limitation, Symptoms, Health concerns, Emotional well-being / Canada; Patients who underwent bilateral PRK for Myopia	7 Scales (41 questions; 66 items) / Global satisfaction (11), Quality of vision without correction (11), Quality of vision with correction (11), Quality of night vision (14), Glare (13), Daytime driving(2) and Night driving (4)	- Following the operation, I believe my main goal was achieved. - As compared to before the operation, my night vision is --- [Two groups of statements: 1. Patient satisfaction and symptoms, and 2. Status after surgery as compared to that before surgery]	- Completely disagree (1), Somewhat disagree (2), Don't know (3), Somewhat agree (4), Completely agree (5) - Much worse (1), Slightly worse (2), The same (3), Slightly better (4), Much better (5) [Bipolar response formats]
6	Prospective Evaluation of Radial Keratotomy (PERK) Study Questionnaire / Bourque (1986)[41] / CTT	Health concerns, Visual symptoms, Emotional well-being / USA; Myopic patients who had radial keratotomy	3 indices (16) / Satisfaction (10), fluctuations in vision(4), glare (2)	- I see as well as anybody. - Since surgery, my vision in both eyes has been the same regardless of the time of day. - I have a lot of trouble with glare in the eye that had surgery.	1 (Strongly agree) to 7 (Strongly disagree) [Bipolar answer format]
7	Institute for Eye Research Multidimensional Quality of Life for Myopia (MQLM) / Erickson (2004)[43] / CTT	Symptoms, Emotional well-being, Activity limitation / Australia; Myopia; Spectacles, Contact lenses and LASIK	5 factors (45) / Symptom tolerance (13), Symptom frequency (13), Health proneness (10), Extraversion/ Introversion (6), Cosmesis (3)	NR-Items reported but question formats not reported	- Wouldn't notice (1), Could tolerate (2), Somewhat bothered (3), Very bothered (4) - Rarely (1), Sometimes (2), Often (3), Constantly (4) - Strongly agree (1), Agree (2), Disagree (3), Strongly Disagree (4) [Three types of response categories]
8	Myopia-specific Quality of Life Questionnaire (MQLQ) / Lee (2005)[43] / CTT	Symptoms, Activity limitation, Health concerns / South Korea; Myopia; LASIK	4 domains (34) / Visual function (11), Visual symptoms (12), Social and role function (5), Psychological well-being (6)	NR-Items reported but question formats not reported	- Scale ranging from 1 (maximal dysfunction) to 5 (minimal dysfunction)
9	Subjective Vision Questionnaire (SVQ) / Fraenkel (2004)[42] / CTT	Activity limitation and Visual symptom / Australia; Myopia and Myopic astigmatism; pre and post LASIK	6 factors (24)/ Driving (9), Glare and lighting (4) Ease with Rx (2), Near vision (3) Bothersome (3), Ghost image / halos / starburst (3)	- To what degree does your vision interfere with night driving? - How well can you read grocery store prices? - What percentage of time are you bothered by fluctuations in vision? - To what degree are you bothered by glare? [Six types of question formats]	Visual analogue scale: 0 to 100; labelled in 20s intervals (descriptors)

10	Visual Function and Quality of Life (VFQOL-16) / Brady (2010)[12] / IRT	Activity limitation, Emotional well-being, Symptoms / Urban India; Refractive errors; Uncorrected	3 strata (16) / Perception (4), Symptoms (3), Activity (9)	- Please respond to the questions as they apply to you over the past 4 weeks (Statements e.g. 'I worry about my vision') - We are interested in whether you experienced certain problems with your eyes or vision over the past 4 weeks (e.g. Glare) - We are interested in whether your vision caused you any difficulty with some common activities during the past 4 weeks (e.g. doing your work)	- Never, Rarely, Sometimes, Always - No trouble at all, A little trouble, Moderate to severe trouble, So much trouble I had to rest my eyes - No difficulty at all, A little difficulty, Moderate to Severe difficulty, So much difficulty I did not do the activity
11	Contact Lens Impact on Quality of Life (CLIQ) / Pesudovs (2006)[46] / IRT	Quality-of-life / UK; Pre-Presbyopic Contact lens wearers	6 domains (28 items) / Activity limitation (2), symptoms (visual/ocular surface) (3), Health concerns(6), Convenience (5), Well-being(9), Economic issues (3)	- How much difficulty do you have --- driving in glare condition? - During the past month how often have you experienced…fluctuating vision? - How much trouble is --- the routine care of your contact lens? - How concerned are you about medical complications from your contact lenses? - How concerned are you about the cost of your next contact lens? - During the past month, how much of the time have you felt happy when wearing CL?	- None at all, A little bit, A moderate, A lot, So much that I can't do this activity - Never, Occasionally, Fairly often, Very often, Always - A little bit, A moderate amount, Quite a lot, Extreme - None, A little bit, A moderate amount, Quite a lot, Extremely [Three types of response categories]
12.1	Student Refractive Error and Eyeglass Questionnaire (SREEQ-38)/ Crescioni (2014)[49]/ IRT	Quality-of-life / USA; Myopia and Myopic astigmatism, Mixed astigmatism & Hyperopia; Spectacle wearers	2 Parts (38) / Part A (15): Perceptions regarding uncorrected vision; Part B (23): Vision related QoL with spectacle correction	- When I don't wear my glasses, I have problems seeing clearly. - When I don't wear my glasses, I am able to see clearly far away. - When I don't wear glasses, my schoolwork is harder to do. - When I wear glasses, I have problems seeing clearly. - I like my frames. [Statements]	- All of the Time, Most of the Time, Some of the Time, None of the Time - Very Much, Somewhat, A little Bit, Not at All [Two types of response categories]
12.2	Student Refractive Error and Eyeglass Questionnaire (SREEQ-R) / Crescioni (2014)[49] / IRT	Same as above	2 Parts (20) / Part A (10): Perceptions regarding uncorrected vision, Part B(10): VRQoL with spectacle correction	-When I (don't) wear glasses, I have problems seeing clearly. -When I (don't) wear my glasses, my vision is very clear. -When I (don't) wear my glasses, I have to squint to see things clearly. [Statements for 10 matched items]	- All of the time, Most/Some of the time, None of the time [For 10 matched items]

13.1	Refractive Error Quality of Life Scale (REQ-Thai -87) / Sukhawarn (2011)[44] / CTT	Quality-of-life / Thailand; Emmetropes, People with refractive error; Spectacles, Contact lenses, Refractive surgery	6 Dimensions (87) / Quality of Vision (8), Visual function (39), Social function (9), psychological function (11), symptoms (6), and Refractive correction problems (14)	NR - Question formats not reported	- 'Not bother or very little negative feeling or do not have difficulty in doing activity (1)' to 'Have a great deal of symptoms or a great deal of negative feeling or a great deal of difficulty (7)' - No symptom or do not have negative feeling or do not do this activity, Not important at all (1) to A very great deal of importance (7) [Two types of response categories [Part A (amount of problem) and Part B (Importance of problem)]; 7 point rating scale converted into 5 point rating scale because of very rare responses in the extreme side of the scale]
13.2	Refractive Error Quality of Life Scale-Short form (REQ-Thai-48) / Sukhawarn (2011)[44] / CTT	Quality-of-life / Thailand; Myopia emmetropia, hyperopia; Spectacles, Contact lenses, Refractive surgery	6 Dimensions (48) / Quality of Vision (6), Visual function (20), Social function (6), psychological function (6), symptoms (3), Refractive correction problems (7)	Same as above	Same as above
14	The Freedom from Glasses Value Scale (FGVS) / Levy[53] and Berdeaux[45] (2010) / CTT	Convenience, Health concerns and Emotional well-being / France and Spain; Presbyopia and cataract patients with multi-focal intraocular lens (IOL) surgery	5 sub-dimensions (21) / Evaluation of the result (2), Feelings (4), Global judgment (3), Practical advantages (5), Psychological advantages (3), Others (4)	NR - Question formats not reported	5-point Likert response scales: - Much worse (1) to Much better (5) - Very negative (1) to Very positive (5) - No, not at all (1) to Yes, absolutely (5) - Totally disagree (1) to Totally agree (5) - Definitely better with glasses (1) to Definitely better without glasses (5)
15	Near Activity Visual Questionnaire (NAVQ-10)/ Buckhurst (2012)[34] / IRT	Activity limitation / UK; Presbyopia; Refractive surgery [Different types of IOLs), Contact lenses, Spectacles	Difficulty (10)	How much difficulty do you have ----- - Reading small print, such as newspaper articles, items on a menu, telephone directories? -Seeing objects close to you in poor or dim light? - Conducting near work without spectacles?	- 4-point response categories [wording NR]

16	Near Vision-related Quality of Life (NVQL) / Patel *et al.* (2006)[54] / CTT	Activity limitation / Tanzania; Presbyopia; With or without spectacles	Difficulty (13)	NR–Question formats not reported [Items: Reading; Writing letters; Writing numbers; Cooking food; Winnowing grain; Sorting rice or grain; Threading a needle; Weeding; Harvesting sorghum; Cutting fingernails and toenails; Dressing children; Lighting and adjusting a lamp; Recognizing faces of people standing near]	- No difficulty (1) to Completely unable to carry out the task (5)
17.1	Contact Lens Dry Eye Questionnaire (CLDEQ) / Begley (2001)[52] / [Psychometric properties not assessed]	Symptom (Dry eye) / USA and Canada; Contact lens wearers (Daily wear - soft; Disposable; Frequent-replacement; Extended wear; Rigid gas permeable)	9 symptom subscales (36) / Discomfort, Dryness, Visual changes, Soreness, Irritation, Grittiness, Scratchiness, Foreign body sensation, Burning, Photophobia and Itching	- During a typical day in the past week, how often did your eyes feel dry? - When your eyes felt dry, how intense was this feeling of dryness: within the first 2 hours of getting up in the morning / in the middle of the day/ at the end of the day (within the last 2 hours before you went to bed)? - If the eyes were bothered enough 'to stop what you were doing and take out your contact lenses.]	- Never(1), Infrequently (2), Frequently (3), Constantly (4), Not sure (5) - Not at all intense (1) to Very intense (5); Not sure (0) - Not at all (1) to Very much (5) [Three types of response categories for Frequency, Severity and CL intolerance for each symptom]
17.2	Contact Lens Dry Eye Questionnaire (CLDEQ-8) / Chalmers (2012)[262] / [Psychometric properties not assessed]	Symptom (dry eye) / USA; Soft contact lens wearers	3 types of domains (8) / Symptom frequency, Symptom intensity and Bothersome	- During a typical day in the past 2 weeks, how often did your eyes feel discomfort while wearing your contact lenses? - When your eyes felt discomfort with your contact lenses, how intense was this feeling of discomfort at the end of your wearing time? - During a typical day in the past 2 weeks, how often did your eyes bother you so much that you wanted to close them? [Three types of question formats for symptom frequency, symptom intensity and bothersome]	- Never (0), Rarely (1), Sometimes (2), Frequently (3), Constantly (4) - Never have it (0), Intense (1), 2, 3, 4 Very intense (5) - Never (0), Rarely (1), Sometimes (2), Frequently (3), Constantly (4) - Never (1), Less than once a week (2), Weekly (3), Several times a week (4), Daily (4), Several times a day(6) [Four types of response categories]
18	Pediatric Refractive Error Profile (PREP) / Walline [ACHIEVE Study] (2006)[48, 251] / [Psychometric properties not assessed]	Quality-of-life / USA; Myopia; Spectacles (237) and Contact lenses (247)	10 subscales (26) / Overall vision (3), Near vision (2), Far vision (2), symptoms (4), Appearance (3), Satisfaction (1), Activities (2), Academics (2), Handling (4), Peer perceptions (3)	- When I wear my ___, I have problems seeing clearly. - When I wear my ___, I am able to see clearly far away. - When I wear my ___, my eyes hurt. - When I wear my ___, I like how I look. - I like to wear my ___. - I never have a problem wearing my ___ when I play outdoors. - When I wear my ___, I do better on tests. - It is easy to clean and take care of my ___. - When I wear my ___, my friends make fun of me.	- Strongly agree, Agree, Neutral, Disagree, Strongly disagree [scored from 1 (negative) to 5 (positive)]

19	Spectacle Survey / Walline [ACHIEVE study] (2006)[48] / [Psychometric properties not assessed]	Activity limitation / USA; Moderate Myopia; Spectacles / Contact lenses	7 subscales (37) / Physical appearance, Athletic competence, Social acceptance, Scholastic competence, Discomfort/inconvenience, Other correction, Satisfaction	- It is hard to play sports or do other physical things (play outside) because of my glasses. - I am not as good at schoolwork because of my glasses. [37 statements]	- Strongly disagree (1), Disagree (2), Neutral (3), Agree (4), Strongly agree (5)
B. Vision but non-refractive PRO instruments					
1	Ocular Surface Disease Index Questionnaire (OSDI) / Hom (2006)[164] / CTT [Originally developed in general dry eye population[414]]	Symptoms (Dry eye) / USA; Contact lens wearers	3 groups (12 items) / Symptoms (5), Symptoms related activity limitations (4), Comfort (3)	- Have you experienced any of the following during the last year: [Eyes that are sensitivity to light/ Eyes feel gritty/Poor vision] - Have problems with your eyes limited you in performing any of the following during the last week? [Reading / Driving at night / Watching TV] - Have your eyes felt uncomfortable in any of the following situations during the last week? [Windy conditions/Areas that are air-conditioned]? [3 types of item wordings]	- All of the time (4), Most of the time (3), Half of the time (2), Some of the time (1) None of the time (0), N/A
2.1	National Eye Institute Visual Function Questionnaire (NEI-VFQ-51)/ Walline (2000)[163] / CTT [Originally developed on people with various eye diseases[248]]	Vision related quality-of-life / USA; Spectacle or contact lens wearers	13 Subscales (51) / General Health (2), General Vision (2), Ocular pain (2), Near Vision (7), Distance vision (7), Vision-specific social functioning (4), Vision-specific mental health (8), Expectation for visual function (3), Vision-specific role functioning (5), Dependency due to vision (5), Driving (4), Peripheral vision (1), Colour vision (1)	- In general, would you say your overall health is ----- (circle one) - At the present time, would you say your eyesight using both eyes (With glasses or contact lenses, if you wear them) is -----? - Because of your eyesight, how much difficulty do you have finding something on a crowded shelf? - How much difficulty do you have driving at night?	- Excellent (1), Very good(2), Good(3), Fair (4), Poor(5) - Excellent (1), Good(2), Fair (3), Poor(4), Very poor(5), Completely blind(6) - No difficulty at all (1), A little difficulty (2), Moderate difficulty (3), Extreme difficulty (4), Stopped doing this because of your eyesight (5) Stopped doing this for other reasons or not interested in doing this (6) - No difficulty at all (1), A little difficulty (2), Moderate difficulty (3), Extreme difficulty (4), Have you stopped doing this because of your eyesight (5) Stopped doing this for other reasons or are not interested in doing this (6)

2.2	National Eye Institute Visual Function Questionnaire (NEI-VFQ- 25) / Coleman (2006)[290] / CTT [Originally developed on patients with different eye diseases[415]]	Vision related quality-of-life/ USA; Elderly with refractive error; Spectacles	13 Subscales (25)/ General Health (1), General Vision (1), Ocular pain (2), Near activities (3), Distance activities (3), Vision-specific social functioning (2), Vision-specific mental health (4), Expectation for visual function (3), Vision-specific role difficulties (2), Vision-specific dependency (3), Driving (3), Peripheral vision (1), Colour vision (1)	- In general, would you say your overall health is ----- (circle one) - How much of the time do you worry about your eyesight? - How much difficulty do you have reading ordinary print in newspapers? Would you say you have ----- - Do you accomplish less than you would like because of your vision? - I stay home most of the time because of my eyesight	- Excellent (1), Very Good(2), Good(3), Fair (4), Poor(5) - None of the time (1), A little of the time(2), Some of the time(3), Most of the time(4), All of the time(5) - No difficulty at all (1), A little difficulty (2), Moderate difficulty (3), Extreme difficulty (4), Stopped doing this because of your eyesight (5), Stopped doing this for other reasons or not interested in doing this (6) - All of the time(1), Most of the time(2), Some of the time(3), A little of the time (4), None of the time(5) - Definitely true(1), Mostly true(2), Not sure(3), Mostly false(4), Definitely False(5)
3	McMonnies Questionnaire / Albietz (2002)[280] / CTT [Originally developed on people with general dry eye [416]]	Symptom (Dry eye) / Australia; Hyperopia; LASIK	Symptom (12)	-Do you ever experience any of the following symptoms: Soreness/ Scratchiness/ Dryness/ Grittiness/ Burning? -How often do you have these symptoms? -Do you experience dryness of the nose, mouth, throat, chest or vagina?	-Yes/No -Constantly, Often, Sometimes -Constantly, Often, Sometimes, Never [5 types of response categories]
4	Ocular Comfort Index (OCI) Evans (2009)[282] / IRT [Originally developed on people with general dry eye [417]]	Symptoms (Dry eye) / UK; Contact lens wearers and non-contact lens wearers (controls)	2 subscales (12)/ Symptom frequency (6), Symptom intensity (6) [6 symptoms: dryness, grittiness, stinging, tiredness, pain, itching]	- In the last week, how often did your eyes feel dry? - When your eyes felt dry, typically, how intense was the dryness?	- Never (0) to Always (6) with descriptors (0, 1,2,3,4,5,6) - Severity: Never had it (0) to Severe (6) With descriptors (0,1,2,3,4,5,6)

5	Dry Eye Questionnaire (DEQ)/ Toit (2001)[418] / CTT [Originally developed on people with general dry eye[419]]	Symptoms (Dry eye) / Canada; Presbyopia; Monovision / Bifocal contact lenses	3 subscales (22) / Frequency (10), Intensity (6), Bothersome (6)	- During a typical day in the past week, how often did your eyes feel dry? - When your eyes felt dry, how intense was this feeling of dryness: within the first 2 hours of getting up in the morning / in the middle of the day/ at the end of the day (within the last 2 hours before you went to bed)? - If the eyes were bothered enough 'to stop what you were doing and take out your contact lenses. - During a typical day in the past week, how often did you experience dryness of the nose, mouth, or vagina? - If you use any of the following treatments for dry eye, how much help do they provide? - Do you think you have dry eye(s)? [Nine types of question formats]	- Never (0), Rarely(1), Sometimes(2), Frequently(3), Constantly(4) - Not at all intense (1) to Very intense (5); Never have it (0) - Not at all bothered(1) to bothered (5) Never have it (0) - No help at all, Complete relief, Do not use - Yes/No [Nine types of response categories]
6	Symptom Assessment in Dry Eye Questionnaire (SANDE) / Chen (2013)[267] / CTT [Originally developed on people with dry eye syndrome[420]]	Symptoms (Dry eye) / USA; Contact lens wearers (Oral contraceptive pills users)	Symptoms (2)	- Please place an 'X' on the line to indicate 'how often', on average, your eyes feel dry and/or irritated: [Frequency of symptoms] - Please place an 'X' on the line to indicate 'how severe', on average, you feel your symptoms of dryness and/or irritation: [Severity of symptoms]	- Rarely ---- All the time [Frequency of symptoms] - Very mild --- Very severe [Severity of symptom] [Two types of response categories recorded on a visual analogue scale 0 to 100 mm]
7	Dry Eye questionnaire and Scoring System (DESS) / Bhargava (2015)[283]/ CTT [Originally developed on people with general dry eye [421]]	Symptom (Dry eye)/ India; Contact lens wearers	Symptoms (6)	- Itching or burning; Sandy or gritty; Sensation; Redness; Blurring of vision; Ocular fatigue; [Excessive blinking (Symptoms vs Response categories: cross tabulation format)]	- Absent(0), Sometimes(1), Frequent(2), Always(3)
8	Salisbury Eye Evaluation Questionnaire (SEEQ) for Dry Eye Symptoms/Wang (2015)[269]/ CTT [Originally developed on people with general dry eye[269]]	Ocular-comfort symptoms / Myopic patients who had Small Incision Lenticule Extraction and femtosecond-LASIK	Symptoms (6)	- Do your eyes ever feel dry? - Do you ever feel gritty or sandy sensation in your eye? - Are your eyes ever red? - Do your eyes ever have a burning sensation? - Do you notice much crusting on your lashes? - Do your eyes ever get stuck shut in the morning?	- Rarely(0), Sometimes(0), Often (1), All the time (1)

9.1	Visual Function Index - 14 (VF-14)/ Rose (2000)[165] / CTT [Originally developed for cataract surgery population[240]]	Activity limitation / UK; Myopia	2 domains (14) / General functioning (12), Driving – Day and night (2)	- Do you have any difficulty, even with glasses, reading small print, such as labels on medicine bottles, a telephone book, food labels? - Have you ever driven a car?	- Not applicable, No(4), Yes, with a little difficulty (3), Yes, with a moderate amount of difficulty (2), Yes, with a great deal of difficulty (1), Yes, and am unable to do the activity (0) - Yes/No
9.2	Visual Function Index - 7 (VF-7)/ Wang (2012)[284] / CTT [Originally developed for cataract surgery population[422]]	Activity limitations / China; High Myopia; Multifocal intraocular lens	Satisfaction (7) / [Items from VF-14 that most correlated with Satisfaction: Reading small print; Seeing steps, stairs, or curbs; Reading traffic, street or store signs; Doing fine handwork; Cooking; Watching television; Night-time driving]	- How much difficulty do you have driving at night because of your vision? Do you have ----- - Do you have any difficulty, even with glasses, watching television?----- If yes, how much difficulty do you currently have?	- No difficulty (1); A little difficulty (2); A moderate amount of difficulty (3); A great deal of difficulty (4) - Yes/No/Not applicable - A little (1), A moderate amount (2), A great deal (3), Are you unable to do the activity?(4)
10	Activities of daily vision scale (ADVS)/ Freitas (1995)[289] / CTT [Originally developed for cataract population[423]]	Activity limitation/ Portugal; Patients undergoing excimer laser PRK	5 Subscales (22) / Daytime driving, Night driving, Near vision, Far vision and Glare disability	- How difficult do oncoming headlights or street lights make driving at night for you? - Would you say that you see faces in bright sunlight with:	- Not difficult at all (5), A little difficult ($), Moderately difficult(3), Extremely difficult(2), So difficult, I no longer drive for this reason (1) - No difficulty at all (5), A little difficulty (4), Moderate difficulty(3),Extreme difficulty(2), Unable to see faces in bright sunlight because of visual problems (1)
11	Vision Related effect on Quality of Life (VQOL / Vision Core Measure-1 (VCM1)) / Rose (2000)[165] / CTT[Originally developed for cataract and other eye condition [424]]	Quality-of-life / UK; Myopia	2 Domains (10) / Concerns (4) Well-being (6)	In the past month: - How often has your eyesight made you concerned or worried about your general safety at home?	-Not at all (0), Very rarely(1), A little of the time (2), A fair amount of the time (3), A lot of the time (4), and All the time (5)
12					

12	Nursing Home Vision-Targeted Health-Related Quality-of-Life (NHVQOL) / Owsley (2007)[160] / CTT [Originally developed for nursing home residents[425]]	Quality-of-life USA; Elderly with uncorrected refractive error; Spectacles	9 Subscales (57) / General vision (6), Reading (3), Ocular symptoms (9), Mobility (7), Psychological stress (10), Activities of daily living (6), Activities/ hobbies(8), Adaptation/ coping (2), and social interaction (6)	- At the present time, would you say your eyesight using both eyes, with glasses if you wear them, is ----- ? - How much of the time do you worry about your eyesight? Would you say: - How much does it bother you that you worry about your eyesight? - Do you have difficulty recognizing people you know from across a room at least partly because of your vision?	-Excellent (1), Very good (2), Good (3), Fair (4), Poor(5), Completely blind (6) - None of the time (1), A little of the time (2) Some of the time (3), Most of the time (4), Most of the time (4), All of the time (5) - Not at all (0), A little (1), A lot (2) - No difficulty at all (1), A little difficulty (2), Moderate difficulty (3), Extreme difficulty (4), Stopped doing this because of your eyesight (5), Stopped doing this for other reasons or not interested in doing this (6), Could do this activity but not given the opportunity (7)
C. Generic PRO instruments in refractive error					
1	Paediatric Impact Of Assistive Devices Scale (PIADS) / Day (1996)[162] / CTT [Originally developed for people with assistive devices such as spectacles[162]]	Psychosocial impact / Canada; Spectacles, Contact lenses	3 domains (26) / Competence (12), Adaptability (6), Self-esteem (8)	NR - Question formats not reported [Domain (Items): Competence (competence, adequacy, efficiency, productivity, usefulness, expertise, capability, performance, skilfulness, independence, quality-of-life, confusion) Adaptability (Willingness to take chances, ability to participate, eagerness to try new things, ability to adapt to ADL, ability to take advantage of opportunities, wellbeing), Self-esteem (self-esteem, security, sense of power, embarrassment, happiness, sense of control, frustration, self-confidence)]	11 point Visual analogue scale (0-10) Altered to -3 to +3 scale
2	Speilberger State Anxiety Scale/ Court (2008)[299] / CTT [Originally developed for patients and general population[426]]	Symptom (Anxiety) / UK; Contact lens wearers	State (20)	Question formats not reported	- Not at all (1), Somewhat (2), Moderately so (3), Very much so (4)

3	General Well-Being Schedule (GWBS)/ Takashima (2001)[301] / CTT [Originally developed for general patients[427]]	Emotional well-being / Pathological Myopia and normal controls	6 subscales (18) / Anxiety(4), Depression(3), Positive well-being (3), Self-control(3), Vitality(3), General health(2)	During the past month: - How have you been feeling in general? - Have you been anxious, worried, or upset? - Have you been waking fresh and rested?	- In excellent spirits (5), In very good spirits (4), In good spirits mostly (3), I've been up and down in spirits a lot (2), In low spirits mostly (1), In very low spirits(0) - Extremely so - to the point of being sick, or almost sick (0), Very much so (1), Quite a bit (2), Some—enough to bother me (3), A little bit (4), Not at all (5) - Every day(1), Most every day (2), Fairly often (3), Less than half the time (4), Rarely(5), None of the time(6)
4	Adjective Check List/ Toczolowski (2001)[302] / CTT [Originally developed for psychological patients or for general population[428]]	Emotional well-being / Radial keratotomy	5 Parts (with 37 scales consisting 300 adjectives)/ Modus operandi (4 scales), Need (15 scales), Topical (9 scales), Transactional analysis (5 scales), Origence-intellectence (4 scales) [Originally developed for general individuals for self-evaluation]	- Mark the adjectives that describe what you are like - Mark the adjectives that describe what you were like before the surgery	[Number of items to be selected from the list of adjectives]
5	General Health Questionnaire (GHQ)/ Kidd (1997) [303] / CTT [Originally designed for screening of psychiatric disorders in non-psychiatric settings[429]]	Emotional well-being / Individuals with Myopia presenting for PRK (cases) or contact lenses (controls)	Psychological distress (30)	- Have you found everything getting on top of you? - Have you been getting scared or panicky for no good reason? - Have you been getting edgy and bad tempered?	- Not at all (0), No more than usual (1), Rather more than usual (2), More than usual (3) [Sum above 4 = anxiety or distress]
6	Hudson Index of Self-Esteem (ISE) / Kidd (1997)[303]/ CTT [Originally designed for screening of low self-esteem[430]]	Individuals with Myopia presenting for PRK (cases) or contact lenses (controls)	Self-esteem (25)	- I feel that people would not like me if they really knew me well. - When I am with others, I feel they are glad I am with them. - I feel ugly. - My friends think very highly of me.	- Rarely or none of the time (1), A little of the time (2), Some of the time (3), A good part of the time (4), Most or all of the time (5) [Hudson score = sum – 25; Scores above 30 = Low self-esteem]
7	Armstrong Laboratory Aviation Personality Survey (ALAPS) Depression scale / Morse (2009)[187] / CTT [Originally developed for use in aviation personnel[431]]	Emotional well-being; USA; Myopia (low to moderate), Astigmatism; Bilateral LASIK	Depression scale (16 items) [This is one of the 15 scales of the ALAPS]	Question formats not reported [Depressed mood, cognitive and vegetative symptoms, and dysphoric affect measured]	- True or False

8	Hospital Anxiety and Depression Scale (HADS)/ Yokoi (2014)[161] / CTT [Originally developed for patients in medical outpatient clinic]	Anxiety and Depression / Pathologic Myopia	2 Scales (14)/ Anxiety (7), Depression(7)	- I feel tense or 'wound up': - I get sudden feelings of panic: - I can sit at ease and feel relaxed: - I still enjoy the things I used to enjoy: - I can laugh and see the funny side of things: - I can enjoy a good book or radio or television program:	- Most of the time (3); A lot of the time (2), From time to time occasionally (1), Not at all (0) -Definitely as much (0), Not quite so much (1), Only a little (2), Hardly at all (3)
9	Geriatric Depression Scale (GDS)/ Owsley (2007)[160] / CTT [Originally developed for elderly people with or without depression[432]]	Emotional well-being / Elderly with refractive correction	Symptoms (15)	- Are you basically satisfied with your life? - Do you feel that your life is empty? - Do you feel full of energy?	- Yes/No
10	Survey of Activities and Fea of Falling in the Elderly (SAFE)/ Elliott (2009)[300] / CTT [Originally developed for general elderly population[433]]	Activity limitation / USA; Elderly with cataract surgery or refractive correction	Activities (11) / [Go to the store Visit a friend or relative, Prepare simple meals, Reach for something over your head, Take a tub bath, Go to a place with crowds, Get out of bed, Walk several blocks outside, Take a walk for exercise, Bend down to get something, Get out when it is slippery]	- Do you currently do the activity? - If you do the activity, when you do it how worried are you that you might fall? - If you do not have to do the activity, do you not do it because you are worried that you might fall? - If you do not do the activity because of worry, are there also other reasons that you do not do it? - If you are not worried, what are the reasons you do not do it? (specify) - Compared to five years ago, would you say that you do it more, about the same or less than you used to?	- Yes/No - Very worried (1), somewhat worried (2), A little worried (3), Not at all worried (4) - More than you used to (1), About the same (2), Less than you used to (3)
11	Cantril Self-Anchoring Striving Scale / Freitas (1995)[289] / CTT [Originally developed for general patients[434]]	General well-being / Portugal; Patients undergoing excimer laser PRK	Well-being (2)	- On which step of the ladder would you say you personally feel you stand at this time? - On which step do you think you will stand about five years from now?	- Best possible life (10) – 987654321– Worst possible life (0)
12	Self-perception profile for children (SPPC) / Walline (2006)[48] / CTT [Originally developed for school-children[435]]	Competence / USA; Moderate Myopia; Spectacles, Contact lenses; (ACHIEVE study population)	6 scales(36)/ Scholastic competence(6) , Social acceptance(6), Athletic competence(6), Physical appearance(6), Behavioural conduct(6), and Global self-worth(6)	- Some kids are often unhappy with themselves BUT Other kids are pretty pleased with themselves - Some kids are very happy being the way they are BUT Other kids wish they were different	- Really true for me / Sort of true for me [The child is asked to decide which kind of child is most like him/her]
13	Symptom Checklist–90-Revised (SCL-90-R)/ Freitas (1995)[289] / CTT [Originally developed for general patients[436]]	General symptom (Psychological) / Portugal; Patients undergoing excimer laser PRK	Symptoms (90)	- For the past week, how much were you bothered by: Headaches; Nervousness or shakiness inside; Unwanted thoughts, words or ideas that won't leave your mind; Troubling falling asleep; Shouting or throwing things; Overeating	- Not at all (0), A little bit (1), Moderately (2), Quite a bit (3), Extremely (4)

14	Modified McGill Pain Questionnaire/ Vetrugno (2000)[304] / CTT [Originally developed for people experiencing significant pain[437]]	Pain / Italy; Myopia; PRK	Two parts (11)/ First part (6) [after reepithelization], Second part (5) [at the end of therapy] [The original McGill Pain questionnaire has 4 subscales (with 78 pain descriptors): Sensory, affective, evaluative and miscellaneous aspects of pain]	-Did you notice persistent watering of the treated eye? -Did your eyes itch? -How strong was your pain? (Please tick one) -Were you able to read or to write?	-Yes/No -Mild (1), Discomforting (2), Distressing (3), Horrible (4), Excruciating (5)
15	Brief Pain Inventory (BPI) / Garcia (2016)[306] / CTT [Originally developed for use in cancer patients[438]]	Pain / Brazil; Myopia; PRK	Two indices (11)/ Pain intensity index (4), Function interference index (7)	Question formats not reported [Intensity of pain and related impairment in the previous 24 hours]	- No pain (0) to Pain as bad as you can imagine (10) - No interference (0) to Complete interference (10)
16	Short-Form (SF-36) Questionnaire / Owsley (2007)[160] / CTT [Originally developed for use in general clinical practice or in population surveys[439]]	Quality-of-life (Functional status, Well-being, Overall evaluation of health) Elderly with refractive correction	8 Dimensions (36) / Physical functioning (10), Social functioning (2), Role limitations-Physical problems (4), Role limitations–emotional problems (3), Mental health (5), Vitality(4), Pain (2), General health perception (5), Health change (1)	- In general, would you say your health is: - Does your health limit you in these activities? If so, how much? [Climbing several flights of stairs; Bending, kneeling or stooping; Walking half a mile] -How much time during the past month did you feel full of life?	- Excellent (1), Very good (2), Good (3), Fair (4), Poor(5) - Yes, Limited a lot; Yes, limited a little; No, not limited at all - All of the time, Most of the time, A good bit of the time, Some of the time, A little of the time, None of the time

Note: ACHIEVE = Adolescent and Child Health Initiative to Encourage Vision Empowerment, LASIK = Laser Assissted Keratomileusis In Situ, PRK = Photo-Refractive Keratectomy.

Appendix D. Published articles and conference presentations

Publications:

1. **Kandel H,** Khadka J, Goggin M, Pesudovs K. Patient-reported outcomes for assessment of quality of life in refractive error: a systematic review. *Optometry and Vision Science* 2017;94(12):1102-19
2. **Kandel H,** Khadka J, Lundstrom M, Goggin M, Pesudovs K. Questionnaires for measuring refractive surgery outcomes. *Journal of Refractive Surgery* 2017;33(6):416-24
3. **Kandel H**, Khadka J, Goggin M, Pesudovs K. Impact of refractive error on quality-of-life: a qualitative study. *Clinical and Experimental Ophthalmology*, 2017,45(7):677-88 [***Note**: published as a lead feature of the issue. An editorial was written on this article. It was selected for CPD points. It was an 'editor's choice free article'. This article was covered by at least eight news outlets.]*
4. **Kandel H,** Khadka J, Shrestha MK, Sharma S, Neupane Kandel S, Dhungana P, Pradhan K, Nepal B, Thapa S, Pesudovs K. Uncorrected and corrected refractive error experiences of Nepalese adults: A qualitative study. *Ophthalmic Epidemiology*, 2018;25(2):147-61
5. **Kandel H,** Khadka J, Fenwick E, Sharma S, Sharma B, Kafle K, Kharal A, Kaiti R, Dhungana P, Shrestha MK, Nepal B, Thapa S, Lamoureux E, Pesudovs K. Constructing item banks for measuring quality-of-life in refractive error. *Optometry and Vision Science* 2018;95(7):575-87
6. **Kandel H.** Thinking beyond a pair of glasses [Internet Blog], International Association for Prevention of Blindness]. 2018 [Accessed on 03 March 2018]. Available from: https://iapb.standardlist.org/thinking-beyond-pair-glasses/

Conference presentations (Oral): abstracts

1. **Kandel H**, Khadka J, Goggin M, Pesudovs K. An Item bank to measure impact of refractive error on quality-of-life. Paper presented at the 2017 ARVO-Asia meeting, Bridging disciplines and disparities: Connecting eye research with health outcomes, Feb 5–8, Brisbane, Australia
2. **Kandel H,** Khadka J, Shrestha MK, Kaiti R, Dhungana P, Poudel R, Pradhan A, Pradhan K, Nepal B, Pesudovs K. Living experiences of people with refractive error–a qualitative study from Nepal. Paper presented at the ARVO 2017 Annual Meeting, Global connections in vision research, May 7-11, in Baltimore, Maryland, USA. [Abstract published*: Invest Ophthalmol Vis Sci 2017;58:3420]*
3. **Kandel H**, Khadka J, Pesudovs K. Comparison of refractive error-specific quality-of-life issues between developed and developing country settings. Paper presented at the Flinders Health Research Week, 08 September 2017

Conference presentations (Poster): abstracts and posters

4. **Kandel H,** Khadka J, Pesudovs K. A pair of glasses alone does not solve the problems: Exploring experiences of people with refractive error. Paper presented at the Australian Society for Medical Research (ASMR)-SA Annual Scientific Meeting. June 2016, Adelaide, Australia
5. **Kandel H**, Khadka J, Pesudovs K. Development and validation of a new measure of convenience in refractive error. Paper presented at the ARVO 2018 Annual Meeting, Stand strong for science: Stand for strong vision science, Apr 29 – May 03, Honolulu, Hawaii, USA. [Abstract published: *Invest Ophthalmol Vis Sci 2018;59(9):4147*]

Note: Appendix 4: publications (**pages 318 – 391**) have been removed due to copyright restrictions.

1. **Kandel H**, Khadka J, Goggin M, Pesudovs K. An Item bank to measure impact of refractive error on quality of life. Paper presented at the 2017 ARVO-Asia meeting, Bridging disciplines and disparities: Connecting eye research with health outcomes, Feb 5 – 8, Brisbane, Australia

Title: An Item bank to measure impact of refractive error on quality of life

Background: This study is a part of the 'Eye-tem Bank' project which aims to develop item banks administered through computer adaptive testing. The aim of this study is to identify minimally representative, most informative and efficient set of items for an item-bank measuring refractive error-specific quality of life (QoL).

Methods: We conducted semi-structured in-depth interviews with people with refractive error. Domains of QoL and items across each domain qualitatively extracted from the transcripts were supplemented to the items from the existing questionnaires, grey literature and the Quality of life Impact of Refractive Correction (QIRC) development item-pool. This was followed by the classification and selection of the unique items using the methods of binning and winnowing based on five item-culling criteria: Redundancy, Clarity, Applicability, Frequency and Relevance. The selected items were worded in a clear language with uniform question stems and response options across the QoL domains.

Results: Forty eight people (median age, 49; age range, 22-76; female, 58.3%; myopia, 64.6%; hyperopia, 20.8%; surgical emmetropia, 14.6%; presbyopia, 47.9%; glasses, 81.3%; contact lenses, 35.4%; refractive surgery, 35.4%) participated in the interviews.
A total 1,884 items were identified from the qualitative study (807 items), literature (700 items) and the QIRC item pool (377 items). After a series of winnowing and expert panel consensus, a total of 348 (18.5%) unique items were identified across the 11 domains: Activity limitation (81), Mobility (20), Visual symptoms (28), Ocular comfort symptoms (17), General symptoms (10), Health concerns (41), Convenience (45), Emotional (58), Social (17), Economic (18) and Coping (13). Slightly more than half of the existing questionnaires were on activity limitations and symptoms. However, this qualitative study identified and supplemented more items on the other domains; concerns about cosmetic appearance, and personal health and safety (visual outcomes, complications, level of care etc.) were the most important issues to people with refractive error.

Conclusion: The qualitative findings identified important issues of QoL in people with refractive error. These data helped us to identify important content area (domains and items) to develop a comprehensive QoL measure for refractive error. The item pool will be piloted and its psychometric properties will be assessed using Rasch analysis.

Key words: Refractive error, Quality of life, Item banking

Lay abstract: An item-bank (long questionnaire) is generated form patient consultation and a literature review. After validation, it will be superior to the existing questionnaires in assessing refractive outcomes.

2. **Kandel H**, Khadka J, Shrestha MK, Kaiti R, Dhungana P, Poudel R, Pradhan A, Pradhan K, Nepal B, Pesudovs K. Living experiences of people with refractive error–a qualitative study from Nepal. Paper presented at the ARVO 2017 Annual Meeting, Global connections in vision research, May 7-11, in Baltimore, Maryland, USA. [Abstract published: *Invest Ophthalmol Vis Sci* 2017;58:3420]

OPEN ACCESS

ARVO Annual Meeting Abstract | June 2017

Living experiences of people with refractive error – A qualitative study from Nepal

Himal Kandel; Jyoti Khadka; Mohan Krishna Shrestha; Purushottam Dhungana; Raju Kaiti; Rupesh Poudel; Asik Pradhan; Kishore Pradhan; Bhagavat Nepal; Konrad Pesudovs

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Investigative Ophthalmology & Visual Science June 2017, Vol.58, 3420. doi:

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Abstract

Purpose : Although refractive error is the commonest ocular abnormality and the commonest cause of global visual impairment, qualitative studies exploring the impact of refractive error in people's lives are sparse. This study was therefore carried out to explore the impact of refractive error on quality of life.

Methods : We conducted 101 semi-structured in-depth interviews with people having refractive error, with or without corrections. Purposive sampling was applied to capture issues of people with diverse spectrum of refractive error. The interviews were recorded, transcribed and analysed using NVivo Software, Version 11 (QSR International Pty Ltd.). The thematic analysis was done using both inductive and deductive processes. We compared quality of life issues among people with various types of refractive error and among people with different refractive corrections.

Results : The median age of the participants was 29 (range: 18 to 74) years. More than half were male (n=55) and myopes (n = 56). Almost one fifth were surgical emmetropes (n = 19). Twenty-nine participants had presbyopia. Nearly half of the participants (n = 47) had uncorrected refractive error. In regards to the refractive correction, sixty participants used glasses to varying frequency. Similarly 20 had surgical correction and 17 used contact lenses.

During thematic analysis, 3,477 comments were coded into 381 nodes under 8 broad themes: Convenience, Activity limitations, Health concerns, Psychosocial well-being, Economic well-being, Visual symptoms, Ocular comfort-symptoms and General symptoms. Inconveniences wearing glasses was the most important issue in glasses wearers. Whereas, possibilities of having side effects or complications were the major concerns for participants wearing contact lenses. Similarly, concerns regarding the possibility of having to wear glasses again due to relapse of refractive error were the major concerns for the participants who had refractive surgery. For participants with uncorrected refractive error, activity limitations and symptoms were the most important issues.

Conclusions : This study enriches the understanding of issues important to people with uncorrected and different types of refractive corrections. The quality of life issues identified in this study will be used to develop item banks to measure refractive error specific quality of life for developing country setting.

This is an abstract that was submitted for the 2017 ARVO Annual Meeting, held in Baltimore, MD, May 7-11, 2017.

3. **Kandel H**, Khadka J, Pesudovs K. Comparison of refractive error-specific quality of life issues between developed and developing country settings. Paper presented at the Flinders Health Research Week, 08 September 2017

Title: Comparison of refractive error-specific quality of life issues between developed and developing country settings

Aim: To compare the refractive error-specific quality of life (QoL) issues between developed and developing country settings, and to determine if separate patient reported outcome instruments are required to measure refractive error-specific QoL in these settings.

Methods: Qualitative studies were conducted in Nepal and Australia to understand the impact of refractive error on QoL. In-depth semi-structured interviews were conducted with adults (>= 18 years old) having refractive error. The interviews were recorded, transcribed and coded in the NVivo software (Version-11). Thematic analysis was carried out using deductive and inductive processes. QoL issues were compared using the coding-query matrices.

Results: We interviewed 48 adults (Median age, 49 years; female, 28; myopia, 31; hyperopia, 10; presbyopia, 23; glass-wearers,39 ; contact lens wearers, 17; refractive surgery, 17) in South Australia. Similarly, we interviewed 101 adults (Median age, 29; female, 46; myopia, 56; hyperopia, 21; presbyopia, 28; glasses, 60; contact lens,17; refractive surgery, 20; uncorrected refractive error, 47) in Nepal. 294 unique QoL issues from 2,367 comments, and 308 unique issues from 3,477 comments were extracted across ten domains of QoL, in Australia and Nepal respectively. There was a difference of more than half of the QoL issues between two settings. Activity limitation and health concerns were the major themes for the participants from Nepal and Australia respectively. The maximum similarity (75%) was observed for ocular-comfort symptoms.

Discussion: The study enriches the understanding of the impact of refractive error on QoL. This study findings indicate a need of separate patient reported outcome measures for developed and developing country settings to assess comprehensive QoL.

Key words: Patient reported outcome, Qualitative study, Quality of Life, Refractive error

4. **Kandel H,** Khadka J, Pesudovs K. A pair of glasses alone does not solve the problems: exploring experiences of people with refractive error. Paper presented at the Australian Society for Medical Research (ASMR)-SA Annual Scientific Meeting. June 2016, Adelaide, Australia

Title: A pair of glasses alone does not solve the problems: exploring experiences of people with refractive error

Background: Refractive error (RE) is the most common cause of visual impairment. The aim of this study was to explore impact of RE and its corrections on quality of life. The overarching aim of this study is to develop technologically advanced patient-reported outcome measure in the form of item banking to be implemented using computer adaptive testing system.

Methods: A qualitative study was carried out to understand the experience of people with RE (including presbyopia), either corrected or uncorrected. In-depth telephone and face-to-face semi-structured interviews were conducted with 45 participants with RE. The participants were recruited from Flinders Vision, Ashford Advanced Eye Care and also through community advertisements. The interviews were audio-recorded, transcribed verbatim, coded and analysed. Coding was done using NVivo Software, Version 10 (QSR International Pty Ltd.). Thematic analysis was done by categorising the codes into themes and sub-themes based on the semantic meaning of the codes. Coding process consisted of both inductive and deductive processes.

Results: The median age of the participants was 49 years (range: 22 to 76 years). The majority (n = 25; 55.6%) were female and most of them (n = 31; 68.9%) had myopia followed by hyperopia (n=12; 26.7%). Nineteen (42.2%) participants had astigmatism. Similarly, 20 (44.4%) of them also were presbyopes. Most of the participants (40; 88.9%) wore glasses; 17 (37.8%) used contact lenses, and 12 (26.7%) had undergone refractive surgery. A total of 2023 comments were coded. Thematic analysis resulted into 9 themes that contribute to the QoL of people with RE. Major themes (number of coded segments) were Health concerns (678), Activity limitations (371), Convenience (261), Symptoms (255) and Emotional well-being (209). Similarly, the minor themes identified were Work and finance (148), Coping (137), Social well-being (70) and Mobility (36). The relative number of coded segments was similar among RE sub-types, and among RE corrections.

Conclusion: The findings of this study enrich the understanding on the issues important in people with RE and its correction. The QoL issues identified will be used to develop a RE-specific item bank. Health concerns and Activity limitations were identified as the most important themes for RE-specific QoL. There was relatively similar number of coded segments in each RE groups which implies that that a single comprehensive item bank may be able to assess QoL across all RE groups.

Key words: Refractive error, Myopia, Hyperopia, Presbyopia, Quality of life, Qualitative study, Interviews

A pair of glasses alone does not solve the problems: Exploring experiences of people with refractive error

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Background

- Refractive error (RE) is the commonest cause of visual impairment in the world.[1] Despite the frequency and magnitude of the burden, qualitative literature exploring impact of RE on people's well-being is sparse but suggests that there is a huge impact on people's quality of life (QoL).[2]
- Patients' viewpoints are crucial in understanding RE, promoting uptake of RE services and choice of refractive corrections.[3,4]

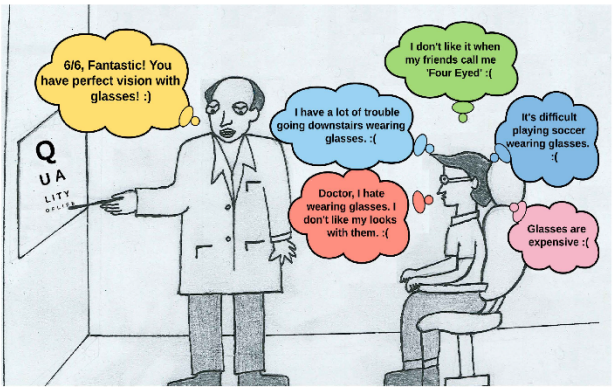

Fig. 1 Disparity between a clinician's and a patient's perspectives

- The aim of this study was to qualitatively explore impact of RE and its corrections on QoL.

Methods

- In-depth telephone and face-to-face semi-structured interviews were conducted with 48 participants with RE.
- The participants were recruited from Flinders Vision, Ashford Advanced Eye Care and also through community advertisements.
- The interviews were audio-recorded, transcribed verbatim, coded and analysed.
- Thematic analysis was done by categorising the codes into themes and sub-themes based on the semantic meaning of the codes. Coding process consisted of both inductive and deductive processes.
- Coding was done using the NVivo Software, Version 10 (QSR International Pty Ltd).

Results

- Median age = 49 (IQR = 24.5) years; 28 Female (58.3%)
- 36 Myopia, 12 Hyperopia; 23 Presbyopia; 22 Astigmatism
- Glasses – 39, Contact lenses (CL) – 17, Refractive surgery – 17
- A total of 2,367 comments were coded. Thematic analysis resulted into 6 themes that contribute to the RE-specific QoL.
- Major themes (number of coded segments) were:

Theme 1: People with RE are worried about their condition. (n=769)

- "I feel bad for passing it onto my child. I know there's nothing I can do about it because it's just a genetics thing and that's way beyond my head, but I don't like that it's happened and I feel bad for him because he's only nine years old and he's got a whole lifetime ahead of him." (43/F, Myopia, Glasses)
- "I'm not technically low vision although I find a lot of low vision strategies very helpful. So people like me sort of fall between the cracks." (49/F, High myopia, Glasses)

Theme 2: People with RE have difficulty doing physical, recreational and day-to-day activities. (n=471)

- "I tried rounders, tennis, basketball, netball and I could never catch the ball." (46/M, Astigmatism, Glasses)
- "When you want to look in the mirror and brush your hair or do your makeup or something like that you think 'oh I can't do my eyes because I can't see to do my eyes'. You know, there's a frustration there." (55/F, Presbyopia, Glasses)

Theme 3: People with RE are bothered by the inconveniences they have to live with. (n = 326)

- "Swimming and stuff like that, I always have to be careful. At the beach I find it quite hard to work out which was the way back to the sand, and if I got back to the sand trying to find out where I might have been to get back to where my towel was and things like that were always hard as well." (54/F, High myopia, Glasses)
- "…you need to clean [contact lenses], you need to put it on and it's always tedious." (49/F, High myopia, Contact lenses)

Theme 4: People with RE live with unwanted ocular and non-ocular sensations. (n = 319)

- "By the end of the night it'd be such a hassle getting them out or, you know, if I'm up studying late they'll really get sore in your eyes." (22/M, Myopia, Contact lenses)
- "I have trouble, particularly with smaller print and things like that. A bit blurry vision, having to hold it a bit further away to get a clear look." (63/F, Presbyopia, Laser surgery)
- "If I'm trying to read a paper on the desk and then looking up and down at the computer I will get really severe headaches extremely quickly and I get very, very dizzy and quite nauseous." (49/F, High myopia, Glasses)

Theme 5: RE affects people's psycho-social well-being. (n=305)

- "I felt depressed but all you could do was just keep getting new prescriptions and just – you know, what can you do?" (42/F, Myopia, Glasses)
- "I didn't get picked in the teams and I suppose, as happens with a lot with people with glasses." (54/M, Hyperopia, Glasses)

Theme 6: RE has huge economic implications in people's lives. (n=177)

- "I just cannot do my job. I could probably do maybe the equivalent of a day's work over an entire week but I certainly can't do professorial level work output at the moment." (49/F, Myope with floaters, Glasses)
- "Cost of laser surgery is a lot of money. So ….when we have to educate the children and we have to look after their medical bills and they're probably going to get braces and things like that, it's just not a priority for me. I just think to myself I'll get by." (43/F, Myopia, Glasses)

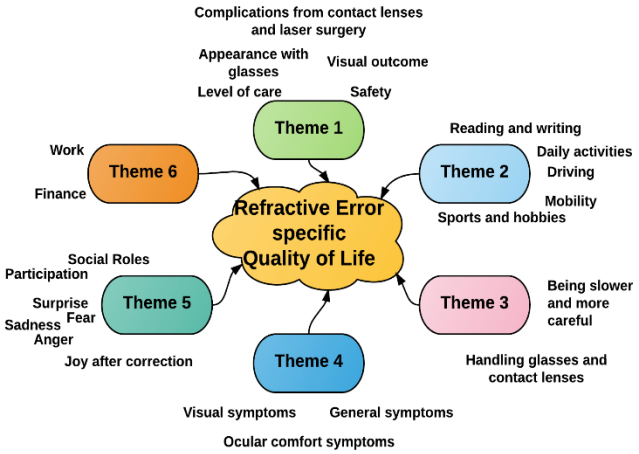

Fig. 2 Subthemes contributing to the major themes

Conclusions

- The findings of this study enrich the understanding on the issues important in people with RE and its correction.
- Concerns about personal health and safety, difficulties in day-to-day activities, and inconveniences rendered in daily life were identified as the most important issues.
- QoL issues identified were similar across people with different types of RE.
- Findings from this study will be used to develop a comprehensive patient reported outcome measure (survey questionnaire) for RE-specific QoL.

References

1. Bourne RRA, Stevens GA, White RA, et al. Causes of vision loss worldwide, 1990–2010: a systematic analysis. The Lancet Global Health. 2013;1(6):e339-e49.
2. Goertz AD, Stewart WC, Burns WR, et al. Review of the impact of presbyopia on quality of life in the developing and developed world. Acta Ophthalmologica 2014;92(6):497-500.
3. Pesudovs K. Patient-centred measurement in ophthalmology – a paradigm shift. BMC Ophthalmol. 2006;6(1):1-4.
4. Khadka J, McAlinden C, Pesudovs K. Quality assessment of ophthalmic questionnaires: Review and recommendations. Optom Vis Sci. 2013;90(8):720-44.

5. **Kandel H,** Khadka J, Pesudovs K. Development and validation of a new measure of convenience in refractive error. Paper presented at the ARVO 2018 Annual Meeting, Stand strong for science: Stand for strong vision science, Apr 29 – May 03, Honolulu, Hawaii, USA. [Abstract published: *Invest Ophthalmol Vis Sci* 2018;59(9:4147]

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ARVO Annual Meeting Abstract | July 2018

Development and validation of a new measure of convenience in refractive error

Himal Kandel; Jyoti Khadka; Konrad Pesudovs

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science July 2018, Vol.59, 4147. doi:

SHARE TOOLS

Abstract

Purpose : Inconvenience (e.g. inconvenience handling glasses and contact lenses) is one of the major quality of life (QoL) issues for people with refractive error and it is one of the domains of refractive-error specific QoL item banks. The aim of this study was to validate the Convenience scale.

Methods : The 64-item convenience item bank was developed from the issues identified from patient consultation and literature review, followed by an iterative content refinement process. The item bank was interviewer-administered to 305 people with refractive error in Nepal. Rasch analysis was conducted using WinSteps V3.92.1 software applying the Andrich Rating Scale Model. Median convenience scores were compared among various demographic and clinical sub-groups.

Results : Mean age of the participants was 30.5±14.1 years (Range: 18-83 years; Male, 50.6%; Rural, 14.8%). Median visual acuity was 0 (range: -0.08 to +1.18)

LogMAR. The mean spherical-equivalent refractive error was -2.40±2.9 (range: -15.0 to +11.0) dioptres. Participants had myopia (n = 227), hyperopia (n=39), astigmatism (n=65) and presbyopia (n=48). They wore glasses (n=257), contact lens (n=37) or underwent refractive surgery (n=25). Rasch analysis revealed that the item-bank had satisfactory psychometric properties: ordered response categories, measurement precision (PSI, 2.9), fit statistics (<1.5 MnSq), targeting (0.96 logits), and unidimensionality.

The participants with high refractive error, from rural areas, and female participants had higher inconvenience (Mann Whitney U; $p < 0.05$). Similarly, the participants wearing contact lenses had the highest inconvenience (0.40 logits) followed by the participants with glasses (0.9 logits), uncorrected refractive error (1.2 logits) and refractive surgery (1.8 logits) [Kurskal Wallis; $p = 0.02$]. Convenience scores mildly correlated with visual acuity (Spearman's rho; -0.21; $p<0.001$) and refractive error (Spearman's rho; -0.21; $p<0.001$). Convenience levels between presbyopes (0.88 logits) and non-presbyopes (0.92 logits), myopia (0.91 logits) and hyperopia (0.82 logits), participants with astigmatism (0.82 logits) and without astigmatism (0.99 logits), were not statistically significant (Mann Whitney U; $p > 0.05$).

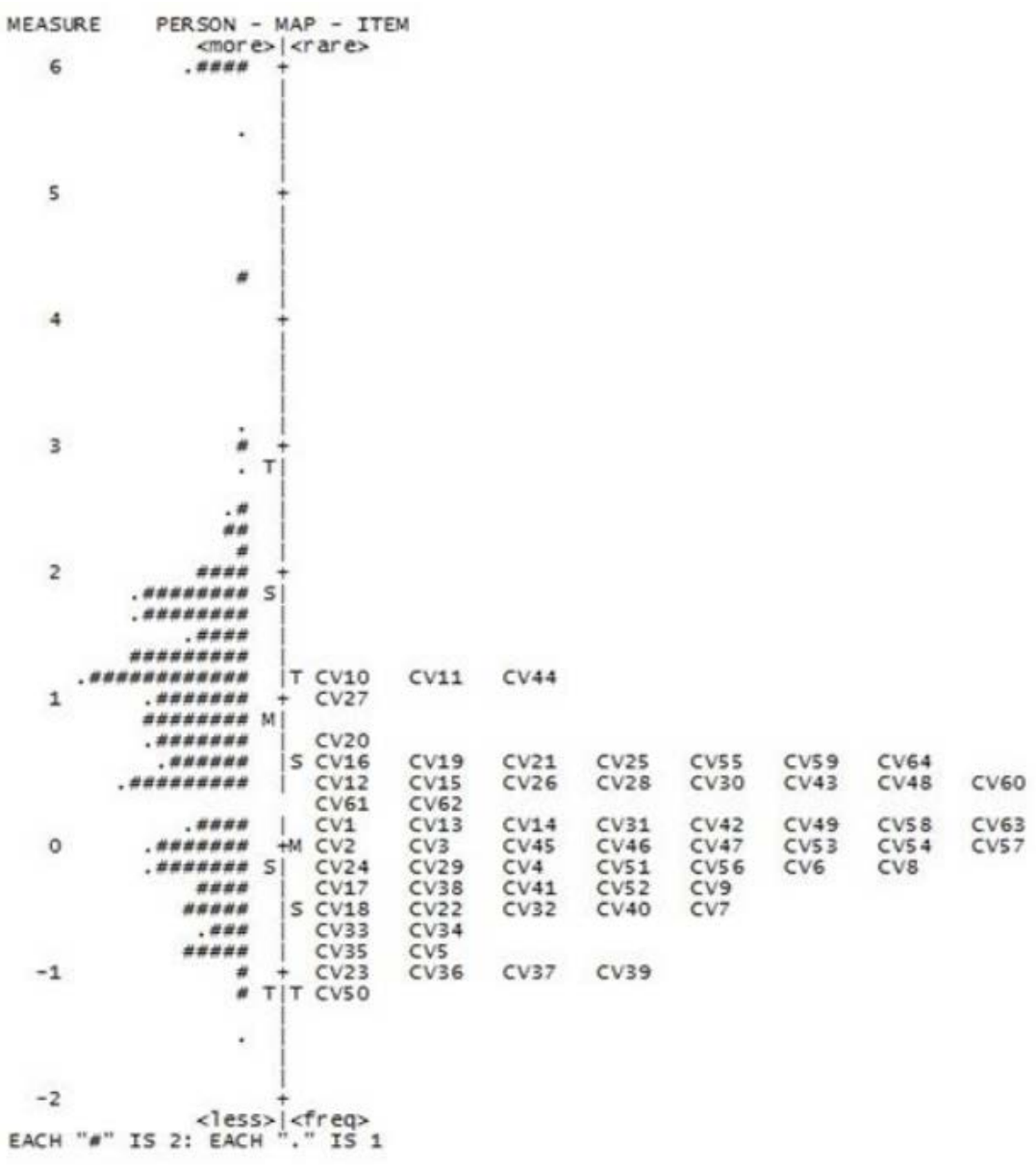
Conclusions : The Convenience item bank is a novel measure of inconvenience in refractive error. It has good psychometric properties and known-group validity.

This is an abstract that was submitted for the 2018 ARVO Annual Meeting, held in Honolulu, Hawaii, April 29 - May 3, 2018.

Layman abstract:

In a qualitative study conducted in Australia and Nepal (published earlier), we found that inconvenience associated with refractive error, such as having to look after glasses and contact lenses, was a major quality of life issue. However, there is no patient reported outcome measure to quantify such an important quality of life domain in people with refractive error. The purpose of this study was to develop and validate a Convenience questionnaire. The questions were derived from an extensive literature review and in-depth interviews with people having refractive error. The questionnaire consists of 64 items. It was completed by 305 participants. The data was subjected to Rasch analysis, one of the modern psychometric methods.

Rasch analysis confirmed that the convenience formed a valid scale with good psychometric properties. It was able to distinguish between different refractive error groups. Contact lens wearers, who also used glasses, had the highest level of inconvenience. The glass wearers had higher inconvenience level than uncorrected refractive error and laser refractive surgery groups, respectively. The novel Convenience questionnaire may be useful as an outcome measure of refractive correction, and may be incorporated into clinical practice and research, ultimately aiding in policy setting for refractive error interventions.



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Persons and items calibrated in a common logit scale

4147. Development and validation of a new measure of convenience in refractive error

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Background

- Refractive error is the most common cause of visual impairment worldwide.[1]
- Inconvenience (e.g. inconvenience handling glasses and contact lenses) is one of the major quality of life issues for people with refractive error, and it is one of the domains of refractive error-specific quality-of-life item-banks.[2]
- In a qualitative study, we found that an individual's comfort, needs, time, desires and purposes may be compromised by having refractive error.[2]

  "I lose my glasses all the time, and have to feel around to find them. I search for them crawling around my room .....with my hands....on my hands and knees because I'm scared I'll step on them. I have to put my face two inches from the glasses to see them. What a helpless feeling!" A high myopic person wearing glasses
- None of the existing patient reported outcome (PRO) instruments in refractive error developed in low resource settings consisted of items related to inconvenience.[3, 4]
- The aim of this study was to develop and validate the Convenience item-bank.

Methods

- **Study sites:** Tilganga Institute of Ophthalmology and Dhulikhel Hospital, Nepal
- **Phase I:** Content was identified from a qualitative study[5] followed by an iterative content refinement process.[6]
  - Qualitative analysis: Thematic analysis was conducted using NVivo Software, Version 11 (QSR International Pty Ltd.)
- **Phase II:** The Convenience item-pool was interviewer-administered to 305 people with refractive error
  - Rasch analysis was conducted using WinSteps V3.92.1 software applying the Andrich Rating Scale Model.
  - Computer adaptive testing (CAT) simulation was carried out using Firestar (Version 1.3.2) and R (Version 3.1.3; The Foundation for Statistical Computing, Vienna, Austria) software.
  - Descriptive analysis was done using SPSS software, Version 23 (SPSS, Chicago, IL, USA)

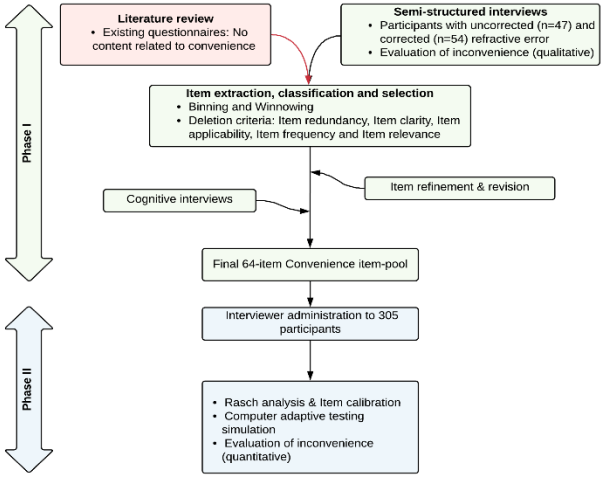

Figure 1. Steps for development and evaluation of the Convenience item-bank

Results

Clinical and demographical characteristics of the participants

Characteristics	Phase I (N = 101)	Phase II (N = 305)
Mean age (Range) years	34.4 ± 15.2 (18 - 74)	30.5 ± 14.07 (18 - 83)
Male	55	154
Type of refractive error		
Myopia (severity)[a]	56 (Low, 27; Moderate, 15; High, 14)	227 (Low, 127; Moderate, 71; High, 29)
Hyperopia (severity)[a]	21 (Low, 12; Moderate, 3; High, 6)	39 (Low, 23; Mod, 12; High, 4)
Presbyopia	28	48
Astigmatism	41	65
Type of refractive correction		
Glasses (frequency of use)	60 (Very often, 31; Quite often, 9; Occasionally, 20)	257 (Very often, 160; Quite often, 53; Occasionally, 44)
Contact lenses (frequency of use)[b]	17 (Very often, 5; Quite often, 3; Occasionally, 6; Rarely, 3)	37 (Very often, 9; Quite often, 6; Occasionally, 22)
Refractive surgery	20	25
Un/under-corrected refractive error	47	57

[a]Grading of myopia and hyperopia (spherical equivalent) in dioptres: Low, |0.50| to |3.00|; Moderate, |3.25| to |6.00|; High, > |6.00|
[b]All participants wearing contact lenses used glasses as well.

- **Qualitative study and content refinement process**
  - Resulted into an item-pool with 64 items.
  - Item root: "Because of your refractive error and/or correction how much trouble is -----?"
  - Response options: 1. Extremely, 2. Quite a lot, 3. A moderate amount, 4. A little bit, 5. None
- **CAT simulation**
  - 38 items with local item dependency (LID) were temporarily set-aside to achieve LID free estimates for CAT simulation.
  - The mean number of items administered for achieving high (SEM = 0.37) and moderate precision (SEM = 0.48) were 8.16 and 4.27 respectively.
- **Psychometric properties of the Convenience item-bank**

Rasch parameters	Convenience item-bank
Response category functioning	**Excellent** [Ordered and well-spaced thresholds and category measures, good infit MnSq and outfit MnSq (<1.30), no floor or ceiling effect]
Measurement precision	**Excellent** (Person separation index = 2.90)
Item fit statistics	**Good** (infit MnSq and outfit MnSq statistics < 1.5)
Targeting	**Satisfactory** (0.96 logits)
Dimensionality	**Essentially unidimensional** (PCA variance explained by the first factor = 49%; Eigen value for the first contrast = 6.3[¶]; Disattenuated correlation between the first and the second item-clusters = high (0.90); Ratio of explained variance by items to unexplained variance by the first contrast = high (3.02))
Measurement range	**Satisfactory** (1.23 logits to -1.13 logits)

[¶]The Eigen value for the first contrast suggested that a cluster of more than 6 items might form a secondary dimension. Eight items had PCA standardised residual loadings >0.40 logits. However those items did not conceptually form a separate meaningful construct. The unexplained variance in the first contrast was low (5.0%).
PCA = Principal component analysis

- **Evaluation of Convenience**
  - The participants with high refractive error, from rural areas, and female participants had higher inconvenience than the participants with low refractive error, from urban areas and male participants respectively (Mann Whitney U test: $p < 0.05$ in all cases).

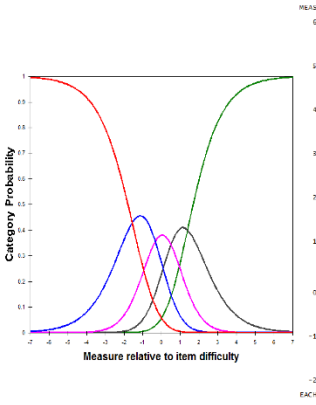

Figure 2. Category probability curves
Note: Red = 1. Extremely, Blue = 2. Quite a lot, Pink = 3. Moderate amount, Black = 4. A little bit, Green = 5. None

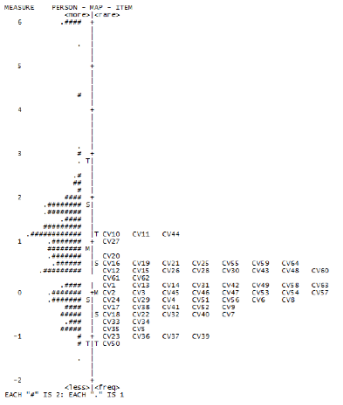

Figure 3. Person-item map
Note: Persons are located in the left, with their abilities in the latent traits from low (at the bottom) to high (at the top). Items are placed at the right side with their difficulty level of the latent trait from low (bottom) to high (top). M = Mean, S = one standard deviation from the mean, T = two standard deviation from the mean

- The participants wearing contact lenses had the highest inconvenience (0.40 logits) followed by the participants with glasses (0.87 logits), uncorrected refractive error (1.19 logits) and refractive surgery (1.79 logits) [Kurskal Wallis test, $p = 0.028$].
- The Convenience scores weakly correlated with visual acuity (Spearman's rho, 0.213; $p < 0.001$). There was a weak negative correlation between the Convenience scores and the refractive error magnitude (Spearman's rho, -0.212; $p < 0.001$).
- Convenience scores between participants with presbyopia (0.88 logits) and no-presbyopia (0.92 logits), myopia (0.91 logits) and hyperopia (0.82 logits), astigmatism (0.82 logits) and no-astigmatism (0.99 logits), were not statistically significant (Mann Whitney U test, $p > 0.05$ in all cases).

Conclusions

- The Convenience item-bank is a novel PRO instrument in refractive error. It has good psychometric properties and known-group validity.
- Convenience item-bank administered through a CAT system may offer efficient and precise measurement of convenience in refractive error.

References

1. Flaxman SR, Bourne RR, Resnikoff S *et al.* Global causes of blindness and distance vision impairment 1990–2020: a systematic review and meta-analysis. *Lancet Glob Health* 2017;5(12):e1221-e34.
2. Kandel H, Khadka J, Goggin M, Pesudovs K. Impact of refractive error on quality of life: a qualitative study. *Clin Exp Ophthalmol* 2017;45:677-88.
3. Kandel H, Khadka J, Goggin M, Pesudovs K. Patient reported outcomes for assessment of quality of life in refractive error: a systematic review. *Optom Vis Sci* 2017;94(12):1102-19.
4. Kandel H, Khadka J, Lundström M, Goggin M, Pesudovs K. Questionnaires for measuring refractive surgery outcomes. *J Refract Surg* 2017;33(6):416-24.
5. Kandel H, Khadka J, Shrestha M *et al.* Uncorrected and corrected refractive error experiences of Nepalese adults: a qualitative study. *Ophthalmic Epidemiol* 2018;25(2):147-61.
6. Kandel H, Khadka J, Fenwick E *et al.* Constructing item banks for measuring quality of life in refractive error. *Optom Vis Sci* [Under Review].

Disclosures: Kandel H (N), Khadka J (N), Pesudovs K (N)
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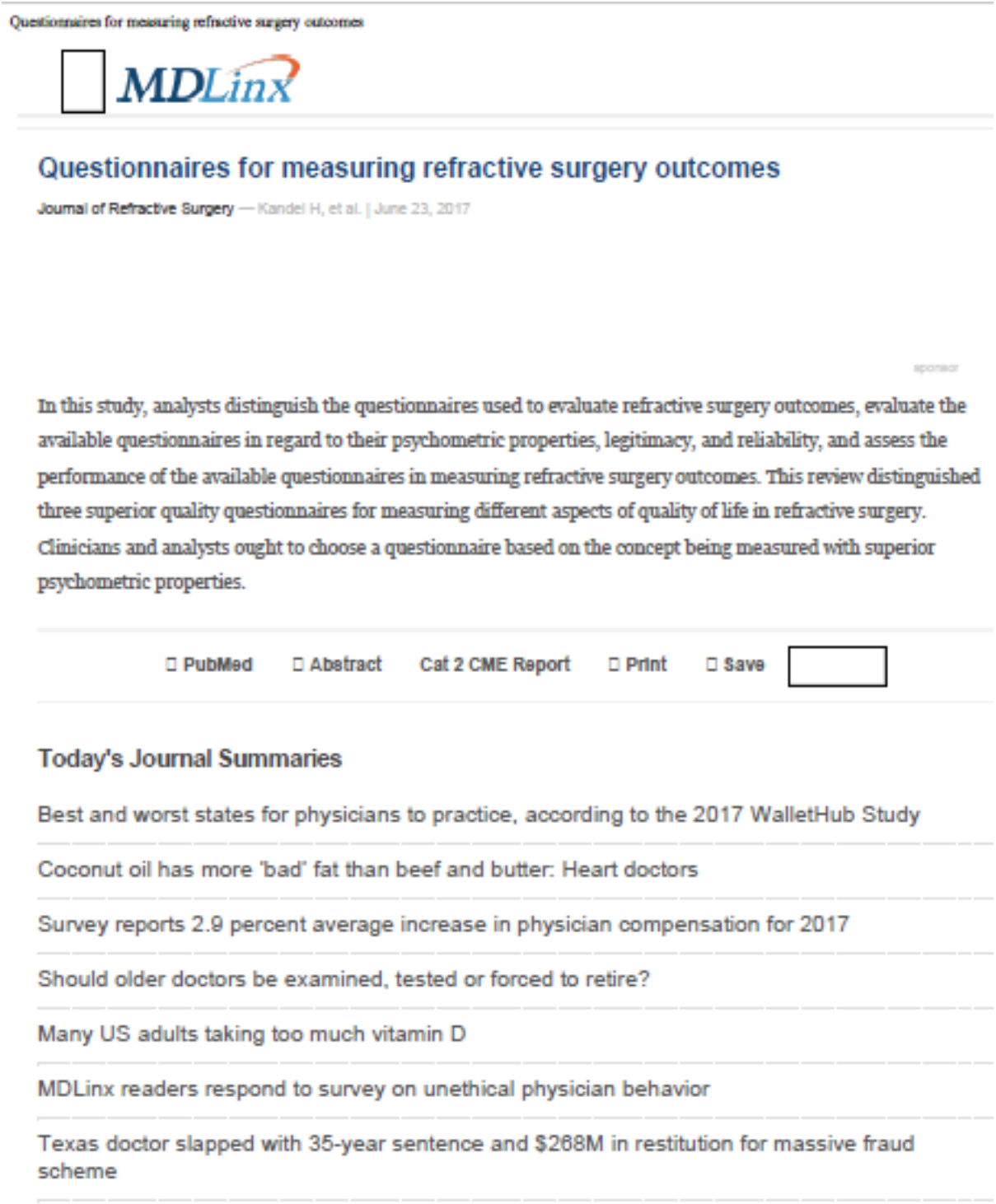
Appendices: 401

Appendix E. News coverage

- News coverage for the article[15] “Kandel *et al.* J Refract Surg. 2017;33(6):416-24”
    - Note: This article was covered by at least two news outlets.
- News coverage for the article[14] “Kandel *et al.* Clin Exp Ophthalmol. 2017;45(7):677-88.”
    - Note: This article was covered by at least eight news outlets.
- A blog on request from the International Agency for Prevention of Blindness (Standard Checklist) was written on the findings from the qualitative studies from Australia[14] and Nepal.[63]

News coverages for the article: *"**Kandel H,** Khadka J, Lundstrom M, Goggin M, Pesudovs K. Questionnaires for measuring refractive surgery outcomes. Journal of Refractive Surgery 2017;33(6):416-424"*

Web link: https://www.mdlinx.com/journal-summaries/2017/06/23/7204707?spec=ophthalmology



Questionnaires for measuring refractive surgery outcomes

MDLinx

Questionnaires for measuring refractive surgery outcomes

Journal of Refractive Surgery — Kandel H, et al. | June 23, 2017

In this study, analysts distinguish the questionnaires used to evaluate refractive surgery outcomes, evaluate the available questionnaires in regard to their psychometric properties, legitimacy, and reliability, and assess the performance of the available questionnaires in measuring refractive surgery outcomes. This review distinguished three superior quality questionnaires for measuring different aspects of quality of life in refractive surgery. Clinicians and analysts ought to choose a questionnaire based on the concept being measured with superior psychometric properties.

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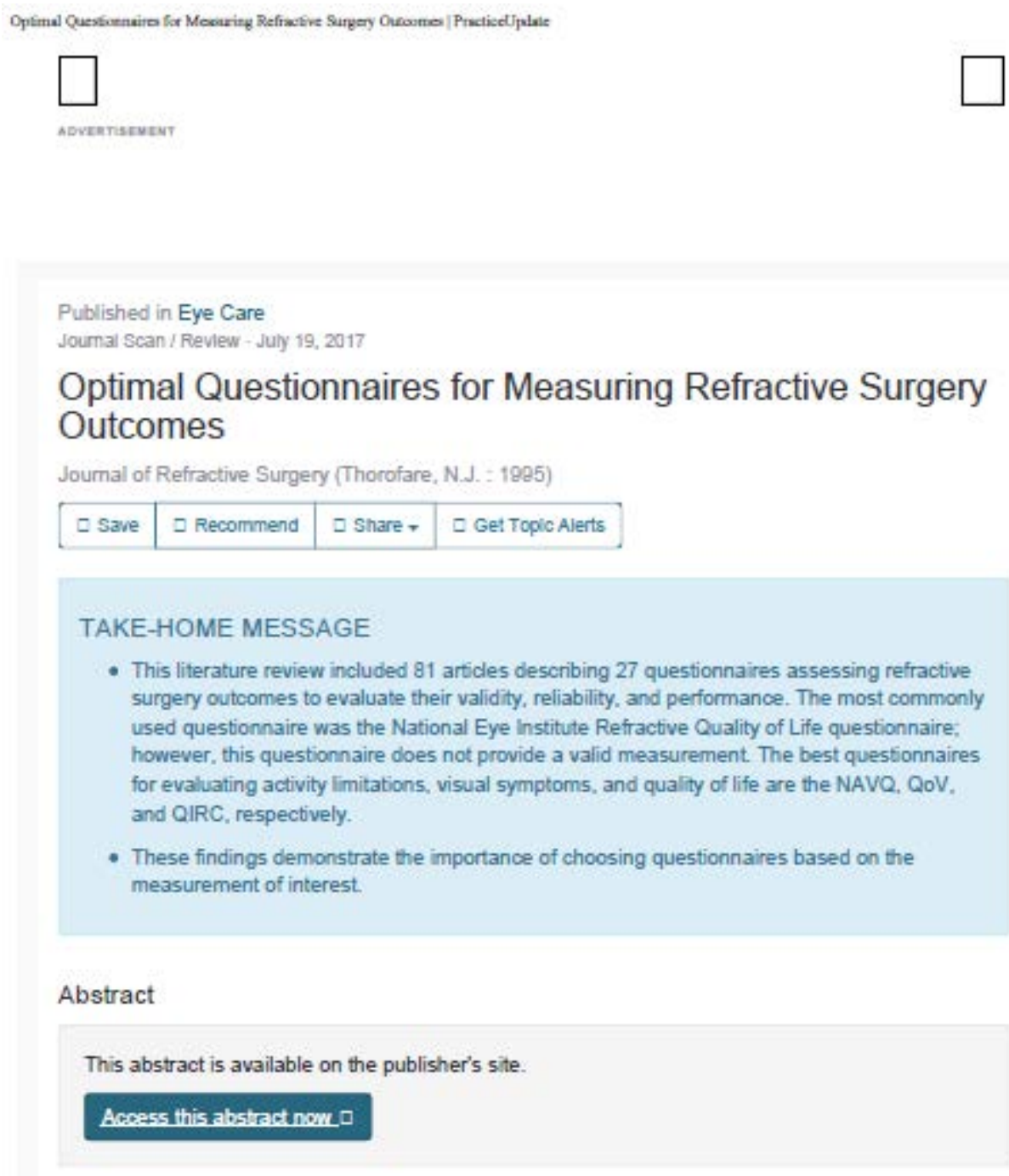
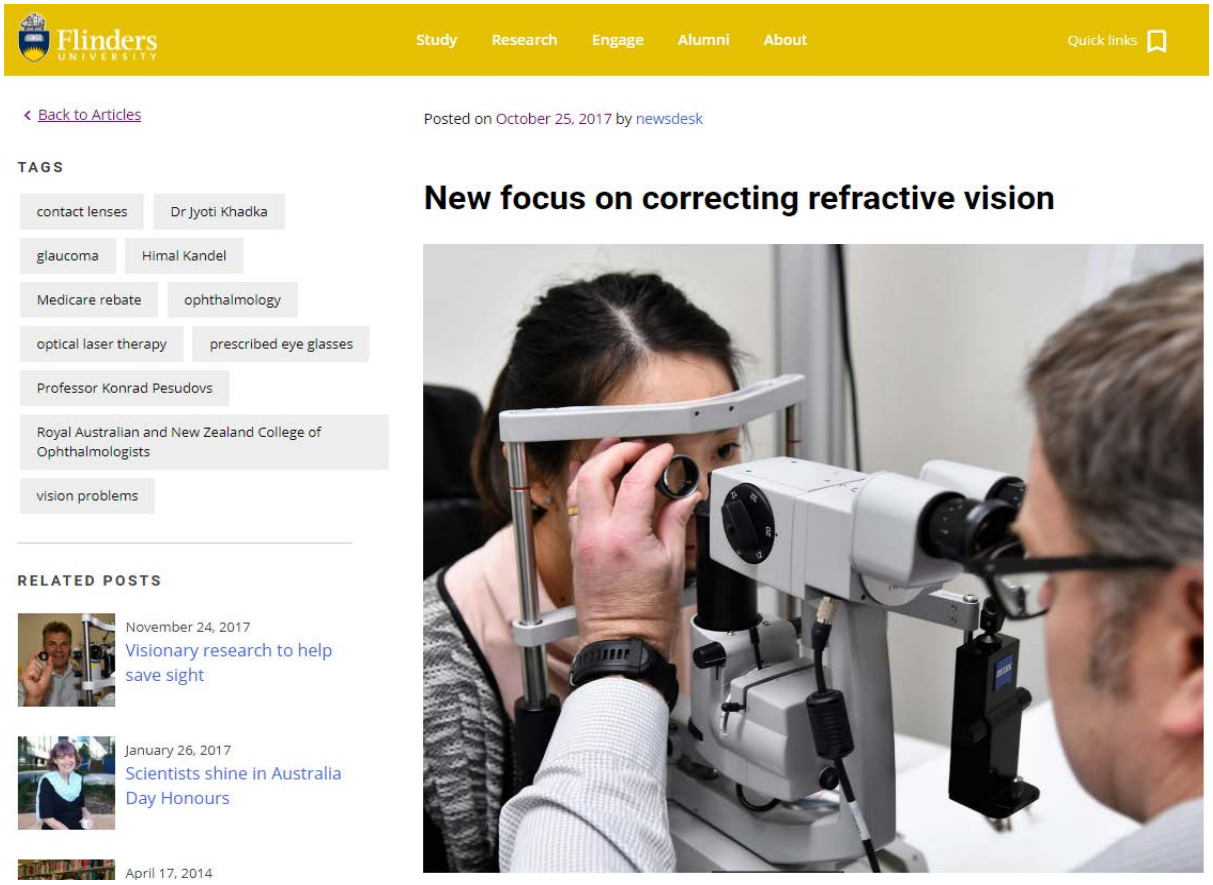
Web link: https://www.practiceupdate.com/content/optimal-questionnaires-for-measuring-refractive-surgery-outcomes/55399/62



News coverages for the article: *"**Kandel H,** Khadka J, Goggin M, Pesudovs K. Impact of refractive error on quality of life: a qualitative study. Clinical and Experimental Ophthalmology, 2017,45(7):677-88"*
[Note: published as a lead feature of the issue. An editorial was written on this article. It was selected for CPD points. It was an 'editor's choice free article'.]

http://news.flinders.edu.au/blog/2017/10/25/new-focus-correcting-refractive-vision/



Prescribing glasses might not be the answer to a patient's comfort.

While doctors take delight in solving the common issue of refractive vision error by prescribing eye glasses, Flinders University researchers have found that many patients are upset with this solution and claim it affects their quality of life.

The results of a qualitative study – "Impact of refractive error on quality of life" – have been published as the lead feature in the latest issue of Clinical and Experimental Ophthalmology, the official journal of the Royal Australian and New Zealand College of Ophthalmologists.

The journal also published an editorial on the findings, underlining its significance to ophthalmologists.

This is the first time patient reaction to optometry has been measured, and the passionate responses of patients raising significant quality of life issues came as a surprise to the article's authors, Flinders research associate Dr Jyoti Khadka and PhD candidate Himal Kandel.

Patients aren’t always happy wearing prescription glasses. Photo: Scott Van Daalen / unsplash.com

“Patients want eye specialists to have a broader perspective and present more options that will offer better quality of life outcomes,” says Dr Khadka, pointing to a raft of patient issues with wearing glasses and contact lenses, and who voiced a clear preference for laser surgery.

The researchers found that patients believe laser surgery is more crucial than a cosmetic surgical option, with some calling it a “life changing solution”, especially for people needing vision aids during activites, from work requirements to sporting activities.

Mr Kandel suggests this finding could be a first step towards optical laser surgery being reclassified and recognised for Medicare rebate.

Professor Konrad Pesudovs, Head of Optometry at Flinders University, says this article represents part of a wider suite of research Flinders is undertaking to measure more outcomes of optometry and ophthalmology practice from a patients’s perspective.

Professor Pesudovs has recently presented at overseas conferences about patient-reported outcomes of glaucoma and other vision problems, and believes this is an important area of medical consideration.

Dr Khadka and Himal Kandel’s research has been selected for Continued Professional Development, with their quantitative studies expected to be completed in six months.

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https://medicalxpress.com/news/2017-10-focus-refractive-vision.html

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Explore further: Looking at outcomes important to patients may improve results of cataract surgery

More information: Himal Kandel et al. Impact of refractive error on quality of life: a qualitative study, *Clinical & Experimental Ophthalmology* (2017). **DOI: 10.1111/ceo.12954**

Provided by: Flinders University

NEWS

Patient's perspective front-and-centre in new research

Saturday, November 4, 2017

By Rhiannon Riches
Assistant Editor

The results from the first qualitative study of patient reaction to refractive correction have been published as the lead article in the September–October issue of *Clinical and Experimental Ophthalmology*.

The journal also published an editorial on the findings.

The study's authors assert that many patients are unhappy with being prescribed spectacles to correct refractive error and claim it affects their quality of life.

The authors, Flinders University research associate Dr Jyoti Khadka and PhD candidate Himal Kandel, say in a media release from the university that patients want eye-care practitioners to have a broader perspective and present more options that will offer better quality of life outcomes.

They note that patients in the study voiced a clear preference for refractive laser surgery, and suggest this could form the first step towards optical laser surgery being reclassified and recognised for Medicare rebate.

Professor Konrad Pesudovs from Flinders University says in the media release that the qualitative study represents part of a wider suite of research Flinders is undertaking to measure more outcomes of optometry and ophthalmology practice from a patient's perspective.

Impact of refractive error on quality of life

This entry was posted by Rhiannon Riches, on Saturday, November 4, 2017

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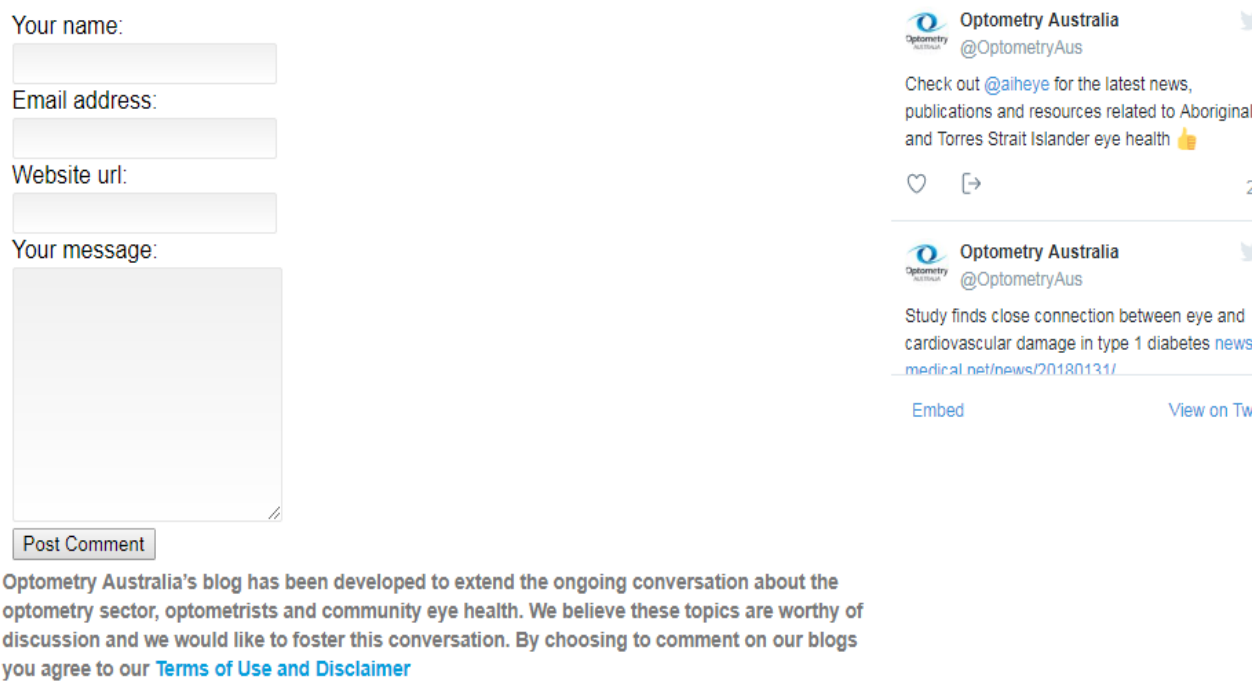

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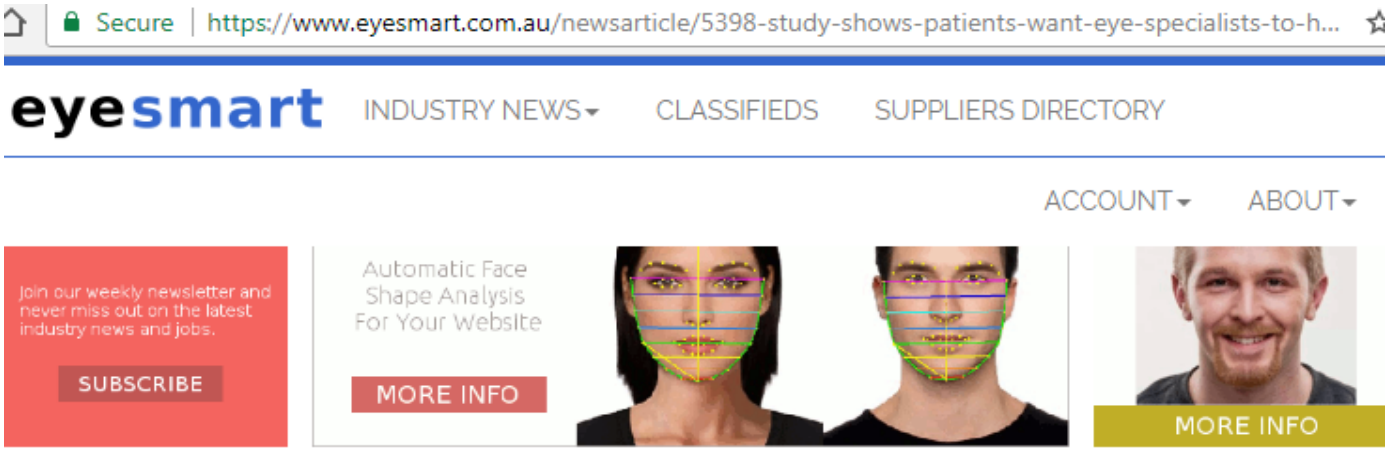

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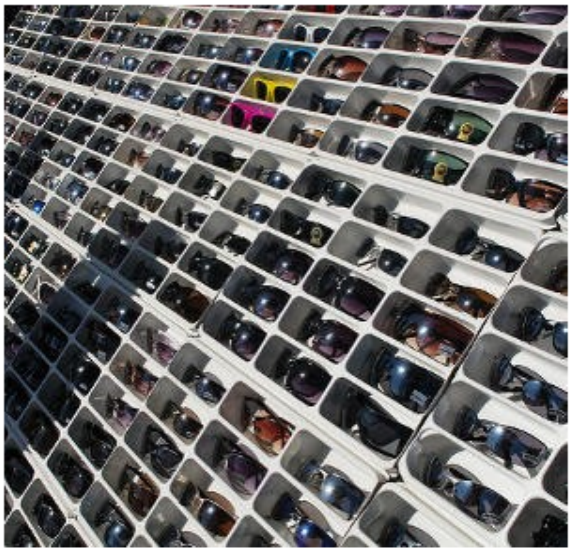
Study Shows Patients Want Eye Specialists To Have Broader Perspective



While doctors take delight in solving the common issue of refractive vision error by prescribing eye glasses, Flinders University researchers have found that many patients are upset with this solution and claim it affects their quality of life.

The results of a qualitative study – "Impact of refractive error on quality of life" – have been published as the lead feature in the latest issue of Clinical and Experimental Ophthalmology, the official journal of the Royal Australian and New Zealand College of Ophthalmologists.

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"Patients want eye specialists to have a broader perspective and present more options that will offer better quality of life outcomes," says Dr Khadka, pointing to a raft of patient issues with wearing glasses and contact lenses, and who voiced a clear preference for laser surgery.

The researchers found that patients believe laser surgery is more crucial than a cosmetic surgical option, with some calling it a "life changing solution", especially for people needing vision aids during activites, from work requirements to sporting activities.

Mr Kandel suggests this finding could be a first step towards optical laser surgery being reclassified and recognised for Medicare rebate.

Professor Konrad Pesudovs, Head of Optometry at Flinders University, says this article represents part of a wider suite of research Flinders is undertaking to measure more outcomes of optometry and ophthalmology practice from a patients's perspective.

https://www.medicalnewser.com/2017/11/10/new-focus-on-correcting-refractive-vision.html?print=print

New focus on correcting refractive vision

Prescribing glasses might not be the answer to a patient's comfort. Credit: Flinders University

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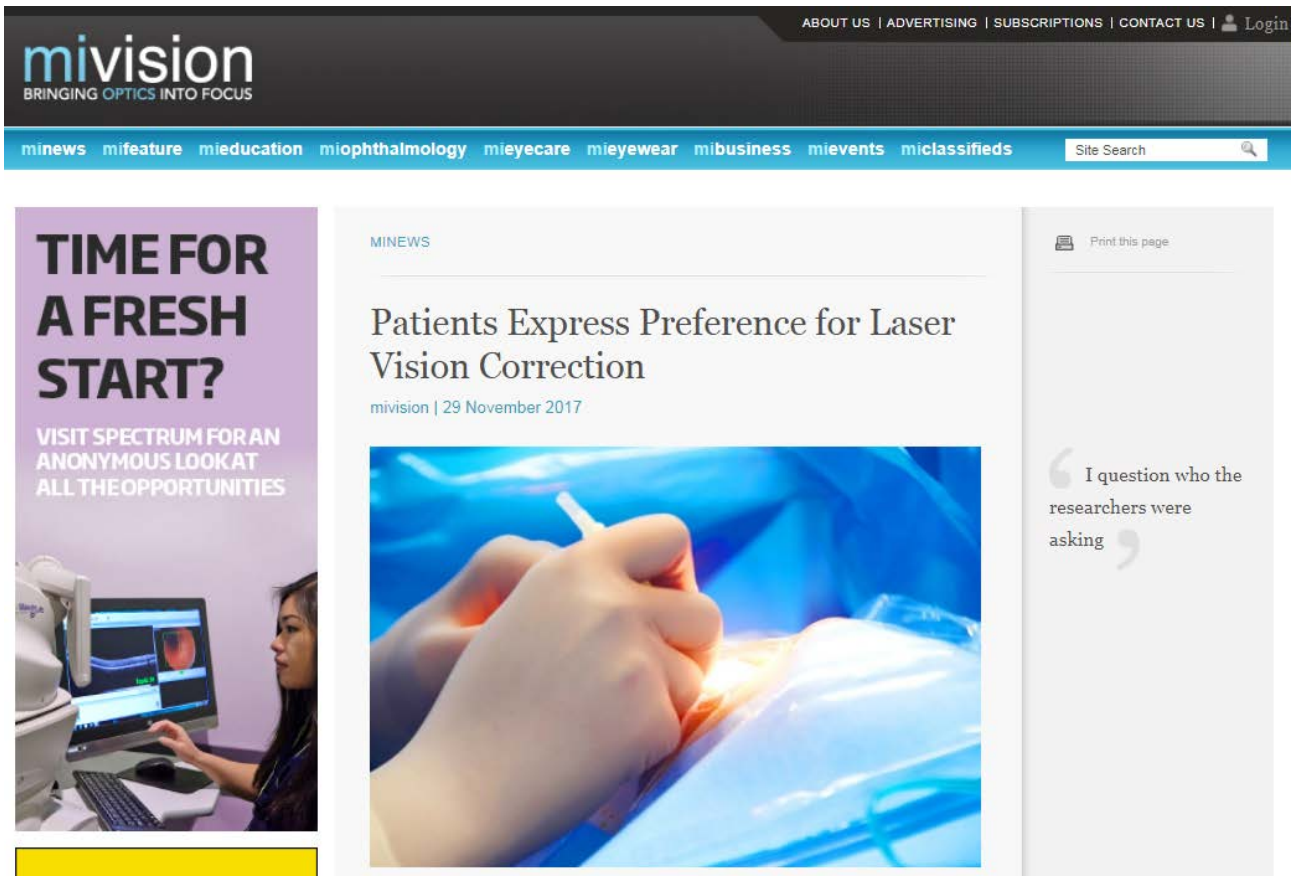
Looking at outcomes important to patients may improve results of cataract surgery

More information:
Himal Kandel et al. Impact of refractive error on quality of life: a qualitative study, *Clinical & Experimental Ophthalmology*(2017). DOI: 10.1111/ceo.12954

Provided by:
Flinders University

http://www.mivision.com.au/patients-express-preference-for-laser-vision-correction/



Surprising qualitative research out of Flinders University, suggesting patients prefer refractive laser surgery over spectacles for vision correction and want “eye care practitioners to have a broader perspective and present more options” has not been embraced by optometrists.

The researchers found that many patients were unhappy being prescribed spectacles and claimed it affected their quality of life.

The study authors, Flinders research associate Dr. Jyoti Khadka and PhD candidate Himal Kandel, said the passionate responses of patients raising significant quality of life issues came as a surprise.

“Patients want eye care practitioners to have a broader perspective and present more options that will offer better quality of life outcomes,” said Dr. Khadka, pointing to a raft of patient issues with wearing glasses and contact lenses, and to patients who voiced a clear preference for refractive laser surgery.

The researchers found that patients believe laser surgery is more crucial than a cosmetic surgical option, with some calling it a “life changing solution”, especially for people needing glasses during activities from work requirements to sporting endeavours. Mr. Kandel suggested the finding could be a first step towards optical laser surgery being reclassified and recognised for Medicare rebate.

The optometrists *mivision* spoke to had reservations about more widely recommending laser corrective surgery.
“The Flinders University study may state that patients prefer laser corrective surgery compared to wearing glasses, but it does not account for complications or risks associated with the surgery,” said Josh Clark from EyeQ Optometrists in Berowra, NSW. “Many patients experience dry eyes, halos and glare for years following laser-corrective surgery.

“It is also a dangerous idea to put in patients’ heads that laser-corrective surgery will replace glasses as it's not an effective treatment for myopia progression. I would think again before routinely offering laser corrective surgery over glasses to my (progressing) myopes! Why not offer orthokeratology or soft contact lenses to these patients?”

Margaret Lam from George and Matilda acknowledged that optometrists in Australia default to prescribing glasses in preference to other prescribing options more than other countries, however she said the idea of prescribing laser correction for all patients over-simplifies things. “The study findings are certainly relevant for us in understanding the impact on vision correction on our patients’ quality of life. To suggest prescribing refractive surgery for all patients without due consideration of their individual circumstances is a step too far, and one that over-simplifies things. There are other less invasive options, such as contact lenses, which can minimise the detrimental quality of life this study highlights.”

Thao Hannaford from Bowral, NSW said offering patients advice to meet their specific needs was most important. “There are many ways we can correct refractive error and they will have their pros and cons: spectacles; contact lenses; orthokeratology; laser surgery and its various types; and clear lens extraction.

“I question who the researchers were asking and where those participants went for their eye care needs… depending on the model of optometry practice, some are geared towards pumping out spectacles and others provide the complete service.

“I like to think I offer the latter and personally I offer my patient the best solution/s to meet their life needs. More often than not, it can be a few solutions.”

Optometrist Jessica Chi said laser is not for everyone. “The idea of being spectacle free is very appealing people who are dependent on refractive correction. I am a myope, and for the most part I manage well with my contact lenses (and sometimes spectacles). However, there are times when they bother me. I am fully aware of how debilitated I would be without them… If I could wave a magic wand and be an emmetrope I would. But would I go and slice and dice every cornea to make this happen? Refractive surgery has been shown to very safe in the appropriate candidate. However let’s not forget that refractive surgery is surgery, and should be proceeded to with caution,” said Ms. Chi.

Medicare Rebate Not Warranted

Ms. Lam did not support the suggestion that optical laser surgery could be reclassified and recognised for Medicare rebate. “A Medicare rebate that encourages all patients to undertake an elective surgery with potential risks and adverse effects is a step too far.”

Ms. Hannaford supported her, “If the aim of this paper is to allow laser to fall under Medicare benefits, then why shouldn’t other methods of refractive error correction be included as well?,” she said.

The results of the qualitative study - “Impact of refractive error on quality of life” - were published as the lead feature in the September/October issue of *Clinical and Experimental Ophthalmology*, the official

journal of the Royal Australian and New Zealand College of Ophthalmologists. The journal also published an editorial on the findings, underlining its significance to eye care professionals.
Dr. Khadka and Mr. Kandel's research has been selected for Continued Professional Development, with their quantitative studies expected to be completed in six months.

Appendix F. Interview guide

Note: The interview guide has been published as an Appendix of the Australian qualitative study (Kandel et al. Clin Exp Ophthalmol. 2017;45(7):677-88).[14]

Introduction

Thank you very much for taking the time to participate in this interview. My name is ---------. I am a ---------- at the Discipline of Optometry, School of Health Sciences, Flinders University. We are currently interested in finding out how your eye condition (i.e. refractive error) impacts on your life as a whole. This includes what you can do and can't do, inconvenience you face, how you feel, relationships with others and specific effects of having to wear/undergo different corrections you have had. We are basically interested in hearing your views, experiences and opinions. This will help us to better understand the needs of people who have refractive error.

My role here involves asking questions and listening. **I won't actually be participating in the conversation**; instead, I would like you to feel free to talk in response to the questions. I will also be responsible for moving the interview from one topic to the next. If you have any specific questions about your condition, we can cover those at the end of this interview session.

I would like to stress that there are no right or wrong answers and we are most interested in your personal views, opinions and experiences. Therefore, whatever you say and share is right and is extremely important to us. I'm audio recording this interview so that I don't miss out any of your comments. However, all the information you provide will remain confidential. Your name will not be attached to any reports arising from this work.

Do you have any question about this interview? Are we happy to move on?

Warm up questions

- When did you start wearing spectacles?

Questions and prompts:

Symptoms

- First, what are some of the symptoms you experience as a result of refractive error or its corrections (i.e. spectacles, contact lenses, refractive surgery including Laser eye surgery)?
    - Can you describe your eyesight/vision with and without corrections? (e.g. blurry vision)
    - What are other eye comfort symptoms with and without corrections? (e.g. painful eye/s, discomfort in your eye/s)
    - Do you experience any general symptoms associated with refractive error?(e.g. headache)

Inconvenience

- In your experiences what are the major inconveniences associated with having refractive error and having to wear corrections (i.e. spectacles, contact lenses) or undergo Laser eye surgery?

Concerns

- Do you have any concerns because of your refractive error and its management? (E.g. passing on the condition to children, refractive surgery outcomes, impact on you and your family)

Correction impacts

I'd now like to move on to talk about types of correction/s you have had.

- What are your experiences with having to wear spectacles?
- What are your experiences with contact lenses?
- What are your experiences with surgical corrections such as laser eye surgery)? Both before and after the procedure.
- What side effects/complications, if any, have you experienced?
- In what ways has refractive error affected your life?

Financial and work impacts

- How does having refractive error impact you financially?
- Do you feel that there have been direct or indirect costs associated with having refractive error? (E.g. cost of spectacles/contact lenses/ surgery, travel, health insurance)
- Has having refractive error affected your work life?

- What aspects of your work are harder to do?
- What things have cost you money because of your refractive error?

Emotions

In other groups I have talked to many people about how their eye problems affect them emotionally. I'm interested in your experience of this.

- Can you describe how having refractive error and having to wear spectacles/contact lenses make you feel emotionally?
  - How do you feel about your refractive error?
  - Do you feel unhappy, anxious, depressed at times because of refractive error and having to use wear spectacles/contact lenses? If so, can you tell us what makes you feel that way.
- Has having refractive error altered the way you view yourself. If so, how has this change?
  - Do you feel that you are different than other people?
  - Do you feel you are in control of your life?

Activity limitations (Everyday tasks)

- What sort of difficulties do you experience in your day-to-day life because of refractive error and having to wear spectacles/contact lenses?
  - What things are harder to do?
  - Have there been any instances in which you need to change the way you complete day-to-day tasks?

Mobility

- Thinking about travelling and getting out and about, can you describe how your refractive error have affected this?
  - Do you find that you have more difficulty getting around? What kind of difficulties have you experienced? (e.g. seeing steps/curbs, Getting around)
  - What things are most difficult when travelling outside or in crowded places?
  - What do you find difficult when moving about in your own home?
  - Do you feel you have more accidents/bump into things more often? Could you describe such instances?
  - Is transportation an issue? If so, how?

Social life and relationships

- In what ways do your refractive error affect your social and family life, community duties?
  - What things are you missing out on because of refractive error and its corrections?
  - What social occasions or leisure activities are affected by symptoms and side-effects associated with refractive error and its correction/s?
  - Has your ability to engage in leisure or social activities been impacted? If so, how?
- How has your refractive error affected your family and personal relationships?
- Can you think of specific examples where your eye problem has caused you or someone else difficulty?
- Do you feel you are burden on family or friends due to your eye problem? If yes, in what ways?

Useful prompts to use throughout the interview:

- Are there any other views on this?
- Is there anything else?
- Would you explain further?
- Can you give me an example of what you mean?

Summary:

Thank you all very much for sharing your experiences. Your input has been really valuable to us. I would like to summarise the key ideas that I have heard.

[**Summarise main points**]

- Is there anything I have missed or that you would like to add to my summary?

Thank you for your contribution to this project. I highly appreciate for your time and patience. Your experience will be very helpful to us in further understanding how refractive error and its correction impacts on people's lives.

Appendix G. Item-pool Australia

- Item-pool (Australia) with the background questionnaire

Introduction:

This is a long questionnaire with questions about the impact of refractive error and its correction on your quality of life. Refractive error is a condition in which light entering the eye is not focused at the retina. It can be corrected by glasses, contact lenses or with laser refractive surgery. The questions were derived from the in-depth interviews with the people having refractive error.

Your responses will be used to validate this questionnaire. This will enable us to develop an advanced measurement system to precisely measure quality of life with the help of only a few questions.

Instructions:

Each question is followed by all possible answers. Please choose the answer that best applies to you.

Please take as much time as you need to answer each question. Your response to each of the questions is very important to us.

Please answer every question unless you need to skip questions because they don't apply to you (if they don't apply to you, please select "This task is not relevant to me / don't do the task"). All your answers and the information you have provided will be regarded as strictly confidential.

Please consider your refractive error and/or its correction when you answer these questions. For example, **if you usually wear reading glasses or distance glasses or contact lenses please answer according to how you can see when wearing them.**

Date: Time started: Time finished: Duration:	Participant ID: Interviewer: Mode: Self / Interviewer administered Face to face / Phone / Combination Paper based survey / Online survey

Background Questionnaire (*Please print or circle options)*

Full Name			
Age			Country of birth:
Address:			
			Postcode:
Telephone Number:	Home:	Work:	Mobile:
E-mail			Sex*:* Male / Female
Do you speak a language other than English?		No / Yes (specify)	
Highest level of education you have achieved:			
Occupation:			
Marital status:			
In general, how would you describe your overall health?		1. Excellent / 2. Very good / 3. Good / 4. Fair / 5. Poor	
Eye Diagnosis:			
How old were you when you first wore glasses?			
Date of last eye exam:			
Do you have other eye disease/s:		No / Yes (specify)	
Do you have other medical conditions or diagnoses?		No / Yes (specify)	
Do you wear glasses?	Never / Occasionally / Quite often / Very often / Only for reading		
Do you wear contact lenses?	Never / Occasionally / Quite often / Very often If Yes, Type:		
Have you had a laser refractive surgery?	Yes / No If Yes, when: _____ Type _____ Eye: Right eye/ Left eye / Both eye		
Do you have refractive correction (glasses, contact lenses or laser refractive surgery) for *: (Please circle)*	Near use only / distance use only / For constant use		
Habitual visual acuity:	RE	LE	BE
Prescription for glasses - RE :	Prescription for glasses - LE :	Near add:	

VISUAL SYMPTOMS														
		How often do you experience…?					How severe is/are the…?					How much of a problem is/are the…?			
		Never	Occasionally	Quite often	Very often		Not at all	Mild	Moderate	Severe		None	A little	Quite a bit	A lot
VS1	Blurred vision	4	3	2	1		4	3	2	1		4	3	2	1
VS2	Hazy vision	4	3	2	1		4	3	2	1		4	3	2	1
VS3	Poor vision in only one eye	4	3	2	1		4	3	2	1		4	3	2	1
VS4	Blurred vision in rain	4	3	2	1		4	3	2	1		4	3	2	1
VS5	Poor vision in dim light	4	3	2	1		4	3	2	1		4	3	2	1
VS6	Blurred vision at distance	4	3	2	1		4	3	2	1		4	3	2	1
VS7	Blurred vision at near	4	3	2	1		4	3	2	1		4	3	2	1
VS8	Fluctuating vision during the day	4	3	2	1		4	3	2	1		4	3	2	1
VS9	Loss of peripheral vision	4	3	2	1		4	3	2	1		4	3	2	1
VS10	**How often do you feel you have** deteriorating vision	4	3	2	1		4	3	2	1		4	3	2	1
VS11	Distorted vision (lines you know are straight appear curved or distorted)	4	3	2	1		4	3	2	1		4	3	2	1
VS12	Double vision	4	3	2	1		4	3	2	1		4	3	2	1
VS13	Seeing objects with ghosts or shadows around them	4	3	2	1		4	3	2	1		4	3	2	1
VS14	Things you see appear bigger or smaller	4	3	2	1		4	3	2	1		4	3	2	1
VS15	Difficulty distinguishing colours	4	3	2	1		4	3	2	1		4	3	2	1

		How often do you experience…?				How severe is/are the…?				How much of a problem is/are the…?			
		Never	Occasionally	Quite often	Very often	Not at all	Mild	Moderate	Severe	None	A little	Quite a bit	A lot
VS16	Difficulty distinguishing contrast (e.g. borders and boundaries)	4	3	2	1	4	3	2	1	4	3	2	1
VS17	Difficulty shifting focus between near and far distances	4	3	2	1	4	3	2	1	4	3	2	1
VS18	Difficulty focusing your eyes	4	3	2	1	4	3	2	1	4	3	2	1
VS19	Floaters in your vision	4	3	2	1	4	3	2	1	4	3	2	1
VS20	Flashes of light from within your eyes	4	3	2	1	4	3	2	1	4	3	2	1
VS21	Glare from lights	4	3	2	1	4	3	2	1	4	3	2	1
VS22	Glare from shiny surfaces, e.g. ice or frost, road surface, glassy surfaces etc.	4	3	2	1	4	3	2	1	4	3	2	1
VS23	Sensitivity to light	4	3	2	1	4	3	2	1	4	3	2	1
VS24	Haloes around lights	4	3	2	1	4	3	2	1	4	3	2	1
VS25	Starbursts (stars around lights)	4	3	2	1	4	3	2	1	4	3	2	1
VS26	Difficulty with depth perception	4	3	2	1	4	3	2	1	4	3	2	1
VS27	Difficulty with adapting to changes in light [bright to dark (e.g. cinema) or dark to bright (e.g. driving through a tunnel)]	4	3	2	1	4	3	2	1	4	3	2	1

OCULAR COMFORT SYMPTOMS														
		How often do you experience…?					How severe is/are the…?					How much of a problem is/are the…?			
		Never	Occasionally	Quite often	Very often		Not at all	Mild	Moderate	Severe		None	A little	Quite a bit	A lot
OS1	Discomfort in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS2	Discomfort caused by your glasses, e.g. soreness on the nose or soreness behind the ears	4	3	2	1		4	3	2	1		4	3	2	1
OS3	Dry eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS4	Burning in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS5	Watery eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS6	Irritation in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS7	Grittiness in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS8	Red eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS9	Stinging in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS10	Itchy eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS11	Discharge in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS12	Swelling of your eyelids	4	3	2	1		4	3	2	1		4	3	2	1
OS13	Tired eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS14	Heavy eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS15	Eye strain	4	3	2	1		4	3	2	1		4	3	2	1
OS16	Pain in your eyes	4	3	2	1		4	3	2	1		4	3	2	1

GENERAL SYMPTOMS														
		How often do you experience …?					How severe is/are the…?					How much of a problem is/are the…?			
		Never	Occasionally	Quite often	Very often		Not at all	Mild	Moderate	Severe		None	A little	Quite a bit	A lot
GS1	Headaches	4	3	2	1		4	3	2	1		4	3	2	1
GS2	Tiredness	4	3	2	1		4	3	2	1		4	3	2	1
GS3	Dizziness	4	3	2	1		4	3	2	1		4	3	2	1
GS4	Nausea or vomiting	4	3	2	1		4	3	2	1		4	3	2	1
GS5	Feeling of confusion or disorientation	4	3	2	1		4	3	2	1		4	3	2	1
GS6	Motion sickness (e.g. during initial adaptation period for glasses)	4	3	2	1		4	3	2	1		4	3	2	1
GS7	Restlessness	4	3	2	1		4	3	2	1		4	3	2	1
GS8	Abnormal head posture	4	3	2	1		4	3	2	1		4	3	2	1
GS9	Feeling sleepy	4	3	2	1		4	3	2	1		4	3	2	1
GS10	Difficulty sleeping	4	3	2	1		4	3	2	1		4	3	2	1

ACTIVITY LIMITATION								
Because of your refractive error or its correction, **How much difficulty do you have…?**		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my vision**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
AL1	Reading store names	5	4	3	2	1	9	8
AL2	Telling the time from a clock	5	4	3	2	1	9	8
AL3	Reading things written on a whiteboard	5	4	3	2	1	9	8
AL4	Reading power-point projected slides	5	4	3	2	1	9	8
AL5	Reading the newspaper	5	4	3	2	1	9	8
AL6	Reading in dim light	5	4	3	2	1	9	8
AL7	Reading glossy and colourful prints, e.g. cook books, magazines	5	4	3	2	1	9	8
AL8	Seeing in bright sunlight	5	4	3	2	1	9	8
AL9	Seeing in glare conditions	5	4	3	2	1	9	8
AL10	Reading a book	5	4	3	2	1	9	8
AL11	Reading small print, e.g. the phone book, medicine bottle	5	4	3	2	1	9	8
AL12	Using a mobile phone	5	4	3	2	1	9	8
AL13	Reading text on your mobile phone screen	5	4	3	2	1	9	8
AL14	Reading digital displays, e.g. cash register, parking meters or ticket machine	5	4	3	2	1	9	8
AL15	Using a fixed telephone	5	4	3	2	1	9	8
AL16	Reading a large print book	5	4	3	2	1	9	8
AL17	Reading price labels in shops	5	4	3	2	1	9	8
AL18	Reading from a computer screen	5	4	3	2	1	9	8
AL19	Using the computer	5	4	3	2	1	9	8
AL20	Seeing at variable distances (at the desk and at the computer)	5	4	3	2	1	9	8
AL21	Reading your Post	5	4	3	2	1	9	8
AL22	Filling out forms	5	4	3	2	1	9	8
AL23	Reading the printed timetable in a railway station or a bus station	5	4	3	2	1	9	8

	Because of your refractive error or its correction, **How much difficulty do you have…?**	**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my vision**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
AL24	Reading the numbers on the front of a bus	5	4	3	2	1	9	8
AL25	Reading a street directory or map	5	4	3	2	1	9	8
AL26	Reading street signs during the day	5	4	3	2	1	9	8
AL27	Reading street signs at night	5	4	3	2	1	9	8
AL28	Reading a watch	5	4	3	2	1	9	8
AL29	Prolonged reading	5	4	3	2	1	9	8
AL30	Doing fine work, e.g. drawing, stippling	5	4	3	2	1	9	8
AL31	Engaging in a hobby or leisure activity, e.g. reading, crafts, photography	5	4	3	2	1	9	8
AL32	Recognising someone across the street	5	4	3	2	1	9	8
AL33	Recognizing a friend up close	5	4	3	2	1	9	8
AL34	Seeing facial expressions	5	4	3	2	1	9	8
AL35	Cooking	5	4	3	2	1	9	8
AL36	Cutting or chopping food	5	4	3	2	1	9	8
AL37	Finding something when it is surrounded by a lot of other things, e.g. on a crowded shelf or in a full drawer	5	4	3	2	1	9	8
AL38	Putting on make-up	5	4	3	2	1	9	8
AL39	Bathing or showering	5	4	3	2	1	9	8
AL40	Eating meals	5	4	3	2	1	9	8
AL41	Recognizing food on your plate	5	4	3	2	1	9	8
AL42	Threading a needle	5	4	3	2	1	9	8
AL43	Using hand tools, e.g. a screwdriver	5	4	3	2	1	9	8
AL44	Noticing when something is dirty or dusty, e.g. a cup, table crumbs	5	4	3	2	1	9	8

	Because of your refractive error or its correction, **How much difficulty do you have…?**	**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my vision**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
AL45	Doing household chores e.g. dusting, cleaning, tidying	5	4	3	2	1	9	8
AL46	Looking after your appearance, e.g. your face, hair, shaving	5	4	3	2	1	9	8
AL47	In dressing yourself	5	4	3	2	1	9	8
AL48	Cutting your fingernails or toenails safely	5	4	3	2	1	9	8
AL49	Crocheting or knitting	5	4	3	2	1	9	8
AL50	Pouring a drink	5	4	3	2	1	9	8
AL51	Sewing	5	4	3	2	1	9	8
AL52	Telling the values of coins or notes	5	4	3	2	1	9	8
AL53	Taking part in recreational activities, e.g. horse riding, walking, skiing, scuba diving	5	4	3	2	1	9	8
AL54	Playing indoor sports, e.g. snooker, fitness classes, gym sessions	5	4	3	2	1	9	8
AL55	Swimming	5	4	3	2	1	9	8
AL56	Judging the ball when playing ball sports, e.g. tennis, netball, cricket	5	4	3	2	1	9	8
AL57	Playing outdoor sports, e.g. cricket, football, netball	5	4	3	2	1	9	8
AL58	Watching live sports events, e.g. cricket, tennis, football	5	4	3	2	1	9	8
AL59	Watching a movie in theatre	5	4	3	2	1	9	8
AL60	Watching television	5	4	3	2	1	9	8
AL61	Reading text on television	5	4	3	2	1	9	8
AL62	Taking care of the garden, e.g. weeding, pruning, mowing the lawn	5	4	3	2	1	9	8
AL63	Playing board games, e.g. bingo, cards, scrabble	5	4	3	2	1	9	8
AL64	Adjusting to dark indoor lighting after being in bright light	5	4	3	2	1	9	8
AL65	Doing grocery shopping	5	4	3	2	1	9	8
AL66	Cycling	5	4	3	2	1	9	8

Because of your refractive error or its correction, **How much difficulty do you have…?**		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my vision**	**Don't drive for other reasons**	**Refuse to answer**
AL67	Driving towards the sun	5	4	3	2	1	9	8
AL68	Driving in familiar areas	5	4	3	2	1	9	8
AL69	Driving in unfamiliar areas	5	4	3	2	1	9	8
AL70	Riding motorcycle/moped	5	4	3	2	1	9	8
AL71	Driving at night	5	4	3	2	1	9	8
AL72	Noticing when the car in front of you is speeding up or slowing down	5	4	3	2	1	9	8
AL73	Driving towards oncoming headlights	5	4	3	2	1	9	8
AL74	Seeing road markings clearly when driving	5	4	3	2	1	9	8
AL75	Driving in bad weather	5	4	3	2	1	9	8
AL76	Driving at dusk or dawn	5	4	3	2	1	9	8
AL77	Parking	5	4	3	2	1	9	8
AL78	Driving during the day	5	4	3	2	1	9	8
AL79	Seeing other objects on the road while driving, e.g. other cars, bikes, pedestrians	5	4	3	2	1	9	8
AL80	Seeing at your car's dashboard clearly, e.g. Satnav screen, speedometer	5	4	3	2	1	9	8

MOBILITY								
Because of your refractive error or its correction, **How much difficulty do you have…?**		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my vision**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
MB1	Walking in the rain (with glasses on)	5	4	3	2	1	9	8
MB2	Walking around with reading glasses	5	4	3	2	1	9	8
MB3	Walking around outdoors	5	4	3	2	1	9	8
MB4	Walking around familiar areas	5	4	3	2	1	9	8
MB5	Walking around your home	5	4	3	2	1	9	8
MB6	Walking around someone else's house	5	4	3	2	1	9	8
MB7	Walking around unfamiliar areas	5	4	3	2	1	9	8
MB8	Walking in a cluttered environment	5	4	3	2	1	9	8
MB9	Walking in crowded situations	5	4	3	2	1	9	8
MB10	Walking in dim light	5	4	3	2	1	9	8
MB11	Walking on uneven ground and negotiating bumps or cracks in your path	5	4	3	2	1	9	8
MB12	Noticing things to the left or right of you while you are walking	5	4	3	2	1	9	8
MB13	Crossing a street	5	4	3	2	1	9	8
MB14	Going up steps or stairs	5	4	3	2	1	9	8
MB15	Using unmarked steps or curbs, e.g. concrete curbs or steps that do not have a coloured strip	5	4	3	2	1	9	8
MB16	Going down steps or stairs	5	4	3	2	1	9	8
MB17	Finding the steps when getting on or off a bus or tram	5	4	3	2	1	9	8
MB18	Using public transport	5	4	3	2	1	9	8
MB19	Travelling somewhere independently	5	4	3	2	1	9	8

EMOTIONAL							
Because of your refractive error or its correction, **How often do you…?**		**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**	**Refuse to answer**
EM1	Feel embarrassed wearing glasses	5	4	3	2	1	8
EM2	Feel like you are different than everyone else	5	4	3	2	1	8
EM3	Feel rejected or dejected	5	4	3	2	1	8
EM4	Feel lonely or isolated	5	4	3	2	1	8
EM5	Feel helpless	5	4	3	2	1	8
EM6	Feel reluctant to socialize	5	4	3	2	1	8
EM7	Feel self-conscious	5	4	3	2	1	8
EM8	Feel self-dislike	5	4	3	2	1	8
EM9	Feel sorry for yourself	5	4	3	2	1	8
EM10	Feel like you have lost your self-esteem	5	4	3	2	1	8
EM11	Feel inferior	5	4	3	2	1	8
EM12	Feel shocked by what your eye specialists have told you about your eyes	5	4	3	2	1	8
EM13	Feel amazed	5	4	3	2	1	8
EM14	Feel surprised	5	4	3	2	1	8
EM15	Feel enthusiastic	5	4	3	2	1	8
EM16	Feel afraid	5	4	3	2	1	8
EM17	Feel nervous	5	4	3	2	1	8
EM18	Feel anxious	5	4	3	2	1	8
EM19	Feel apprehensive	5	4	3	2	1	8
EM20	Feel insecure	5	4	3	2	1	8
EM21	Feel you look your best	5	4	3	2	1	8
EM22	Feel complimented and flattered	5	4	3	2	1	8
EM23	Feel older than you really are	5	4	3	2	1	8
EM24	Feel efficient	5	4	3	2	1	8
EM25	Feel incompetent	5	4	3	2	1	8
EM26	Feel sad or low	5	4	3	2	1	8
EM27	Feel upset	5	4	3	2	1	8
EM28	Feel unhappy	5	4	3	2	1	8
	Because of your refractive error or	**None**	**A little**	**Some of**	**Most**	**All of**	**Refuse**

	its correction, **How often do you…?**	**of the time**	**of the time**	**the time**	**of the time**	**the time**	**to answer**
EM29	Feel depressed	5	4	3	2	1	8
EM30	Feel disappointed	5	4	3	2	1	8
EM31	Feel bad about yourself	5	4	3	2	1	8
EM32	Feel like you have nothing to offer	5	4	3	2	1	8
EM33	Feel you have reduced energy	5	4	3	2	1	8
EM34	Feel you have low spirits	5	4	3	2	1	8
EM35	Feel stressed	5	4	3	2	1	8
EM36	Feel worried	5	4	3	2	1	8
EM37	Feel like crying	5	4	3	2	1	8
EM38	Feel regretful or guilty about your eye care in the past	5	4	3	2	1	8
EM39	Feel like you've lost your confidence doing usual activities	5	4	3	2	1	8
EM40	Feel irritated	5	4	3	2	1	8
EM41	Feel jealous	5	4	3	2	1	8
EM42	Feel frustrated	5	4	3	2	1	8
EM43	Feel annoyed	5	4	3	2	1	8
EM44	Feel angry	5	4	3	2	1	8
EM45	Feel a sense of loss	5	4	3	2	1	8
EM46	Experience mood swings	5	4	3	2	1	8
EM47	Feel confused	5	4	3	2	1	8
EM48	Feel emotionally drained	5	4	3	2	1	8
EM49	Feel vulnerable	5	4	3	2	1	8
EM50	Feel pessimistic	5	4	3	2	1	8
EM51	Feel reluctant to try new things	5	4	3	2	1	8
EM52	Feel dissatisfied	5	4	3	2	1	8
EM53	Feel like you are being held back in life	5	4	3	2	1	8

HEALTH CONCERNS								
Because of your refractive error or its correction, **How concerned are you about…?**		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**This issue is not relevant to me**	**Refuse to answer**
HC1	The cosmetic appearance of your eyes with glasses	5	4	3	2	1	9	8
HC2	What other people say about your looks	5	4	3	2	1	9	8
HC3	Getting teased	5	4	3	2	1	9	8
HC4	The way people react to you	5	4	3	2	1		8
HC5	People not understanding your eye condition	5	4	3	2	1	9	8
HC6	Being treated differently	5	4	3	2	1	9	8
HC7	Frequent change in the strength of your glasses (prescription)	5	4	3	2	1	9	8
HC8	Your eyesight getting worse	5	4	3	2	1		8
HC9	Going blind	5	4	3	2	1		8
HC10	Losing independence in the future	5	4	3	2	1		8
HC11	Losing driver's license	5	4	3	2	1	9	8
HC12	Not knowing what's going to happen in the future	5	4	3	2	1		8
HC13	Your understanding of your laser refractive surgery	5	4	3	2	1	9	8
HC14	Not getting perfect vision with your glasses or contact lenses	5	4	3	2	1	9	8
HC15	Vision after undergoing laser refractive surgery	5	4	3	2	1	9	8
HC16	Your vision not being as good as it could be	5	4	3	2	1	9	8
HC17	Possibilities of having to wear glasses even after laser surgery	5	4	3	2	1	9	8
HC18	Side effects of contact lens wear, e.g. redness, soreness, discomfort, irritation	5	4	3	2	1	9	8
HC19	Side effects of laser refractive surgery, e.g. dryness, light sensitivity	5	4	3	2	1	9	8
HC20	Complications from contact lens wear e.g. infection	5	4	3	2	1	9	8
HC21	Complications from laser refractive surgery e.g. infection, scarring	5	4	3	2	1	9	8
HC22	Recovery being difficult (long or painful) after laser refractive surgery	5	4	3	2	1	9	8

	Because of your refractive error or its correction, **How concerned are you about…?**	**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**This issue is not relevant to me**	**Refuse to answer**
HC23	Having unwanted consequences of high refractive error, e.g. retinal tears, vitreous detachment	5	4	3	2	1	9	8
HC24	Having to choose between different types of refractive corrections (glasses, contact lenses and laser surgery)	5	4	3	2	1	9	8
HC25	The way your eye specialists and medical staff communicate with you about your refractive error and refractive correction outcomes	5	4	3	2	1	9	8
HC26	The way you are treated by your eye care practitioner	5	4	3	2	1	9	8
HC27	The quality of care you get from your eye specialist and medical staff	5	4	3	2	1	9	8
HC28	Not getting correct prescription for your glasses or contact lenses	5	4	3	2	1	9	8
HC29	Not getting enough information or explanation from medical staff	5	4	3	2	1	9	8
HC30	Not being able to wear contact lenses, e.g. because of severe dryness, corneal scar	5	4	3	2	1	9	8
HC31	Not being able to wear your glasses or contact lenses as long as you need to	5	4	3	2	1	9	8
HC32	Not being suitable for laser refractive surgery	5	4	3	2	1	9	8
HC33	Your personal safety	5	4	3	2	1	9	8
HC34	Falling	5	4	3	2	1	9	8
HC35	Tripping	5	4	3	2	1	9	8
HC36	Being at risk of eye injuries when playing contact sports, e.g. playing ball games	5	4	3	2	1	9	8
HC37	Passing refractive error onto your children	5	4	3	2	1	9	8
HC38	The impact your eye condition (refractive error) has on your family members	5	4	3	2	1	9	8
HC39	Putting other people in danger by driving	5	4	3	2	1	9	8
SC40	Not being aware of what other people around you are doing, e.g. while swimming	5	4	3	2	1	9	8
HC41	Your academic performance being affected	5	4	3	2	1	9	8

SOCIAL								
Because of your refractive error or its correction, **How much of a problem do you have…?**		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my vision**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
SC1	Attending organised social functions like weddings, parties, BBQs	5	4	3	2	1	9	8
SC2	Participating in social activities at night	5	4	3	2	1	9	8
SC3	Going out with family and friends	5	4	3	2	1	9	8
SC4	Meeting friends or family socially	5	4	3	2	1	9	8
SC5	Meeting people for the first time	5	4	3	2	1	9	8
SC6	Chatting with people	5	4	3	2	1	9	8
SC7	Making new friends	5	4	3	2	1	9	8
SC8	Making social relationships	5	4	3	2	1	9	8
SC9	Getting help and support from your family and friends	5	4	3	2	1	9	8
SC10	Engaging with your children or grandchildren	5	4	3	2	1	9	8
SC11	Maintaining your usual social activities or social life	5	4	3	2	1	9	8
SC12	Maintaining your roles and responsibilities in social or friendship groups	5	4	3	2	1	9	8
SC13	Maintaining your roles and responsibilities in the family	5	4	3	2	1	9	8
SC14	Maintaining your close personal relationships, e.g. marriage, partner, living companion, steady relationship, family members	5	4	3	2	1	9	8
SC15	Maintaining your role as parents	5	4	3	2	1	9	8
SC16	With friends getting annoyed at you when you can't do something or if you make a mistake	5	4	3	2	1	9	8

CONVENIENCE								
Because of your refractive error or its correction, **How much trouble is…?**		**None**	**A little bit**	**A moderate amount**	**Quite a lot**	**Extremely**	**This is not relevant to me**	**Refuse to answer**
CV1	Getting optical correction, e.g. visiting optometrist, examinations, travelling	5	4	3	2	1	9	8
CV2	Having to wait for new pair of glasses or contact lenses	5	4	3	2	1	9	8
CV3	Having to wait for laser surgery until the prescription gets stable	5	4	3	2	1	9	8
CV4	Adjusting to your new refractive correction, e.g. glasses, contact lenses	5	4	3	2	1	9	8
CV5	Looking through wrong section or below or above your glasses, e.g. multifocal glasses, reading glasses	5	4	3	2	1	9	8
CV6	Having to hold reading material too close or too far	5	4	3	2	1	9	8
CV7	Having to rely on your refractive correction for doing tasks, e.g. reading, driving, travelling	5	4	3	2	1	9	8
CV8	Having to rely on others for help	5	4	3	2	1	9	8
CV9	Having to carry glasses or contact lenses	5	4	3	2	1	9	8
CV10	Having to carry additional cleaning supplies for glasses and contact lenses when travelling.	5	4	3	2	1	9	8
CV11	Forgetting to carry your glasses with you	5	4	3	2	1	9	8
CV12	Losing or misplacing glasses or contact lenses	5	4	3	2	1	9	8
CV13	Having to remove glasses when doing some tasks, e.g. cleaning, taking shower	5	4	3	2	1	9	8
CV14	Putting glasses on and off	5	4	3	2	1	9	8
CV15	Having to wear goggles over your glasses, e.g. watching 3D movies, snorkelling, skiing	5	4	3	2	1	9	8

	Because of your refractive error or its correction, **How much trouble is…?**	**None**	**A little bit**	**A moderate amount**	**Quite a lot**	**Extremely**	**This is not relevant to me**	**Refuse to answer**
CV16	Having to swap glasses, e.g. between reading glasses and distance glasses, prescription glasses and sunglasses	5	4	3	2	1	9	8
CV17	Getting contact lenses in and out of your eyes	5	4	3	2	1	9	8
CV18	Falling asleep with your glasses or contact lenses	5	4	3	2	1	9	8
CV19	Having to administer eye drops (after laser refractive surgery or contact lens wear related dryness)	5	4	3	2	1	9	8
CV20	Having to look after your glasses or contact lenses	5	4	3	2	1	9	8
CV21	Breaking your glasses	5	4	3	2	1	9	8
CV22	Glasses getting scratched	5	4	3	2	1	9	8
CV23	Your glasses or contact lenses getting dirty	5	4	3	2	1	9	8
CV24	Wearing glasses in rain	5	4	3	2	1	9	8
CV25	Wearing glasses in hot environment	5	4	3	2	1	9	8
CV26	Wearing glasses in cold environment	5	4	3	2	1	9	8
CV27	Wearing glasses in dusty or dirty environment	5	4	3	2	1	9	8
CV28	Wearing contact lenses in dusty or dirty environment	5	4	3	2	1	9	8
CV29	Wearing contact lenses in windy, dry or air-conditioned environment	5	4	3	2	1	9	8
CV30	Your glasses getting fogged-up or steamed-up, e.g. when cooking, playing sports, running	5	4	3	2	1	9	8
CV31	Glasses sliding down your nose or falling off your face, e.g. when playing sports, travelling and doing other physical activities	5	4	3	2	1	9	8
CV32	Having to think about glasses or contact lenses, e.g. when travelling, playing sports	5	4	3	2	1	9	8

	Because of your refractive error or its correction, **How much trouble is…?**	**None**	**A little bit**	**A moderate amount**	**Quite a lot**	**Extremely**	**This is not relevant to me**	**Refuse to answer**
CV33	Wearing your glasses or contact lenses when you are at the gym, doing physical activities, or playing sports	5	4	3	2	1	9	8
CV34	Not being able to see when doing activities for which you don't use glasses or contact lenses e.g. swimming	5	4	3	2	1	9	8
CV35	Not being able to use off-the-shelf (non-prescription) sunglasses	5	4	3	2	1	9	8
CV36	Difficulty finding frames that suit	5	4	3	2	1	9	8
CV37	Not being able to do what you want to do	5	4	3	2	1	9	8
CV38	Not being able to have good, comfortable vision all the time, e.g. just after waking up, while swimming	5	4	3	2	1	9	8
CV39	Having to take breaks when doing work, e.g. using a computer	5	4	3	2	1	9	8
CV40	Having to drive slower and more carefully	5	4	3	2	1	9	8
CV41	Having to be slower and more careful	5	4	3	2	1	9	8
CV42	Needing longer to do things	5	4	3	2	1	9	8
CV43	Not being able to do things as well as you used to	5	4	3	2	1	9	8
CV44	Having to go closer to see things clearly	5	4	3	2	1	9	8

ECONOMIC								
Because of your refractive error or its correction, **How concerned are you about...?**		**Not at all**	**A little bit**	**A moderate amount**	**Quite a bit**	**Extremely**	**This issue is not relevant to me**	**Refuse to answer**
EC1	The cost associated with seeing your eye care practitioner	5	4	3	2	1	9	8
EC2	The initial and ongoing cost to buy your glasses	5	4	3	2	1	9	8
EC3	The cost of unscheduled maintenance of your glasses, e.g. replacing glasses due to breakage, loss	5	4	3	2	1	9	8
EC4	The initial and ongoing cost to buy your contact lenses	5	4	3	2	1	9	8
EC5	The cost involved in care and maintenance of your contact lenses, e.g. cost to buy contact lens care kit	5	4	3	2	1	9	8
EC6	Cost of having refractive surgery	5	4	3	2	1	9	8
EC7	The cost of private health insurance to cover laser surgery, contact lenses or glasses	5	4	3	2	1	9	8
EC8	Your optical correction restricting your choice of career e.g. air force, army, navy	5	4	3	2	1	9	8
EC9	Your ability to find employment or get a new job	5	4	3	2	1	9	8
EC10	Your career being compromised	5	4	3	2	1	9	8
EC11	Your work tasks being affected	5	4	3	2	1	9	8
EC12	Not being able to work	5	4	3	2	1		8
EC13	Having to reduce your work hours	5	4	3	2	1	9	8
EC14	Having to take time off work, e.g. due to time taken for replacing glasses or for adjustment	5	4	3	2	1	9	8
EC15	Losing your job	5	4	3	2	1	9	8
EC16	Keeping up with things at work, e.g. feeling like you have to catch up all the time	5	4	3	2	1	9	8
EC17	Strain on your work relationships, e.g. because of time off or overall performance	5	4	3	2	1	9	8
EC18	The financial impact from loss of income, e.g. due to breakage, adjustment, loss	5	4	3	2	1	9	8

COPING							
Because of your refractive error or its correction, **do you cope by...?**		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**Refuse to answer**
CP1	Squinting or squeezing your eyes to see clearly	5	4	3	2	1	8
CP2	Accepting your eye condition	5	4	3	2	1	8
CP3	Learning to live with your refractive error and/or its corrections	5	4	3	2	1	8
CP4	Learning to do things in a different way than you used to do before, e.g. increasing font size, using pen with a light, holding onto railings when going downstairs	5	4	3	2	1	8
CP5	Spreading out your workload over the day	5	4	3	2	1	8
CP6	Thinking there are people much worse than you	5	4	3	2	1	8
CP7	Getting professional support	5	4	3	2	1	8
CP8	Having peer support	5	4	3	2	1	8
CP9	Trying to be positive	5	4	3	2	1	8
CP10	Trying to balance your life with positive and negative thoughts	5	4	3	2	1	8
CP11	Trying not to think about it	5	4	3	2	1	8
CP12	Avoiding some tasks, e.g. participating in group activities, swimming	5	4	3	2	1	8
CP13	Not wearing glasses or contact lenses to avoid problems caused by them, e.g. being teased	5	4	3	2	1	8

Thank you for your time and support!

Appendix H. Item-pool Nepal

- Item-pool (Nepal) with the background questionnaire, with English translations

रिफ्र्याक्टिभ एरर् प्रश्न संगालो

परिचय: ***Introduction:***

तल दिइएका सबै प्रश्नहरु रिफ्र्याक्टिभ एरर् तथा यसको उपचार (चश्मा, कन्ट्याक्ट लेन्स वा लेजर अप्रेशन)ले गर्दा तपाईको जीवनको गुणस्तरमा पार्ने प्रभावको बारेमा सोधिएका छन् । रिफ्र्याक्टिभ एरर् यस्तो अवस्था हो जसमा प्रवेश गरेको प्रकाश रेटिना/पर्दामा केन्द्रित हुँदैन । चश्मा, कन्ट्याक्ट लेन्स वा लेजर अप्रेशनले यसको उपचार गरिन्छ । *All the following questions are about the impact of refractive error and its correction on your quality of life. Refractive error is a condition in which light entering the eye is not focused at the retina. It can be corrected by glasses, contact lenses or with laser refractive surgery.*

निर्देशन ***Instructions:***

म तपाईलाई प्रत्यक प्रश्न पढेर सुनाउने छु । हरेक प्रश्नपछि सम्भावित उत्तरहरु पनि पढ्नेछु । तीमध्ये आफुलाई सबैभन्दा उचित लाग्ने उत्तर दिनुहोला । उत्तर दिनको लागि तपाईले प्रशस्त समय उपयोग गर्न सक्नु हुनेछ । *I will read each question out to you. After each question, I will read you possible answers. Please choose the answer that best applies to you.* Please take as much time as you need to answer each question.

कृपया सकेसम्म सबै प्रश्नहरुको उत्तर दिनुहोला । यदि कुनै प्रश्न तपाईलाई नमिल्ने खालको छ भने "यो कार्य मेरो लागि सान्दर्भिक छैन/गर्दिन" विकल्प छान्नुहोला । तपाईका सबै उत्तरहरु तथा अन्य व्यक्तिगत जानकारीहरु अत्यन्त गोप्य राखिने छन् । *Please answer every question unless you need to skip questions because they don't apply to you (if they don't apply to you, please select "This task is not relevant to me / don't do the task"). All your answers and the information you have provided will be regarded as strictly confidential.*

कृपया प्रश्नहरुको जवाफ दिँदा आफ्नो रिफ्र्याक्टिभ एरर् र/अथवा आफुले प्रयोग गर्नुभएको उपचार (चश्मा, कन्ट्याक्ट लेन्स वा लेजर अप्रेशन) लाई ध्यानमा राखी दिनुहोला । उदाहरणको लागि यदि तपाईले नजिकको वा टाढाको लागि चश्मा वा कन्ट्याक्ट लेन्स लगाउनुहुन्छ भने सो प्रयोग गर्दा देखिने दृष्टि अनुसार उत्तर दिनुहोला। ***Please consider your refractive error and/or its correction when you answer these questions. For example, if you usually wear reading glasses or distance glasses or contact lenses please answer according to how you can see when wearing them.***

मिति *Date*: ————————	सहभागिताको ID *Participant ID:* ————————
शुरु गरेको समय *Time started:* ————————	सोधकर्ता *Interviewer:* ————————
समाप्त भएको समय *Time finished*:——————	माध्यम *Mode:* स्वयं *Self* / प्रत्यक्ष *Face to face* / फोन *Phone*

पृष्ठभूमि प्रश्नावली *Background Questionnaire*

नाम *Name*:---------- जन्म मिति *DOB*: ----------

लिङ्ग *Gender (गोलो लगाउनुहोस Please circle)* महिला *Female* / पुरुष *Male*

ठेगाना *Address*----------

फोन न *Contact Number:* ---------- ईमेल *Email:* ---------- -----

पेशा *Occupation*---------- शिक्षा *Educational qualifications* ----------

वैवाहिक अवस्था *Marital status:* ---------- धर्म *Religion:* ---------- ----

समान्यतया आफ्नो स्वास्थ्य कस्तो छ ? In general, how would you describe your overall health?

१ उत्कृष्ट 1. Excellent / २ धेरै राम्रो 2. Very good / ३ राम्रो 3. Good /
४ ठिकै 4. Fair / ५ कमजोर 5. Poor

अन्तिम पटक आँखा जचाएको मिति Date of last eye exam: ----------

आँखाको समस्या *Ocular diagnosis*: ----------

तपाईले चश्मा लगाउन सरु गरेको कति वर्ष भयो *When did you first wear glasses?*----------

रिफ्र्याक्टिभ एरर् कुन आँखामा छ *Eye/s involved ? (गोलो लगाउनुहोस Please circle)*:

दायाँ आँखा *Right eye* / वायाँ आँखा *Left eye* / दुबै आँखा *Both eyes*

आँखा सम्बन्धि अन्य समस्या *Do you have other eye disease/s?: (गोलो लगाउनुहोस Please circle)* :

कुनै समस्या छैन *None* / मोतिविन्दु *Cataract* / जलविन्दु *Glaucoma* / मधुमेहले गर्दा आँखामा पर्ने समस्या *Diabetic eye disease* / अन्य आँखा समस्या *Other* ----------

स्वास्थ्य सम्बन्धि अन्य समस्या *Other medical condition/s* : ----------

रिफ्र्याक्टिभ एरर्को उपचार: *Refractive correction:*

- के तपाई चश्मा लगाउनुहुन्छ *Do you wear glasses? (गोलो लगाउनुहोस Please circle)*
  - कहिले पनि लगाउँदिन *Never* / कहिले काहीं लगाउँछु *Occasionally* / धेरै जसो लगाउँछु *Quite often* / सधैँजसो लगाउँछु *Very often*

- के तपाई कन्ट्याक्ट लेन्स लगाउनुहुन्छ *Do you wear contact lenses? (गोलो लगाउनुहोस Please circle)*
    - कहिले पनि लगाउँदिन *Never* / कहिले काहीं लगाउँछु *Occasionally* / धेरै जसो लगाउँछु *Quite often* / सधैंजसो लगाउँछु *Very often*
- के तपाईले रिफ्र्याक्टिभ एरर्को लागि लेजर अप्रेशन गराउनुभएको छ *Have you had a laser refractive surgery? (गोलो लगाउनुहोस Please circle)*
    - छ *Yes* / छैन *No*
        - (यदि छ भने कहिले *If Yes, when?*----------
        - प्रकार *Type* ----------
        - कुन आँखा *Eye* : दायाँ आँखा *Right eye/* बायाँ आँखा *Left eye /* दुबै आँखा *Both eye*

दृष्टि *Habitual visual acuity:*

दायाँ आँखा *RE*: ----------

बायाँ आँखा *LE*: ----------

दुबै आँखा *BE* ----------

चश्माको पावर *Prescription* :

दायाँ आँखा *RE*:----------

बायाँ आँखा *LE*:----------

नजिकको थप पावर *Near add*:----------

कैफियत Remarks ----------

दृश्य लक्षणहरु (Visual Symptoms)															
		तपाईले ------- कत्तिको अनुभव गर्नुहुन्छ? *How often do you experience...?*					तपाईलाई ------कति मात्रामा छ? *How severe is/are the...?*					तपाईलाई --- ले कत्तिको समस्या/ कष्ठ दिन्छ? *How much of a problem is/are the...?*			
		कहिल्यै पनि गर्दिन *Never*	कहिले काहिँ *Occasionally*	धेरै जसो *Quite often*	सधैँ जसो *Very often*		कत्ति पनि छैन *Not at all*	थोरै *Mild*	मध्यम *Moderate*	धेरै *Severe*		कत्ति पनि दिदैन *None*	थोरै *A little*	धेरै *Quite a bit*	एकदम धेरै *A lot*
VS1	धमिलो दृष्टि Blurred vision	४	३	२	१		४	३	२	१		४	३	२	१
VS2	बादल लागेको जस्तो दृष्टि Cloudy vision	४	३	२	१		४	३	२	१		४	३	२	१
VS3	तिरिमिरी दृष्टि Dazzled vision	४	३	२	१		४	३	२	१		४	३	२	१
VS4	आँखामा जालो लागेको जस्तो हुने समस्या Sensation like having a layer/net over the eyes	४	३	२	१		४	३	२	१		४	३	२	१
VS5	कुनै एक आँखामा मात्र कम दृष्टि Poor vision in only one eye	४	३	२	१		४	३	२	१		४	३	२	१
VS6	पानी पर्दा धमिलो दृष्टि Blurred vision in rain	४	३	२	१		४	३	२	१		४	३	२	१
VS7	मधुरो प्रकाशमा धमिलो दृष्टि Poor vision in dim light	४	३	२	१		४	३	२	१		४	३	२	१
VS8	टाढाको लागी धमिलो दृष्टि Blurred vision at distance	४	३	२	१		४	३	२	१		४	३	२	१
VS9	नजिक हेर्दा धमिलो दृष्टि Blurred vision at near	४	३	२	१		४	३	२	१		४	३	२	१
VS10	आफ्नो छेउछाउको (परिधिय वा साइड)दृष्टि कम हुँदै गएको Loss of peripheral vision	४	३	२	१		४	३	२	१		४	३	२	१
VS11	बाङ्गोटिङ्गो दृष्टि (सीधा रेखाहरु छड्के / बाङ्गो देखिने) Distorted vision (lines you know are straight appear curved or distorted)	४	३	२	१		४	३	२	१		४	३	२	१
VS12	एउटै चीज दुइटा देखिने समस्या Double vision	४	३	२	१		४	३	२	१		४	३	२	१

VS13	वस्तुको वरिपरि वा साइडमा डबल भाग खप्टिएको देखिने Seeing objects with ghosts or shadows around them	४	३	२	१		४	३	२	१		४	३	२	१
VS14	रङ्गहरु चिन्न समस्या Difficulty distinguishing colours	४	३	२	१		४	३	२	१		४	३	२	१
VS15	कुनै एक वस्तुलाई सफासँग हेरिरहन(फोकस गर्न) Difficulty focussing your eyes	४	३	२	१		४	३	२	१		४	३	२	१
VS16	रौं वा किरा उडेको जस्तो देखिने समस्या (फ्लोटर्स) Floaters in your vision	४	३	२	१		४	३	२	१		४	३	२	१
VS17	बत्तीको झिल्का वा तोरी फुलेको जस्तो देखिने समस्या Flashes of light from within your eyes	४	३	२	१		४	३	२	१		४	३	२	१
VS18	उज्यालो बत्तीमा हेर्दा टल्किने समस्या Glare from lights	४	३	२	१		४	३	२	१		४	३	२	१
VS19	उज्यालो प्रकाशसँग संवेदनशीलता Sensitivity to light	४	३	२	१		४	३	२	१		४	३	२	१
VS20	बत्तीको वरिपरि इन्द्रेणी देखिने समस्या Haloes around lights	४	३	२	१		४	३	२	१		४	३	२	१
VS21	बत्तीको वरिपरि ताराजस्तो धर्साहरु देखिने समस्या Starbursts (stars around lights)	४	३	२	१		४	३	२	१		४	३	२	१
VS22	उज्यालोबाट अँध्यारोमा वा अँध्यारोबाट उज्यालोमा जाँदा हुने समस्या Difficulty with adapting to changes in light	४	३	२	१		४	३	२	१		४	३	२	१
VS23	सम्म बाटो खाल्टो जस्तो देखिने (गहिराई अनुमान गर्न समस्या) Plain/even roads look like uneven (difficulty depth perception)	४	३	२	१		४	३	२	१		४	३	२	१

आँखालाई असहज हुने लक्षणहरु /आँखामा हुने असहजता/ अफ्ठ्यारा सम्बन्धी लक्षणहरु (Ocular Comfort Symptoms)														
		तपाईले ------- कत्तिको अनुभव गर्नुहुन्छ? *How often do you experience...?*					तपाईलाई ------कति मात्रामा छ? *How severe is/are the...?*				तपाईलाई --- ले कत्तिको समस्या/ कष्ठ दिन्छ? *How much of a problem is/are the...?*			
		कहिल्यै पनि गर्दिन *Never*	कहिले काहिँ *Occasionally*	धेरै जसो *Quite often*	सधैँ जसो *Very often*		कत्ति पनि छैन *Not at all*	थोरै *Mild*	मध्यम *Moderate*	धेरै *Severe*		कत्ति पनि दिदैन *None*	थोरै *A little*	धेरै *Quite a bit*	एकदम धेरै *A lot*
OS1	आँखामा अफ्ठ्यारोपना/ असहजता Discomfort in your eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS2	चश्माको फ्रेमले हुने असहजता, जस्तैः नाकको माथिल्लो भाग वा कान पछाडि रातो हुने वा दुख्ने समस्या Discomfort caused by your glasses, e.g. soreness on the nose or soreness behind the ears	४	३	२	१		४	३	२	१		४	३	२	१
OS3	सुख्खा आँखा Dry eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS4	आँखा पिरो हुने वा पोल्ने Burning in your eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS5	आँखाबाट आँशु बग्ने समस्या Watery eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS6	आँखामा बालुवा परेजस्तै बिझाउने Grittiness in your eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS7	आँखा रातो हुने Red eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS8	आँखामा सियोले घोचे जस्तै तीखो दुखाइ Stinging in your eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS9	आँखा चिलाउने Itchy eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS10	आँखामा चिप्रा वा कचेरा लाग्ने Discharge in your eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS11	आँखाको ढकनि सुन्निने समस्या Swelling of your eyelids	४	३	२	१		४	३	२	१		४	३	२	१

OS12	थकित आँखा Tired eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS13	आँखा भारी हुने Heavy eyes	४	३	२	१		४	३	२	१		४	३	२	१
OS14	आँखामा दुखाइ Pain in your eyes	४	३	२	१		४	३	२	१		४	३	२	१

आँखाको कारण शरीरको अन्य भागमा हुने लक्षणहरु (General Symptoms)

		तपाईले ——————— कत्तिको अनुभव गर्नुहुन्छ? *How often do you experience...?*					तपाईलाई ——————कति मात्रामा छ? *How severe is/are the...?*					तपाईलाई ——— ले कत्तिको समस्या/ कष्ठ दिन्छ? *How much of a problem is/are the...?*			
		कहिल्यै पनि गर्दिन *Never*	कहिले काहिँ *Occasionally*	धेरै जसो *Quite often*	सधैँ जसो *Very often*		कत्ति पनि छैन *Not at all*	थोरै *Mild*	मध्यम *Moderate*	धेरै *Severe*		कत्ति पनि दिँदैन *None*	थोरै *A little*	धेरै *Quite a bit*	एकदम धेरै *A lot*
GS1	टाउको दुख्ने समस्या Headaches	४	३	२	१		४	३	२	१		४	३	२	१
GS2	रिंगटा लाग्ने समस्या Giddiness or dizziness	४	३	२	१		४	३	२	१		४	३	२	१
GS3	वाकवाकी लाग्ने वा उल्टी आउने समस्या Nausea or vomiting	४	३	२	१		४	३	२	१		४	३	२	१
GS4	आफ्नो शरीर सन्तुलित नभए जस्तो Feeling like loss of balance	४	३	२	१		४	३	२	१		४	३	२	१
GS5	आफू बिरामी वा कमजोर भए जस्तो Feeling ill	४	३	२	१		४	३	२	१		४	३	२	१

दैनिक कार्यहरु गर्न कठिनाइ(Activity Limitation)								
आफ्नो आँखाको समस्या (रिफ्र्याक्टिभ एरर् तथा यसको उपचार)को कारण Because of your refractive error or its correction, **तपाईलाई ———कत्तिको गाह्रो /कठिन छ ?** ***How much difficulty do you have…?***		कत्ति पनि छैन *None*	थोरै मात्र छ *A little*	ठीकै – ठीकै *Quite a bit*	धेरै छ *A lot*	आँखाको अवस्थाको कारण (यो कार्य) गर्न सक्दिन *Unable to do because of my eye condition*	यो कार्य मेरो लागि सान्दर्भिक छैन / गर्दिन *This task is not relevant to me / don't do the task*	जवाफ दिन इच्छुक छैन *Refuse to answer*
AL1	टाढाको अक्षर चिन्न (पसलको नाम, होर्डिङ बोर्ड Reading at far e.g. store names, hoarding boards	५	४	३	२	१	९	८
AL2	भित्ते घडीमा समय हेर्न Telling the time from a clock	५	४	३	२	१	९	८
AL3	टाढा बोर्डमा लेखेको कुरा पढ्न (कक्षाकोठा, conference hall) Reading things written on a whiteboard (class room, conference hall)	५	४	३	२	१	९	८
AL4	प्रोजेक्टरबाट प्रदर्शित पावर पोइन्ट स्लाइडहरु पढ्न (कक्षाकोठा, conference hall) Reading power-point projected slides (class room, conference hall)	५	४	३	२	१	९	८
AL5	पत्र-पत्रिका पढ्न Reading the newspaper	५	४	३	२	१	९	८
AL6	मधुरो प्रकाशमा पढ्न Reading in dim light	५	४	३	२	१	९	८
AL7	मधुरो प्रकाशमा काम गर्न Working in dim light	५	४	३	२	१	९	८
AL8	चम्किलो तथा रङ्गीन प्रिन्ट पढ्न जस्तैः म्यागेजिन, कुकबुक Reading glossy and colourful prints, e.g. cook books, magazines	५	४	३	२	१	९	८
AL9	चहकिलो घाममा हेर्न Seeing in bright sunlight	५	४	३	२	१	९	८
AL10	किताब पढ्न Reading a book	५	४	३	२	१	९	८
AL11	साना अक्षरहरु पढ्न : औषधिको लेबल, फोन डायरी Reading small print, e.g. the phone book, medicine bottle	५	४	३	२	१	९	८
AL12	मोबाइल फोन प्रयोग गर्न Using a mobile phone	५	४	३	२	१	९	८

AL13	मोबाइल रिचार्ज गर्न Reloading money on a mobile phone using a recharge card	५	४	३	२	१	९	८
AL14	ठूलो अक्षरहरु पढ्न Reading large print	५	४	३	२	१	९	८
AL15	कम्प्यूटर प्रयोग गर्न Using the computer	५	४	३	२	१	९	८
AL16	चिठी पढ्न Reading your posts	५	४	३	२	१	९	८
AL17	भित्ते पात्रो हेर्न Reading a wall-mounted calender	५	४	३	२	१	९	८
AL18	सही / दस्तखत गर्न Signing / putting on a signature	५	४	३	२	१	९	८
AL19	लेख्न Writing	५	४	३	२	१	९	८
AL20	चेकमा लेख्न Writing on a cheque	५	४	३	२	१	९	८
AL21	बस वा बाइकमा लेखिएको नम्बर वा अक्षर पढ्न Reading numbers or letters on the front of a bus or a motorcycle	५	४	३	२	१	९	८
AL22	हाते घडीमा समय हेर्न Reading a watch	५	४	३	२	१	९	८
AL23	लामो समयसम्म पढिरहन Prolonged reading	५	४	३	२	१	९	८
AL24	टाढाको व्यक्तिलाई पहिचान गर्न Recognising someone across the street	५	४	३	२	१	९	८
AL25	खाना पकाउन Cooking	५	४	३	२	१	९	८
AL26	खानेकुरा (तरकारी, फलफुल) काटकुट गर्न Cutting or chopping food (vegetable, fruit)	५	४	३	२	१	९	८
AL27	धेरै वस्तुहरुबीच (दराज वा तखतामा) आफूलाई चाहिएको वस्तु भेट्टाउन Finding something when it is surrounded by a lot of other things, e.g. on a crowded shelf or in a full drawer	५	४	३	२	१	९	८
AL28	मेक-अप (लाली,गाजल इत्यादि) लगाउन Putting on make-up	५	४	३	२	१	९	८
AL29	नुहाउन Bathing or showering	५	४	३	२	१	९	८
AL30	खाना खान Eating meals	५	४	३	२	१	९	८
AL31	ब्रस चिन्न Identifying / recognizing your tooth-brush	५	४	३	२	१	९	८
AL32	खानामा रौं, घुर वा किरा देख्न Finding hair, insect or dirt on a meal	५	४	३	२	१	९	८
AL33	पोते उन्न Beading a necklace or a chain	५	४	३	२	१	९	८

AL34	सफासँग फोटो देख्न Recognizing faces and objects on a photograph	५	४	३	२	१	९	८
AL35	चामल केलाउन वा चामलमा वियाँ वा किरा देख्न Winnowing rice	५	४	३	२	१	९	८
AL36	तरकारीमा साना किरा देख्न Seeing small insect pests in vegetables	५	४	३	२	१	९	८
AL37	बत्ति कात्न Making cotton wicks	५	४	३	२	१	९	८
AL38	मुख धुन Washing your face	५	४	३	२	१	९	८
AL39	टाढाको वस्तु पहिचान गर्न Recognizing objects at far	५	४	३	२	१	९	८
AL40	टेलिस्कोप, माइक्रोस्कोप मा काम गर्न Using a telescope or a microscope	५	४	३	२	१	९	८
AL41	सियोमा धागो छिराउन Threading a needle	५	४	३	२	१	९	८
AL42	हाते औजारहरु जस्तैः पेचकस, हथौडा चलाउन Using hand tools, e.g. a screwdriver, hammer	५	४	३	२	१	९	८
AL43	घरको काम गर्न जस्तै घर सफा गर्न, पुछपाछ गर्न, कुचो लगाउन Doing household chores e.g. dusting, cleaning, sweeping	५	४	३	२	१	९	८
AL44	आफ्नो रुपरङ्गको ख्याल / हेरचाह गर्न जस्तैः अनुहार सफा राख्न, कपाल कोर्न, दाह्री काट्न Looking after your appearance, e.g. your face, hair, shaving	५	४	३	२	१	९	८
AL45	हातको वा खुट्टाको नङ्ग शुरक्षितसँग काट्न Cutting your fingernails or toenails safely	५	४	३	२	१	९	८
AL46	सिलाई बुनाई गर्न/ बुट्टा भर्न Crocheting or knitting	५	४	३	२	१	९	८
AL47	लुगा सिउन Sewing	५	४	३	२	१	९	८
AL48	किसान काम गर्न जस्तै खेतको काम, धान काट्ने, गोडमेल गर्ने Doing agricultural works like working in the fields, harvesting grains, weeding	५	४	३	२	१	९	८
AL49	निहुरिएर काम गर्न जस्तै जुत्ताको तुना बान्न, खसेको सामान उठाउन Bending down to do some tasks e.g. tying shoe laces, picking up things from floor	५	४	३	२	१	९	८
AL50	पशुहरुको स्याहार गर्न Looking after domestic animals or pets	५	४	३	२	१	९	८

AL51	किसान काम गर्दा किरा फट्याङ्ग्रा देख्न जस्तै घाँस काट्दा Seeing insects while doing agricultural works e.g. when cutting grass	५	४	३	२	१	९	८
AL52	भारी बोक्न (चश्मा लगाएर) Carrying loads with a 'namlo' (e.g. basket full of grass)	५	४	३	२	१	९	८
AL53	मनोरञ्जनात्मक कार्यहरुमा भाग लिन जस्तैः नाच्न Taking part in recreational activities, e.g. dancing	५	४	३	२	१	९	८
AL54	इन्डोर खेल खेल्न जस्तैः पुल-स्नुकर, व्यायाम / कसरत Playing indoor sports, e.g. snooker, fitness classes, gym sessions	५	४	३	२	१	९	८
AL55	कम्प्यूटरमा गेम खेल्न Playing computer games	५	४	३	२	१	९	८
AL56	दौडिन वा कसरत गर्न Jogging or exercising	५	४	३	२	१	९	८
AL57	पौडी खेल्न Swimming	५	४	३	२	१	९	८
AL58	बल गेम खेल्दा बलको गति तथा दुरी अनुमान गर्न जस्तै : किकेट, टेवलटेनिस, भलिबल Judging the ball when playing ball sports, e.g. tennis, volleyball, cricket	५	४	३	२	१	९	८
AL59	बाहिर मैदानमा खेल खेल्न जस्तैः किकेट, फुटबल, भलीबल Playing outdoor sports, e.g. cricket, football, volleyball	५	४	३	२	१	९	८
AL60	हलमा चलचित्र हेर्न Watching a movie in theatre	५	४	३	२	१	९	८
AL61	टिभि हेर्न Watching television	५	४	३	२	१	९	८
AL62	छुट्टीमा घुमफिर गर्न जान Going on a holiday	५	४	३	२	१	९	८
AL63	उज्यालो ठाउँबाट अँध्यारो ठाउमा गएपछि आँखालाई बानी पार्न Adjusting to dark indoor lighting after being in bright light	५	४	३	२	१	९	८
AL64	गतीमा भएको वस्तु हेर्न जस्तै चलिरहेको बाइक वा गाडी बाट हेर्न Seeing things in a relative motion e.g. seeing things from a moving vehicle	५	४	३	२	१	९	८
AL65	यात्रा गर्न Travelling	५	४	३	२	१	९	८
AL66	साइकल चलाउन Cycling	५	४	३	२	१	९	८

	आफ्नो आँखाको समस्या (रिफ्र्याक्टिभ एरर् तथा यसको उपचार)को कारण Because of your refractive error or its correction, **तपाईलाई ––– कत्तिको गाह्रो / कठिन छ ? *How much difficulty do you have…?***	कत्ति पनि छैन *None*	थोरै मात्र छ *A little*	ठीकै – ठीकै *Quite a bit*	धेरै छ *A lot*	आँखाको अवस्थाको कारण (यो कार्य) गर्न सक्दिन *Unable to do because of my eye condition*	अरु कारणले गर्दा गाडी चलाउँदिन *Don't drive for other reasons*	जवाफ दिन इच्छुक छैन *Refuse to answer*
AL67	सूर्य भएतिर बाइक वा गाडी चलाउन Driving or riding a motorcycle towards the sun	५	४	३	२	१	९	८
AL68	अपरिचित ठाँउहरुमा बाइक वा गाडी चलाउन Driving or riding a motorcycle in unfamiliar areas	५	४	३	२	१	९	८
AL69	मोटरसाइकल वा स्कुटर चलाउन Riding motorcycle/moped	५	४	३	२	१	९	८
AL70	राती बाइक वा गाडी चलाउन Driving or riding a motorcycle at night	५	४	३	२	१	९	८
AL71	पानी परेको बेला बाइक चलाउन Riding a motorcycle in rain	५	४	३	२	१	९	८
AL72	हेडलाइट बालेको सवारीसाधनतिर आफ्नो बाइक वा गाडी चलाउन Driving or riding a motorcycle towards oncoming headlights	५	४	३	२	१	९	८

हिंडडुल गर्दा हुने कठिनाइ (Mobility)								
आफ्नो आँखाको समस्या (रिफ्र्याक्टिभ एरर् तथा यसको उपचार)को कारण Because of your refractive error or its correction, **तपाईलाई ––– कत्तिको गाह्रो/कठिन छ ?** ***How much difficulty do you have…?***		कत्ति पनि छैन *None*	थोरै मात्र छ *A little*	ठीकै–ठीकै *Quite a bit*	धेरै छ *A lot*	आँखाको अवस्थाको कारण (यो कार्य) गर्न सक्दिन *Unable to do because of my eye condition*	यो कार्य मेरो लागि सान्दर्भिक छैन/गर्दिन *This task is not relevant to me / don't do the task*	जवाफ दिन इच्छुक छैन *Refuse to answer*
MB1	हिंडडुल गर्न Walking	५	४	३	२	१	९	८
MB2	पानी परेको बेला चश्मा लगाएर हिंड्न Walking in the rain (with glasses on)	५	४	३	२	१	९	८
MB3	मिरमिरे वा सन्ध्याकालिन समयमा हिडडुल गर्न Walking in dawn or dusk	५	४	३	२	१	९	८
MB4	नजिकको लागी पावर भएको (नजिक देख्नको लागि लगाउने) चश्मा लगाएर हिड्न Walking around with reading glasses	५	४	३	२	१	९	८
MB5	अपरिचित ठाउँमा हिंडडुल गर्न Walking around unfamiliar areas	५	४	३	२	१	९	८
MB6	भीडभाडमा हिंडडुल गर्न Walking in a crowded environment	५	४	३	२	१	९	८
MB7	मधुरो प्रकाश भएको ठाउँमा हिंडडुल गर्न Walking in dim light	५	४	३	२	१	९	८
MB8	खाल्डा-खुल्डी वा थुम्को भएको बाटोमा हिड्न Walking on uneven ground and negotiating bumps or cracks in your path	५	४	३	२	१	९	८
MB9	बाटो काट्न / सडक पार गर्न Crossing a street	५	४	३	२	१	९	८
MB10	सिंडी वा भऱ्याङ चढ्न Going up steps or stairs	५	४	३	२	१	९	८
MB11	सिंडी वा भऱ्याङ ओर्लिन Going down steps or stairs	५	४	३	२	१	९	८
MB12	सार्वजनिक यातायात प्रयोग गर्न Using public transport	५	४	३	२	१	९	८
MB13	साँघुरो बाटोमा हिँड्न Walking in narrow roads	५	४	३	२	१	९	८
MB14	उकालो ओरालो बाटोमा हिँड्न Going uphill or downhill	५	४	३	२	१	९	८

मानसिक वा मनोवैज्ञानिक स्वास्थ्य सम्बन्धी (Emotional)							
आफ्नो आँखाको समस्या (रिफ्र्याक्टिभ एरर् तथा यसको उपचार)को कारण Because of your refractive error or its correction, **तपाईंलाई ––– कत्तिको हुन्छ ? *How often do you...?***		कहिल्यै पनि हुँदैन *None of the time*	कुनै-कुनै बेलामा मात्र *A little of the time*	बेला-बेलामा *Some of the time*	धेरै जसो *Most of the time*	सधैं जसो *All the time*	जवाफ दिन इच्छुक छैन *Refuse to answer*
EM1	लज्जित महशुस Feel embarrassed wearing glasses	५	४	३	२	१	८
EM2	आफू अरुभन्दा भिन्न छु जस्तो महशुस Feel like you are different than everyone else	५	४	३	२	१	८
EM3	आफ्नो रुपरङ्गको बारेमा बढी सचेत महशुस Feel more conscious about your appearance	५	४	३	२	१	८
EM4	आत्मसम्मान गुमाएको जस्तो महशुस Feel like you have lost your self-esteem	५	४	३	२	१	८
EM5	डराएको महशुस Feel afraid	५	४	३	२	१	८
EM6	आशंकित महशुस Feel nervous	५	४	३	२	१	८
EM7	आनन्दित महशुस Feel relaxed	५	४	३	२	१	८
EM8	अपमानित महशुस Feel humiliated	५	४	३	२	१	८
EM9	उत्साहित महशुस Feel excited	५	४	३	२	१	८
EM10	अरुले आफ्नो रुपरङ्गको प्रशसा गरेको महशुस Feel complimented and flattered	५	४	३	२	१	८
EM11	वास्तविक उमेरभन्दा बूढो भएको जस्तो महशुस Feel older than you really are	५	४	३	२	१	८
EM12	दुःखी महशुस Feel sad or low	५	४	३	२	१	८
EM13	खुसी महशुस Feel happy	५	४	३	२	१	८
EM14	निराश (डिप्रेशन) महशुस Feel depressed	५	४	३	२	१	८
EM15	खिन्न महशुस Feel disappointed	५	४	३	२	१	८
EM16	आफ्नो मनोबल बढेको जस्तो महशुस Feel like you have gained your confidence	५	४	३	२	१	८
EM17	चिन्तित महशुस Feel worried	५	४	३	२	१	८
EM18	रोउँरोउँ जस्तो महशुस Feel like crying	५	४	३	२	१	८
EM19	विगतमा आफुले आँखाको हेरचाह राम्रो सँग गर्न नसकेकोमा पश्चाताप महशुस Feel regretful or guilty about your eye care in the past	५	४	३	२	१	८
EM20	नरमाइलो महशुस Feel bored	५	४	३	२	१	८
EM21	झर्को/ झिँजो महशुस Feel irritated	५	४	३	२	१	८
EM22	दिक्क / दिक्दार महशुस Feel frustrated	५	४	३	२	१	८

EM23	रिस उठ्ने Feel angry	५	४	३	२	१	८
EM24	कमजोर महशुस Feel weak	५	४	३	२	१	८
EM25	असन्तुष्ट महशुस Feel dissatisfied	५	४	३	२	१	८
EM26	जीवनमा अधि बढ्न नसकेको जस्तो महशुस Feel like you are being held back in life	५	४	३	२	१	८
EM27	अपाङ्ग महशुस Feel disabled	५	४	३	२	१	८
EM28	हेपिएको महशुस Feel insulted	५	४	३	२	१	८
EM29	मन दुख्ने Feel hurt	५	४	३	२	१	८
EM30	मुड खराब भएको महशुस Feel being in bad mood	५	४	३	२	१	८
EM31	पिर लाग्ने Feel stressed	५	४	३	२	१	८
EM32	स्वतन्त्र महशुस Feel like gaining freedom	५	४	३	२	१	८

आँखा-स्वास्थ्य सम्बन्धि चासो वा चिन्ता (Health Concerns)								
आफ्नो आँखाको समस्या (रिफ्र्याक्टिभ एरर् तथा यसको उपचार)को कारण Because of your refractive error or its correction, **तपाईलाई ––– बारेमा कत्तिको चासो वा चिन्ता छ? *How concerned are you about...?***		कत्ति पनि छैन *Not at all*	थोरै *A littl e bit*	ठिकै/ मध्यम *A mod erate amo unt*	धेरै *A lot*	एकदम धेरै *Extre mely*	यो कुरा मेरो लागिसान्दर्भिक छैन *This issue is not relevant to me*	जवाफ दिन इच्छुक छैन *Refus e to answ er*
HC1	चश्मा लगाउँदा आफ्नो अनुहारको रुपरङ्ग The cosmetic appearance of your eyes with glasses	५	४	३	२	१	९	८
HC2	चश्मा आफ्नो लुगा सँग नमिल्ने Glasses not going well with all types of dresses	५	४	३	२	१	९	८
HC3	फोटो खिच्दा राम्रो नदेखिने (चश्माले गर्दा) Not looking nice in the photographs (due to glasses)	५	४	३	२	१	९	८
HC4	अरुले जिस्क्याउँछन् कि भन्ने Getting teased	५	४	३	२	१	९	८
HC5	अरुले हेप्छन् कि भन्ने Getting insulted	५	४	३	२	१	९	८
HC6	अरुले के भन्लान भन्ने What other people say about you	५	४	३	२	१	९	८
HC7	अरुले आँफूसँग गर्ने व्यवहार Being treated differently	५	४	३	२	१	९	८
HC8	अरुले आफ्नो आँखाको समस्या नबुझ्ने People not understanding your eye condition	५	४	३	२	१	९	८
HC9	आफ्नो चश्माको पावर बारम्बर बदलिरहने Frequent change in the strength of your glasses (prescription)	५	४	३	२	१	९	८
HC10	आफ्नो दृष्टि कमजोर हुँदै/ खस्कँदै जान सक्ने Your eyesight getting worse	५	४	३	२	१		८
HC11	दृष्टिविहिन हुने सक्ने सम्भावना Going blind	५	४	३	२	१		८
HC12	भविष्यमा के हुन सक्छ भन्ने Not knowing what's going to happen in the future	५	४	३	२	१		८
HC13	चश्माको पावर बढ्न सक्ने सम्भावना Your prescription (strength of glasses) getting worse	५	४	३	२	१	९	८
HC14	चश्मा वा लेन्स लगाएर पनि सफा नदेख्ने Not getting perfect vision with your glasses or contact lenses	५	४	३	२	१	९	८
HC15	लेजर अप्रेशन पछिको आफ्नो दृष्टि Vision after undergoing laser refractive surgery	५	४	३	२	१	९	८
HC16	आफ्नो दृष्टि हुनुपर्ने जति राम्रो नभएको Your vision not being as good as it could be	५	४	३	२	१	९	८
HC17	लेजर अप्रेशन पछिपनि चश्मा लगाउन पर्न सक्ने संभावना Possibilities of having to	५	४	३	२	१	९	८

	wear glasses even after laser surgery							
HC18	चश्माले नाक वा कान ओरिपरि दाग बसाउन सक्ने (आँखाको आकार तथा बनोट परिवर्तन) Glasses changing anatomical structure of your eyes or surrounding tissues causing bumps, dents or marks on your nose	५	४	३	२	१	९	८
HC19	लेजर अपरेशन पछि आफ्नो आँखालाई बढि हेरचाहा गर्नु पर्ने Having to be more careful about looking after your eyes after laser refractive surgery	५	४	३	२	१	९	८
HC20	कन्ट्याक्ट लेन्स लगाउनुका साइड-इफेक्टहरु जस्तैः आँखा रातो हुने, दुख्ने, बिझाउने Side effects of contact lens wear, e.g. redness, soreness, discomfort, irritation	५	४	३	२	१	९	८
HC21	लेजर अपरेशनका साइड-इफेक्टहरु जस्तैः आँखा सुख्खा हुने, घाममा हेर्न गाह्रो हुने Side effects of laser refractive surgery, e.g. dryness, light sensitivity	५	४	३	२	१	९	८
HC22	कन्ट्याक्ट लेन्स लगाउँदा हुन सक्ने जटिलताहरु जस्तैः संक्रमण Complications from contact lens wear e.g. infection	५	४	३	२	१	९	८
HC23	लेजर अप्रेशन गर्दा हुन सक्ने जटिलताहरु जस्तैःसंक्रमण, नानीमा दाग Complications from laser refractive surgery e.g. infection, scarring	५	४	३	२	१	९	८
HC24	लेजर अप्रेशन पछि निको हुन लामो समय लाग्न सक्ने वा धेरै दुखाइ हुने संभावना Recovery being difficult (long or painful) after laser refractive surgery	५	४	३	२	१	९	८
HC25	चश्मा, कन्ट्याक्ट लेन्स वा लेजर अप्रेशन मध्ये आफूलाई उपयूक्त विधि छान्न Having to choose between different types of refractive corrections (glasses, contact lenses and laser surgery)	५	४	३	२	१	९	८
HC26	आँखा विशेषज्ञ र स्वास्थ्यकर्मीले आफ्नो रिफ्याक्टिभ एरर् तथा यसको उपचारको परिणाम बारेमा जानकारी दिने तरिका The way your eye specialists and medical staff communicate with you about your refractive error and refractive correction outcomes	५	४	३	२	१	९	८
HC27	आँखा विशेषज्ञ र स्वास्थ्यकर्मीले आफूलाई दिने सेवाको गुणस्तर The way you are treated by your eye care practitioner	५	४	३	२	१	९	८
HC28	डाक्टरले आफ्नो सबै समस्या नसुनिदिने Doctors not listening well to your problems	५	४	३	२	१	९	८
HC29	आफ्नो चश्मा वा कन्ट्याक्ट लेन्सको लागि	५	४	३	२	१	९	८

	सहि पावर निर्धारण नहुन सक्ने Not getting correct prescription for your glasses or contact lenses							
HC30	आँखा स्वास्थ्यकमीबाट प्रयाप्त जानकारी नपाउन सक्ने Not getting enough information or explanation from medical staff	५	४	३	२	१	९	८
HC31	कन्ट्याक्ट लेन्स लगाउन योग्य नहुने संभावना (जस्तै:गम्भिर सुख्खापन , नानीमा खत/ घाउको कारण) Not being able to wear contact lenses, e.g. because of severe dryness, corneal scar	५	४	३	२	१	९	८
HC32	लेजर अप्रेशनको लागि योग्य हुन नसक्ने संभावना Not being suitable for laser refractive surgery	५	४	३	२	१	९	८
HC33	आफ्नो व्यक्तिगत शुरक्षा Your personal safety	५	४	३	२	१		८
HC34	लढ्न सक्ने Falling	५	४	३	२	१		८
HC35	ठेस लाग्ने Tripping	५	४	३	२	१		८
HC36	हराइन्छ कि भन्ने Getting lost	५	४	३	२	१	९	८
HC37	आँखामा चोट लाग्न सक्ने Being at risk of eye injuries when playing contact sports, e.g. playing ball games	५	४	३	२	१	९	८
HC38	आफ्नो सन्ततिलाई पनि चश्मा लगाउन पर्न सक्ने Passing refractive error onto your children	५	४	३	२	१		८
HC39	आफ्नो पढाइमा असर परेको Your academic performance being affected	५	४	३	२	१	९	८

सामाजिक जीवनको गुणस्तर सम्बन्धी (Social)								
आफ्नो आँखाको समस्या (रिफ्र्याक्टिभ एरर् तथा यसको उपचार)को कारण Because of your refractive error or its correction, **तपाईंलाई ––– कति समस्या पर्छ ? *How much of a problem do you have…?***		कत्ति पनि पर्दैन *None*	थोरै / अलि कति *A little*	धेरै *Quite a bit*	एक दमै धेरै *A lot*	आँखाको अवस्थाको कारण (यो कार्य) गर्न सक्दिन *Unable to do because of my eye condition*	यो कार्य मेरो लागि सान्दर्भिक छैन / गर्दिन *This task is not relevant to me / don't do the task*	जवाफ दिन इच्छुक छैन *Refuse to answer*
SC1	विवाह, भोज, मेला जस्ता सामाजिक कार्यक्रममा जान Attending organised social functions like weddings, parties	५	४	३	२	१	९	८
SC2	राति सामाजिक गतिविधिमा भाग लिन Participating in social activities at night	५	४	३	२	१	९	८
SC3	परिवार वा साथीभाइसँग रमाइलो गर्न कतै जान Going out with family and friends	५	४	३	२	१	९	८
SC4	परिवार वा साथीभाइसँग भेटघाट गर्न Meeting friends or family socially	५	४	३	२	१	९	८
SC5	अरु मानिसहरुसँग कुराकानी गर्न Talking to others	५	४	३	२	१	९	८
SC6	नयाँ साथी बनाउन Making new friends	५	४	३	२	१	९	८
SC7	आफ्नो परिवार र साथीहरुबाट सहयोग र समर्थन पाउन Getting help and support from your family and friends	५	४	३	२	१	९	८
SC8	बच्चाबच्चिहरुसँग खेल्न वा घुलमिल हुन Engaging with your children or grandchildren	५	४	३	२	१	९	८
SC9	समाजमा आफ्नो भूमिका तथा जिम्मेवारी निभाउन Maintaining your usual social activities or social life	५	४	३	२	१	९	८
SC10	परिवारमा आफ्नो भूमिका तथा जिम्मेवारी निभाउन Maintaining your roles and responsibilities in the family	५	४	३	२	१	९	८
SC11	अभिभावकको भूमिका निभाउन Maintaining your role as parents	५	४	३	२	१	९	८
SC12	बच्चा पढाउन, सिकाउन Helping children with their studies	५	४	३	२	१	९	८
SC13	बच्चाबच्चिको हेरचाह गर्न Looking after children	५	४	३	२	१	९	८
SC14	बिहे गर्न वा जिवन साथी पाउन Getting a life-partner or getting married	५	४	३	२	१	९	८
SC15	नचिनेको मान्छे वा पहिलो पटक कसैसँग भेटघाट गर्न Meeting people for the first time	५	४	३	२	१	९	८
SC16	आफ्नो कारणले परिवारलाई वा साथीभाइलाई असर पर्दा Your family or friends being affected by you	५	४	३	२	१	९	८

जीवनमा पर्ने असुविधा सम्बन्धी (Convenience)								
आफ्नो आँखाको समस्या (रिफ्र्याक्टिभ एरर् तथा यसको उपचार)को कारण Because of your refractive error or its correction, **तपाईंलाई ––– कत्तिको असुविधा हुन्छ ? *How much trouble is...?***		कत्ति पनि हुँदैन *None*	थोरै / अलि कति *A little bit*	मध्यम / ठीकै *A moderate amount*	धेरै *Quite a lot*	एकदमै धेरै *Extremely*	यो कार्य मेरो लागि सान्दर्भिक छैन / गर्दिन *This is not relevant to me*	जवाफ दिन इच्छुक छैन *Refuse to answer*
CV1	नयाँ चश्मा वा कन्ट्याक्ट लेन्सको लागि प्रतिक्षा गर्नुपर्दा Having to wait for new pair of glasses or contact lenses	५	४	३	२	१	९	८
CV2	नयाँ चश्मा लगाउन बानी पार्दा Adjusting to your new glasses	५	४	३	२	१	९	८
CV3	कन्ट्याक्ट लेन्स लगाउन बानी पार्दा Adjusting to your new contact lenses	५	४	३	२	१	९	८
CV4	चश्माको तल माथि वा गलत खण्डबाट हेर्नुपर्दा Looking through wrong section or below or above your glasses, e.g. multifocal glasses, reading glasses	५	४	३	२	१	९	८
CV5	पढ्ने सामाग्री धेरै नजिक वा धेरै टाढा राख्नुपर्दा Having to hold reading material too close or too far	५	४	३	२	१		८
CV6	केही काम गर्न (जस्तै पढ्न, गाडी चलाउन, यात्रा गर्न) चश्मा वा कन्ट्याक्ट लेन्समा भर पर्नु पर्दा Having to rely on your refractive correction for doing tasks, e.g. reading, driving, travelling	५	४	३	२	१		८
CV7	अरुको भर पर्नु पर्दा Having to rely on others for help	५	४	३	२	१	९	८
CV8	चश्मा वा कन्ट्याक्ट लेन्स आफूसँग लिएर हिँड्नुपर्दा Having to carry glasses or contact lenses	५	४	३	२	१	९	८
CV9	चश्मा वा कन्ट्याक्ट लेन्स सफा गर्ने सामान लिएर हिँड्नुपर्दा Having to carry additional cleaning supplies for glasses and contact lenses when travelling.	५	४	३	२	१	९	८
CV10	चश्मा वा कन्ट्याक्ट लेन्स बिर्सँदा Forgetting to carry your glasses or contact lens with you	५	४	३	२	१	९	८
CV11	चश्मा वा कन्ट्याक्ट लेन्स हराउँदा वा नभेटिदा Losing or misplacing glasses or contact lenses	५	४	३	२	१	९	८
CV12	कुनै कामहरु (जस्तै नुहाउँदा, सरसफाइ गर्दा) चश्मा खोलेर गर्नु पर्दा Having to remove glasses when doing some tasks, e.g. cleaning, taking shower	५	४	३	२	१	९	८
CV13	चश्मा निकाल्ने लगाउने गरिरहन पर्दा Putting glasses on and off	५	४	३	२	१	९	८

CV14	चश्मा साटिरहन पर्दा (जस्तै नजिक र टाढाको चश्मा, पावरवाला र कालो चश्मा/गगल्स) Having to swap glasses, e.g. between reading glasses and distance glasses, prescription glasses and sunglasses	५	४	३	२	१	९	८
CV15	कन्ट्याक्ट लेन्स आँखामा राख्न वा आँखाबाट निकाल्न Getting contact lenses in and out of your eyes	५	४	३	२	१	९	८
CV16	चश्मा वा कन्ट्याक्ट लेन्स लगाएर निदाउँदा Falling asleep with your glasses or contact lenses	५	४	३	२	१	९	८
CV17	आँखामा औषधि राख्नुपर्दा (लेजर अप्रेशन पछि वा कन्ट्याक्ट लेन्सको कारण हुनसक्ने सुख्खापनको उपचार गर्न) Having to administer eye drops (after laser refractive surgery or contact lens wear related dryness)	५	४	३	२	१	९	८
CV18	चश्मा वा कन्ट्याक्ट लेन्सको हेरचाह/रेखदेख गर्नु पर्दा Having to look after your glasses or contact lenses	५	४	३	२	१	९	८
CV19	चश्मा भाँचिन/ फुट्न सक्ने हुँदा Breaking your glasses	५	४	३	२	१	९	८
CV20	चश्मा कोरिँदा Glasses getting scratched	५	४	३	२	१	९	८
CV21	पानी परेको बेला चश्मा लगाउन Wearing glasses in rain	५	४	३	२	१	९	८
CV22	गर्मी वातावरणमा चश्मा लगाउन Wearing glasses in hot environment	५	४	३	२	१	९	८
CV23	चिसो/ जाडो वातावरणमा भएको ठाउँमा चश्मा लगाउन Wearing glasses in cold environment	५	४	३	२	१	९	८
CV24	फोहोर वा धुलो भएको ठाउँमा चश्मा लगाउन Wearing glasses in dusty or dirty environment	५	४	३	२	१	९	८
CV25	फोहोर वा धुलो भएको ठाउँमा कन्ट्याक्ट लेन्स लगाउन Wearing contact lenses in dusty or dirty environment	५	४	३	२	१	९	८
CV26	सुख्खा वातावरणमा, हावा चलेको वा पंखा चलेको बेलामा कन्ट्याक्ट लेन्स लगाउन Wearing contact lenses in windy, dry or air-conditioned environment	५	४	३	२	१	९	८
CV27	चश्मा वाफिँदा (जस्तै खाना पकाउँदा, खेल खेल्दा) Your glasses getting fogged-up or steamed-up, e.g. when cooking, playing sports, running	५	४	३	२	१	९	८
CV28	चश्मा (नाकमा) चिप्लेर झरिराख्दा (जस्तै खेल खेल्दा, दौडिँदा) Glasses sliding down your nose or falling off your face, e.g. when playing sports, travelling and doing other physical activities	५	४	३	२	१	९	८

CV29	आफ्नो चश्मा वा कन्ट्याक्ट लेन्स बारे ख्याल राखिरहन पर्दा (जस्तै यात्रा गर्दा, खेल खेल्दा) Having to think about glasses or contact lenses, e.g. when travelling, playing sports	५	४	३	२	१	९	८
CV30	चश्मा वा कन्ट्याक्ट लेन्स लगाएर जिम जाँदा, शारीरिक कार्यकलाप गर्दा वा खेल खेल्दा Wearing your glasses or contact lenses when you are at the gym, doing physical activities, or playing sports	५	४	३	२	१	९	८
CV31	सामान्य खालको कालो चश्मा (गगल्स) प्रयोग गर्न नसक्दा Not being able to use off-the-shelf (non-prescription) sunglasses	५	४	३	२	१	९	८
CV32	आफूले गर्न खोजेको कुरा गर्न नसक्दा Not being able to do what you want to do	५	४	३	२	१	९	८
CV33	कुनै काम गर्दा विश्राम लिइरहन पर्दा, जस्तै कम्प्यूटर प्रयोग गर्दा Having to take breaks when doing works, e.g. using a computer	५	४	३	२	१	९	८
CV34	विस्तारै वा थप होशियारपूर्वक बाइक वा गाडी चलाउनु पर्दा Having to drive slower and more carefully	५	४	३	२	१	९	८
CV35	कुनै काम विस्तारै वा थप होशियारपूर्वक गर्नु पर्दा Having to be slower and more careful	५	४	३	२	१	९	८
CV36	कुनै काम गर्न थप समय लाग्दा Needing longer to do things	५	४	३	२	१	९	८
CV37	कामहरु पहिलेजस्तो राम्ररी गर्न नसक्दा Not being able to do things as well as you used to	५	४	३	२	१	९	८
CV38	कुनै चीज प्रष्टसँग देख्न नजिकै जानु पर्दा Having to go closer to see things clearly	५	४	३	२	१	९	८
CV39	आफूबाट कुनै गल्ती हुँदा It when you make a mistake	५	४	३	२	१	९	८
CV40	आँखा जचाउन वा चश्मा बनाउन टाढा जानु पर्दा Having to travel long distance to have eyes examined or to make glasses	५	४	३	२	१	९	८
CV41	आँखामा राख्ने औषधी लिएर हिड्न बिर्सिदा Forgetting to carry eye drops with you	५	४	३	२	१	९	८
CV42	बारम्बार आँखा जचाइराख्नु पर्दा Getting your eyes tested regularly	५	४	३	२	१	९	८
CV43	बिहान उठ्ने वित्तिकै चश्मा खोज्नु पर्दा Finding your glasses as soon as you wake up	५	४	३	२	१	९	८
CV44	मास्क लगाउन नमिल्दा (चश्मा बाफिदा) Not being able to wear a filtering face-mask (due to glasses getting fogged-up)	५	४	३	२	१	९	८
CV45	चश्मा गह्रौं वा मोटो हुँदा Wearing heavy or thick glasses	५	४	३	२	१	९	८
CV46	चश्मा खस्न सक्ने हुँदा Glassing falling off	५	४	३	२	१	९	८
CV47	चश्मा लगाउदा हेडफोन प्रयोग गर्न अफ्ठेरो हुँदा Difficulty using headphones due to glasses	५	४	३	२	१	९	८

CV48	चश्मा लगाएर लुगा खोल्दा Taking off clothes because of wearing glasses	५	४	३	२	१	९	८
CV49	चश्मा वा कन्ट्याक्ट लेन्स बारम्बार फेरिरहन पर्दा Having to frequently replace glasses or contact lenses	५	४	३	२	१	९	८
CV50	चश्माको खोल बिर्सिदा Forgetting to carry a case for glasses	५	४	३	२	१	९	८
CV51	कन्ट्याक्ट लेन्स आँखामा सर्दा It when contact lens moves on your eye	५	४	३	२	१	९	८
CV52	कन्ट्याक्ट लेन्स खस्न सक्ने हुदा Your contact lens falling off your eyes	५	४	३	२	१	९	८
CV53	कन्ट्याक्ट लेन्स लगाउदा पनि चश्मा लिएर हिड्नु पर्दा Having to carry glasses even when wearing contact lenses	५	४	३	२	१	९	८
CV54	कन्ट्याक्ट लेन्स लगाउन निकाल्न धेरै समय लाग्दा It when it takes a long time to wear or remove contact lenses	५	४	३	२	१	९	८
CV55	कन्ट्याक्ट लेन्स लगाएको बेला आँखामा धुलो वा केहि छिर्दा It when dust or dirt goes into your eye while you are wearing contact lens	५	४	३	२	१	९	८
CV56	कन्ट्याक्ट लेन्स सफा गर्दा वा हाइजिन मेनटेन गर्दा Cleaning contact lens or maintaining hygiene	५	४	३	२	१	९	८
CV57	कन्ट्याक्ट लेन्सको बट्टा लिएर हिंड्न बिर्सदा Forgetting to carry contact ens case with you	५	४	३	२	१	९	८
CV58	कन्ट्याक्ट लेन्स फुट्न सक्ने वा च्यातिन सक्ने हुँदा Your contact lens getting torn or broken	५	४	३	२	१	९	८
CV59	अस्पतालमा लाइन बस्नु पर्दा Queuing up for your turn in hospital	५	४	३	२	१	९	८
CV60	कुनै काम जस्तै मुख धुने, नुहाउने,सुत्ने आदी गर्दा चश्मा खोल्न बिर्सिदा Forgetting to take your glasses off when doing some tasks e.g. washing face, bathing, sleeping	५	४	३	२	१	९	८
CV61	लेजर सर्जरी पछि सावधानीहरु लिनु पर्दा जस्तै धुलो बाट बच्ने Having to take precautions after laser surgery e.g. avoiding dust	५	४	३	२	१	९	८
CV62	चश्माको कारण हेलमेट लगाउन (बाइक वा स्कुटर चलाउँदा) अफ्ठेरो हुदा Wearing helmet on (while riding a motorcycle/moped) due to glasses	५	४	३	२	१	९	८
CV63	कन्ट्याक्ट लेन्स आँखामा टाँसिदा वा अड्कीदा It when contact lens sticks on your eye	५	४	३	२	१	९	८
CV64	आफुले चाहेको समय सम्म (लामो समय) कन्ट्याक्ट लेन्स लगाउन नमिल्दा Not being able to wear contact lens as long as you want to	५	४	३	२	१	९	८

पेशागत तथा आर्थिक (Economic)								
आफ्नो आँखाको समस्या (रिफ्र्याक्टिभ एरर् तथा यसको उपचार)को कारण Because of your refractive error or its correction, **हाल तपाईंलाई ––– बारेमा कत्तिको चासो वा चिन्ता छ ?** ***How concerned are you about...?***		कत्ति पनि छैन *Not at all*	थोरै *A littl e bit*	मध्यम / ठीकै *A mod erate amo unt*	धेरै *Qui te a bit*	एक दमै धेरै *Extr eme ly*	यो कुरा मेरो लागि सान्दर्भिक छैन *This issue is not relevant to me*	जवाफ दिन इच्छुक छैन *Refuse to answer*
EC1	आफ्नो आँखा जचाउन लाग्ने खर्च The cost associated with seeing your eye care practitioner	५	४	३	२	१	९	८
EC2	चश्मा किन्न लाग्ने खर्च The initial and ongoing cost to buy your glasses	५	४	३	२	१	९	८
EC3	कन्ट्याक्ट लेन्स किन्न लाग्ने खर्च The initial and ongoing cost to buy your contact lenses	५	४	३	२	१	९	८
EC4	कन्ट्याक्ट लेन्सको हेरचाहको लागि लाग्ने खर्च जस्तै कन्ट्याक्ट लेन्स किट, सोलुसन किन्न The cost involved in care and maintenance of your contact lenses, e.g. cost to buy contact lens care kit	५	४	३	२	१	९	८
EC5	लेजर अप्रेशन गर्न लाग्ने खर्च Cost of having refractive surgery	५	४	३	२	१	९	८
EC6	आषधी किन्न लाग्ने खर्च The cost of buying eye drops	५	४	३	२	१	९	८
EC7	आँखा जाँच गर्न जाँदा लाग्ने बाटो खर्च The cost for travel to have eye examined	५	४	३	२	१	९	८
EC8	आँखाको कारण आफूले रोजेको पेशा गर्न नपाउने (जस्तै सेना, पाइलट, एयर होस्टेस्) Your optical correction restricting your choice of career e.g. air force, army, navy	५	४	३	२	१	९	८
EC9	नयाँ जागिर प्राप्त गर्न सक्ने क्षमता Your ability to find employment or get a new job	५	४	३	२	१	९	८
EC10	आफ्नो पेशाको कामहरु वा जिम्मेवारीमा असर पर्ने Your work tasks being affected	५	४	३	२	१	९	८
EC11	आफ्नो काम वा जागिर गर्ने नसक्ने Not being able to work	५	४	३	२	१	९	८
EC12	आफ्नो काममा ध्यान दिन नसक्ने Not being able to concentrate on your work	५	४	३	२	१	९	८
EC13	आफ्नो काम गर्न ढिला हुने Needing longer time to do your work	५	४	३	२	१	९	८
EC14	कामबाट वा जागिरबाट विदा लिनुपर्ने अवस्था जस्तै चश्मा मर्मत गर्न वा फेर्न समय लाग्नाले Having to take time off work, e.g. due to time taken for replacing glasses or for adjustment	५	४	३	२	१	९	८
EC15	काम गर्ने ठाउँमा हाकिम वा अन्य कर्मचारीसँग तनाव पर्न सक्ने सम्भावना, जस्तै जागिरबाट छुट्टी लिइरहन परेर वा समग्र प्रदर्शन कमजोर भएर Strain on your work relationships, e.g. because of time off or overall performance	५	४	३	२	१	९	८

सान्त्वना(Coping)							
आफ्नो आँखाको समस्या (रिफ्र्याक्टिभ एरर् तथा यसको उपचार)को कारण Because of your refractive error or its correction, **आफ्नो आँखाको समस्याको बारेमा जानकारी भइसकेपछि तपाईंले ––– सान्त्वना लिनुहुन्छ ? *Given that you know your eye condition, do you cope by...?***		कत्ति पनि लिँदिन *Not at all*	थोरै / अलिकति *A little bit*	मध्यम मात्र *A moderate amount*	धेरै *A lot*	एकदमै धेरै *Extremely*	जवाफ दिन इच्छुक छैन *Refuse to answer*
CP1	स्पष्टसँग देख्नको लागि आँखा झिम्क्याएर (सानो बनाएर) हेरेर Squinting or squeezing your eyes to see clearly	५	४	३	२	१	८
CP2	आफ्नो कमजोरी लुकाएर Not showing (hiding) your weaknesses	५	४	३	२	१	८
CP3	अरु इन्द्रिय प्रयोग गरेर Using your other senses	५	४	३	२	१	८
CP4	आफ्नो आँखाको अवस्था स्वीकारेर Accepting your eye condition	५	४	३	२	१	८
CP5	भगवानले सहयोग गर्नु हुन्छ भन्ने सोचेर Thinking the God will help you	५	४	३	२	१	८
CP6	उमेरको कारणले हो भन्ने सोचेर Thinking it is because of your age	५	४	३	२	१	८
CP7	पहिलेभन्दा फरक तरिकाले काम गर्न सिकेर (जस्तै कम्प्यूटरमा अक्षरको आकार बढाएर, बत्तीवाला कलम प्रयोग गरेर, भर्याङ् झर्दा रेलिङ् समाएर) Learning to do things in a different way than you used to do before, e.g. increasing font size, using pen with a light, holding onto railings when going downstairs	५	४	३	२	१	८
CP8	आफूभन्दा अझ कमजोर अवस्थाका मानिसहरु पनि छन् भन्ने सोचेर Thinking there are people much worse than you	५	४	३	२	१	८
CP9	विशेषज्ञ सेवा लिएर Getting professional support	५	४	३	२	१	८
CP10	साथीभाइको सहयोग लिएर Having peer support	५	४	३	२	१	८
CP11	सकारात्मक रहन कोशिस गरेर Trying to be positive	५	४	३	२	१	८
CP12	यसको बारेमा नसोचेर Trying not to think about it	५	४	३	२	१	८
CP13	कामहरु पन्छाएर वा नगरेर, जस्तै सामुहिक काममा भाग नलिने, पौडी नखेल्ने Avoiding some tasks, e.g. participating in group activities, swimming	५	४	३	२	१	८
CP14	चश्मा वा कन्ट्याक्ट लेन्सको कारणले हुने समस्या पन्छाउनको लागि सो प्रयोग नगरेर (जस्तै अरुले जिस्क्याउने समस्या) Not wearing glasses or contact lenses to avoid problems caused by them, e.g. being teased	५	४	३	२	१	८

समय र सहयोगको लागि धन्यबाद ! Thank you for your time and support!

Appendix I. Item measures and fit statistics

Appendix I.01 Item measures and fit statistics for Convenience item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	CV50	-1.13 (0.09)	0.98	0.87
2	CV39	-1.06 (0.09)	1.41	1.11
3	CV36	-1.04 (0.09)	1.04	0.92
4	CV23	-0.99 (0.09)	1.46	1.35
5	CV37	-0.93 (0.08)	1.34	1.19
6	CV35	-0.90 (0.08)	0.89	0.79
7	CV5	-0.77 (0.08)	1.42	1.38
8	CV33	-0.73 (0.08)	1.06	0.95
9	CV34	-0.73 (0.10)	0.89	0.81
10	CV22	-0.58 (0.08)	1.14	1.10
11	CV40	-0.55 (0.08)	1.14	1.00
12	CV7	-0.54 (0.08)	1.27	1.14
13	CV32	-0.48 (0.08)	1.02	0.89
14	CV18	-0.45 (0.08)	0.95	0.97
15	CV41	-0.40 (0.08)	0.82	0.74
16	CV38	-0.35 (0.07)	1.03	0.93
17	CV17	-0.32 (0.10)	0.94	0.96
18	CV52	-0.30 (0.17)	1.24	1.30
19	CV9	-0.27 (0.08)	1.28	1.19
20	CV4	-0.21 (0.09)	0.93	0.93
21	CV8	-0.21 (0.07)	1.09	1.00
22	CV56	-0.12 (0.16)	0.62	0.63
23	CV6	-0.11 (0.07)	1.20	1.26
24	CV51	-0.10 (0.16)	1.15	1.18
25	CV24	-0.09 (0.07)	1.13	1.14
26	CV29	-0.09 (0.07)	0.85	0.84
27	CV3	-0.08 (0.14)	0.90	0.83
28	CV2	-0.05 (0.07)	0.74	0.76
29	CV54	-0.03 (0.16)	1.15	1.16
30	CV57	-0.03 (0.16)	1.01	0.99
31	CV45	0.01 (0.08)	1.02	1.03
32	CV46	0.02 (0.07)	0.78	0.74
33	CV53	0.05 (0.16)	0.80	0.78
34	CV47	0.07 (0.08)	1.02	0.97
35	CV1	0.10 (0.07)	1.04	1.09
36	CV49	0.12 (0.07)	0.59	0.57
37	CV14	0.13 (0.09)	0.79	0.77
38	CV42	0.13 (0.07)	0.76	0.85
39	CV31	0.20 (0.07)	1.29	1.27
40	CV63	0.21 (0.17)	1.30	1.32
41	CV58	0.22 (0.15)	0.98	1.00
42	CV13	0.25 (0.08)	0.92	0.87
43	CV26	0.27 (0.12)	1.25	1.21
44	CV12	0.32 (0.07)	0.90	0.89
45	CV30	0.32 (0.08)	1.04	1.03
46	CV61	0.32 (0.13)	0.82	1.08
47	CV43	0.33 (0.07)	1.11	1.21
48	CV48	0.36 (0.07)	0.80	0.79
49	CV15	0.37 (0.13)	0.88	0.86
50	CV60	0.37 (0.07)	0.90	0.89

51	CV62	0.39 (0.09)	1.22	1.25
52	CV28	0.40 (0.07)	0.69	0.68
53	CV19	0.44 (0.07)	0.80	0.79
54	CV59	0.44 (0.07)	1.06	1.07
55	CV25	0.46 (0.13)	0.93	0.87
56	CV64	0.48 (0.18)	0.79	0.83
57	CV16	0.52 (0.08)	1.10	1.09
58	CV55	0.52 (0.16)	1.08	1.08
59	CV21	0.54 (0.07)	0.97	0.95
60	CV20	0.60 (0.07)	0.61	0.61
61	CV27	1.08 (0.07)	1.10	1.14
62	CV44	1.15 (0.07)	1.19	1.19
63	CV10	1.23 (0.07)	1.12	1.09
64	CV11	1.23 (0.07)	1.18	1.16

Note: CV = Convenience, MnSq = Mean square, SE = Standard error.

Appendix I.02 Item measures and fit statistics for Health concerns item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	HC36	-1.35 (0.11)	1.40	1.07
2	HC7	-0.93 (0.09)	1.11	0.84
3	HC5	-0.91 (0.09)	1.22	0.94
4	HC35	-0.86 (0.09)	0.85	0.69
5	HC34	-0.84 (0.09)	0.85	0.67
6	HC6	-0.48 (0.08)	0.99	0.87
7	HC4	-0.47 (0.08)	1.20	0.97
8	HC33	-0.46 (0.08)	1.29	1.17
9	HC25	-0.45 (0.08)	1.13	1.05
10	HC11	-0.38 (0.07)	1.09	0.85
11	HC30	-0.31 (0.07)	0.91	0.75
12	HC39	-0.30 (0.08)	1.36	1.31
13	HC29	-0.26 (0.07)	0.88	0.85
14	HC14	-0.23 (0.07)	0.83	0.84
15	HC28	-0.23 (0.07)	1.00	0.95
16	HC37	-0.15 (0.07)	1.02	0.87
17	HC8	-0.14 (0.07)	0.97	0.82
18	HC12	-0.12 (0.07)	0.77	0.66
19	HC26	-0.06 (0.07)	1.02	1.23
20	HC16	-0.05 (0.07)	0.74	0.68
21	HC27	0 (0.07)	1.24	1.38
22	HC2	0.05 (0.07)	1.07	1.02
23	HC31	0.10 (0.11)	0.98	0.95
24	HC38	0.26 (0.06)	1.29	1.26
25	HC9	0.40 (0.06)	1.12	1.21
26	HC17	0.42 (0.10)	1.13	1.03
27	HC10	0.44 (0.06)	0.78	0.75
28	HC32	0.45 (0.10)	0.99	1.08

29	HC1	0.46 (0.06)	1.17	1.38
30	HC15	0.49 (0.10)	1.10	1.00
31	HC22	0.54 (0.11)	0.87	0.80
32	HC13	0.57 (0.06)	0.91	1.04
33	HC20	0.58 (0.11)	0.93	0.86
34	HC24	0.58 (0.11)	1.09	1.32
35	HC18	0.59 (0.06)	0.90	0.89
36	HC3	0.64 (0.06)	1.31	1.43
37	HC23	0.73 (0.10)	1.14	1.13
38	HC19	0.81 (0.10)	1.22	1.21
39	HC21	0.85 (0.10)	1.04	0.98

Note: HC = Health concerns, MnSq = Mean square, SE = Standard error.

Appendix I.03 Item measures and fit statistics for Economic item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	EC15	-1.30 (0.14)	0.95	0.72
2	EC12	-1.05 (0.12)	0.82	0.74
3	EC11	-0.94 (0.12)	1.02	0.76
4	EC13	-0.86 (0.12)	0.95	1.13
5	EC14	-0.84 (0.13)	1.16	0.96
6	EC10	-0.37 (0.11)	0.94	1.08
7	EC7	-0.20 (0.11)	1.28	1.14
8	EC9	-0.20 (0.12)	1.25	1.11
9	EC6	0.35 (0.11)	1.05	1.00
10	EC1	0.59 (0.10)	0.96	0.93
11	EC2	0.76 (0.10)	0.92	0.91
12	EC4	1.03 (0.20)	0.88	0.81
13	EC3	1.20 (0.19)	0.73	0.70
14	EC5	1.81 (0.18)	1.42	1.37

Note: EC = Economic, MnSq = Mean square, SE = Standard error; Deleted item: EC8.

Appendix I.04 Item measures and fit statistics for Activity limitation item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	AL31	-2.25 (0.24)	1.23	0.92
2	AL30	-2.05 (0.22)	1.06	0.89
3	AL18	-1.93 (0.22)	0.97	0.50
4	AL38	-1.87 (0.20)	1.17	0.67
5	AL20	-1.75 (0.20)	1.02	0.57
6	AL26	-1.60 (0.19)	0.92	0.58
7	AL29	-1.58 (0.18)	1.17	1.07
8	AL19	-1.43 (0.18)	0.81	0.48

9	AL45	-1.37 (0.16)	0.85	0.49
10	AL43	-1.25 (0.17)	0.88	0.64
11	AL22	-1.20 (0.16)	0.75	0.37
12	AL28	-1.20 (0.19)	1.31	1.10
13	AL44	-1.16 (0.15)	0.99	0.81
14	AL14	-1.10 (0.15)	1.10	0.65
15	AL32	-0.99 (0.14)	0.88	0.56
16	AL50	-0.77 (0.19)	1.02	0.84
17	AL42	-0.70 (0.15)	0.82	0.50
18	AL27	-0.57 (0.12)	1.01	0.68
19	AL51	-0.57 (0.17)	0.68	0.70
20	AL37	-0.51 (0.16)	1.47	0.92
21	AL65	-0.50 (0.12)	0.93	0.66
22	AL16	-0.44 (0.12)	1.06	0.87
23	AL62	-0.35 (0.11)	1.11	0.81
24	AL34	-0.34 (0.11)	0.82	0.60
25	AL48	-0.32 (0.15)	1.00	0.76
26	AL12	-0.25 (0.11)	1.18	1.06
27	AL47	-0.25 (0.14)	1.04	0.72
28	AL49	-0.20 (0.11)	0.93	0.84
29	AL17	-0.17 (0.11)	1.12	0.83
30	AL35	-0.11 (0.12)	0.76	0.68
31	AL13	-0.10 (0.11)	0.99	1.05
32	AL36	-0.08 (0.11)	0.73	0.68
33	AL46	-0.06 (0.15)	0.93	0.63
34	AL66	-0.01 (0.13)	1.03	0.72
35	AL5	0.02 (0.10)	1.09	1.35
36	AL8	0.10 (0.10)	0.98	1.07
37	AL15	0.11 (0.11)	1.19	1.11
38	AL10	0.14 (0.10)	0.97	1.06
39	AL11	0.15 (0.10)	1.00	1.12
40	AL61	0.15 (0.10)	1.05	0.77
41	AL21	0.24 (0.09)	0.99	0.77
42	AL55	0.25 (0.11)	0.68	0.66
43	AL33	0.28 (0.13)	1.03	0.86
44	AL64	0.31 (0.09)	1.06	1.07
45	AL54	0.33 (0.11)	1.29	1.31
46	AL63	0.39 (0.09)	1.13	1.54
47	AL2	0.41 (0.09)	1.19	1.06
48	AL60	0.44 (0.10)	1.10	0.86
49	AL53	0.62 (0.10)	1.52	1.36
50	AL41	0.63 (0.10)	1.28	1.33
51	AL24	0.64 (0.09)	0.90	0.78
52	AL40	0.73 (0.13)	1.29	0.93
53	AL39	0.75 (0.09)	0.87	0.83

54	AL52	0.76 (0.14)	1.10	0.96
55	AL7	0.80 (0.08)	0.68	0.83
56	AL68	0.80 (0.12)	1.02	1.05
57	AL69	0.85 (0.12)	0.99	0.85
58	AL6	0.91 (0.08)	0.83	0.89
59	AL23	0.93 (0.08)	0.91	1.25
60	AL56	0.94 (0.09)	1.45	1.41
61	AL1	1.11 (0.08)	1.13	1.55
62	AL58	1.14 (0.10)	0.93	0.92
63	AL69	1.16 (0.10)	1.47	1.54
64	AL9	1.22 (0.08)	1.21	1.24
65	AL3	1.26 (0.09)	0.93	0.95
66	AL4	1.26 (0.09)	1.00	0.94
67	AL67	1.64 (0.11)	0.95	1.22
68	AL70	1.65 (0.11)	1.08	1.05
69	AL57	1.83 (0.10)	1.53	1.42
70	AL71	1.92 (0.11)	1.53	1.56
71	AL72	2.14 (0.10)	1.30	1.34

Note: AL=Activity limitation, MnSq = Mean square, SE = Standard error; Deleted item = AL25.

Appendix I.05 Item measures and fit statistics for Mobility item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	MB1	-1.21 (0.19)	1.42	0.69
2	MB10	-1.05 (0.18)	0.76	0.48
3	MB13	-0.98 (0.18)	0.70	0.36
4	MB14	-0.83 (0.17)	0.69	0.91
5	MB11	-0.74 (0.17)	0.80	0.48
6	MB12	-0.71 (0.17)	0.87	0.71
7	MB9	-0.67 (0.17)	1.20	0.60
8	MB5	-0.61 (0.17)	0.88	0.47
9	MB6	0.26 (0.15)	0.92	0.70
10	MB8	0.64 (0.14)	0.71	0.69
11	MB3	0.66 (0.14)	1.48	1.28
12	MB7	1.11 (0.13)	1.29	1.32
13	MB2	4.14 (0.12)	1.46	1.54

Note: MB = Mobility, SE = Standard error; Deleted item: MB4.

Appendix I.06 Item measures and fit statistics for Emotional item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	EM5	-1.33 (0.18)	1.43	0.64
2	EM8	-1.30 (0.18)	1.15	0.59

3	EM6	-1.27 (0.18)	1.06	0.55
4	EM18	-0.92 (0.16)	0.92	0.67
5	EM28	-0.90 (0.16)	1.21	0.67
6	EM27	-0.60 (0.15)	1.37	1.26
7	EM4	-0.37 (0.14)	1.12	0.89
8	EM14	-0.34 (0.14)	0.85	0.86
9	EM26	-0.34 (0.14)	1.05	1.22
10	EM30	-0.30 (0.14)	0.84	0.71
11	EM29	-0.11 (0.13)	0.95	0.73
12	EM15	-0.03 (0.13)	0.75	0.93
13	EM12	0.19 (0.12)	0.85	0.67
14	EM24	0.23 (0.12)	0.79	0.84
15	EM17	0.56 (0.11)	1.13	1.13
16	EM31	0.59 (0.11)	0.97	0.98
17	EM23	0.61 (0.11)	0.91	0.76
18	EM25	0.83 (0.11)	1.02	1.27
19	EM1	0.84 (0.11)	1.47	1.29
20	EM2	0.89 (0.10)	1.31	1.48
21	EM20	0.90 (0.10)	0.94	1.01
22	EM22	0.96 (0.10)	1.19	1.21
23	EM21	1.20 (0.10)	1.05	1.02

Note: EM = Emotional, MnSq = Mean square, SE = Standard error; Deleted items: EM3, EM7, EM9, EM10, EM11, EM13, EM16, EM19, EM32

Appendix I.07 Item measures and fit statistics for Social item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	SC10	-0.85 (0.15)	0.74	0.63
2	SC11	-0.79 (0.17)	0.84	0.67
3	SC7	-0.70 (0.14)	0.94	1.11
4	SC6	-0.6 (0.14)	0.90	1.09
5	SC9	-0.51 (0.14)	1.01	1.03
6	SC5	-0.41 (0.13)	0.95	0.78
7	SC15	-0.34 (0.13)	0.93	0.69
8	SC16	-0.33 (0.13)	1.16	1.12
9	SC12	-0.07 (0.15)	1.31	1.15
10	SC14	-0.01 (0.14)	1.24	1.18
11	SC13	0.07 (0.14)	1.00	0.88
12	SC4	0.08 (0.12)	0.78	0.68
13	SC8	0.57 (0.12)	1.49	1.41
14	SC3	0.78 (0.11)	0.92	0.84
15	SC2	1.50 (0.10)	1.16	1.08
16	SC1	1.61 (0.10)	1.28	1.25

Note: SC = Social, SE = Standard error.

Appendix I.08 Item measures and fit statistics for Visual symptoms – frequency item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	VSF14	-2.69 (0.33)	1.39	0.34
2	VSF11	-1.71 (0.22)	0.97	0.50
3	VSF12	-1.37 (0.19)	1.37	0.74
4	VSF13	-1.07 (0.17)	1.24	0.57
5	VSF10	-1.05 (0.17)	1.30	0.98
6	VSF17	-0.93 (0.17)	0.99	1.04
7	VSF5	-0.54 (0.15)	1.40	0.94
8	VSF4	-0.52 (0.15)	1.02	0.71
9	VSF20	-0.43 (0.14)	1.14	0.85
10	VSF23	-0.35 (0.14)	0.98	0.72
11	VSF21	-0.07 (0.13)	1.22	1.05
12	VSF9	0.14 (0.12)	1.40	1.36
13	VSF2	0.44 (0.11)	0.89	0.72
14	VSF16	0.50 (0.11)	0.95	0.97
15	VSF3	0.62 (0.11)	0.74	0.68
16	VSF6	0.66 (0.11)	1.20	1.24
17	VSF15	0.79 (0.10)	1.05	0.96
18	VSF22	0.86 (0.10)	1.02	0.88
19	VSF7	1.05 (0.10)	0.82	0.81
20	VSF18	1.18 (0.10)	1.06	1.12
21	VSF19	1.27 (0.09)	1.25	1.48
22	VSF1	1.57 (0.09)	0.87	0.85
23	VSF8	1.63 (0.09)	1.01	0.99

Note VSF = Visual symptoms – frequency, MnSq = Mean square, SE = Standard error

Appendix I.09 Item measures and fit statistics for Comfort symptoms – frequency item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	GSF3	-1.95 (0.18)	1.05	0.85
2	OSF8	-1.58 (0.16)	1.26	0.97
3	GSF4	-1.32 (0.15)	1.20	0.82
4	OSF11	-1.28 (0.15)	1.21	0.90
5	GSF5	-1.19 (0.14)	1.06	0.81
6	GSF2	-0.44 (0.12)	1.20	1.15
7	OSF6	-0.22 (0.11)	0.97	0.78
8	OSF10	-0.15 (0.11)	0.96	0.84
9	OSF14	0.06 (0.11)	0.88	0.80
10	OSF7	0.08 (0.11)	1.02	1.04
11	OSF13	0.50 (0.10)	0.92	0.83
12	OSF5	0.52 (0.10)	0.83	0.80
13	OSF2	0.67 (0.10)	1.45	1.37
14	OSF12	0.81 (0.10)	0.98	0.95

15	GSF1	0.89 (0.10)	1.27	1.27
16	OSF9	1.06 (0.09)	0.82	0.86
17	OSF3	1.10 (0.09)	1.13	1.11
18	OSF4	1.22 (0.09)	0.80	0.83
19	OSF1	1.25 (0.09)	0.74	0.80

Note: CSF = Comfort symptoms – frequency, GSF = General symptoms – frequency, MnSq = Mean square, OSF = Ocular symptoms – frequency, SE = Standard error.

Appendix I.10 Item measures and fit statistics for Visual symtpoms – severity item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	VSS14	-2.63 (0.33)	1.44	0.39
2	VSS11	-1.72 (0.22)	0.98	0.53
3	VSS12	-1.30 (0.19)	1.26	0.70
4	VSS13	-1.05 (0.17)	1.11	0.63
5	VSS10	-1.02 (0.17)	1.32	0.87
6	VSS17	-0.64 (0.15)	1.20	1.00
7	VSS4	-0.54 (0.14)	1.14	0.73
8	VSS20	-0.46 (0.14)	1.02	0.73
9	VSS23	-0.44 (0.14)	1.03	0.75
10	VSS5	-0.24 (0.13)	1.56	1.10
11	VSS21	-0.22 (0.13)	1.11	0.98
12	VSS9	0.15 (0.12)	1.47	1.42
13	VSS16	0.53 (0.11)	1.03	1.05
14	VSS2	0.54 (0.10)	1.02	0.77
15	VSS3	0.63 (0.10)	0.80	0.72
16	VSS6	0.65 (0.10)	1.16	1.19
17	VSS15	0.69 (0.10)	0.95	0.89
18	VSS22	0.71 (0.10)	1.01	0.86
19	VSS18	1.04 (0.09)	1.03	1.12
20	VSS7	1.06 (0.09)	0.78	0.75
21	VSS19	1.09 (0.09)	1.17	1.47
22	VSS8	1.55 (0.09)	0.97	0.95
23	VSS1	1.63 (0.09)	1.01	1.01

Note: Visual symtpoms – severity (VSS), MnSq = Mean square, SE = Standard error.

Appendix I.11 Item measures and fit statistics for Comfort symptoms – severity item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	GSS3	-1.68 (0.17)	1.15	0.87
2	OSS8	-1.48 (0.15)	1.18	0.89
3	GSS4	-1.28 (0.15)	1.14	0.76
4	OSS11	-1.19 (0.14)	1.29	0.88

5	GSS5	-1.19 (0.14)	1.13	0.81
6	GSS2	-0.35 (0.11)	1.27	1.16
7	OSS6	-0.24 (0.11)	1.06	0.81
8	OSS10	-0.10 (0.11)	0.99	0.91
9	OSS7	0.08 (0.10)	1.00	1.00
10	OSS14	0.22 (0.10)	0.90	0.80
11	OSS13	0.40 (0.10)	0.92	0.81
12	OSS5	0.44 (0.10)	0.83	0.80
13	OSS2	0.64 (0.09)	1.39	1.48
14	OSS12	0.64 (0.09)	0.95	0.90
15	OSS3	0.91 (0.09)	1.08	1.06
16	OSS9	0.92 (0.09)	0.76	0.80
17	GSS1	1.03 (0.09)	1.40	1.40
18	OSS4	1.07 (0.09)	0.76	0.78
19	OSS1	1.16 (0.09)	0.78	0.84

Note: CSS = Comfort symptoms – severity, GSS = General symptoms – severity, MnSq = Mean square, OSS = Ocular-comfort symptoms – severity, SE = Standard error.

Appendix I.12 Item measures and fit statistics for Visual symproms – bothersome item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	VSB14	-2.56 (0.33)	1.14	0.52
2	VSB11	-1.73 (0.23)	1.07	0.73
3	VSB12	-1.49 (0.21)	0.96	0.46
4	VSB10	-1.17 (0.19)	1.03	0.97
5	VSB13	-1.01 (0.18)	1.15	0.61
6	VSB5	-0.62 (0.15)	1.47	0.96
7	VSB17	-0.60 (0.15)	1.07	0.90
8	VSB4	-0.58 (0.15)	1.05	0.63
9	VSB20	-0.49 (0.15)	0.98	0.72
10	VSB23	-0.44 (0.15)	0.99	0.74
11	VSB21	-0.26 (0.14)	1.18	0.92
12	VSB9	0.21 (0.12)	1.36	1.38
13	VSB2	0.45 (0.11)	1.01	0.80
14	VSB3	0.65 (0.11)	0.74	0.66
15	VSB16	0.65 (0.11)	1.12	1.07
16	VSB6	0.68 (0.11)	1.24	1.25
17	VSB15	0.80 (0.10)	0.97	0.97
18	VSB22	0.81 (0.11)	1.03	0.87
19	VSB7	1.09 (0.10)	0.79	0.76
20	VSB18	1.19 (0.10)	1.15	1.20
21	VSB19	1.25 (0.10)	1.21	1.47
22	VSB8	1.56 (0.09)	0.98	0.95
23	VSB1	1.60 (0.09)	0.89	0.91

Note: MnSq = Mean square, VSB = Visual symproms – bothersome, SE = Standard error.

Appendix I.13 Item measures and fit statistics for Comfort symptoms – bothersome item bank

SN	Item	Item measure (SE)	Infit MnSq	Outfit MnSq
1	GSB3	-1.69 (0.17)	1.19	0.96
2	OSB8	-1.47 (0.16)	1.27	0.87
3	OSB11	-1.35 (0.15)	1.33	1.03
4	GSB4	-1.18 (0.14)	1.21	0.83
5	GSB5	-1.10 (0.14)	1.28	0.89
6	GSB2	-0.36 (0.12)	1.24	1.19
7	OSB10	-0.29 (0.11)	0.90	0.85
8	OSB6	-0.19 (0.11)	0.97	0.76
9	OSB7	-0.13 (0.11)	1.00	0.97
10	OSB14	0.22 (0.10)	0.89	0.79
11	OSB5	0.42 (0.10)	0.80	0.78
12	OSB13	0.49 (0.10)	0.99	0.90
13	OSB2	0.70 (0.09)	1.45	1.45
14	OSB12	0.75 (0.09)	0.84	0.78
15	OSB9	0.90 (0.09)	0.77	0.83
16	OSB3	0.95 (0.09)	1.06	1.05
17	OSB4	1.07 (0.09)	0.76	0.78
18	GSB1	1.09 (0.09)	1.36	1.38
19	OSB1	1.15 (0.09)	0.79	0.86

Note: CSB = Comfort symptoms – bothersome, GSB = General symptoms – bothersome, MnSq = Mean square, OSB = Ocular-comfort symptoms – bothersome, SE = Standard error.

Appendix J. Differential item functioning

(Items with DIF contrast > 1.0 and p value < 0.05)

	Gender	Rural or urban	VA Category	RE magnitude	Myopia or hyperopia	Astigmatism	Presbyopia	URE or CRE	Spectacles	Contact lens	Refractive surgery	Surgical emmetropia
CV	No	No	CV31: 1.16 (0.0029)	No	CV3: 1.08 (0.000); CV5: -1.29 (0.000); CV55: 1.62 (0.000); CV56: -1.64 (0.000); CV58: 1.24 (0.000)	No	CV5: -1.78 (<0.0001); CV31: 1.05 (0.0002)	CV31: 1.19 (0.0001); CV62: 1.07 (0.0011)	CV11: 1.37 (0.0281); CV44: 1.98 (0.0012); CV48: 1.41 (0.0452)	CV5: 1.54 (0.0001); CV9: -1.08 (0.000); CV26: -1.04 (0.0002)	CV32: -1.30 (0.0462), CV44: -1.56 (0.0257)	CV44: 2.17 (0.0223)
HC	No	No	No	No	No	No	No	No	No	HC32: -1.02 (0.0009); HC36: 1.01 (0.0311)	HC33: -1.11 (0.0029); HC38: 1.07 (0.0353)	HC:33 -1.08 (0.0055)

	Gender	Rural or urban	VA Category	RE magnitude	Myopia or hyperopia	Astigmatism	Presbyopia	URE or CRE	Spectacles	Contact lens	Refractive surgery	Surgical emmetropia
EC	No	No	No	No	EC4: -1.50 (<0.0001)	No	No	No	EC5: -1.35 (0.0114)	No	EC7: -1.85 (0.0082)	EC1: -2.38 (0.0022); EC7: -1.85 (0.0082)

	Gender	Rural or urban	VA Category	RE magnitude	Myopia or hyperopia	Astigmatism	Presbyopia	URE or CRE	Spectacles	Contact lens	Refractive surgery	Surgical emmetropia
AL	AL20: -1.02 (0.025); AL33: -1.11 (0.0019); AL37: -1.07 (0.0140)	AL18: -1.07 (0.0365); AL53: 1.48 (0.0001); AL57: 1.01 (0.0043)	No	No	Al5: -1.22(<0.0001); AL13: -1.08 (<0.0001); AL18: -1.46 (0.0023); AL27: 1.19 (0.0039); AL60: 1.11 (0.0032); AL61: 1.03 (0.0009)	No	AL1: 1.03 (<0.0001); AL3: 1.08 (0.0233); AL5: -1.90 (<0.0001); AL10: -1.16(<0.0001); AL11: -1.14 (<0.0001); AL13: -1.51 (<0.0001); Al16: -1.10 (<0.0001); AL18: -1.01 (0.0252); AL19: -1.11 (0.0024); AL29: 1.10 (0.0290); AL33: -1.07 (0.0038); AL35: -1.30 (<0.0001); AL37: -1.51 (0.0001); AL41: -1.02 (0.0002); AL46: -1.19 (0.0045); AL47: -1.52 (<0.0001); AL59: 1.47 (0.0216); AL62: 1.02 (0.0011); AL63: 1.22 (<0.0001); AL67: 1.02 (0.0365); AL71: 1.14 (0.0182)	AL18: -1.48 (0.0012); AL19: -1.05 (0.0060); AL56: 1.18 (0.0001); AL57: 1.28 (0.0014); AL59: 1.01 (0.0022); AL71: 1.07 (0.0039)	AL5: -1.10 (0.0015); AL10: -1.06 (0.0016); AL11: -1.06 (0.0017); AL53: 1.15 (0.0262); AL56: 1.67 (0.0042); AL57: 1.32 (0.0117)	AL11: 1.44 (0.0223); AL62: -1.15 (0.0007)	AL63: -1.53 (0.0118)	AL63: -1.59 (0.0177)
MB	No	MB2: 1.08 (0.0046)	MB7: 1.14 (0.0271)	MB9: 1.38 (0.0002)	No	MB10: -1.05 (0.0089)	No	No	No	MB2: -1.16 (0.0016); MB3: 1.26 (0.0224)	No	No

	Gender	Rural or urban	VA Category	RE magnitude	Myopia or hyperopia	Astigmatism	Presbyopia	URE or CRE	Spectacles	Contact lens	Refractive surgery	Surgical emmetropia
EM	No	No	EM27: -1.13 (0.0131)	EM27: -1.03 (0.0016)	No	No	No	No	EM2: 1.39 (0.0214); EM20: 1.40 (0.0206);EM26: -1.13 (0.0324)	No	EM2: 2.20 (0.0329);EM26: -1.78 (0.0181)	EM2: 2.18 (0.0395)
SC	SC1: -1.11 (<0.00010)	SC12: -1.37 (0.0003); SC14: 1.13 (0.0261); SC16: -1.25 (0.0003)	SC12: -1.18 (0.0075)	No	No	No	SC12: -1.45 (0.0001); SC14: 1.85 (0.0268)	No	No	SC10: 1.09 (0.0462);SC13: 1.17 (0.0343)	SC6: -1.91 (0.0433)	No
VSF	No	No	VS11: -1.96 (0.0001); VS14: -1.63 (0.0245); VS20: 1.34 (0.0152); VS22: 1.17 (0.0019)	No	VS4: -1.07 (0.0025); VS9: -1.68 (<0.0001)	VS11: -1.51 (0.0011)	VS5: 1.43 (0.0037); VS6: 1.16 (0.0004); VS22: 1.30 (0.0001); VS9: -2.60 (<0.0001); VS12: -1.06 (0.0097)	VS11: -1.53 (0.0010); VS15: -1.40 (0.0419); VS17: 1.18 (0.0179); VS19: 1.30 (<0.0001); VS21: 1.14 (0.0025)	VS5: -1.24 (0.0014); VS22: 1.08 (0.0111)	VS9: 1.16 (0.0296)	VS5: -1.24 (0.0328); VS21: -1.26 (0.0165)	VS5: -1.35 (0.0235); VS21: -1.15 (0.0375)
CSF	GS1: -1.01 (<0.0001)	GS5: -1.25 (0.0004)	OS2: 1.24 (0.0029); GS3: -1.32 (0.0002)	No	OS11: -1.05 (0.0043)	No	OS12: 1.03 (0.0007)	OS2: 1.15 (0.0001); OS4: 1.03 (<0.0001)	OS2: 2.19 (0.001); OS7: -1.37 (<0.0001); OS8: -1.29 (0.0026)	No	OS3: -1.25 (0.0029); OS7: -1.95 (0.0001); OS8: -2.12 (0.0002); OS10: 1.79 (0.0392)	OS3: -1.25 (0.0029); OS7: -1.95 (0.0001); OS8: -2.12 (0.0002); OS10: 1.79 (0.0392)

	Gender	Rural or urban	VA Category	RE magnitude	Myopia or hyperopia	Astigmatism	Presbyopia	URE or CRE	Spectacles	Contact lens	Refractive surgery	Surgical emmetropia
VSS	No	No	VS11: -1.94 (0.0001); VS22: 1.04 (0.0051)	No	VS4: -1.10 (0.001); VS9: -1.50 (<0.0001)	VS11: -1.51 (0.014)	VS9: -2.40 (<0.0001); VS22: 1.19 (<0.0001)	VS11: -1.57 (0.008); VS16: 1.02 (0.008); VS19: 1.09 (0.0001)	No	VS9: 1.44 (0.013)	VS19: -1.23 (0.009)	VS19: -1.23 (0.009)
CSS	GS3: -1.06 (0.006)	GS5: -1.21 (0.003)	GS3: -1.08 (0.012)	No	No	OS8: 1.11 (0.019)	GS3: 1.27 (0.047)	No	OS2: 2.44 (0.0004)	OS5: 1.33 (0.004)	No	OS7: -1.58 (0.003); OS8: -1.45 (0.036)
VSB	No	No	VS11: -2.21 (0.0001); VS15: 1.20 (0.0023)	VS11: 1.44 (0.0182)	VS4: -1.34 (0.0002); VS6: 1.15 (0.0017); VS9: -1.48 (<0.0001)	VS11: -1.69 (0.0008)	VS4: -1.25 (0.0002); VS6: 1.29 (0.0001); VS9: -2.43 (<0.0001); VS10: 1.44 (0.027); VS22: 1.43 (<0.0001)	VS11: -1.71 (0.0006); VS19: 1.10 (0.0001)	VS9: -1.14 (0.004); VS11: -1.57 (0.0122); VS22: 1.24 (0.0314)	VS19: -1.00 (0.0007)	VS7: -1.22 (0.033)	VS7: -1.43 (0.0226)
CSB	GS1: -1.05 (<0.0001); GS3: -1.10 (0.0068)	GS5: -1.23 (0.0003)	GS3: -1.30 (0.0028)	No	No	OS8: 1.33 (0.01)	OS8: 1.15 (0.0443)	GS5: -1.04 (0.0011)	OS2: 2.78 (0.0008); OS6: 1.78 (0.0262); OS14: 1.46 (0.0142)	OS5: 1.14 (0.0013)	No	No

Note: Values in the parenthesis are the p values (Rasch-Welch t-test) for the DIF contrast. AL = Activity limitation, CP = Coping, CRE = Corrected refractive error, CSB = Comfort symptoms – bothersome, CSF = Comfort symptoms – frequency, CSS = Comfort symptoms – severity, CV = Convenience, EC = Economic, EM = Emotional, GS = General symptoms, HC = Health concerns, MB = Mobility, MnSq = Mean square, OS = Ocular-comfort symptoms, RE = Refractive error, SC = Social, URE = Uncorrected refractive error, VA = Visual acuity, VS = Visual symptoms, VSB = Visual symptoms – bothersome, VSF = Visual symptoms – frequency, VSS = Visual symptoms – severity;

Groups(in the same order as in the table)**:** Gender: 1 = Male, 2 = Female; Rural or urban: 1 = Urban, 2 = Rural; VA category: 1 = VA better than 0.30, 2 = VA worse than 0.30; RE magnitude: 1 = Low, 2 = High + Moderate; Myopia or hyperopia: 1 = Myopia, 2 = Hyperopia; Astigmatism: 1 = No, 2 = Yes; Presbyopia: 1 = No, 2 = Yes; URE/CRE: 1 = CRE, 2 = URE; Spectacles: 1 = Yes, 2 = No; Contact lens: 1 = No, 2 = Yes; Refractive surgery: 1 = No, 2 = Yes; Surgical emmetropia: 1 = No, 2 = Yes.

Appendix K. Rasch parameters of the iterations after person-anchoring

Parameters*	Convenience	Health concerns	Economic	Activity limitation	Mobility	Emotional	Social
Disordered thresholds	No	No	No	No	No	No	No
No. of items (Ni) / No of persons (Np)	Ni = 64 / Np = 289	Ni = 39 / Np = 290	Ni = 14 / Np = 292	Ni = 71 / Np = 296	NI = 13 / Np = 212	23; Np = 215	Ni = 16 / Np = 209#
PSI (person reliability)	3.17 (0.91)	2.64 (0.87)	2.17 (0.82)	3.53 (0.93)	2.26 (0.84)	2.47 (0.86)	1.98 (0.80)
ISI (item reliability)	4.97 (0.96)	6.17(0.97)	6.35 (0.98)	7.05 (0.98)	8.13 (0.99)	5.32 (0.97)	5.13 (0.96)
PCA, variance by first factor	48.9%	42.3%	65.6%	47.9%	65.5%	52.2%	43.5%
PCA, eigen-value for first contrast (% unexplained variance)/ Disattenuated correlation between first and second item-clusters (r_d)	6.04 (4.8%) / r_d = 0.97	4.90 (7.3%)/ r_d = 0.93	4.09 (10.1%) / r_d = 1	8.4 (6.2%) / r_d = 1	2.48 (6.6%) / r_d = 1	3.18 (6.6%) / r_d = 1	3.45 (12.2%) / r_d = 1
PCA, % raw variance explained by items	14.3 %	12.2%	13.8%	16%	26.1%	9.7%	12.7%
Item infit (MnSq) > 1.5	0	0	0	3 (57: 1.79; 53: 1.67; 37: 1.60)	1 (3: 1.53)	0	0
Item outfit (MnSq) > 1.5	0	0	0	AL57 (1.62)	0	0	0
Measurement range (logits)	1.30 to -1.17	0.82 to -1.55	1.49 to -1.43	2.34 to -2.21	4.23 to -1.78	1.09 to -1.42	1.82 to -0.69
Targeting, difference between person & item means (logits)	0.96	1.21	2.80	2.48	5.14	2.73	2.92
Items with PCA standardised residual loadings > 0.40	6 items: 16, 44, 48, 10, 11, 63 (close to 0.40: 43, 51)	6 items: 21, 23, 19, 17, 22, 24 (close to 0.40: 15, 20)	6 items: 12, 13, 11, 15, 10, 4	10 items: 13, 11, 16, 5, 19, 10, 18, 20, 36, 32 (close to 0.4: 12, 33, 47, 35)	4 items: MB10, MB11, MB12, MB14	4 Items 27-30	4 items: (SC1-4)

Appendix K continued.

Parameters*	Visual symptoms – frequency	Comfort symptoms – frequency	Visual symptoms – severity	Comfort symptoms – severity	Visual symptoms – bothersome	Comfort symptoms – bothersome
Disordered thresholds	No	No	No	No	No	No
No. of items (Ni) / No of persons (Np)	Ni = 23/ Np = 277	Ni = 19/ Np = 298	Ni = 23/ Np = 270	Ni = 19 / Np = 294	Ni = 23/ Np = 260	Ni = 19/ Np = 294
PSI (person reliability)	1.81 (0.77)	2.09 (0.81)	1.80 (0.76)	2.03 (0.81)	1.88 (0.78)	2.04 (0.81)
ISI (item reliability)	6.90 (0.98)	7.89 (0.99)	6.59 (0.98)	7.55 (0.98)	6.76 (0.98)	7.32 (0.98)
PCA, variance by first factor	39.5%	42.6%	39.4%	42%	40.3%	42.2%
PCA, eigen-value for first contrast (% unexplained variance)/ Disattenuated correlation between first and second item-clusters (r_d)	3.12 (8.2%) / r_d = 1	2.83 (8.6%) / r_d = 1	2.69 (7.1%) / r_d = 1	2.73 (8.3%) / r_d = 1	2.81 (7.3%) / r_d = 1	2.74 (8.4%) / r_d = 1
PCA, % raw variance explained by items	14.8%	15.0%	13.8%	13.8%	14.1%	13.3%
Item infit (MnSq)	0	0	1 (5: 1.55)	0	0	0
Item outfit (MnSq)	0	0	0	0	0	0
Measurement range (logits)	1.65 to -2.70	1.21 to -2.0	1.72 to -2.53	1.11 to -1.73	1.69 to -2.48	1.16 to -1.75
Targeting, difference between person & item means (logits) [<1.0]	2.67	2.34	2.53	2.17	2.62	2.29
Items with PCA standardised residual loadings > 0.40	4 items: 1,2,8,3 (close to 0.4: 4 11)	5 GS items	3 items: 1, 2, 8 (close to 0.4: 3)	GS1, OS8	4 items: 1, 2, 8, 3	GS1-GS5

Note: Person-anchoring was done to avoid the influence of locally dependent items. ISI = Item separation index, MnSq = Mean square, PCA = Principal component analysis, PSI = Person separation index; # Participants with extreme responses were dropped/removed. *Ideal values for each item bank: PSI >2.0 (reliability >0.80); ISI >3.0 (reliability > 0.90); PCA, variance by first factor >50%; PCA, eigen-value for first contrast (% unexplained variance) < 3.0, (< 5.0%); Targeting <1.0 logits.

Appendix L. Demographic and clinical characteristics of Phase II (Australia) participants

General characteristics of the participants for Phase II (Australia), *N = 144**	
Gender *(N = 141)*	Female, 96; Male, 45
Median age (min, Q1, Q2, Max)	32 (18, 24, 44.5, 73) years
Country of Birth *(N = 139)*	Australia, 73; Nepal, 22; UK, 10; Other Asian countries, 10; USA, 7; China, 5; South Africa, 3; Sweden, 3; Other European countries, 2; Others, 2; Missing, 5
Language other than English *(N = 140)*	No, 78; Yes (25 languages), 62
Highest level of school *(N = 127)*	Year 12 or equivalent, 119; Lower than year 12, 8
Highest post-school education *(N = 127)*	Higher degree or postgraduate diploma, 48; Bachelor degree, 40; No post-school qualification, 20; Others, 19
Marital status *(N = 135)*	Never married, 58; Married, 53; De facto, 11; Divorced, 6; Separated but not divorced, 3; Widowed, 2
Overall rating of general health *(N = 138)*	Excellent, 42; Very good, 56; Good, 33; Fair, 3; Poor, 2
Median spherical equivalent refractive error (Min, Q1, Q3, Max)	-2.25 (-11.50, -4.25, -1.00, +10.00) Dioptres
Refractive error type *(N = 133)*[&]	Myopia, 98 (low: 47%, moderate: 19%, high: 14%); Hyperopia, 10 (low: 70%, moderate: 10%, high: 20%); Astigmatism, 43; Presbyopia, 38; Surgical emmetropia for distance, 20
Age at diagnosis [for distance refractive error only]	
Mean (SD)	13.72 (6.02) years
Median (Min, Q1, Q3, Max)	13 (1.5, 10, 16.75, 32) years
Frequency of spectacle wear *(N = 142)*	Never, 5; Used them in the past – not now, 19; Occasionally, 11; Quite often, 15; Very often, 86; Only for reading, 4
Frequency of contact lens wear (Soft/GP; spherical/toric; daily/ monthly/ yearly disposable; Multifocal; OrthoK) *(N = 142)*	Never, 62; Used them in the past – not now, 22; Occasionally, 31; Quite often, 3; Very often, 22; Missing, 2
History of refractive surgery *(N = 143)*	Yes, 23 (from 2004 to 2017 [LASIK, SMILE, T-PRK, PRK, Wavefront guided LASIK]); No, 118
Refractive correction for *(N = 120)*	Near use only, 10; For constant use, 108

Note: Better eye, i.e. the eye with lesser refractive error magnitude was considered for refractive error magnitude or type. *Due to missing data, the total no of participants for parameters is not always equal to 144. Actual number is mentioned in the parenthesis. [&]Grading of severity of myopia and hyperopia (spherical equivalent) in dioptres: Low, |0.50| to |3.00|; Moderate |3.25| to |6.00|; High > |6.00|.

The psychometric assessment of the Phase II (Australia) data was not performed at this stage as a need of more data was realized. Some refractive error sub-groups (e.g. hyperopia) have low sample size. One of the major reasons for the low sample size was the availability of limited resources. Collection and analysis of PRO data is a resource-intensive process.[157] More data will be collected post-PhD, with a focus on sub-groups which currently have lower sample size.