A randomised controlled trial evaluating the use of a self-management support intervention program to improve the quality of life in obese osteoarthritis patients awaiting hip or knee arthroplasty

by

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ABBREVIATIONS

%BF	percentage body fat
ABS	Australian Bureau of Statistics
ADP	air displacement plethysmography
AIHW	Australian Institute of Health and Welfare
APD	Accredited Practising Dietitians
ASMP	Arthritis Self-Management Program
BIS	bioimpedance spectroscopy (device)
BMI	body mass index
C&R	cue and response (interview)
CDSMP	(Stanford) Chronic Disease Self-Management Program
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials (guidelines)
COREQ	Consolidated Criteria for Reporting Qualitative Research (guidelines)
CT	computed tomography
DEXA	dual-energy X-ray absorptiometry
ECF	extracellular fluid
ECG	electrocardiogram
ESCAPE	Enabling Self-management and Coping with Arthritic Knee Pain through Exercise (program)
EULAR	League against Rheumatism
FFM	fat-free mass
FHBHRU	Flinders Human Behaviour and Health Research Unit
FM	fat mass
FP	Flinders Program
GI	glycaemic index
GP	general practitioner
HRQoL	health-related quality of life
ICD	implantable cardioverter defibrillator
ICF	intracellular fluid
ITT	intention-to-treat
IWQoL	impact of weight on quality of life
IWQoL-Lite	impact of weight on quality of life-lite
kHz	kilohertz
LCD	low-calorie diet
MAR	missing at random
MCS	mental component summary

MF-BIA	multiple-frequency bioelectrical impedance analysis
MFP	multi-frequency processed (file format)
MFU	multi-frequency unprocessed (file format)
MRI	magnetic resonance imaging
NHMRC	National Health and Medical Research Council
NJRR	National Joint Replacement Registry
NSAID	non-steroidal anti-inflammatory drug
OA	osteoarthritis
OAK	Osteoarthritis of the Knee (self-management program)
OAKHQoL	osteoarthritis of knee or hip quality of life
OARSI	Osteoarthritis Research Society International
P&G	problem and goals (assessment)
PCS	physical component summary
PIH	Partners in Health (scale)
PP	per protocol
QoL	quality of life
RACGP	Royal Australian College of General Practitioners
*r*ANOVA	univariate repeated measures analysis of variance
RCT	randomised controlled trial
RDNS	Royal District Nursing Service
RGH	Repatriation General Hospital
*r*MANOVA	multivariate repeated measures analysis of variance
SA	South Australia(n)
SAC HREC	Southern Adelaide Clinical Human Research Ethics Committee
SD	standard deviation
SE	standard error
Seg-BIA	segmental bioelectrical impedance analysis
SF-12	12-item Short-Form Health Survey
SF-36	36-item Short-Form Health Survey
SF-BIA	single-frequency bioelectrical impedance analysis
SMART	specific, measurable, action-oriented, realistic and timely
SMS	self-management support
SRT	self-regulation theory
TBW	total body water
TV	television
UK	United Kingdom
US/USA	United States/United States of America
VLCD	very-low-calorie diet

WC	waist circumference
WHO	World Health Organization
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
WHtR	waist-to-height ratio

SUMMARY

Osteoarthritis is a leading cause of disability and has a significant impact on health-related quality of life. The prevalence of hip or knee osteoarthritis continues to rise, due to an ageing population and the increasing prevalence of obesity. The treatment of choice for end-stage hip and knee osteoarthritis patients suffering extensive pain and deformity is arthroplasty or total joint replacement when other treatments have failed. Obesity is acknowledged as the most modifiable risk factor for both osteoarthritis and total hip or knee replacement.

The aim of this study was to introduce interventions that addressed the lifestyle and comorbidity problems faced by patients with obesity on a hip or knee joint replacement waiting list in order to improve their health-related quality of life prior to and following joint replacement surgery.

This study was a two-group randomised, parallel trial with obese osteoarthritis patients on a total hip or knee replacement waiting list at the Repatriation General Hospital in Adelaide, South Australia. The study sought to test the efficacy of a self-management support intervention program to improve health-related quality of life. A blocked randomisation method with stratification at gender and body mass index (BMI) groups was used to randomise eligible patients to either a control group receiving usual care or an intervention group receiving the telephone-delivered Flinders Program based self-management support program for six months.

Participants in the intervention group achieved a significantly greater improvement in the emotional role domain of SF36 than in the control group ($p = 0.009$), but not in other SF36 domains. For the second primary outcome OAKHQoL, the differences in improvements of physical activity, mental health, social activities and spouse relation scores across time were significant in favour of the intervention group ($p < 0.050$) and social support approaching significance ($p = 0.070$).

This study showed the Flinders Program based self-management support program helps obese osteoarthritis patients awaiting total hip or knee replacement mentally, socially and in some cases physically and is worth considering in clinics and hospitals.

DECLARATION

I, Ladan Sahafi, certify that this thesis does not incorporate without acknowledgement 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.

Signed..... .....

Date.....

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PUBLICATIONS

The following papers are based on the work described in this thesis:

Sahafi, L., Bramwell, D., Harris, M., Krishnan, J. & Battersby, M. 2015. A Practice-Focused Overview of Methods to Assess Obesity Before Arthroplasty. *Musculoskleletal Care,* 13**,** 258-263.

Sahafi, L., Smith, D., Georgiou, K., Krishnan, J. & Battersby, M. 2016. Efficacy of the Flinders chronic condition management program in obese patients with hip or knee osteoarthritis: A study rationale and protocol. *Australasian Medical Journal,* 9**,** 297–307.

PERSONAL BACKGROUND

After I finished my undergraduate degree in Computer Engineering, I worked on computer systems and programming for a few years. Then I completed a masters by research in Mechatronics at the University of Adelaide, when I got interested in research and teaching. This showed how important it was for me to work with people. After I finished my degree, I decided to do a PhD in a discipline that was more people-centred than engineering. Then, one day I heard from a friend who worked at the Orthopaedics department that there is a long waiting list for hip/knee replacement surgery patients and that obese patients are struggling. I got interested in the topic and that was the beginning of my PhD journey.

1. THESIS OVERVIEW

1.1 Background

Osteoarthritis is a leading cause of disability and has a significant impact on health-related quality of life (HRQoL). The prevalence of hip or knee osteoarthritis continues to rise, due to an ageing population and the increasing prevalence of obesity. The treatment of choice for end-stage hip and knee osteoarthritis patients suffering extensive pain and deformity is arthroplasty or total joint replacement when other treatments have failed. Obesity is also acknowledged as the most modifiable risk factor for both osteoarthritis and total hip or knee replacement. Studies evaluating the impact of obesity on HRQoL outcomes of total hip or knee replacements are limited and lack methodological rigour. The reasons include the diversity of obesity definitions, the focus on various classes of obesity and, more importantly, disregarding specific aspects of HRQoL. This study was designed with the intent of addressing the issues experienced by patients with obesity and osteoarthritis while on a waiting list for hip or knee replacement surgery.

Best practice for these patients comprises weight loss and incorporates an appropriate diet and exercise, such as muscle strengthening and aquatic exercises, accompanied with pain-coping skills and other self-management skills. The aim of this study was to introduce a program of such interventions tailored to the individual to achieve a positive impact on HRQoL prior to and following joint replacement surgery by controlling the chronic condition, improving the patients' lives and potentially assisting in their weight loss. Among the many different existing self-management programs, the Flinders Program provides a strong partnership between the patients and health care providers and, at the same time, it does not require ongoing attendance at the hospital. These aspects are fundamental for obese people with advanced hip or knee osteoarthritis, as they need support as well as learning skills to manage their unique debilitating condition, while most of them are restricted in terms of travelling. Given this, and due to the availability of this program at Flinders University in Adelaide, the Flinders Program was chosen as the framework for the

proposed intervention for this study. The Flinders Program is administered by a health care provider who has completed a 2-day training course: it is delivered in an individual format in one face-to-face session with follow-up phone calls on days and at times agreed between the patient and the health care provider.

1.2 Research aims

The main aim of this research is to investigate the effectiveness of a self-management support intervention program on health-related quality of life in obese individuals with osteoarthritis waiting for hip or knee replacement surgery. This study was designed as a two-group randomised, parallel trial with obese osteoarthritis patients on a total hip or knee replacement waiting list and registered at the Repatriation General Hospital in Adelaide, South Australia.

1.3 Structure of this thesis

This thesis outlines the study which was conducted in three phases:

- Phase 1: Literature review to justify a new study and form the intervention program;
- Phase 2: Randomised controlled trial (RCT) to investigate the intervention effects; and
- Phase 3: Qualitative interviews to explore participants' perceptions of the intervention program and provide information for improvement.

Chapter 2 provides a background on osteoarthritis and obesity, as well as a review of the literature on the impacts of obesity on the outcomes of total hip or knee replacement surgery and on obesity interventions, and identifies the gap in the research. A relevant self-management support intervention program is introduced in Chapter 3 where a literature review of self-management programs is conducted and various such programs are discussed. Chapter 4 then presents the methods of conducting the study and data analysis. Chapter 5 describes the findings of the randomised controlled trial (RCT) (Phase 2 of this study). Phase 3 is presented in Chapter 6 where the qualitative interviews and their findings are described and discussed. The thesis concludes with Chapter 7 where the findings of the study are discussed, the strengths and limitations of the study

are presented, and the final conclusions are drawn.

2. BACKGROUND AND LITERATURE REVIEW

2.1 Osteoarthritis

Osteoarthritis is characterised by the progressive degeneration of articular cartilage as well as changes in the underlying subchondral bone and synovial inflammation resulting in pain and stiffness (Sokolove and Lepus, 2013). This leads to significant disability and functional limitations, for example, in standing and walking (Mcdonough and Jette, 2010).

The increasing prevalence of osteoarthritis is well documented in epidemiological reports. For example, the osteoarthritis prevalence rose from 7.8% to 9.2% between 2004 and 2014 in Australia (AIHW, 2017, AIHW, 2018). Osteoarthritis places a large economic burden on health care systems and individuals. In 2012, the health care expenditure for osteoarthritis in Australia was $3.75B, half of this for joint replacements (Print, 2018).

Various risk factors are associated with the development and progression of osteoarthritis. These can be categorised into intrinsic risk factors such as age, genetic polymorphism, gender and hormonal status; and extrinsic risk factors such as joint injury, repetitive joint-loading activities, muscle weakness and obesity (Arden et al., 2014, Blagojevic et al., 2010, Clouet et al., 2009). Among the intrinsic risk factors of osteoarthritis, age plays a major role (Clouet et al., 2009, Nelson et al., 2014). In 2004, 26% of people aged between 65 and 74 suffered from osteoarthritis in Australia, while it involved 31% of people over 75 years of age (AIHW, 2018). The United Nations reported a rapid ageing of the world's population with the percentage of people older than 60 years of age estimated to be 22% (i.e. 2 billion) by 2050 (Shan et al., 2014). As life expectancy increases, the number of people living with osteoarthritis for long periods is expected to grow (Fernandes et al., 2013). After adjusting for age, the prevalence of osteoarthritis is greater in women than in men mostly due to the hormonal changes as a result of menopause (AIHW, 2017, Szoeke et al., 2006).

One of the most well-established extrinsic risk factors of osteoarthritis is obesity (Arden et al.,

2014, Clouet et al., 2009). The impacts of obesity on the development and progression of osteoarthritis include the excess load on weight-bearing joints and metabolic factors such as circulating adipocytokines, lipid abnormalities and chronic inflammation (Arden et al., 2014, Glyn-Jones et al., 2015). Obese individuals are more likely to develop osteoarthritis at a younger age compared to non-obese people with osteoarthritis (Dowsey and Choong, 2013, Odum et al., 2013). Being a modifiable risk factor, obesity is a key factor on which to focus in the preventative and symptomatic management of osteoarthritis.

2.2 Obesity – a risk factor

Obesity is defined by the World Health Organization (WHO) as excess body fat in terms of the body mass index (BMI), which was first introduced into population studies in 1835 by the Belgian polymath Adolphe Quetelet and is measured as $\text{weight(kg)}/[\text{height(m)}]^2$ (Bray, 2004). The WHO defines obesity as a BMI of 30 kg/m^2 and above. Two further subcategories of obesity are defined as severe obesity with a BMI of between 35 and 40 kg/m^2, and morbid obesity with a BMI of 40kg/m^2 and above (WHO, 2014).

Obesity is increasing in both developed and developing countries. According to the WHO, the worldwide figure in 2000 was 300 million obese adults (James, 2004). This figure grew to over 500 million by 2008 and then to over 900 million by 2014 (WHO, 2014). Australia is a part of this worldwide trend with an increase of obesity prevalence from about 7% in 1980 to 27.9% in 2014 (ABS, 2011, ABS, 2015).

Understanding the reasons for the rising prevalence in obesity requires an insight into the causes of obesity. The proximate cause of obesity is a long-term imbalance between energy intake and energy expenditure (Chandaria, 2014). Some hormones, such as leptin, have been found to have an effect on this balance (Chandaria, 2014). Leptin, when released by adipocytes, sends a signal of the adiposity amount to the brain which then regulates both energy intake by decreasing the appetite,

and energy expenditure by increasing adaptive thermogenesis (Chandaria, 2014).

Many other hormones are released by the stomach and pancreas, and are sensed by the brain in order to adjust the appetite and energy expenditure. Metabolic dysfunction, either due to an abnormal amount of these hormones or to their malfunction, disrupts energy homeostasis (Chandaria, 2014). Genetic factors are one of the underlying explanations for metabolic dysfunction. However, this does not explain the increasing trend of obesity, as the genes of populations do not change rapidly in a few decades. This trend appears to be associated with environmental changes, another potential underlying disruptor of metabolic function (Chandaria, 2014). The environmental changes that seem to account for the increasing obesity prevalence include the increased popularity of fast food consumption and its comparatively cheaper prices (Dunn, 2010), as well as the growing tendency towards an inactive lifestyle (Chandaria, 2014). Aside from environmental factors, some psychological factors, such as depression and anxiety, can alter specific hormones and neurotransmitters and result in obesity (Incledon et al., 2011). Conscientiousness, reflecting self-control, is also found to be consistently and robustly associated with obesity risk in general populations from the United States (US), the United Kingdom (UK), Germany and Australia (Jokela et al., 2012).

2.2.1 Health impacts of obesity

Obesity has been shown to increase the risk of many diseases, such as type 2 diabetes (Esser et al., 2014); sleep apnoea (Usmani et al., 2013); various cancers (Chen, 2011); cardiovascular disease (Apovian and Gokce, 2012); mental health problems (Sharma, 2012); and osteoarthritis (Lievense et al., 2002, Zheng and Chen, 2015). Two in three obese adults develop osteoarthritis in their lifetime (Wluka et al., 2013). Furthermore, obesity has an independent diminishing effect on quality of life (Withrow and Alter, 2011).

Health problems related to obesity impose a substantial financial burden on the health care system, individuals, families and communities. This includes direct costs, such as the costs of running

hospitals and nursing homes, general practitioners (GPs), specialist services, pharmaceuticals, research; and indirect costs, such as productivity losses or any decrease in economic activity. Withrow and Alter (2011) estimated that obesity accounts for 0.7% to 2.8% of the direct health care expenditure of a country. For morbidly obese individuals, these costs rise by up to twofold or threefold greater than for individuals of normal weight. In Australia, the direct financial cost of obesity in 2008 was estimated to be $8.283 billion. The overall cost (direct and indirect) of obesity to Australian society and the government was $58.2 billion in 2008 alone (Colagiuri et al., 2010). This figure was significantly lower at $21.0 billion in 2005 (Colagiuri et al., 2010).

As mentioned previously, obesity increases the risk of osteoarthritis and accelerates the progress of this disease. A positive association is found between obesity and both hip and knee osteoarthritis; however, the association between obesity and hip osteoarthritis is weaker than that with knee osteoarthritis (Bliddal et al., 2011, Holliday et al., 2011). A 5-unit increase in BMI has been shown to be associated with an 11% increased risk of hip osteoarthritis as compared to a 33% increased risk of knee osteoarthritis (Jiang et al., 2011). This positive association is explained by a variety of mechanisms including joint loading, malalignment, and meta-inflammation which are the metabolic and inflammatory factors associated with increased adiposity (Bliddal and Christensen, 2006, Clouet et al., 2009, Janssen and Mark, 2006, Wluka et al., 2013). The combined effect of these mechanisms can negatively influence the bone and cartilage function and subsequently accelerate the progress of osteoarthritis (Clouet et al., 2009, Vincent et al., 2012, Wluka et al., 2013).

One issue concerning obesity and osteoarthritis is that individuals with both conditions are likely to be trapped in a vicious cycle. Obesity increases the progress of osteoarthritis as well as joint loading but also results in diminishing exercise capability and, consequently, muscle strength reduction, which increases joint problems and pain, a barrier to physical activity. Reduced physical activities contribute to reducing energy expenditure and muscle mass and, hence, increasing obesity, and the cycle continues (Bliddal and Christensen, 2006, Wluka et al., 2013).

2.2.2 Measuring obesity – Is BMI the best tool?

Given the detrimental impact of obesity on people with osteoarthritis, it is important to find the most reliable method to measure obesity in our study. The BMI is almost the only index used for evaluating obesity in the literature on hip and knee osteoarthritis, whereas many other indices and instruments have been developed to assess obesity and body composition. Some of these are accepted and used in monitoring diseases such as cardiovascular disease (De Souza and De Oliveira, 2013, Lee et al., 2008, Sahafi et al., 2015). While BMI offers a viable approach for categorising individuals based on body mass and height, its use to indicate individuals' obesity has several limitations, including an inability to distinguish between fat mass and fat-free mass (Okorodudu et al., 2010, Sahafi et al., 2015, Wickel, 2013). This is important in evaluating obesity, as muscle mass can contribute substantially to a higher BMI in leaner individuals of the same height (Sahafi et al., 2015, Vasarhelyi and MacDonald, 2012). In osteoarthritis patients in particular, decreased muscle mass resulting from inactivity can reduce a patient's BMI without providing clinically relevant information (Bölgen Çimen et al., 2004, Sahafi et al., 2015).

Other measures and instruments are used to assess body composition and provide arthroplasty-relevant information about anatomical fat and its distribution. Given that the BMI fails to accurately determine body composition, it might be important to consider other approaches (Sahafi et al., 2015, Wang et al., 2009).

Some of these measures are inexpensive and simple methods for measuring obesity, but they are not particularly reliable as they do not provide body composition assessment. They are, however, useful for categorisation. This group comprises measures of body dimensions, such as height, weight and circumferences of the waist and hip, which are fed into standardised regression equations to calculate an index to quantify obesity (Ralston et al., 2012, Sahafi et al., 2015). These measures include the BMI and central obesity measures such as waist circumference (WC) or the waist-to-height ratio (WHtR). In terms of osteoarthritis risk, studies comparing WC and BMI show

conflicting results, with some researchers concluding that WC is a better indicator than BMI (Huxley et al., 2010, Sahafi et al., 2015). The waist-to-height ratio (WHtR), calculated as waist (cm)/height (cm), can be considered as WC corrected for height (Sahafi et al., 2015, Wakabayashi, 2013). Some studies suggest that the WHtR is a more sensitive index than BMI for body fat, and has the potential to rectify the misclassification of BMI (Browning et al., 2010, Kagawa et al., 2008, Sahafi et al., 2015). One of the advantages of the WHtR is the use of the same cut-off point for men and women (i.e. 0.5) (Browning et al., 2010, Ravensbergen et al., 2014, Sahafi et al., 2015).

The most reliable methods of body composition assessment include air displacement plethysmography (ADP), dual-energy X-ray absorptiometry (DEXA) and computed tomography (CT) scanning (Sahafi et al., 2015). In ADP, body volume is determined by measuring air displacement, allowing the percentage body fat to be calculated (McGuire and Ross, 2010). DEXA and CT scanning assess body composition by sending X-rays through the body and measuring the differential attenuation of the X-rays (Duren et al., 2008, Minocci et al., 2005). However, these methods are complex and costly (Sahafi et al., 2015).

Another group of obesity measures consists of relatively inexpensive and relatively reliable methods of body composition assessment. This group includes bioelectrical impedance analysis (BIA) methods (Sahafi et al., 2015). In BIA, small electrical currents are passed between electrodes which are connected from one leg to the other, or to the arm, in order to form a circuit and measure the voltage drop, determine impedance and, therefore, total body water. As the water content of different tissues varies, they have varying resistance, with fat tissue being a poor conductor of the current due to its low water content, and fat-free tissue, which has higher water content, being a good conductor (Beechy et al., 2012, Mialich et al., 2014, Sahafi et al., 2015). Multiple-frequency BIA (MF-BIA) and segmental BIA (Seg-BIA), which transmit currents at wide ranges of frequencies through various parts of the body, fall into this group. In these methods, the low frequencies measure extracellular water, while high frequencies measure intracellular water,

allowing total body water and fat-free mass to be determined (Brock et al., 2013, Mialich et al., 2014, Sahafi et al., 2015).

The exclusive use of a single instrument potentially generates biased results (Wakabayashi, 2013). Often a combination of some of these measures is used to provide the best method of determining individuals' obesity (Sahafi et al., 2015).

2.3 Treatments for osteoarthritis

Although currently no cure has been found for osteoarthritis, prescribed treatments can manage the disease (Arden et al., 2014, Zhang et al., 2008). Treatment of hip or knee osteoarthritis aims to reduce joint pain and stiffness, improve mobility of the joint and educate patients about the disease and its management (Zhang et al., 2008). Evidence-based treatments of hip or knee osteoarthritis are divided into three main categories, namely, non-pharmacological, pharmacological and surgical (Fernandes et al., 2013, Nelson et al., 2014). Guidelines recommend the hierarchy of management should consist of non-pharmacological approaches first, then pharmacological and then surgery, as can be seen in Figure 1 (Arden et al., 2014).

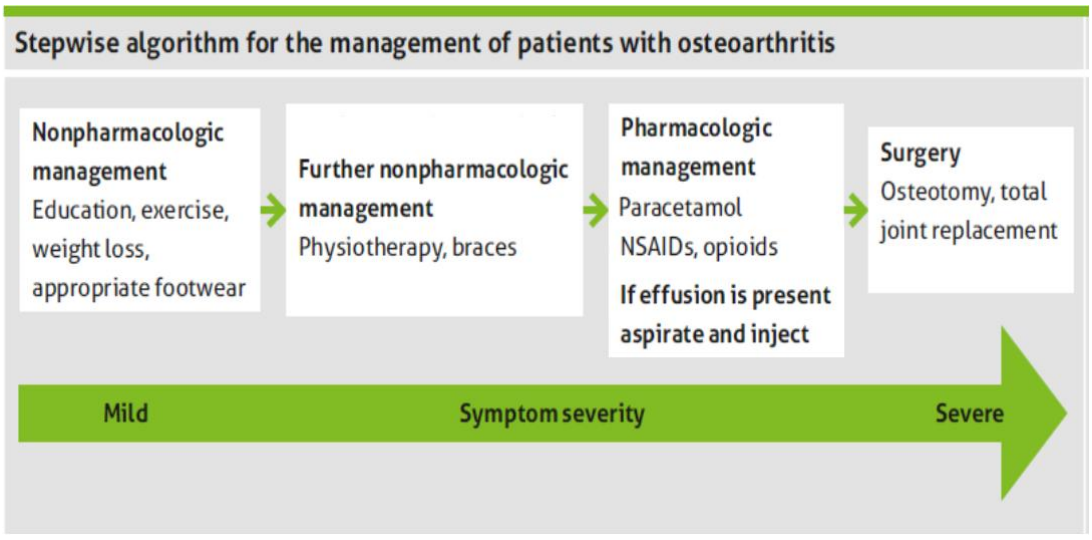


Figure 1: Stepwise algorithm for osteoarthritis management (Arden et al., 2014)

2.3.1 Non-pharmacological treatments

Evidence-based non-pharmacological modalities of osteoarthritis treatment include: referral to a

physiotherapist; encouragement to regularly undertake muscle strengthening and a range of motion exercises; use of assistive devices; thermotherapy; pacing through regular rests; weight reduction for those who are obese; education about the treatments and the importance of lifestyle changes; and last, but not least, self-management support (Bennell et al., 2012, Wallis and Taylor, 2011).

Guidelines such as EULAR (The European League Against Rheumatism), OARSI (OA Research Society International) and RACGP routinely advocate exercise for hip and knee osteoarthritis management (Fernandes et al., 2013, McAlindon et al., 2014, RACGP, 2018), especially given the deficits in muscle function present with osteoarthritis. Physical activities focusing on improving muscle strength and aerobic capacity play an important role in disease management (Gay et al., 2016). Aquatic exercise provides a better option for people with severe functional limitations (Bennell et al., 2012). While exercise is a core treatment for osteoarthritis management, adherence is difficult to maintain, with research indicating that lack of adherence hinders long-term effectiveness (Bennell et al., 2012, Jordan et al., 2010).

Most osteoarthritis guidelines advocate weight loss for obese individuals with hip or knee osteoarthritis (Fernandes et al., 2013, McAlindon et al., 2014). Weight loss in obese patients reduces the risk of symptomatic osteoarthritis progression (Messier et al., 2005), and improvements are evident through the use of morphological and physiological magnetic resonance imaging (MRI) and several biochemical markers (Glyn-Jones et al., 2015). Weight loss interventions specific for osteoarthritis patients including exercise interventions will be reviewed in section 2.6.2.

Osteoarthritis patients may benefit from participating in self-management support programs that offer information on the natural history of osteoarthritis and provide resources for social support and instructions on coping skills (Arden et al., 2014, Bennell et al., 2012). Self-management support programs are recommended by most treatment guidelines for osteoarthritis management (Nelson et al., 2014, Zhang et al., 2008), and are increasingly used in the management of chronic conditions (Coleman et al., 2010, McKnight et al., 2010). Many self-management support models

have been developed to enhance self-efficacy in participants and to assist them in managing a long-term condition (Coleman et al., 2012, Coleman et al., 2010).

Numerous studies have investigated the effectiveness of various self-management support programs in the disease management of osteoarthritis patients. Lorig and colleagues developed the Arthritis Self-Management Program (ASMP) at Stanford University (Lorig and Holman, 1993, Lorig et al., 1984), and showed that this program produced improvements in activity, stress, pain and fatigue management in arthritis patients (Lorig et al., 2005, Lorig et al., 1993). Kao et al. (2012) reported the positive impact of a self-management support program known as the Taipei Osteoarthritis Program (TOAP) on the psychological well-being of knee osteoarthritis patients. However, the positive impact of the utilised self-management support program on the physical and functional ability of patients was reported as low and slow (Kao et al., 2012, Wu et al., 2011). In another study, Coleman et al. (2012) assessed the osteoarthritis of the knee self-management program (OAK). They reported a statistically significant improvement in the pain, functional ability and QoL of knee osteoarthritis patients who participated in this program (Coleman et al., 2012). Kao et al. (2016) showed that a self-management intervention using self-regulation theory (SRT) improved knee pain, knee function and the QoL of people with knee osteoarthritis (Kao et al., 2016). McKnight et al. (2010) evaluated the effectiveness of a combination program of self-management and strength training on patients with early knee osteoarthritis. The program aimed at enhancing coping and self-efficacy skills, as well as muscle strengthening, balance and flexibility (McKnight et al., 2010). These authors reported a significant improvement in functional ability and pain reduction in participants (McKnight et al., 2010). Self-management support programs are further discussed in Chapter 3.

The Royal Australian College of General Practitioners (RACGP) provide information on the strength of evidence of these non-pharmacological treatments in patients with hip or knee osteoarthritis. Table 1 shows these grades where B indicates that ‘body of evidence can be trusted to

guide practice in most situations', and C indicates that 'body of evidence provides some support for recommendation but care should be taken in its application' (RACGP, 2009). According to this grading, body of evidence provides some support for recommendation of self-management programs but care should be taken in its application. This was confirmed in a more recent RACGP guidelines (RACGP, 2018).

Table 1: Non-pharmacological treatments and their strength of evidence

Non-pharmacological treatment	NHMRC Grade of recommendations
Land-based exercise	B
Aquatic exercise	C
Physiotherapy	C
Thermotherapy	C
Weight loss	B
Self-management programs	C

Abbreviations: NHMRC = National Health and Medical Research Council.

If non-pharmacological modalities do not provide sufficient relief, the use of pharmacological treatments is inevitable. In such a situation, the optimal management of osteoarthritis requires a combination of non-pharmacological and pharmacological modalities (Clouet et al., 2009, Zhang et al., 2008).

2.3.2 Pharmacological treatments

The pharmacological management of osteoarthritis recommended by the guidelines for hip and knee osteoarthritis, such as OARSI (Osteoarthritis Research Society International) and EULAR (League against Rheumatism), include simple analgesics such as paracetamol/acetaminophen for the treatment of mild to moderate pain and non-steroidal anti-inflammatory drugs (NSAIDs) including both traditional and specific COX-2 inhibitors, which are very effective in the treatment of pain and inflammation, but exhibit a range of adverse effects (Arden et al., 2014). Some of the guidelines recommend intra-articular therapies (corticosteroids, hyaluronic acid); however, a systematic review found that the pain relief from the use of these therapies greatly varies without known predicting factors (Hirsch et al., 2013). Given their high cost and potential adverse effects, the evidence to support their use is limited (Arden et al., 2014, Glyn-Jones et al., 2015).

As some people with hip or knee osteoarthritis also have depression and neuropathic pain symptoms (shooting or burning pain, pins and needles), the role of antidepressants including selective serotonin and noradrenaline (norepinephrine) reuptake inhibitors has been investigated. No systematic review has yet been done on the role of antidepressants for pain management in osteoarthritis, however, in an RCT of duloxetine versus a placebo, 65% of participants in the duloxetine group reported a pain reduction, compared with just 44% in the placebo group (Chappell et al., 2011). If the osteoarthritis cannot be managed by using a combination of pharmacological and non-pharmacological, surgical treatments are considered.

2.3.3 Surgical treatments

Surgical treatments are mostly considered the ultimate procedure when other treatments have failed to produce a satisfactory outcome for the patient. The three surgical procedures comprise arthroscopy, osteotomy and arthroplasty (Arden et al., 2014, Clouet et al., 2009, Glyn-Jones et al., 2015, Zhang et al., 2008).

Arthroscopy is a surgical procedure in which an arthroscope is inserted into the joint allowing for lavage, a procedure that removes particulate material such as cartilage fragments and calcium crystals. It also allows for debridement, by which articular surfaces can be smoothed. The goal of this procedure is to reduce synovitis and eliminate mechanical interference with joint motion (Kirkley et al., 2008). Systematic reviews show that arthroscopy is not effective in the treatment of knee and hip osteoarthritis (Barlow et al., 2015, Kemp et al., 2014, Piuzzi et al., 2016, Thorlund et al., 2015).

Another surgical treatment is osteotomy which involves the removal of a wedge of bone near the affected joint in order to realign the joint and redistribute the load to healthy cartilage and, hence, to reduce the mechanical stress on the damaged part of the joint (Clouet et al., 2009). The success of this treatment relies on the joint axis location (Clouet et al., 2009). Osteotomy is mostly performed in young adults with early osteoarthritis and may delay its progress and the need for more serious

surgical treatments for up to 10 years (Chahla et al., 2016). Therefore, osteotomy may not be a treatment option for people with advanced osteoarthritis.

Finally, arthroplasty or total joint replacement is reserved for the most advanced stage of osteoarthritis, or for patients with persistent moderate to severe pain and functional limitation despite receiving a combination of non-pharmacological and pharmacological treatments. Arthroplasty involves replacing the bony parts of the joint with artificial components, known as a prosthesis (Arden et al., 2014, Clouet et al., 2009, Zhang et al., 2008). Arthroplasties for hip and knee are routinely and successfully performed, have been shown to be more effective than other surgical modalities, and are known to be the most substantial advancement in osteoarthritis treatment in the past century (Skou et al., 2015).

2.4 Arthroplasty (or total joint replacement)

This thesis will test an intervention for obese osteoarthritis patients awaiting hip/knee arthroplasty; hence, this section will focus on arthroplasty, its outcomes and risk factors. Arthroplasty or total joint replacement for hip and knee is the most practical treatment for end-stage hip and knee osteoarthritis patients suffering extensive pain and deformity when other treatments have failed. Osteoarthritis is also the most common reason for total hip and knee replacements (Ethgen et al., 2004, Felson et al., 2000, Wood et al., 2013).

In Australia, the National Joint Replacement Registry (NJRR) records information about joint replacements performed every year. The number of hip and knee replacements has been substantially increasing each year (Dowsey and Choong, 2008, Dowsey and Choong, 2013). In Australia in 2004, 31,875 knee replacements and 30,167 hip replacements (i.e. 62,042 hip or knee replacements in total) were performed, with 41,108 (or 66%) of these operations performed on people with osteoarthritis (NJRR, 2007). In 2016, 400,331 total hip replacements and 547,407 total knee replacements were performed in Australia. This shows that since 2003, primary total knee replacement has increased by 139.8%, and the number of hip replacement procedures undertaken

has increased by 94.4% (NJRR, 2017). Total joint replacement in younger patients is also on the rise especially for the knee, and this may be partly due to the increase of obesity (Dowsey and Choong, 2013). The summary of these figures is presented in Table 2.

Table 2: Summary of hip/knee Arthroplasty in Australia

	Number of Knee arthroplasty	Number of Hip arthroplasty
In 2004	31,875	30,167
In 2016	547,407	400,331

2.4.1 Outcomes and risk factors

Outcomes

The outcomes of total joint replacement are commonly assessed in the categories of functional ability, pain, complications and health-related quality of life (HRQoL) (Vissers et al., 2012). Functional outcomes represent physical functioning capabilities, such as walking time without support; stair climbing; ability to put on socks and shoes; sitting and rising; range of motion; and pain (Busato et al., 2008, Dowsey and Choong, 2013, Vincent et al., 2012). However, as pain is the most disturbing problem for people with osteoarthritis, to the extent where it impairs their daily activities, it is commonly further assessed separately (Dowsey and Choong, 2013). Complications include infection (both superficial and deep), nerve injury, revision due to dislocation, loosening, fracture, etc. (Huddleston et al., 2012, Kerkhoffs et al., 2012, Springer et al., 2013). Health-related quality of life (HRQoL) represents domains directly related to the health of a person, and HRQoL outcomes describe the person's physical functioning, and mental and psychological health as well as their social status and role functioning (Jones and Pohar, 2012, Shan et al., 2014). Health-related quality of life outcomes are the focus of this thesis and are therefore discussed further in section 2.4.2.

Risk factors

These outcomes of total joint replacement are influenced by several factors which can be categorised as modifiable and non-modifiable risk factors. Age, gender and socio-economic status

fall into non-modifiable risk factors. Modifiable risk factors include psychological state, comorbidity and obesity (Guh et al., 2009, Kerkhoffs et al., 2012, Santaguida et al., 2008).

2.4.1.1 Non-modifiable risk factors

Age

Many studies have shown that age is associated with higher risks of complications after a total hip or knee replacement as a result of physiological changes related to ageing itself, such as deterioration of the immune system, decreased ability to tolerate the trauma of surgery, and vascular deterioration (Easterlin et al., 2013). However, age is not a barrier to pain reduction, functional improvements and satisfaction (Santaguida et al., 2008). Singh and Lewallen (2009) reported better pain outcomes from a total hip or knee replacement in older individuals compared with younger patients which may be due to higher pain tolerance and lower expectations.

Gender

Female gender is associated with higher pain and more functional limitations. This is due to women commonly seeking joint replacement at a later stage than men, by which time, their status in terms of pain and functional impairment is worse than that of men (Dowsey and Choong, 2013, Singh and Lewallen, 2009).

Socio-economic status

Various socio-economic status indicators, such as education level, household income and living arrangements, may have an influence on the outcomes of a total hip or knee replacement. An association has been reported between lower levels of education and higher incidence of obesity (Vulcano et al., 2013). There are conflicting reports of poorer outcomes in socio-economically disadvantaged groups, especially for total hip replacement (Dowsey and Choong, 2013, Vulcano et al., 2013).

2.4.1.2 Modifiable risk factors

Psychological state

Psychological distress, including depression, anxiety and poor coping, is associated with poorer outcomes for both pain and functional ability after a total hip or knee replacement (Dowsey et al., 2011, Singh and Lewallen, 2009). In a systematic review by Vissers et al. (2012), it was shown that mental health, psychological distress and pain catastrophising (a tendency to focus excessively on pain sensations) affect post-operative outcomes of total hip or knee replacements. However, only a few studies have investigated the effect of psychological distress separately. These authors also reported conflicting evidence of the influence of depression and low self-efficacy on the outcomes of total hip or knee replacements (Vissers et al., 2012). Other psychological factors such as poor self-esteem are also associated with poorer outcomes after a total hip or knee replacement (Dowsey and Choong, 2013).

Comorbidity

Patients undergoing total joint replacements commonly have multiple comorbidities, such as diabetes, and cardiovascular and respiratory disease (Dowsey and Choong, 2013). A recent systematic review showed that patients with comorbid conditions are more likely to have a readmission after a joint replacement, but there is little evidence that patients benefit significantly less from a joint replacement in terms of health-related quality of life, function and pain compared with patients with no comorbidities (Podmore et al., 2018).

Obesity and its impact on a total hip or knee replacement

Obesity is associated with a higher rate of complications, including infection and revision, after a total hip or knee replacement. This association has been found significantly stronger in the case of morbid obesity (Amin et al., 2006, Chee et al., 2010, Huddleston et al., 2012, Kerkhoffs et al., 2012, Krushell and Fingeroth, 2007, Springer et al., 2013, Vasarhelyi and MacDonald, 2012, Waters, 2014). However, conflicting evidence is found regarding revision rates. Yeung et al. (2011) showed no significant differences between non-obese and obese patients in revision rates at 11 years. Similar results were presented by McLaughlin and Lee (2006) for total hip replacement patients at

10–18 years post-operation. Furthermore, Napier et al. (2014) has shown no significantly higher rates of complications between morbidly obese patients and obese or non-obese patients up to one year after a total hip replacement.

In addition, other studies have reported poorer outcomes for pain and functional ability for obese patients after a total hip or knee replacement when compared to the outcomes for non-obese patients (Lübbeke et al., 2007, Singh and Lewallen, 2010). However, some studies have shown some pain relief and functional improvements for obese patients (Dowsey and Choong, 2013).

Michalka et al. (2012) reported similar short-term pain and functional improvement outcomes of a primary total hip replacement for obese and non-obese patients, but worse outcomes for morbidly obese patients. However, Andrew et al. (2008) showed no significant difference in changes in functional outcomes of a total hip replacement between morbidly obese patients compared to obese and non-obese patients. Judge et al. (2012) indicated that obesity was not a predictor of the difference in functional outcomes of a total knee replacement. In another study on total hip or knee replacements, Yeung et al. (2011) showed that obese patients had better outcomes for pain relief than for functional ability including range of motion. They reported the reduced range of motion in the obese to be mostly due to the existence of fat tissue in extreme positions rather than the physical ability of the patient (Yeung et al., 2011). This may represent an improvement from a surgical point of view. However, it shows that obese patients continue to have functional limitations.

Conversely, Singh and Lewallen (2009) reported that obese patients experienced more pain and functional limitations compared to non-obese patients at both two and five years after a revision total hip replacement. This was more significant in the case of morbidly obese patients (Singh and Lewallen, 2009). Many other studies also reported poorer functional outcomes for obese patients after a total hip replacement (Busato et al., 2008, Dowsey and Choong, 2013, Dowsey et al., 2010, Le Duff et al., 2007, Lübbeke et al., 2010, Naylor et al., 2008, Vincent et al., 2012). Vulcano et al. (2013) showed an association between the increasing scale of obesity and poorer functional

outcomes after a total knee replacement. Amin et al. (2006) reported worse pain outcomes after a total knee replacement for morbidly obese patients compared to those of non-obese patients. Dowsey and Choong (2013) also reported poorer outcomes for pain and functional ability for obese patients after a total knee replacement; however, they reported no link between the increasing scale of obesity and outcome deterioration (Dowsey and Choong, 2013). It can be said that a total knee replacement in morbidly obese patients can have the benefits of pain reduction and functional improvements; however, these benefits are less in obese patients than in those who are non-obese (Krushell and Fingeroth, 2007).

The disagreement in the literature as to the impact of obesity on the outcomes of a total hip or knee replacement (Dowsey and Choong, 2013, Wood et al., 2013) may be partly due to the differences in their emphasis on various scales of obesity, namely, morbid obesity ($BMI \geq 40$), severe obesity ($35 \leq BMI < 40$) or obesity in general ($30 < BMI \leq 35$). Another explanation for this disagreement could be related to the quality of these studies such as not being completely randomised and inadequate blinding. Despite this finding, the consistent recommendation is that it is beneficial for obese patients to lose weight before total hip or knee replacement surgery (Wood et al., 2013).

In their study, Dowsey et al. (2011) compared the costs of a primary total joint replacement between non-obese and obese patients in Australia. They evaluated inpatient costs for both the index total knee replacement and the entire episode of post-surgery care up to 12 months, excluding rehabilitation costs. They found that inpatient costs were significantly higher for obese patients compared to non-obese patients regardless of the length of stay in hospital. This was most likely due to the higher rates for complications and readmissions among obese patients (Dowsey et al., 2011). In 2014, a larger study was conducted by Kremers et al. (2014) to examine the effect of obesity on direct medical costs in total knee arthroplasty in the US, and found that obesity was associated with significantly longer hospital stays and costs. More specifically, they found that

every 5-unit increase in body mass index beyond 30 kg/m²was associated with approximately US$250 to US$300 higher hospitalisation costs in primary total knee arthroplasty (Kremers et al., 2014).

The higher risk of complications and the lower benefits for morbidly obese patients (Singh and Lewallen, 2009, Waters, 2014) deter some orthopaedic surgeons from operating for a total hip or knee replacement on morbidly obese patients (Amin et al., 2006). Moreover, surgical procedures in obese patients tend to take longer (Napier et al., 2014), and are more likely to be inflicted by the additional challenges of component malposition and prosthesis loosening and dislocation (AAHKS, 2013, Lui et al., 2015). Many researchers believe that obese patients should be informed of the risks and the possibility of poor outcomes and be advised to lose weight prior to a total hip or knee replacement, as well as maintaining the weight reduction (Amin et al., 2006, Krushell and Fingeroth, 2007, Waters, 2014).

The last category of total hip or knee replacement outcomes is health-related quality of life (HRQoL). To study the impact of obesity on this group of outcomes, they need to be discussed further in the following section, due to their intangible definition.

2.4.2 Health-related quality of life (HRQoL)

The use of quality of life (QoL) as an outcome measure in medical research originated in 1966: since then, ever-increasing criticism has been that QoL is neglected by modern medicine in comparison to technical matters (Katschnig et al., 2009). During the last few decades, QoL instruments have been developed for many diseases. Nonetheless, QoL is still not sufficiently represented in clinical practices: furthermore, it has no clear and widely accepted definition (Katschnig et al., 2009).

Overall, health-related quality of life (HRQoL) is one aspect of QoL that focuses on the QoL dimensions directly associated with the health of an individual. As health encompasses various

facets ranging from physical to mental and social, HRQoL likewise is a multidimensional concept. Hence, HRQoL describes physical and mental health as well as psychological well-being and social and role functioning (Fontaine and Barofsky, 2001, Jones and Pohar, 2012, Katschnig et al., 2009, Shan et al., 2014).

The assessment of HRQoL in chronic diseases, such as osteoarthritis, is necessary to measure the broad health-related impacts of the disease and the costs and benefits of the treatment provided. Information on HRQoL can then be used to improve the management of the disease and the related policy making (Jones and Pohar, 2012, Shan et al., 2014). The two basic forms of HRQoL assessment are generic and disease-specific (Jones and Pohar, 2012, Shan et al., 2014).

The generic HRQoL instruments attempt to measure its broad aspects and to provide a generalised HRQoL assessment (Fontaine and Barofsky, 2001, Jones and Pohar, 2012). The main advantage of these instruments is that they can provide HRQoL comparisons across a wide scope of medical conditions. Furthermore, they are applicable to different populations (Fontaine and Barofsky, 2001, Jones and Pohar, 2012). On the other hand, as a result of having a broad scope, the responsiveness of generic instruments may be inadequate when subtle changes occur in specific areas relevant to the specific chronic condition (Fontaine and Barofsky, 2001, Jones and Pohar, 2012).

Many generic HRQoL instruments have been developed, the most well-known of which is the 36-item Short-Form Health Survey (or SF-36) (Ware and Sherbourne, 1992). The SF-36 instrument measures HRQoL in eight domains of physical functioning: role limitations due to physical problems; bodily pain; general health perception; vitality; social limitations owing to emotional problems; role limitations due to emotional problems; and mental health. The first four domains generate the physical component summary (PCS) and the last four domains produce the mental component summary (MCS); therefore, SF-36 quantifies the overall HRQoL into two physical and mental component summary scores (Beechy et al., 2012, Fontaine and Barofsky, 2001, Jones and Pohar, 2012). Being a generic instrument, SF-36 may overlook changes within specific domains

(Beechy et al., 2012, Jones and Pohar, 2012). For example, the SF-36 assessment of obese individuals does not measure the impact of obesity on important domains such as self-esteem or sex life, which can be significant issues for obese individuals, and thus may overlook lowered resultant mental and social functionalities (Beechy et al., 2012, Fontaine and Barofsky, 2001). The 12-item Short-Form Health Survey (SF-12) is essentially an abridged variant of SF-36 that, in a concise way, generates physical and mental component summary scores similar to those of SF-36 (Jones and Pohar, 2012).

Another category of HRQoL instruments are specifically designed for a disease (e.g. osteoarthritis) or a population (e.g. elderly or obese) (Fontaine and Barofsky, 2001). These instruments focus on dimensions that are more relevant to the specific disease or population and, therefore, are more sensitive to changes in the areas of interest. However, these instruments are less compelling at drawing comparisons between various populations (Fontaine and Barofsky, 2001, Jones and Pohar, 2012).

The most widely used disease-specific instrument for hip or knee osteoarthritis is the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). This disease-specific instrument was developed in the early 1980s to measure patient-reported health status and concentrates on activities with which people with osteoarthritis might struggle (McConnell et al., 2001). In 1988, WOMAC was validated by Bellamy et al. (1988) for measuring patient-relevant outcomes after a total hip or knee replacement: since then, it has been widely used to measure pain and functional outcomes as well as HRQoL outcomes of total hip or knee replacements. This instrument quantifies the three domains of pain, stiffness and physical function which are the main technical problems of individuals with osteoarthritis undergoing a total hip or knee replacement (McConnell et al., 2001). WOMAC measures pain and functionality without taking other HRQoL domains, such as social and mental domains, into account (Rat et al., 2005, Sahafi et al., 2016).

Another disease-specific HRQoL instrument for hip or knee osteoarthritis was developed in 2004

and is being increasingly used. The osteoarthritis of knee or hip quality of life (OAKHQoL) instrument measures HRQoL in the five domains of physical activity, mental health, pain, social support and social functioning (Rat et al., 2005). This instrument is a 43-item scale which comprises common problems for osteoarthritis patients, in which each item is rated on a 1-10 Likert scale. The OAKHQoL has been validated in previous studies (Goetz et al., 2011, Rat et al., 2008), and has also been adapted and validated in various countries and languages (Duruöz et al., 2013, Gonzalez Sáenz de Tejada et al., 2011, Serhier et al., 2012). A summary of these instruments is presented in Table 3Table 3.

Table 3: Summary of HRQoL instruments

Generic instruments		**Disease-specific instrument**	
SF-36	Physical component summary score consisting of • Physical functioning • role limitations due to physical problems; • bodily pain; • general health perception; and mental component summary score consisting of • vitality; • social limitations owing to emotional problems; • role limitations due to emotional problems; • mental health	OAKHQoL	Measures five domains of • physical activity, • mental health, • pain, • social support • social functioning
SF-12	Same domains as SF-36 but fewer questions.	WOMAC	Measures domains of • pain, • stiffness, • physical function

Other instruments specific to the obese population have been developed in order to measure the influences of obesity on health-related quality of life (HRQoL). A common example is known as the 'impact of weight on quality of life' (IWQoL) and, more commonly, its abridged version (IWQoL-Lite) (Beechy et al., 2012). The latter, IWQoL-Lite, evaluates the impacts of weight on QoL in dimensions of physical function, self-esteem, sexual life, public distress and work (Beechy et al., 2012).

In addition to the above-mentioned measures, numerous generic and disease-specific instruments are available. All in all, the consensus indicates a tendency towards using a combination of generic and disease-specific instruments to thoroughly assess HRQoL (Fontaine and Barofsky, 2001). For

example, numerous studies use a combination of SF-36 and WOMAC to evaluate the HRQoL outcomes of total hip or knee replacements for people with osteoarthritis (Núñez et al., 2009, Salmon et al., 2001). Nonetheless, most medical researchers are inclined to acknowledge one aspect of HRQoL while neglecting its other aspects (Katschnig et al., 2009). In arthroplasty research, the tendency in HRQoL assessment for total hip or knee replacement patients is to concentrate on physical dimensions such as pain and function, and to disregard social functioning and psychological and mental states. These dimensions are extremely important, as people with osteoarthritis tend to become affected socially and mentally due to their limitation of movement (Katschnig et al., 2009). Moreover, the HRQoL of a person is likely to be favourable in one area and unsatisfactory in others; thus, in order to comprehensively assess HRQoL, all domains of HRQoL must be evenly acknowledged (Katschnig et al., 2009). A combination of instruments is used in this thesis to measure HRQoL (Section 4.9.1). This thesis investigates HRQoL in hip or knee osteoarthritis patients, and since obesity is a modifiable risk factor, its impacts on HRQoL need to be reviewed.

2.4.3 Impacts of obesity on HRQoL outcomes of arthroplasty

In their systematic review, Samson et al. (2010) found that obesity has a negative impact in physical function improvements after knee arthroplasty, but there are no systematic reviews of trials investigating impacts of obesity on HRQoL as a whole. Nuñez et al. (2007) used WOMAC in their study, to evaluate the HRQoL in patients with osteoarthritis at the 36-month follow-up after a total knee replacement and reported a significant HRQoL improvement for severely obese patients. However, this was only regarding the pain aspect of HRQoL outcomes. In a later study, Nuñez et al. (2011) reported lower, but not significantly lower, HRQoL changes at 12 months after a total knee replacement for severely and morbidly obese patients, in comparison to the outcomes for non-obese patients. As WOMAC was the only instrument used in these two studies, the mental and social aspects of HRQoL were not evaluated. Kauppila et al. (2009) reported a lower level of improvement

in all aspects of HRQoL after a total knee replacement for obese patients as compared to that experienced by non-obese patients. The study utilised the conventional cut-off for BMI, as defined by the WHO (BMI of 30 kg/m²) to categorise the patients, while WOMAC was the HRQoL instrument used. In a study based on a combination of SF-36 and WOMAC, Baker et al. (2013) reported similar improvements in HRQoL functional outcomes after a total knee replacement for patients with a normal weight and those in different classes of obesity. These authors showed that severely obese patients achieved lower improvements in the physical components of HRQoL, in comparison to non-obese patients, up to one-year post-operation. However, from one to three years' post-operation, severely obese patients had a lower drop in the physical component score (Baker et al., 2013).

Many other studies have evaluated the impacts of obesity on HRQoL in patients with hip osteoarthritis. Stevens et al. (2012) reported an association between obesity and lower levels of improvement in the HRQoL functional outcomes for a total hip replacement. However, they considered this association less strong than that of comorbidities and total hip replacement outcomes, with WOMAC the instrument used in this study. In a review, Vincent et al. (2012) showed that the physical component of HRQoL is lower in obese patients after a total hip replacement. Zhang et al. (2012) used SF-36 to compare the HRQoL between patients of normal weight and obese patients after a total hip replacement and found that obese patients achieved greater improvements in both mental and physical components than patients of normal weight. However, the obese patients were categorised as those with a BMI value of 28 kg/m² or above. In their retrospective study, Foster et al. (2015) found both obese and non-obese patients achieved significant improvements in HRQoL measured by EQ-5D after total hip replacement, but not morbidly obese patients (Foster et al., 2015).

Studies evaluating the impact of obesity on the HRQoL outcomes of patients having total hip or knee replacements are limited and lack methodological rigour. The reasons include the diversity of

obesity definitions, focusing on various classes of obesity and, more importantly, disregarding specific HRQoL aspects.

On the other hand, given the higher risk of complications and lower level of functional improvements after a hip or knee replacement for obese patients, it may be valuable to postpone the operations and pursue weight loss programs (Vasarhelyi and MacDonald, 2012). Although obese patients should not be denied surgery purely based on their obesity, they should be given information about the associated risks, and be advised to lose weight.

2.5 Obesity interventions (weight loss programs)

Lui et al. (2015) conducted a review of studies that evaluated the effect of weight loss interventions on obese patients prior to hip or knee arthroplasty. They found two retrospective studies and reported insufficient evidence to support the recommendation of weight loss for obese patients within the year prior to a total hip or knee replacement (Inacio et al., 2014, Lui et al., 2015). However, it is important to note that no information was provided in these studies on how weight loss was achieved (Inacio et al., 2014, Lui et al., 2015), leaving the possibility of the weight loss's unintended consequences (e.g. malnutrition) possibly being associated with poor outcomes after the operation. However, a pilot study in 2014 showed that a structured dietitian-led weight loss intervention in obese patients undergoing a total hip or knee replacement can result in improvement in physical health scores at 12 months' post-operation (Simmance et al., 2014).

As weight loss is recommended to obese osteoarthritis patients in order to achieve better outcomes, various types of obesity interventions (i.e. weight loss programs) are reviewed in this section. Given the epidemic growth of obesity and its impacts on health, many studies have been conducted on the topic of obesity intervention or weight loss. Non-surgical non-pharmacological obesity interventions, in general, can be categorised into dietary programs, physical activity and behaviour management, or a combination thereof (Mullin et al., 2014).

2.5.1 Dietary programs

The human body can be considered a system which performs based upon food intake and energy expenditure. Hence, among other reasons for obesity, one seems to be the imbalance between these two. This makes diet a cornerstone of weight management programs (Lang and Sivarajan, 2006). Several types of dietary interventions have been investigated including low-fat diets (Dyson, 2008); low-carbohydrate diets (Klimcakova et al., 2010); very-low-calorie diets (VLCDs) (Hart et al., 2015); low-glycaemic-index (GI) diets (Mirza et al., 2013); Mediterranean diets (Mancini et al., 2016). However, it should be noted that merely modifying the macronutrient content of the diet to achieve weight loss is complex (Mullin et al., 2014). The carbohydrate content of the diet could be chosen in several ways, for instance, based on the glycaemic index (GI), on the fibre content or on complex versus refined, each of which has a different effect on blood sugar and hormonal levels (Mullin et al., 2014). The same applies to fats, which can be categorised as monounsaturated, polyunsaturated, saturated fats and trans fats, with each affecting the body differently (Mullin et al., 2014). The guiding point in deciding on the diet is that, as the percentage of the macronutrient intake of either carbohydrate, fat or protein is reduced in the diet, the percentage of the other two will increase (Mullin et al., 2014).

2.5.1.1 Low-fat diets

Low-fat diets have been the backbone of weight loss programs for decades, widely being used in RCTs and commercial dietary programs (Dyson, 2008, Mullin et al., 2014). In a systematic review, Tobias et al. (2015) showed that evidence does not support low-fat diets over other dietary interventions. Low-fat diets are designed to reduce the daily fats intake from 30% to 10%–15% of total calories (Dyson, 2008, Hite et al., 2011). In some programs, this results in increased carbohydrate and protein intake to make up the required calories, in which case the weight loss program may not be effective (Hite et al., 2011). One misinterpretation of the low-fat diets used in commercial products is that some people assume they can eat any amount of the food as long as it is

low fat (Mullin et al., 2014).

2.5.1.2 Low-carbohydrate diets

Low-carbohydrate diets are not a new dietary concept. In 1852, Jean Brillat-Savarin offered such a diet that restricted everything containing flour (Hite et al., 2011). Today, a low-carbohydrate diet limits daily carbohydrate intake to 30–130 g/day or 800–1500 kcal/day (Hite et al., 2011, Klimcakova et al., 2010, Lang and Sivarajan, 2006). The foundation for choosing to limit carbohydrates is that lower glucose availability results in energy being derived from dietary fat, protein and body fat stores (Mullin et al., 2014).

Ongoing debate has been continuing between advocates of low-fat diets and those in favour of low-carbohydrate diets (Apovian, 2015). Although low-fat diets have been conventionally popular and are still the standard routine of many commercial weight loss programs, a 2009 systematic review and more recent studies have shown that low-carbohydrate diets are associated with greater weight loss compared to that achieved with low-fat diets (Hession et al., 2009, Hu et al., 2016). This may be due to fat being replaced by carbohydrates in low-fat diets to compensate for the required calories which, in turn, increases blood sugar and body fat.

2.5.1.3 Very-low-calorie diets

Very-low-calorie diets (VLCDs) typically provide < 30 g/day of carbohydrate or < 800 kcal/day or ~3300 kJ per day (Dyson, 2008, Hite et al., 2011, Klimcakova et al., 2010). Very-low-calorie diets (VLCDs) are often in the form of liquid meal replacements: compared to low-calorie diets (LCDs), VLCDs show greater loss of weight in the short term but similar weight loss over the long term (Dyson, 2008, Hart et al., 2015). In a recent systematic review, Andela et al. (2019) showed that VLCDs are effective for weight loss among children and adolescents (Andela et al., 2019). In another study, González-Pérez et al. (2013) investigated a very-low-calorie diet with home ingredients on morbidly obese patients and found it effective in weight loss.

2.5.1.4 Low-GI diets

The glycaemic index (GI) was first developed to assist individuals with diabetes to manage their carbohydrate intake relative to their insulin requirements (Ludwig, 2007, Mullin et al., 2014). Low GI diets focus on carbohydrate quality rather than quantity with the aim of controlling the rise of blood glucose after food consumption (Mirza et al., 2013). The GI is a ranking of carbohydrates that measures the rate at which blood glucose levels rise and drop after food ingestion. Typically, foods are rated high (> 70), moderate (56–69) or low (< 55) GI (Mullin et al., 2014).

Low GI diets contain carbohydrates that are digested and absorbed more slowly, and are therefore more satisfying as they give the feeling of satiety for longer (Dyson, 2008, Mirza et al., 2013, Zafar et al., 2019). High GI foods cause a sequence of hormonal events that temporarily challenge glucose homoeostasis. Shortly after the intake of high GI food, the blood insulin level rises and, within 60 minutes, blood glucose drops below the fasting level. This, in turn, stimulates the feeling of hunger and can result in overeating (Ludwig, 2007, Zafar et al., 2019). Ebbeling et al. (2007) showed that the low-GI diet contributed to a greater weight loss in adults than the low-fat diet. However, the GI has been the subject of criticism by some, as the GI load of carbohydrates tends to change when paired with other foods (Mullin et al., 2014). In a recent systematic review, Zafar et al. (2019) showed that low GI diets are moderately effective in weight loss, but efforts should be made to increase compliance with low GI diets in people with overweight and obesity (Zafar et al., 2019).

2.5.1.5 Mediterranean diets

The Mediterranean diet emerged from various Mediterranean countries long ago, but it was only in the late twentieth century that the health benefits of this diet and the low mortality rates in countries around the north shore of the Mediterranean came to broader attention (Gerber and Hoffman, 2015). The Mediterranean diet is characterised by high intakes of olive oil, fruit and vegetables; moderate consumption of poultry, fish and dairy; and a low amount of red meat (Dyson, 2008, Gerber and Hoffman, 2015, Mancini et al., 2016).

Shai et al. (2008) compared 2-year dietary interventions of a low-fat diet, a low-carbohydrate diet and a Mediterranean diet, and found that the Mediterranean and low-carbohydrate diets were effective alternatives to the low-fat diet for weight loss. They also showed that a low-carbohydrate, non-restricted-calorie diet is optimal for obese individuals who will not follow a restricted-calorie dietary regimen (Shai et al., 2008). An RCT in Spain showed that an unrestricted-calorie Mediterranean diet containing healthy vegetable fats, such as olive oil and nuts, is effective in weight management and that, in order to lose weight, the overall food intake needs to be reduced (Estruch et al., 2016). A recent systematic review has shown that Mediterranean diets are superior to low-fat diets for long-term weight loss (Mancini et al., 2016).

In general, adherence to the program seems to be more important than the macronutrient composition of diets for weight loss (Hu et al., 2016, Johnston et al., 2014, Pagoto and Appelhans, 2013). The most effective dietary program is a diet that is individually planned in alignment with personal food preferences, and therefore achieves greater adherence in the long term (Hu et al., 2016, McVay et al., 2014, Pagoto and Appelhans, 2013). However, the centrepiece of dietary therapy should be slow but progressive weight loss. Generally, rapid weight reduction impedes the diet's long-term adoption in eating behaviour, which is a key element to successful long-term weight maintenance (Lang and Sivarajan, 2006). However, in a randomised controlled trial in Melbourne, Australia, Purcell et al. (2014) showed that with a weight maintenance diet, the rate of weight loss did not affect the rate of weight regain in obese individuals.

A summary of diets and their features are presented in Table 4.

Table 4: Diet types and their features

Diet Types	**Specific features**
Low-fat diets	Reducing daily fat intake from 30% to 10%–15% of total calories
Low-carbohydrate diets	Limiting daily carbohydrate intake to 30–130 g/day or 800–1500 kcal/day
Very-low-calorie diets	Limiting daily food intake to < 800 kcal/day or ~3300 kJ per day
Low-GI diets	Limiting carbohydrate intake to low (< 55) GI carbohydrates that are digested and absorbed more slowly such as wholegrains
Mediterranean diets	high intake of olive oil, fruit and vegetables; moderate consumption of poultry, fish and dairy; and a low amount of red meat

2.5.2 Physical activity

Given that creating a negative energy balance is essential to losing weight, enhancing energy expenditure through increasing physical activities as part of weight loss programs seems obvious (Lang and Sivarajan, 2006, Mullin et al., 2014). Some of these programs encourage participants to accomplish increased physical activity both as structured exercises, such as swimming or aerobic exercises, and lifestyle physical activities, such as using stairs instead of lifts or avoiding the use of a car for short distances (Lang and Sivarajan, 2006, Mullin et al., 2014). Some programs prescribe time-based physical activity (Delany et al., 2014, Jakicic et al., 2015); however, these programs might not achieve a weight loss in the case of low adherence to the program (Delany et al., 2014).

Resistance training increases muscle mass which helps to increase daily energy expenditure and reduce fat mass, although changes in overall body mass may be minimal, due to the higher weight of muscle mass compared to fat mass (Mullin et al., 2014). In their study, Ho et al. (2012) showed that a structured program combining aerobic and resistance training modalities results in greater success in fat loss in obese individuals.

While physical activity appears to improve the rates of weight loss, increasing energy expenditure while keeping energy intake constant has been shown to have only a modest effect (Dyson, 2008, Lang and Sivarajan, 2006, Mullin et al., 2014). No global recommendations are available on the amount of time per day that obese adults need to commit to physical activity in order to lose weight; however, the current guidelines recommend personalised physical activity combined with dietary advice (Mabire, 2016). For obese sedentary individuals, it may be better to start slowly with physical activity, such as walking, and then gradually increase the intensity of activity (Lang and Sivarajan, 2006, Loew et al., 2012).

2.5.3 Behaviour management approaches

Given that a combined program of exercise and dietary modalities offers more successful weight loss than each of these modalities individually (Foster-Schubert et al., 2012), some weight loss

programs apply a behaviour management approach. As weight loss is recommended to obese osteoarthritis patients, behaviour management as part of weight loss is reviewed in this section. Behavioural weight loss programs aim to help individuals to change their behaviour and habits, such as eating habits and exercise behaviour that are learned components and can be re-learned (Jakicic et al., 2015, Lang and Sivarajan, 2006, Mullin et al., 2014). Changing one's lifestyle requires changes in the environmental cues and reinforcers that control one's behaviours (Lang and Sivarajan, 2006). This is typically achieved by helping individuals to set realistic weight loss goals, and by training them to monitor their eating habits and exercise behaviours, and informing them of the consequences thereof (Mullin et al., 2014). Various strategies can be employed for behaviour management with there being no single best method (Lang and Sivarajan, 2006).

Self-monitoring

Self-monitoring is a foundation skill in behaviour management programs that helps with accomplishing dietary and exercise programs (Burke et al., 2011b). Planning dietary intake and exercise programs in advance and then recording the dietary and exercise behaviours can be very effective (Lang and Sivarajan, 2006). The records allow individuals to track their progress toward their goal and to assess the effectiveness of their behaviour (Mullin et al., 2014, Peterson et al., 2014), while also helping health care professionals to assess progress and to make specific suggestions for additional problem solving (Lang and Sivarajan, 2006). Some behaviour management programs encourage participants to also record the thoughts and circumstances that surround the behaviour (Burke et al., 2011b, Yu et al., 2015).

In a systematic review, Burke et al. (2011a) found that self-monitoring had a positive effect on successful weight management but several factors including consistency, frequency and detail of self-monitoring can affect its effectiveness (Yu et al., 2015). Krukowski et al. (2013) showed the importance of consistency in self-monitoring and its influence on clinically notable weight loss in a 6-month behaviour management program. In their recent study, Peterson et al. (2014) found that

obese participants who performed self-monitoring both regularly and consistently achieved weight loss and maintained their weight changes more effectively compared to those who failed to self-monitor as often or as consistently.

As is the case in any other weight loss program, lack of adherence is a significant barrier to self-monitoring (Yu et al., 2015). Several studies have found that the adherence to self-monitoring decreases from the fourth week of the program (Greaney et al., 2012, Krukowski et al., 2013). Greaney et al. (2012) showed that a reminder is beneficial for promoting adherence to self-monitoring. In another study, Webber et al. (2010) showed that autonomous motivation (i.e. personal and internal reasons for change) enhances adherence to self-monitoring and weight loss.

Stimulus control

Changing patterns of behaviour is a difficult task, particularly when the environment draws the individual to established habits. Stimulus control techniques are an effective tool for reducing the impact of the environment. Eating signals in the environment are abundant and often outside an individual's conscious awareness (Sobal and Wansink, 2007). It is helpful to identify stimuli and high-risk situations that may encourage incidental eating. Controlling strategies include shopping selectively for healthy food; keeping high-calorie foods out of the house; limiting and planning the times and places of eating; and consciously avoiding situations in which overeating occurs (Lang and Sivarajan, 2006).

Cognitive restructuring

Cognitive factors play a key role in the success of weight loss programs (Mullin et al., 2014). In behaviour management programs, participants are encouraged to modify negative thoughts, unrealistic goals and inaccurate beliefs about weight loss, while focusing on the positive side of their new lifestyle and preparing in advance for relapses (Lang and Sivarajan, 2006). Mindfulness may help with tolerating the discomforts associated with weight loss, allowing individuals to

continue the tasks toward the goal (Olson and Emery, 2015).

Social support

Social support is considered to be a key factor in successful behavioural weight loss (Kiernan et al., 2012). A strong and positive system of social support can facilitate weight reduction. Family members, friends or colleagues can assist in maintaining motivation and providing positive reinforcement (Lang and Sivarajan, 2006). However, given that other people can have both positive and negative effects on weight loss efforts, behaviour management programs should offer strategies to accept the support and manage the sabotage from outside (Kiernan et al., 2012). Gorin et al. (2008) indicated that, in addition to participants in weight loss programs, their spouses also lose weight, naming it a 'ripple effect' for health benefits within a family.

Alternative interventions

Foster and Gore (2006) reviewed the literature that evaluated whether reducing the amount of time spent watching television (TV) is an effective behavioural intervention for obesity treatment among adults. Several cross-sectional studies that examined the relationship between TV viewing time and obesity showed a positive relationship between the two. Strategies to alter TV viewing habits have been demonstrated as effective among children but have not been tested on adults (Foster and Gore, 2006).

A combination of these behaviour management techniques could be used in a weight loss program; however, the choice of these techniques depends on an initial assessment of the behavioural and psychological factors affecting the individual's weight. The initial assessment should also consider potential triggers for overeating such as incidental snacking or so-called tempting foods at home, dining out or poor sleep (Mullin et al., 2014).

2.5.4 Weight loss intervention specific for osteoarthritis patients

Current guidelines universally recommend weight loss for reducing the symptoms of hip and knee

osteoarthritis in obese people (Brosseau et al., 2014, Fernandes et al., 2013, Lui et al., 2015, Zhang et al., 2008). In a systematic review, Christensen et al. (2007) have shown that a loss of 10% of body weight results in moderate to large clinical effect according to self-reported disability in knee osteoarthritis patients. In a recent study in Australia, Atukorala et al. (2016) found a dose-response relationship between weight loss and improvement in pain and function in obese and overweight people with knee osteoarthritis. They showed that a weight loss of at least 7.7% was required for a minimum clinically important improvement, while for those with lower levels of function at baseline, it required a weight loss of 10% (Atukorala et al., 2016).

Bliddal et al. (2011) conducted an RCT in Denmark to evaluate the effectiveness of a 52-week low-energy diet in overweight and obese knee osteoarthritis patients, and found a significant weight loss and improvement in pain and function (Bliddal et al., 2011). In a recent RCT, Christensen et al. (2017) compared the effect of intermittent low-energy diet with daily meal replacements on weight loss maintenance after an original 10% weight loss in knee osteoarthritis patients, and showed both groups resulted in weight loss maintenance for 3 years. They found no indications of harmful effects either from weight cycling or the more steady weight loss (Christensen et al., 2017). There are no published RCTs to confirm comparable benefits from weight loss in patients with hip osteoarthritis.

Although weight loss is recommended, Henriksen et al. (2012) showed in a prospective cohort study that weight loss through diet alone was accompanied by loss of some muscle tissue and strength, even though the weight loss significantly reduced the level of disability in obese people with knee osteoarthritis. Muscle mass loss remains a major obstacle for people with osteoarthritis; accordingly, combining diet and exercise can assist weight loss while slowing the loss of muscle mass (Chomentowski et al., 2009). In their systematic review, Quintrec et al. (2014) highlighted that recommendations on exercise for knee osteoarthritis patients also apply to older patients (i.e. those 70–80 years of age).

Diet and exercise were discussed in the previous section as the main weight loss approaches. Messier et al. (2004) conducted an RCT in the US to compare the effects of exercise only, diet only, exercise and diet, and usual care. They found that the combination of diet and exercise was the most effective weight loss program in overweight and obese knee osteoarthritis patients (Messier et al., 2004). In a recent systematic review, Hall et al. (2019) found that combined diet and exercise programs are more likely to reduce pain and improve physical function in overweight and obese people with knee osteoarthritis than diet or exercise alone (Hall et al., 2019). However, some types of exercise could lead to low compliance with exercise programs owing to pain (Bliddal and Christensen, 2006). Both aerobic walking and home-based muscle strengthening exercises are suitable for people with knee osteoarthritis, with no difference between their effectiveness (Bliddal et al., 2014, Loew et al., 2012, Roddy et al., 2005). Aquatic and land-based exercises showed similar effectiveness for pain and function in knee osteoarthritis patients (Wang et al., 2011). Aquatic exercises may have small effects on pain and function in hip osteoarthritis patients (Bartels et al., 2016). The pain-relieving effects of hot water immediately after each exercise session and the next day make aquatic exercises more appealing to advanced osteoarthritis patients who are waiting for hip or knee replacement surgery (Gill et al., 2004). Fransen et al. (2007), in an RCT, supported the beneficial influence of both hydrotherapy and Tai Chi sessions on people with advanced hip or knee osteoarthritis. Partial immersion alleviates the pain stemming from movements by decreasing the muscular work required for exercise (Fransen et al., 2007), and reduces the risk of falls for individuals with unstable balance (Hale et al., 2012), making aquatic exercises a good alternative for those who cannot tolerate land-based exercises.

Most obese people with hip or knee osteoarthritis believe that one of the major barriers to weight loss is pain which leads to their low mobility (Howarth et al., 2010). However, Inacio et al. (2013) conducted a systematic review on whether these patients lose weight after a total hip or knee replacement once they regain their mobility, and found no evidence of weight loss for this cohort of

patients after surgery. This finding has been supported by other studies (Dowsey et al., 2010, Vasarhelyi and MacDonald, 2012, Waters, 2014). Howarth et al. (2010) conducted a study to investigate the barriers to weight loss in obese people with knee osteoarthritis, and found that the lack of motivation was a greater barrier than knee pain to achieving weight loss. This, and the importance of adhering to a weight loss program combined with exercise emphasises the role of self-management.

2.6 Chapter summary

Osteoarthritis is a leading cause of disability and has a significant impact on health-related quality of life (HRQoL). The prevalence of hip or knee osteoarthritis continues to rise, due to an ageing population and the increasing prevalence of obesity, with obesity acknowledged as the most modifiable risk factor for both osteoarthritis and total hip or knee replacement. Weight loss, incorporating an appropriate diet and exercise, such as muscle strengthening and aquatic exercises, and accompanied with pain-coping and other self-management skills, is an important approach for obese people with advanced hip or knee osteoarthritis prior to joint replacement surgery. Therefore, a well-developed self-management support program may help obese osteoarthritis patients improve HRQoL by controlling the chronic condition, improving their lives and potentially assisting in their weight loss (Sahafi et al., 2016).

3. SELF-MANAGEMENT SUPPORT PROGRAMS

The literature review, presented in the previous chapter, has highlighted that the best approach to help obese people with advanced hip or knee osteoarthritis to lose weight before joint replacement surgery and gain better outcomes from the operation is a self-management support program that focuses on relevant lifestyle modifications. This chapter explores the evidence for the effectiveness of various self-management support programs and their applicability to obese people with advanced hip or knee osteoarthritis, so as to inform a practical and suitable intervention program.

Although a previous systematic review has suggested that self-management programs offer modest benefits for people with osteoarthritis (Kroone et al., 2014), these findings were tentative due to mostly low quality studies, for example, a lack of transparency in reporting randomisation methods or the concealment of allocation (Sahafi et al., 2016).

3.1 Self-management support programs

One of the first uses of the term 'self-management' appeared in an article by Thomas Creer on the rehabilitation of children with chronic asthma (Creer et al., 1976), with the term used to indicate that the patient is an active participant in the treatment (Lorig and Holman, 2003). Self-management is now established with its meaning understood to be the day-to-day tasks an individual must undertake in order to control the impact of a chronic disease on their lives, and the knowledge and skills they must have to cope with the psychosocial problems resulting from that chronic disease (Barlow et al., 2002, Kao et al., 2016, Nolte et al., 2013).

3.1.1 What is a self-management support program?

Self-management support (SMS) includes both formal and informal actions by health care providers as well as family and carers to assist the patient with self-management (Wagner et al., 2001). Since the 1980s, a wide range of self-management support initiatives have been developed, including care and action plans; health coaching; self-help groups; and disease-specific and generic self-

management education programs for both individuals and groups (Williams et al., 2013). Self-management support (SMS) programs generally aim to increase the active role of the person with a chronic condition in monitoring their health, making decisions about care, or both (Battersby et al., 2010b, Sahafi et al., 2016), and therefore are distinct from mere patient education or skills training alone (Kroone et al., 2014). SMS programs are complex behavioural interventions targeted at patient education and behaviour modification (Kroone et al., 2014).

Behavioural modification is very complex, with the Stages of Change Model developed by Prochaska et al. (2008) suggesting that behavioural modification can be achieved through the following stages:

1. Pre-contemplation (not thinking of change or not believing in one's ability or capacity for change)
2. Contemplation (thinking of change)
3. Determination (taking preliminary steps to change)
4. Action (actively engaging in behavioural change)
5. Maintenance (sustaining behavioural change)
6. Relapse (can occur at any point).

In general, SMS programs can result in behavioural changes in people with chronic conditions by going through these stages.

Social learning theory, or social cognitive theory, developed by Albert Bandura in the 1970s, describes how human beings acquire information purely by observing other individuals (Bandura, 1977). The key principles of this theory can be applied to chronic condition self-management as disease management skills can be learnt, behaviour is self-directed and support can be received from the social environment.

Lorig and Holman (2003), in describing three sets of tasks through which self-management is achieved, identified the first set as involving the medical management of the condition, such as taking medication or adhering to a special diet. The second set of tasks comprises adopting and maintaining new relevant behaviours and, finally, the third set deals with the emotional consequences generated by the chronic condition. Emotions commonly experienced by individuals with a chronic condition include anger, fear, frustration and depression; therefore, learning to manage these emotions becomes an important part of self-management (Lorig and Holman, 2003).

Furthermore, support is an essential aspect of SMS programs. This addition makes self-management the product of a partnership between the patient, their family and health care providers (Battersby et al., 2010b). A partnership and collaborative management occur when the patient and care providers have shared goals, an ongoing working relationship, mutual understanding of roles and responsibilities, and the necessary skills for performing their roles (Von Korff et al., 1997).

The disease itself and other factors, such as patients' personal attributes and social and cultural factors, can influence the capacity of patients to self-manage. As self-management is focused on the patient's concerns (Lorig and Holman, 2003), an initial assessment including determining the ability to self-manage therefore needs to be performed as the first step (Lawn and Schoo, 2010, Lorig and Holman, 2003).

Battersby et al. (2010b) developed evidence-based principles for self-management within the framework of Wagner's Chronic Care Model (Wagner et al., 2001) and Lorig's extensive work on self-management (Battersby et al., 2010b, Lorig and Holman, 1993), with this summarised as follows.

- In order to guide self-management support, it is essential to undertake an initial assessment of the condition's severity, the patient's problems and goals, their self-management competency and the barriers they face with regard to self-management.

- Mere information is insufficient to improve patient outcomes. Shared decision making between the patient and the health care provider determines the appropriate educational interventions for the patient.

- Using a non-judgemental approach while providing evidence-based information improves the effectiveness of SMS (Battersby et al., 2010b). Patients need to feel listened to and acknowledged; therefore, health professionals need the skills to promote an understanding from the patient's perspective (Lawn and Schoo, 2010).

- The collaborative identification of problems, priorities, goals and plans is fundamental to a successful SMS program.

- SMS delivery could be either by health professionals or by laypersons provided tasks and roles are clearly defined and they are trained to use evidence-based interventions.

- Enhancing the patient's self-efficacy regarding chronic disease management tasks improves the process and outcomes of SMS programs (Battersby et al., 2010b, Lorig and Holman, 2003). Bandura (1977) defines self-efficacy as confidence in one's ability to perform a specific behaviour or to change a specific cognition.

- Ongoing follow-up including feedback and reminders helps to sustain self-management behaviours and improves patient outcomes (Battersby et al., 2010b).

Based on these principles, chronic condition self-management support programs comprise the following: having knowledge of the condition and its management; adopting a self-management care plan agreed to and negotiated in partnership with health professionals, significant others, carers and other supporters; actively sharing in decision making with them; monitoring and managing signs and symptoms of the condition; managing the physical, emotional, occupational and social effects of the disease; adopting a lifestyle that addresses risk factors; and having access to, and

confidence in the ability to use support services (Battersby et al., 2010b, Lawn and Schoo, 2010).

3.1.2 Self-management skills

Lorig and Holman (2003) list the core self-management skills as problem solving, decision making, resource utilisation, forming a patient/health care provider partnership and taking action.

Problem solving is a fundamental self-management skill which individuals with a chronic condition are taught how to use in a self-management support program (Battersby et al., 2010b, Lorig and Holman, 2003). Problem solving includes problem definition, brainstorming possible solutions with family, friends and health care professionals, implementing the solution and evaluation of the results (Lorig and Holman, 2003). Problem solving helps to achieve the successful adoption of new behaviours and to overcome barriers to change (Battersby et al., 2010b). In the process of living with a chronic condition as well as adopting a new lifestyle, decision-making skills are required, for example, in situations such as when choosing to take analgesics in case of pain and when to stop exercising (Lorig and Holman, 2003).

Although patients receive information about their chronic condition and its treatments, those with a chronic condition have an ongoing need for information. Knowing how to find and utilise resources is a skill that should be taught in a self-management support program (Lorig and Holman, 2003).

Although taking action may seem more like a decision than a skill, to take action, skills are needed, the most important of which is making a short-term action plan. An action plan involves a period of one or two weeks and is very behaviour-specific, as it breaks the goal into numerous realistic tasks that the person is confident in accomplishing (Lorig and Holman, 2003).

3.1.3 Barriers to improved self-management

Obstacles to individuals effectively self-managing their condition arise from internal factors relevant to the person and their situation and/or external factors relevant to the person's environment. Barriers may include literacy standards, disability, financial resources, comorbidity,

low self-efficacy, motivation, incapacity to access support and services, and non-supportive family and friend(s) (Bratzke et al., 2015). Barriers for health professionals include reluctance to share decision making with patients, low knowledge and confidence in providing self-management practice, and perceived limits on time (Bayliss et al., 2007, Coventry et al., 2014).

Self-management support programs need to consider these barriers and make provisions to reduce their influence.

3.1.4 Motivational interviewing

One aspect of improving program adherence requires health professionals to acknowledge both differences in the patients' focus on problems and their support system. Different patients are at diverse stages of change and, therefore, individualised programs should correspond to their readiness to change (Lawn and Schoo, 2010). Within this framework, motivational interviewing is a directive counselling method to assist patients to move from one stage of change to the next, specifically from pre-contemplation to contemplation and from contemplation to action by enhancing their intrinsic motivation to change (Lawn and Schoo, 2010, Schoo, 2008) and promoting changes in their lifestyle behaviours (Armstrong et al., 2011, Pignataro and Huddleston, 2015).

During the interview, uncertainty is explored and resolved within an atmosphere of acceptance and compassion (Lawn and Schoo, 2010). The most fundamental attribute of motivational interviewing is its non-judgemental and collaborative nature (Battersby et al., 2010b). Other principles of motivational interviewing include expressing empathy, developing an understanding of discrepancy, avoiding argumentation and supporting self-efficacy. Motivational interviewing requires the building of trust and reflective listening (Lawn and Schoo, 2010).

In a systematic review, Armstrong et al. (2011) found that motivational interviewing has an impact on achieving weight loss: it has also been shown to be effective in chronic disease management

(Linden et al., 2010, Pignataro and Huddleston, 2015). In another systematic review and meta-analysis, O'Halloran et al. (2014) showed that motivational interviewing has a small positive effect (a small effect size) on physical activity in obese individuals. Their subgroup analysis revealed small to moderate positive effects for people who were overweight, obese or who had hypertension or hypercholesterolemia, cardiovascular conditions or multiple sclerosis (O'Halloran et al., 2014). It has been established that two factors determine people's motivation to change: the importance of change; and self-efficacy, or the confidence, in one's ability to change. As change is difficult, in order to increase patients' readiness for change, they must believe that their current behaviour is leading to negative consequences and that they are able to change. This can be done through motivational interviewing in which health professionals understand and acknowledge that people with complex life decisions tend to hesitate and resist change, and then help them to resolve these uncertainties (Zuckoff, 2012).

3.1.5 Types of self-management support programs

SMS programs come in various types. Disease-specific programs provide organised learning experiences that assist with adopting new relevant behaviours for one particular condition and are usually delivered by health professionals. These programs have been criticised with regard to their application for people dealing with multiple morbidities (Battersby et al., 2010a, Sahafi et al., 2016).

Lay-led group programs aim to improve participants' confidence in managing both their chronic condition, in partnership with health professionals, and their lives (Battersby et al., 2010a, Sahafi et al., 2016). These programs are delivered by laypersons with the same chronic conditions and who are trained to deliver the program. These programs can be used for all chronic conditions (Battersby et al., 2010a). A previous Cochrane review involved 17 medium quality randomised controlled trials investigating lay-led self-management programs in individuals with chronic conditions including arthritis, diabetes, hypertension and chronic pain. Their findings indicated that while the

interventions may lead to small short-term improvements in outcomes such as self-efficacy, no evidence was found of the effect of these programs on symptoms or on participants' quality of life (QoL) (Foster et al., 2007).

Generic self-management support programs take a more holistic approach to managing the overall general well-being of the individual with a chronic condition (or conditions) (Lawn and Schoo, 2010).

The ways in which self-management support programs are delivered are very diverse, such as: the mode (face-to-face, Internet, telephone, self-instruction manual); the audience (group, individual); the length (one session, several months, ongoing); the frequency (weekly, monthly, etc.); the format (booklets, lectures, role plays, sharing experiences, motivational interviewing); the setting (clinics, clients' homes); and the provider (health care professionals, lay leaders with chronic conditions trained to deliver the intervention) (Barlow et al., 2002, Battersby et al., 2010b, Kroone et al., 2014, Lawn and Schoo, 2010).

3.2 Stanford Program

One widely recognised generic chronic disease self-management support program is the Stanford Chronic Disease Self-Management Program (CDSMP). The Stanford CDSMP was developed by Lorig et al. (1999) with three underlying assumptions: (1) that people with different chronic diseases have similar self-management problems; (2) that patients can learn to take responsibility for the day-to-day management of their disease; and (3) that confident, knowledgeable patients performing self-management will gain improved health.

The Stanford CDSMP is a community-based program consisting of a face-to-face small groups (10–15 participants), with 2.5-hour weekly sessions over a 6-week period delivered by two trained lay leaders (Lorig et al., 1999, Ritter et al., 2011, Williams et al., 2013). The range of topics include: exercise; symptom management techniques; diet; fatigue and pain management; community

resources; use of medications; dealing with fear, anger and depression; communication with health care providers; problem-solving skills; and decision-making skills (Ritter et al., 2011, Williams et al., 2013).

In an RCT with 952 participants 40 years of age or older with a physician-confirmed diagnosis of arthritis, stroke, heart disease or lung disease, the Stanford CDSMP was found to be associated with moderate and statistically significant improvements in health behaviours and health status, and to decrease hospitalisation compared to participants in the control group at six months. These results were maintained for up to two years (Lorig et al., 1999).

The effectiveness of the Stanford CDSMP has been challenged for overstating the evidence for effectiveness, with concerns about participation rates and perceived bias in the types of people who join, for example, those who are already competent at self-management (Battersby, 2006, Newbould et al., 2006). Its greatest criticism is that the program does not reach the most disadvantaged people who have the greatest need for self-management skills. However, this may be associated with selection bias in recruiting.

3.3 Flinders Program

Battersby and colleagues developed the Flinders Chronic Condition Management Program (Flinders Program) from the South Australian (SA) HealthPlus coordinated care trial, with this incorporating both self-management principles and tasks as established by Gruman, Von Korff and Lorig (Battersby, 2005, Battersby et al., 2007, Battersby et al., 2010b). The Flinders Program is a generic self-management support program and uses a semi-structured framework to enable health workers and patients to collaboratively assess self-management behaviours, identify problems, set goals and develop individual care plans (Battersby et al., 2010b).

The program is supported by seven evidence-based self-management principles comprising: knowledge about the condition and its treatment; adopting an agreed self-management care plan

negotiated in partnership with health professionals, significant others and other supporters; actively sharing in decision making with them; symptom management; managing the physical, emotional and social impacts of the condition; adopting a lifestyle that addresses risk factors; and having access to support services (Battersby et al., 2010b).

The Flinders Program is administered by a health care provider who has completed a 2-day training course (Lawn and Schoo, 2010), and is delivered in an individual format in one face-to-face session and follow-up phone calls on days and times agreed between the patient and the health care provider. During the Flinders Program's initial face-to-face session, the participant fills out the self-rated Partners in Health (PIH) scale. This scale is a short precise tool comprising 12 self-rated items to reflect the participant's self-management knowledge, attitudes, behaviour and the impacts of their chronic condition (Battersby et al., 2010b).

The health care provider then conducts a motivational interview (named a 'cue and response' interview) to explore the same items with open-ended questions, and with discussions where the views held by the participant and the health professional are inconsistent with the participant's identified self-management capacities from the PIH scale (Lawn and Schoo, 2010, Sahafi et al., 2016). It is during this stage that a partnership between the two is meant to be built. The health professional then rates the items from her/his perspective and shares this with the participant.

These tools prepare both the participant and the health professional to next use the problem and goals (P&G) assessment tool to determine the participant-identified problems and to formulate goals to address those problems, with the use of open-ended questions. The goals must be specific, measurable, action-oriented, realistic and timely (SMART) (Battersby et al., 2010b, Lawn and Schoo, 2010, Sahafi et al., 2016). These tools help in the decision making about what strategies and interventions may be helpful.

The strengths, barriers and priorities identified through this collaborative discussion using the first

three tools are incorporated into a fully negotiated evidence-based care plan including issues identified by the health worker and the participant, management aims, agreed interventions, responsibilities and review dates (Battersby et al., 2010b, Lawn and Schoo, 2010, Sahafi et al., 2016). These detailed personalised care plans are effective tools to equip patients for self-management and to enhance communication between the patient and health care providers and support services.

The Flinders Program has been validated and successfully implemented for various target groups, including patients with obstructive sleep apnoea and Vietnam veterans with comorbid alcohol misuse and psychiatric and medical conditions (Battersby et al., 2013, Battersby et al., 2010b, Heatley et al., 2013, Lawn and Schoo, 2010, Sahafi et al., 2016). In a pilot study on patients with sleep apnoea, Antic et al. (2011) showed that nine (9) of the 11 participants achieved an average weight loss of 8.8 kg and an average BMI reduction of three units with the help of the Flinders Program. This program has also been implemented in Aboriginal communities with complex chronic conditions such as diabetes, heart disease and respiratory illness (Harvey et al., 2013, Sahafi et al., 2016).

Moreover, Crotty et al. (2009) conducted an RCT to evaluate the efficacy of a self-management support program for osteoarthritis patients on a waiting list for arthroplasty. The program comprised a combination of the first one-on-one session of the Flinders Program which encouraged patients to join a 6-week self-management education course, and individualised phone support executed by peer volunteers over a 6-month period. The authors showed that this program provided modest improvements in exercise and skill acquisition as well as in stiffness, but no change in emotional well-being or self-monitoring. It was suggested that phone support by health care providers may have had more impact compared to phone support provided by peer volunteers (Crotty et al., 2009).

In addition, an RCT was conducted to evaluate the effectiveness of the Flinders self-management care planning approach in improving competencies in patients discharged from hospital and also

those recruited from the community with multiple chronic conditions (Battersby et al., 2010b). This trial showed that the Flinders Program can be used as a generic self-management support program for people with multiple chronic diseases to improve the physical component of their quality of life (QoL) (Battersby et al., 2015).

The success of the Flinders Program which has been experienced across a diverse cohort of sub-populations reflects its generic properties for a broad range of disorders and risk factors. Because of its generic nature, this program may provide a mechanism for patients who suffer from osteoarthritis and co-occurring obesity to better manage their conditions before a hip or knee replacement and, subsequently, to experience improvements in their quality of life (QoL) (Sahafi et al., 2016).

3.4 Osteoarthritis self-management support programs

Osteoarthritis self-management support programs cover the skills required for people affected by osteoarthritis to manage their daily tasks and the consequences of osteoarthritis in different aspects of their lives. People with hip or knee osteoarthritis need some skills similar to those with other chronic conditions, for example, how to use medications properly; necessary behaviour modifications to improve their symptoms; accurately interpreting and reporting their symptoms to health care providers; developing a partnership with health professionals; and the use of community services (Holman and Lorig, 1997). The pain and difficulty when a person with osteoarthritis moves can restrict his/her social life and work capacity. Maintaining social activities and preparing for the workplace are other vital skills for people with hip or knee osteoarthritis (Holman and Lorig, 1997). Given that pain is the primary concern of people with osteoarthritis (Gill et al., 2004), exercise programs that are tailored to tackle pain are more appealing to people with hip or knee osteoarthritis. Yet, pain does not completely disappear. Pain-coping skills training (PCST) is an approach based on cognitive behavioural principles to target the psychological factors behind pain, and has been shown in randomised controlled trials effective in providing clinically meaningful

improvements in pain and physical function in knee osteoarthritis patients (Bennell et al., 2017). Somers et al. (2012) conducted an RCT on obese osteoarthritis patients and showed weight loss to be significantly beneficial when combined with pain-coping skills training. In a systematic review, Ismail et al. (2017) showed that PCST alone is not effective in managing knee pain, but when combined with exercise or behavioural weight management, provides clinically important improvement in pain. The constant pain and incapacity to perform tasks that used to be easy may cause negative emotions such as frustration, anxiety and depression. Coping with these emotions and not perceiving these incapacities as personal failures are also crucial (Holman and Lorig, 1997). Therefore, self-management support programs for osteoarthritis are mainly multi-component, including interventions that focus on education, use of medication, management of symptoms, managing the psychosocial impacts of osteoarthritis, social support, communication and exercise (Barlow et al., 2002).

Current guidelines strongly recommend aquatic and land-based exercises, and conditionally recommend Tai Chi depending on the patient's functional capability and preferences (Brand et al., 2013). Quintrec et al. (2014) conducted a systematic review of studies about exercise programs for people 70 years of age or older with hip or knee osteoarthritis, and found that land-based exercises should be performed between one and three times a week, with the duration depending on the type of exercise, for example, 25 minutes of bike riding. It is recommended that the duration of exercise for older patients should not exceed one hour per session (Quintrec et al., 2014). Muscle strengthening exercises with or without weight bearing were shown in a systematic review to be effective for pain relief in knee osteoarthritis patients (Tanaka et al., 2013).

Several self-management support programs have been developed for osteoarthritis patients, so it was decided to conduct a literature review using Cochrane methods.

3.4.1 Search strategy

PubMed and Embase were searched for articles. The search strategy was developed with a

combination of keywords for hip/knee osteoarthritis, self-management and randomised controlled trial. The specific question was written in PICO format (P: hip or knee osteoarthritis patients, I: Self-management support, C: usual care, O: Health-related quality of life). The search findings are reported in Figure 2. The found articles were imported to Endnote where duplicates were deleted. Studies were then screened at two stages by the PhD candidate (LS): first by titles and abstracts, and then by reading full texts. Only randomised controlled trials and written in English language were included. Nine studies were included in the review. Study details (aims and sample size), population characteristics (age, condition, symptoms duration), interventions, outcome measures and assessment points were extracted.

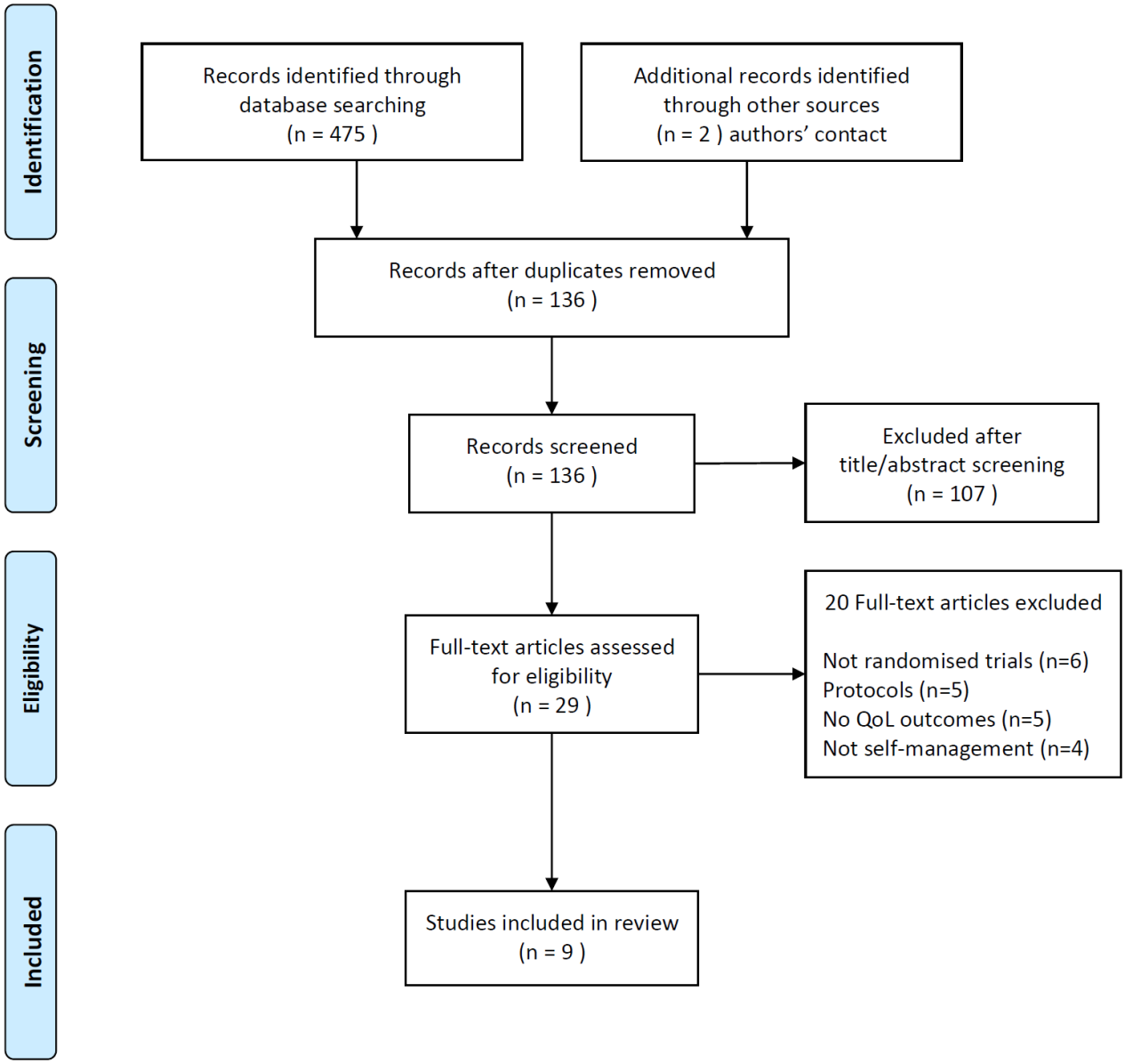


Figure 2: Search flow diagram

3.4.2 Risk of bias assessment

The Cochrane Risk of Bias assessment tool was used to assess quality of individual studies to rate selection bias, performance bias, detection bias, attrition bias and reporting bias (Figure 3). Five studies described adequate random sequence generation and allocation concealment, and were therefore considered as being at low risk of selection bias (Ackerman et al., 2012, Bennell et al., 2016, Crotty et al., 2009, Helminen et al., 2015, Ravaud et al., 2009). One study had unclear risk of bias in random sequence generation and high risk of bias in the concealment of allocation (Hurley et al., 2007). Two trials had adequate allocation concealment but high risk of bias in random sequence

generation (Coleman et al., 2012, Marconcin et al., 2018). One study was assessed as having high risk of bias in both random sequence generation and allocation concealment (Kwok et al., 2016). Since it is not possible to blind health care providers delivering self-management support programs, and participants were aware of receiving such programs, all studies were at high risk of performance bias. All studies were also at high risk of detection bias due to the nature of HRQoL outcomes as self-reported outcomes. Three trials were assessed as high risk of attrition bias (Crotty et al., 2009, Kwok et al., 2016, Marconcin et al., 2018). All studies were at low risk of reporting bias. Another source of bias was differences in adherence between groups that was identified in two studies (Ackerman et al., 2012, Hurley et al., 2007).

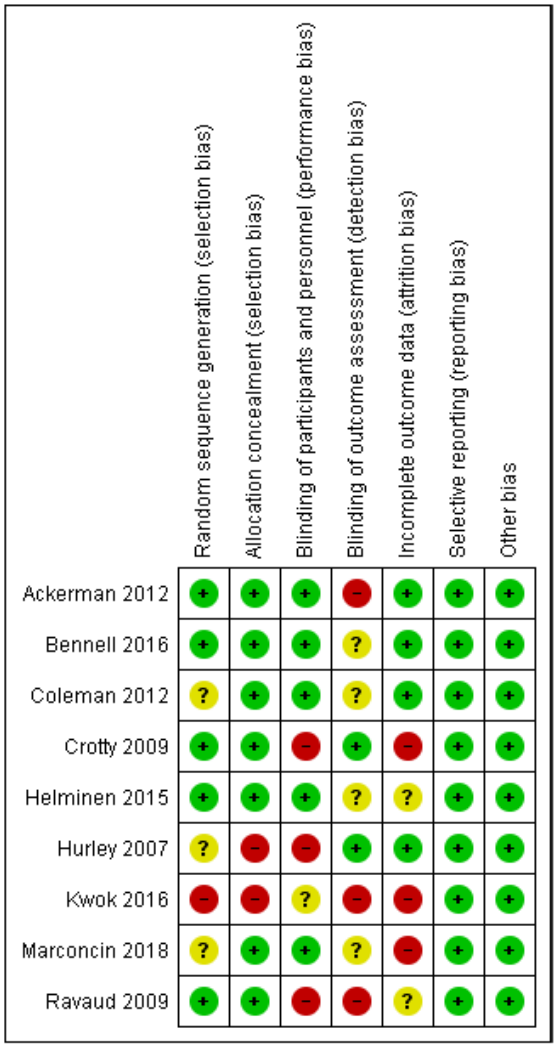


Figure 3: Evaluation of included studies using the Cochrane Collaboration's 'Risk of bias' tool for self-management interventions

3.4.3 Summary of found studies

The summary of included studies is presented in Table 5. Four studies were conducted in Australia (Ackerman et al., 2012, Bennell et al., 2016, Coleman et al., 2012, Crotty et al., 2009), four in Europe (Helminen et al., 2015, Hurley et al., 2007, Marconcin et al., 2018, Ravaud et al., 2009) and one in Hong Kong (Kwok et al., 2016). Except one 3-arm RCT (Bennell et al., 2016), all had a 2-arm RCT design. All studies had knee osteoarthritis patients as participants, except only one trial that included hip or knee osteoarthritis patients (Crotty et al., 2009). One other study included obesity as an inclusion criterion (Ravaud et al., 2009). SF-36 and its shorter version SF-12 were the HRQoL outcome in four studies (Coleman et al., 2012, Helminen et al., 2015, Kwok et al., 2016, Ravaud et al., 2009). Three studies (Ackerman et al., 2012, Bennell et al., 2016, Crotty et al., 2009) used the generic AQoL (Assessment of Quality of Life) instrument which measures HRQoL in eight domains of independent living, senses such as vision and hearing, pain, mental health, happiness, self-worth, coping and relationships (Osborne et al., 2003). In one trial (Hurley et al., 2007), the HRQoL outcome measure was MACTAR (McMaster Toronto Arthritis), a questionnaire to measure changes in rheumatoid arthritis (RA) activity (Verhoeven et al., 2000). One other study (Marconcin et al., 2018) used EuroQoL as their HRQoL outcome measure. EuroQoL is a generic HRQoL instrument that measures quality of life in five dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (EuroQoL, 1990). Effect sizes (Cohen's d) for these studies are reported in Table 5 and are interpreted using conventional standards of 0.2 to 0.49 as small, 0.5 to 0.79 as medium and 0.8 or above as large effect size (Cohen, 2013). Three studies showed a small effect on HRQoL (Bennell et al., 2016, Coleman et al., 2012, Hurley et al., 2007), and one study showed a large effect (Kwok et al., 2016). The effect size in one study (Helminen et al., 2015) could not be extracted as the reported data was incomplete, and the effort in contacting the authors was unsuccessful.

Self-management support programs used in these studies are summarised in the next section.

Table 5: Summary of included studies

Study	Setting	Design	Inclusion criteria	Intervention	QoL measure	Effect size
(Ackerman et al., 2012)	Melbourne, Australia	2-arm RCT	Age ≥18, hip/knee OA, referred to an orthopaedic surgeon	Intervention: ASMP Control: mailed arthritis self-help book	Primary: AQoL	Cohen's d: 0.12 (-0.30 – 0.53)
(Bennell et al., 2016)	Melbourne & Brisbane, Australia	3-arm parallel RCT	Age ≥50, knee OA, knee pain≥ 3 months	Arm 1: Exercise intervention Arm 2: PCST intervention Arm 3: PCST + exercise intervention	Secondary: AQoL	Arm3 wrt arm1 Cohen's d: 0.41 (0.06 – 0.77) Arm3 wrt arm2 Cohen's d: 0.24 (-0.11 – 0.59)
(Coleman et al., 2012)	Perth, Australia	2-arm RCT	Age ≥18, knee OA	Intervention: OAK Control: waiting list	Primary: SF-36	For SF-36 pain p<0.005 Cohen's d: 0.38 (0.04 – 0.72)
(Crotty et al., 2009)	South Adelaide, Australia	2-arm RCT	Referred to have non-urgent hip/knee replacement	Intervention: Flinders University Chronic Disease Self-Management Model Control: usual care	Secondary: AQoL	Cohen's d: 0.15 (-0.17 – 0.47)
(Helminen et al., 2015)	Finland	Single-blind 2-arm RCT	Age ≤ 75 and ≥35, knee OA	Intervention: 6-week group sessions supervised by a psychologist and a physiotherapist Control: usual GP care	Secondary: SF-36	-
(Hurley et al., 2007)	London, UK	Single-blind 2-arm cluster RCT	Age ≥50, knee pain≥ 6 months	Intervention: ESCAPE Control: usual care	Secondary: MACTAR	Cohen's d : 0.27 (0.04 – 0.50)
(Kwok et al., 2016)	Hong Kong	Single-blind 2-arm RCT	Age ≥60, knee pain≥ 3 months	Intervention: ASMP Control: received exercise pamphlets	Secondary: SF-36	For SF-36 physical p<0.005 Cohen's d: 0.85 (0.23 – 1.46)
(Marconcin et al., 2016)	Lisbon, Portugal	Single-blind 2-arm RCT	Age ≥60, knee OA, functionally independent	Intervention: PLE2NO program Control: educational	Secondary: EuroQoL	Cohen's d: 0.07 (-0.47 – 0.49)
(Ravaud et al., 2009)	France	2-arm cluster RCT	Age ≤ 75 and ≥45, knee OA, BMI between 25 and 35 (obese or severely obese)	Intervention: 3 one-on-one educational sessions on OA, exercise and weight loss Control: usual care	Secondary: SF-12	SF-36 physical Cohen's d: 0.17 (-0.05 – 0.38) SF-36 Mental Cohen's d: 0.05 (-0.16 – 0.27)

ASMP: Arthritis Self-Management Program. PCST: Pain Coping Skills Training. OAK: Osteoarthritis of the Knee. ESCAPE: Enabling Self-management and Coping with Arthritic Knee Pain through Exercise
Effect sizes include 95% confidence intervals.

3.4.4 Summary of osteoarthritis self-management support programs

Osteoarthritis self-management support programs found from the literature review in the previous section are summarised in this section.

3.4.4.1 Arthritis Self-Management Program (ASMP)

The Arthritis Self-Management Program (ASMP), developed by Lorig and colleagues at Stanford University, is the most rigorously evaluated community-based program (Lorig and Holman, 1993, Lorig et al., 1984). The ASMP is a 6-week program taught by peers in weekly 2-hour sessions. The sessions start with presentations introducing topics including information about osteoarthritis, self-management principles, exercise, symptom management, dealing with depression, communication and goal setting. The presentations are then followed by interactive group discussion, problem solving and role play (Lorig and Holman, 2003, Patel et al., 2016). Kwok et al. (2016) showed significant improvements in physical quality of life after three months of receiving ASMP; however, Ackerman et al. (2012) in their RCT showed no significant improvements in HRQoL after 12 months of receiving ASMP. The difference in these results could be related to difference in the inclusion criteria of the studies. The participants in Ackerman et al. (2012)‘s study were hip/knee OA patients who were referred to a surgeon and therefore had severe OA, unlike the participants in Kwok et al. (2016)’s study who only had knee pain for over three months.

3.4.4.2 ESCAPE program

The Enabling Self-management and Coping with Arthritic Knee Pain through Exercise (ESCAPE) program developed by Hurley et al. (2007) at Kings College in London, integrates a 6-week exercise intervention with education about self-management skills, such as coping skills. The program comprises 12 sessions of 10–15-minute themed discussion about the disease, its causes and consequences, coping skills and problem solving, guided by a physiotherapist. Each discussion session is followed by 30–45 minutes of exercise, designed to increase strength, balance and coordination, all supervised by the physiotherapist. After 12 sessions, participants are given home

exercise instructions, and advice about local community exercise facilities, classes and self-help groups (Hurley et al., 2010). In an RCT, the ESCAPE program was shown to significantly improve self-reported physical functioning, pain, anxiety, depression and exercise self-efficacy, but had little effect on muscle strength (Hurley et al., 2007).

3.4.4.3 Osteoarthritis of the Knee (OAK) self-management program

The Osteoarthritis of the Knee (OAK) self-management support program developed by Coleman et al. (2008) in Western Australia is a self-management community-based group program designed for people with knee osteoarthritis. This program is delivered by health care professionals to enhance participants' self-efficacy and to promote long-term behavioural changes. The OAK self-management program is conducted in six weekly sessions of 2.5 hours each, with the initial assessment taking place one week before the program and a final assessment one week after the completion of the program. In an RCT, the OAK program showed statistically significant improvements with regard to pain, QoL and function based on WOMAC and SF-36 measures (Coleman et al., 2012).

3.4.4.4 PLE2NO program

The PLE2NO program (in Portuguese: free program of education and exercise for osteoarthritis) was developed by Marconcin et al. (2016) in Portugal for elderly patients with knee osteoarthritis for a duration of three months. This program involves group sessions of 30 minutes self-management and 60 minutes exercise, twice weekly. The self-management component includes information about self-management principles, symptom management, communication skills, medication management and healthy eating and activities. The exercise component contains muscle resistance and strengthening, and physical fitness exercises. This component is led by a physiotherapist (Marconcin et al., 2016). It was shown in an RCT that this program did not significantly improve health related quality of life in patients with knee osteoarthritis after three months (Marconcin et al., 2018).

3.4.4.5 Other osteoarthritis self-management programs

There are a few other osteoarthritis self-management support programs that have been used in trials. One such program involves 10 physiotherapist-delivered individual sessions consisting of a combination of training in cognitive and behavioural pain coping skills (PCST) such as problem solving and identifying and challenging negative thoughts, and muscle strengthening exercise over 12 weeks (Bennell et al., 2016). Participants are also asked to practice skills daily. Bennell et al. (2016)'s RCT showed the combination of exercise and PCST significantly improves HRQoL in knee osteoarthritis patients when compared with exercise alone or PCST alone

Another osteoarthritis self-management program consists of six weekly group sessions of 7-13 persons, led by a psychologist and a physiotherapist. Each session takes two hours with a 15-20 minute for peer support. The sessions involve knowledge education, problem solving and skills training. In an RCT in Finland, Helminen et al. (2015) showed significant emotional improvements in knee osteoarthritis patients gained through this program.

Another osteoarthritis-specific self-management education program, led by a rheumatologist and conducted in France, consists of three in-person visits over 30 days. In the first visit, the participants are provided with information about osteoarthritis and its treatment. Two weeks later, participants are informed about how to protect their joints and the need for exercise, and receive instruction on a progressive exercise schedule consisting of three sessions of 30 minutes a week. This increases to three sessions of 60 minutes a week of walking or cycling, depending on the participant's preference. At the final visit after the completion of day 30, participants are educated about the impact of obesity on osteoarthritis and about weight loss strategies (Ravaud et al., 2009). An RCT was conducted to evaluate the impact of this program on knee osteoarthritis patients, and found some improvements in physical activities, pain and function (Ravaud et al., 2009). This program mainly consists of patient education about the disease and exercise, rather than self-management skills.

Overall, of the nine randomised controlled trials, four showed significant improvements in health-related quality of life in hip or knee osteoarthritis patients who received self-management support compared to the control group (Bennell et al., 2016, Coleman et al., 2012, Hurley et al., 2007, Kwok et al., 2016). Of these four studies, one low-quality study showed a large effect size (Kwok et al., 2016), and three relatively high-quality studies showed a low effect size (Bennell et al., 2016, Coleman et al., 2012, Hurley et al., 2007). Awaiting surgery was not an inclusion criteria for participants in any of these four studies, and two studies (Bennell et al., 2016, Coleman et al., 2012) even excluded patients who were awaiting surgery. Furthermore, none of these studies targeted obese patients. This justifies the need for a randomised controlled trial targeting obese hip/knee osteoarthritis patients awaiting replacement surgery.

3.5 Proposed study intervention

It was established that the intervention for the current study must be a self-management support program targeting the issues of obese people with advanced hip or knee osteoarthritis awaiting joint replacement surgery. As this was to be a complex intervention, it should contain several interacting components (Craig et al., 2008) including weight loss, diet, exercise and behavioural modification.

People with advanced hip or knee osteoarthritis face barriers to their participation in these self-management programs, the most significant being travel difficulties (Ackerman et al., 2012), especially if they live far from where the program is offered. The comorbidity of osteoarthritis and obesity, and potentially other chronic conditions which the target group of this study may experience, is a further barrier to engagement in a self-management program (Bayliss et al., 2007, Coventry et al., 2014). As explained in Section 3.2, the Flinders Program has been presented as effective for patients with comorbid conditions. Moreover, it has been shown that the partnership between the patient and the health care provider, and the continuing contact, whether in person or through telephone communication, is a key factor in achieving weight loss (Bliddal et al., 2014, Wadden et al., 2004). Given that the Flinders Program creates a strong partnership between the

patient and health professionals, it can provide a powerful framework for interventions for obese people with hip or knee osteoarthritis.

Given that the Flinders Program was available locally by the developers of the Flinders Program at Flinders University, this program was chosen as the framework to guide the components of the intervention for the study.

With the framework of the Flinders Program, the intervention has three main categories of diet, exercise and self-management skills, with the latter dealing with everyday tasks, self-monitoring and pain coping to cover the problems of and goals for both osteoarthritis and obesity. It also addresses any other problems such as depression, anxiety, sleep disturbance or low social interaction that may affect the patient's life, as identified by the patient and the health professional.

The initial session, as summarised in Figure 4, takes approximately one hour. During this session, the Flinders Program tool, the Partners in Health (PIH) scale, is used to help the patient think about and rate her/his self-management knowledge and behaviour, as well as the physical, emotional and social impacts of their condition on her/his life. Subsequently, more detailed information is obtained from the motivational cue and response interview. The knowledge gap and barriers to self-management are identified as issues. Further questions may arise, such as the ways in which obesity impedes the patient's management of their daily life and their tasks that are affected by osteoarthritis. Here, the health professional through being understanding, empathetic and non-judgemental can establish a partnership with the patient. This step is followed by the problem and goals (P&G) assessment tool that is used to determine medical or psychological problems that are the most concerning to the patient. The SMART goals are then formulated by both the patient and the health professional and a mutually agreed individual care plan is created. In order to decide on actions, depending on the problems and issues identified by both the health care provider and the patient, information about diet, exercise, self-monitoring and pain coping is given to the patient. Dietary information could be a brief explanation of various types of diets, especially the

Mediterranean diet, but, more importantly, could be about different types of macronutrients (carbohydrates, fats and proteins) and the timing of food consumption. Some behavioural advice can also be given, such as not keeping unhealthy snacks at home and not having regular take-away meals. Information about exercise is given very gently, as most of these patients avoid exercise due to pain. The benefits of strengthening exercises are explained and advice is also given on how they can be incorporated into the life of an osteoarthritis patient. Self-monitoring is a fundamental part of self-management for these patients, as pain can impede their adherence to the program. Self-monitoring techniques, such as recording their diet and exercise, are explained. Pain-coping techniques such as the hierarchy of medications are also discussed. The patients are also prepared for potential relapses. A copy of the care plan is given to the patient, preparing them to take on the self-management task.

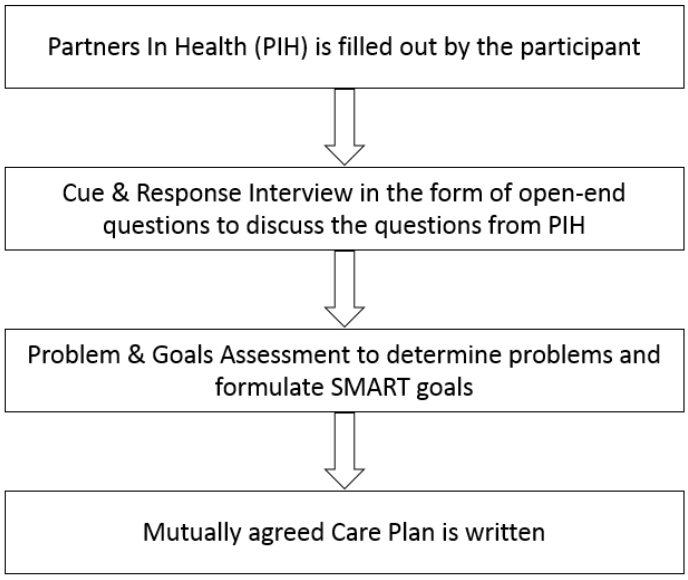


Figure 4: Summary of the session of the intervention program

After the initial session, patients are to be provided with fortnightly phone call follow-ups by the same health care provider for six months to monitor progress, provide feedback and motivation, and conduct problem-solving training (Sahafi et al., 2016).

3.6 Chapter summary

This chapter presented a review of existing self-management support programs, and highlighted how the Flinders Program provides a strong partnership between patients and health care providers while, at the same time, it does not require ongoing attendance at the hospital. These aspects are fundamental for obese people with advanced hip or knee osteoarthritis, as they need support as well as learning skills to manage their unique debilitating condition, with most also restricted in terms of travelling. Therefore, the Flinders Program was chosen as the framework of the proposed intervention for the current study.

4. METHODS

The findings from the literature review presented in Chapter 2 and 3 provide the framework for this study to evaluate the effectiveness of a self-management support program on health-related quality of life (HRQoL) and weight loss in obese osteoarthritis patients awaiting hip or knee replacement surgery.

4.1 Aims and hypotheses

The main aim of this study was to evaluate the effectiveness of the Flinders Program based intervention plus treatment as usual to improve HRQoL in obese patients with osteoarthritis who are on a waiting list for hip or knee replacement surgery in comparison to the existing clinical pathway (usual care) for these patients.

Hypothesis 1: At 10-month follow-up, there will be a statistically significant difference in health-related quality of life of obese osteoarthritis patients awaiting hip or knee replacement surgery who receive the Flinders Program versus treatment as usual.

Secondary questions related to whether the intervention program can assist obese osteoarthritis patients on a waiting list for total hip or knee replacement to lose weight and which demographic and psychosocial factors contribute to QoL and weight loss in such patients.

Hypothesis 2: At 10-month follow-up, there will be a statistically significant difference in (1) weight loss and (2) self-management competency in obese osteoarthritis patients awaiting hip or knee replacement surgery who receive the Flinders Program versus treatment as usual.

4.2 Study design

This study comprised a two-group parallel design, with balanced randomisation (1:1), involving obese osteoarthritis patients on a total hip or knee replacement waiting list registered at the Repatriation General Hospital (RGH) in Adelaide, South Australia. The aim of the study was to

recruit 94 patients over a 6-month enrolment period starting July 2015 with follow-ups at six months or before the surgery (whichever was earlier), and at 10 months. Eligible patients were randomised to either a control group receiving usual care or an intervention group receiving the self-management support program plus usual care for six months.

4.3 Study participants

4.3.1 Eligibility criteria

Patients were invited to participate if they met the following criteria:

- had a BMI of 30 kg/m² or above;
- had been on a hip or knee replacement waiting list due to osteoarthritis; and
- had agreed to provide a signed informed consent form to participate in the study.

Patients with the following criteria were excluded from the study:

- had an emotional or neurological condition that would pre-empt their ability or willingness to participate in the study, including a mental illness, intellectual disability, or drug or alcohol abuse, as reported to the hospital's waiting list by the patient's GP;
- had had surgery within the past three months; or
- had dementia.

Patients who had a pacemaker or implantable cardioverter defibrillator (ICD) were excluded from the body fat measurement test.

4.3.2 Participant recruitment

Participants were drawn from osteoarthritis patients who were on the hip or knee replacement waiting list of the Repatriation General Hospital (RGH) in Adelaide, South Australia. Eligible participants, initially identified through patient information provided by RGH staff, were sent an invitation letter (Appendix D) to participate in the study, along with the patient information sheet (Appendix C). A week later, a follow-up phone call was made by the PhD candidate (LS) to each individual patient to ascertain their willingness to participate in the study. For patients who agreed

to be part of the study, a visit time, based on their availability, at the location of the study was then arranged to obtain their written consent and proceed with enrolment.

4.4 Ethical considerations

Currently, a clinical pathway has been developed to care for such patients at the Repatriation General Hospital (RGH) in South Australia. Therefore, a logical step was the direct comparison of usual care and the self-management support program. As this study was motivated by uncertainty about the clinical superiority of the intervention program over the current care pathway at the RGH, the principle of clinical equipoise applied with participants not disadvantaged by assignment to either the usual care or the self-management support group. The study received approval from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) (Appendix A), and was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12615000674538). Participants were given an information sheet regarding the study and asked to provide written informed consent at the first visit before data collection began (Appendices B and C, respectively).

4.5 Sample size

The primary research question was: does the self-management support program plus treatment as usual improve the HRQoL in patients with obesity and osteoarthritis who are on a waiting list for joint replacement surgery of the hip or knee in comparison to the existing clinical pathway (usual care) for the management of patients with obesity and osteoarthritis? Being non-invasive and a patient-centred approach to behavioural change, the Flinders Program is a safe intervention and little harm was expected in the widespread application of such a program. In fact, some benefits, such as self-management competency, might be gained, even if the intervention program does not directly reduce obesity or improve all aspects of health-related quality of life (HRQoL). Therefore, the consequences of a Type I error (incorrectly rejecting the null hypothesis) are minimal. In contrast, the consequences of a Type II error (incorrectly retaining the null hypothesis) are more

serious, because the opportunity for a safe, inexpensive, and possibly effective intervention may be missed. In exploratory studies of this type, a strong rationale is presented for using a less stringent statistical significance (i.e. α=0.10) (Piantadosi, 2005). This design parameter is frequently used in exploratory or Phase II studies, including those involving biological and psychotherapeutic interventions (Calcaterra et al., 2015, Lieberman, 2013). Moreover, as the control group in this study receives the existing clinical pathway, which includes information and minimal personal connection, a clinically meaningful difference with a moderate effect size was expected in favour of the intervention group. Therefore, based on a Type I error rate of 10%, power of 80% and a two-tailed test, to detect an effect size of 0.6, 36 participants were required in each arm of the study. The statistical software package Stata 13 was used to calculate the sample size (StataCorp, 2013). The power for a two-sided test $\pi = 1 - \beta$ is computed using the following: $\pi = \emptyset\left(\frac{\delta}{\sigma D} - z_{1-\frac{\alpha}{2}}\right) + \emptyset(-\frac{\delta}{\sigma D} - z_{1-\frac{\alpha}{2}})$ where $\emptyset()$ is the cdf (cumulative distribution function of a standard normal distribution, α is the significance level, β is the probability of a type II error, $\sigma D = \sqrt{\frac{\alpha_1^2}{n_1} + \frac{\alpha_2^2}{n_2}}$ is the standard deviation of the difference between the two sample means, and $z_{1-\frac{\alpha}{2}}$ is the $(1 - \frac{\alpha}{2})$th quantiles of a standard normal distribution (StataCorp, 2013). With a potential anticipated dropout rate of 30%, the aim was to recruit 47 participants in each group of the study, resulting in a total sample size of 94 participants.

Since we are at an early stage of testing the Flinders Program in this study's population of interest, the primary goal was to evaluate efficacy, feasibility/process (e.g. from qualitative interviews), and description. This meant finding a balance in the study's design in terms of available resources i.e. statistical significance with the magnitude of effect, the quality of the study and with findings from other studies. On this note, a previous relevant study was (Battersby et al., 2013)'s investigation of Flinders Program in Vietnam veterans where a medium effect size was found on primary outcome. This was considered a meaningful and beneficial effect, thus considered appropriate for sample size

calculation for the current study. Taken together, a key objective of this study was to achieve high internal validity as a precursor to a future high-quality, large scale clinical trial to establish external validity or generalisability across a large and diverse population.

4.6 Randomisation and allocation concealment

Following enrolment of the participants by the PhD candidate (LS), baseline assessments were conducted. Participants were then randomly assigned to one of two groups, either control or intervention with a 1:1 allocation ratio. Randomisation was blocked to ensure approximately similar group sizes, using varying block sizes (two and four) to protect concealment. As found in the literature review (Section 2.4.3), various classes of obesity may be associated with different levels of improvements in HRQoL after hip or knee replacement surgery. Furthermore, obese men and women have been shown to be associated with different levels of health-related quality of life (HRQoL). Therefore, to achieve balance in each arm on the observed patient characteristics, randomisation was stratified on gender and BMI groups. The BMI groups were stratified as 30–34.9 (obese), 35–39.9 (severely obese) and 40 and above (morbidly obese). A biostatistician independently generated stratified blocked randomisation sequences using Stata 14.1 (StataCorp, 2014) statistical software and delivered this to the RGH's clinical trial pharmacy. Once the baseline measurements were taken for each participant, an independent staff member contacted the clinical trial pharmacy and provided the gender and BMI group of the participant and was given the allocation group of that participant.

4.7 Interventions

4.7.1 Usual care

Usual care comprised a one-hour group information session at the RGH in which a nurse from the hospital provided information about hip and knee replacement, while showing a replica of joints, and also informed patients about what to expect after surgery and how to accelerate recovery by committing to the exercises that they were advised to perform. Patients were given information

about healthy weight, setting weight loss goals and where to get help, such as from practising dietitians from the Accredited Practising Dietitians (APD), community health centres and weight loss groups such as Weight Watchers. In addition, they were given information about monitoring their weight loss progress through a food/activity diary as well as information about acknowledging and rewarding progress. Furthermore, patients were provided with information about pain management such as anti-inflammatory and pain relief medications, and supplements such as fish oil. An expert from Arthritis Australia then provided information about exercises for hip and knee replacement patients before and after surgery with information also provided to guide patients in managing their chronic condition, including preparing the home environment to create less impact on their affected joints, and about how to access resources, such as community services for home care and support (e.g. RDNS – Royal District Nursing Service) and physiotherapists. After the information sessions, patients were contacted by phone once or twice by nurses to provide general support.

4.7.2 Intervention program

Participants in the intervention group received usual care as well as the self-management support program which was delivered by a registered orthopaedic nurse with 40 years of experience who had been specifically trained for the Flinders Program at the Flinders Human Behaviour and Health Research Unit (FHBHRU) prior to the start of the study. The intervention program was delivered in an individual format in one face-to-face session and fortnightly follow-up phone calls for six months, on a day and time agreed between the nurse and the patient. During the initial face-to-face session, the participant filled out the self-rated Partners in Health (PIH) scale. The scale is a short precise tool comprising 12 self-rated items which reflect the definition of chronic condition self-management (Battersby et al., 2010a). The intervention-administering nurse then explored the same questions in detail in the form of a motivational interview, namely, the cue and response (C&R) interview, rated the items from her perspective and shared this with the patient. All problems

expressed by the participant were considered. However, if the participant disregarded obesity as a problem, the intervention-administering nurse would explain in an understanding, empathetic and non-judgemental manner how osteoarthritis impacts on various aspects of life and how obesity impedes the management of daily life and the tasks affected by osteoarthritis.

The problem and goals (P&G) assessment tool was then used to determine the identified problems and to formulate SMART goals to address those problems. This information was used to produce a fully negotiated individual care plan including identified priority issues, management aims, agreed interventions, responsibilities and review dates. The three main categories of diet, exercise and self-management skills, such as dealing with everyday tasks, self-monitoring and pain coping, as mentioned in Section 3.4, were covered. The initial session took approximately one hour. A copy of the care plan was given to the patient, preparing them to take on self-management activities.

After the initial session, patients were provided with fortnightly phone call follow-ups by the same health care provider for six months to monitor progress, and to provide feedback, motivation and problem-solving training (Sahafi et al., 2016).

4.8 Blinding

Baseline measurements were obtained before randomisation and were therefore free of any assignment-related bias. As all participants were informed that the intervention was a self-management support program, they were therefore aware of whether they were receiving such a program. Participants were advised not to discuss their allocation with the PhD candidate (LS) who performed the data collection. The clinician delivering the intervention program was unblinded. Random assignments were concealed and recorded in a separate database accessed from a separate computer. Data analysis was performed by the PhD candidate (LS) who was blinded to treatment allocation by non-informative labels for group variables. To ensure the delivery of the intervention program was without any bias, the clinician delivering the intervention program did not have access to the outcome measures.

4.9 Outcomes

All outcome measures (shown in Table 6) were collected by the PhD candidate (LS). Demographic data included age as a continuous variable, gender, living arrangements (alone, with partner, with children, other), work status (unemployed, retired, full-time job, part-time job), and education level (primary school, secondary school, undergraduate, postgraduate).

4.9.1 Primary outcome measures

Outcome measures were administered at baseline assessment, pre-surgery (approximately six (6) months' post-baseline visit) and 10 months' post-baseline visit. The primary outcome measure was Health-Related Quality of Life (HRQoL). To thoroughly assess HRQoL, the use of both generic and

Table 6: Measures

Measurements	Intervention period		Maintenance period
	Baseline	6 months	10 months
Demographics	✓		
HRQoL			
SF-36	✓	✓	✓
OAKHQoL	✓	✓	✓
Self-management			
PIH scale	✓	✓	✓
Obesity	✓	✓	✓
BMI	✓	✓	✓
WC			
WHtR	✓	✓	✓
%BF	✓	✓	✓

Abbreviations: HRQoL = health-related quality of life; OAKHQoL = osteoarthritis knee or hip quality of life; PIH = partners in health; BMI = body mass index; WC = waist circumference; WHtR = waist-to-height ratio; %BF = percentage body fat.

disease-specific instruments is recommended. Based on the literature review, the 36-item Short-Form Health Survey (SF-36) questionnaire was used to measure generic HRQoL in this study (Ware and Sherbourne, 1992). The SF-36 measures HRQoL in eight domains of physical functioning: role limitations due to physical problems; bodily pain; general health perception; vitality; social

limitations owing to emotional problems; role limitations due to emotional problems; and mental health, with these summarised in two component scores, physical and mental (Ware and Sherbourne, 1992). The OAKHQoL (osteoarthritis of knee or hip quality of life) measures the disease-specific HRQoL of osteoarthritis in five domains, namely, physical activity, mental health, pain, social support and social functioning (Rat et al., 2005). This instrument is a 43-item scale in which each item is rated on a 1–10 Likert scale: the instrument has been validated in previous studies (Goetz et al., 2011, Rat et al., 2008). As pain and functional ability are both very important for patients, these QoL aspects were measured as part of both SF-36 and OAKHQoL. No obesity-specific HRQoL instrument was used in this study, as the questions IWQoL (impact of weight on quality of life) overlapped the questions in SF-36 and OAKHQoL combined.

To ensure the maximum return rate, questionnaires were mailed out or the questions were asked on the phone if participants did not attend their follow-up appointments.

4.9.2 Secondary outcome measures

Self-management competency was measured using the Flinders Program's Partners in Health (PIH) scale. In conjunction with patient assessment and goal-setting processes, the PIH scale is an important part of the Flinders Program, measuring the degree of participants' active involvement in managing their chronic condition, and is a structurally valid instrument for measuring chronic condition self-management in an Australian community (Smith et al., 2016). The PIH scale is a 12-item self-rated questionnaire on a 0–8 Likert scale, designed based on principles of self-management, and assessing self-management in the domains of knowledge, partnership in treatment, recognition and management of symptoms, and coping (Smith et al., 2016). Changes in self-management competency were assessed by the comparison of changes in the control group and the intervention group between baseline and follow-ups and between groups over time. This examined whether the changes in self-management competency that took place could be attributed to the intervention program. This questionnaire, along with SF-36 and OAKHQoL, were prepared

in the form of a booklet to be easier for participants to fill out (Appendix E).

Obesity was also identified as a secondary outcome (Section 2.2.2 Measuring obesity – Is BMI the best tool?). Obesity outcome is commonly measured using the BMI, an index based on height and weight information. However, it is now known that the BMI as an index of obesity has several limitations such as its inability to distinguish between fat mass and fat-free mass (Sahafi et al., 2015). Nevertheless, the BMI still provides a simple and straightforward method of measuring obesity. To balance the BMI's limitations, two simple and inexpensive measurements of central obesity were also collected; waist circumference (WC) and waist-to-height ratio (WHtR) (Sahafi et al., 2015). To have a more accurate body composition measurement to compensate for the limitations of the anthropometric measures of the BMI, WC and WHtR in estimating body composition and obesity (Beechy et al., 2012), the whole-body fat percentage was measured using a multiple-frequency bioelectrical impedance analysis (MF-BIA) device (IMP^{tm} SFB7 Bio Impedance Spectroscopy–ImpediMed), a validated measurement tool. The

4.9.2.1 IMP^{tm} SFB7 measurement

IMP^{tm} SFB7 is a single-channel, tetra-polar bioimpedance spectroscopy (BIS) device that scans 256 frequencies between 4 kilohertz (kHz) and 1000 kHz. The device utilises Cole-Cole modelling with Hanai mixture theory to determine total body water (TBW), extracellular fluid (ECF) and intracellular fluid (ICF) from impedance data. Fat-free mass (FFM) and fat mass (FM) are then calculated by the device. It is not recommended that people with a pacemaker or an implantable cardioverter defibrillator (ICD) be tested using this device, and they were therefore excluded from this stage of the data collection. To measure the percentage of body fat, the study used the IMP^{tm} SFB7 with this device set to repeat the measurement five times to minimise measurement errors. Disposable pre-gelled electrocardiogram (ECG)-style electrodes were attached to the hands, wrists, ankles and feet as can be seen in Figure 5 and the leads of the device were attached to the electrodes in the correct order for the readings. The participants remained in a supine position on a non-

conductive hospital bed during all measurements.

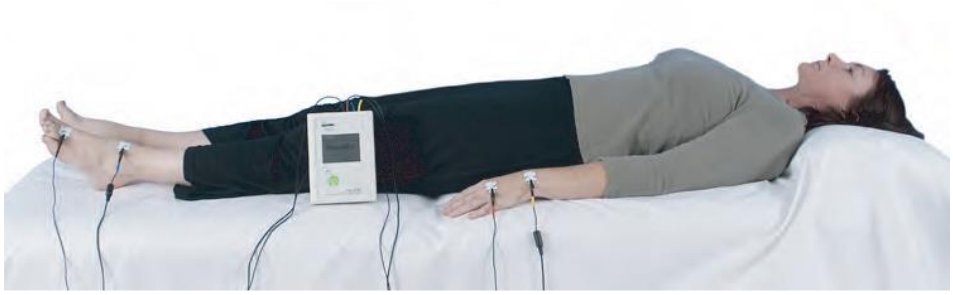


Figure 5: Electrodes placement for measuring total body water

Whole-Body Impedance processing software version 5.2.2.0, provided by ImpediMed, was used for data recording, storage and processing. This software requires the height, weight and gender information (as can be seen in Figure 6), and generates multi-frequency unprocessed (MFU) files, and then the processed files (MFP format).

The measured impedance (Z) is composed of resistance (R) caused by total body water, and reactance (Xc) caused by the capacitance of the cell membrane which is known (Khalil et al., 2014, Kyle et al., 2004). Total body water (TBW) can then be calculated using the measured impedance at a high frequency according to the following:

$$TBW = \rho \frac{L^2}{Z}$$

where ρ is the specific resistivity and L is the distance between electrodes (Khalil et al., 2014). The human body comprises fat mass (FM), which is a non-conductor of electric currents, and fat-free mass (FFM), which is a conductor of electric currents due to electrolytes within:

$$FM = Weight - FFM$$

Total body water is the main constituent of FFM in people without fluid abnormalities (Khalil et al., 2014):

$$TBW = 0.73\ FFM$$

Fat mass can then be calculated.

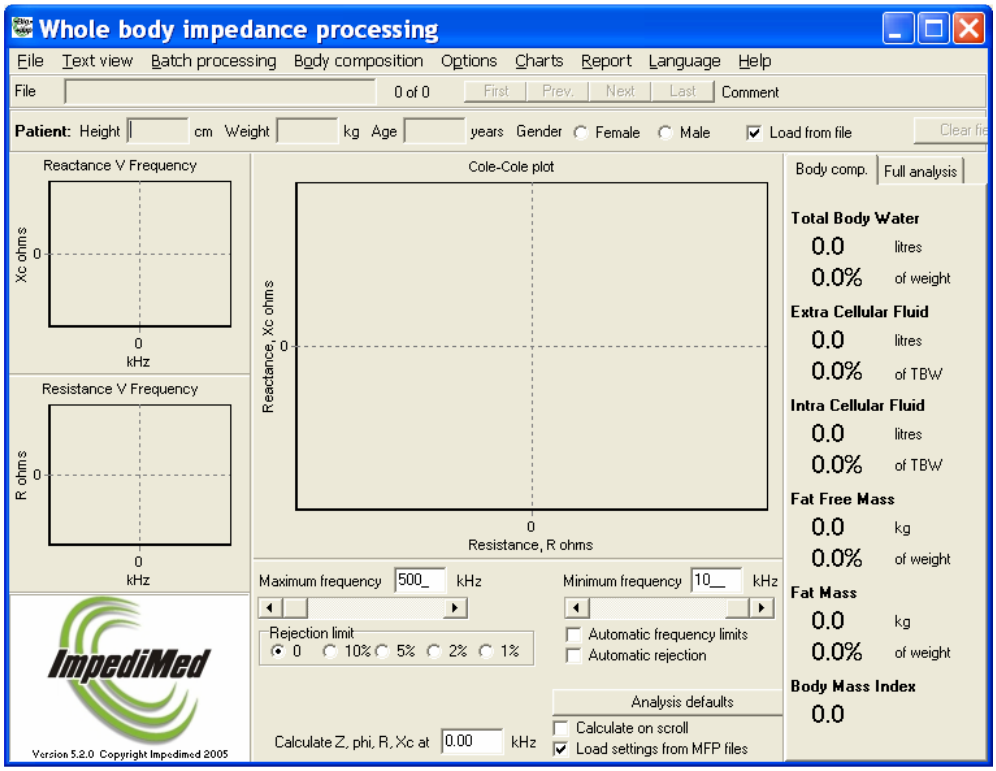


Figure 6: Whole-body impedance processing: software view

Five measurements per participant were taken by the PhD candidate (LS). This took under three minutes from the start to the end. Batch processing was then used to allow all five analysis results to be viewed across the whole set of input data files. These files were uploaded to the computer when all measurements had been taken. Participants were measured on both right and left body sides, in case of a fluid imbalance in the body. The average of the right and left body fat percentage was then used.

4.10 Study management

4.10.1 Adverse events

Minimum adverse events were expected in this study. However, in the unlikely case of an adverse event occurring due to the study, the patient was to be referred to the appropriate health professional for further care. Such a referral was to be immediately reported to the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC).

4.10.2 Data management

The responses to the SF-36 questionnaire were entered in the scoring software 4.5 provided by QualityMetric Health Outcomes ™. This software generates a spreadsheet in a comma-delimited (.csv) format containing the responses to all questions, the raw scores and normalised scores of all eight domains as well as the total physical score and the total mental score. A program using Python programming software was written by the PhD candidate (LS) to extract the useful normalised scores of the eight domains and total physical and mental scores, and was used to export the data to the master database.

The score calculation formula for OAKHQoL (Rat et al., 2005) was provided by A. C. Rat through personal communications. A spreadsheet was then generated in which the data could be entered. The calculated scores in the five domains were then exported to the master database.

Whole-Body Impedance processing software version 5.2.2.0, provided by ImpediMed, was used to perform batch processing on all 10 body fat measurements (including measurements of the right whole body and the left whole body) for each visit and to generate an Excel spreadsheet containing all the measurements undertaken by IMP^{tm} SFB7. A program using Python programming software was written by the PhD candidate (LS) to calculate right and left whole-body fat percentages followed by the average whole-body fat percentage and to extract the fat mass measurement for each participant at each visit. All the obesity-related measurements were then exported to the master database. The PIH scale score and subscales were also entered in the master database. Data files were held on a secure database and backed up weekly.

4.10.3 Study drop-outs

Participants were advised that they could voluntarily withdraw from the study at any time. If a participant withdrew from the study, they were to be asked the reason(s) with this documented in the study results.

4.10.4 Treatment non-completers

Participants in the intervention group who did not complete a minimum adequate trial were not considered study drop-outs, with this reflecting the effectiveness of the program in the real world. Not all individuals need the same dose of contact to achieve motivation and support, however based on the experience of the supervisory team for delivering the Flinders Program, those participants who received less than one-third of the maximum possible intervention phone calls (i.e. four of the maximum one phone call every two weeks for six months, a total of 12 phone calls) were considered treatment non-completers. In other words, those participants who received less than four intervention phone calls were considered treatment non-completers.

4.11 Data analysis

All statistical analyses were conducted using Stata 14.1 (StataCorp, College Station, TX, USA) software. For the data analysis, statistical analysis using intention-to-treat (ITT) was planned. In ITT analysis, outcomes are compared between all participants according to the group to which they are assigned after randomisation, regardless of adherence to the treatment protocol or lack thereof. The ITT analysis therefore aims to investigate the effectiveness of an intervention in everyday health care settings. The main analyses were conducted on an ITT basis, and involved all participants who were randomly assigned to either the control group or the intervention group.

To account for participant attrition and lack of treatment completion, a per protocol (PP) analysis was also conducted to evaluate the efficacy of the intervention under near-perfect conditions in which participants adhere to their assigned intervention protocol. Exploratory analyses were also conducted to evaluate the impact of socio-demographic characteristics, self-management (PIH scale) and the BMI on the changes in the primary outcome and weight loss.

Among various methods used for statistical analysis, the analysis of repeated measures on each participant across a period of time provides more in-depth information than traditional methods of end-point analysis such as a *t*-test. However, these methods can encounter challenges such as

missing data, heterogeneity and unbalanced measurement occasions (Gibbons et al., 2010, Newgard and Lewis, 2015). Heterogeneity relates to the deviation of individual correlated responses from the average or population response (Gibbons et al., 2010). For example, some individual trend lines differ from the average trend line. Modelling this unobserved heterogeneity in terms of variance components, often called random effects, at the individual level better describes individual differences (Gibbons et al., 2010). Missing data are also common in medical studies, even in RCTs that are considered the gold standard for evaluating a direct causal link between an intervention and an outcome (Dziura et al., 2013).

Traditional statistical approaches for handling repeated measures, including univariate repeated measures analysis of variance (rANOVA) and multivariate repeated measures ANOVA (rMANOVA) or multivariate growth-curve analysis, do not handle the above-mentioned challenges very well. For example, missing data in these methods are handled using list-wise deletion as the default (Gueorguieva and Krystal, 2004). On the other hand, generalised mixed-effects models use all available data to model different variance–covariance patterns at the individual level, and model time as a continuous covariate where longitudinal data sets are unbalanced, that is, different assessment time points across individual participants. Mixed-effects models also use maximum likelihood estimation and assume data are missing at random (MAR) (Gueorguieva and Krystal, 2004).

In this study, mixed-effects models were used for the repeated measures of primary and secondary continuous and categorical outcomes. The fixed effects in the models comprised the treatment group (the intervention program versus usual care); time points of the baseline (0 weeks), first follow-up (24 weeks), and second follow-up (40 weeks); and interaction between groups and time. Random effects were at the study participant level and represent an upward or downward shift in the outcome measure from an overall regression line and the rate of change over time. The model included both random intercept and random slope terms at the individual level. The correlation

between baseline scores (intercepts) and the rate of change across time was tested via the independent covariance–variance structure versus unstructured, with a better fitting model found using the independent covariance–variance structure and a quadratic term for time, as the relationship between HRQoL and time is normally curvilinear (Awick et al., 2015, Robert et al., 2013). Adjustment for stratification variables is not sensible because those variables are not directly related to outcomes (Kahan and Morris, 2012, Pocock et al., 2002). The model was used to test for treatment group effect at the completion of the intervention period and for maintenance effects, and estimates were presented along with 95% confidence intervals (CIs). The predicted estimates of outcomes at each time point were calculated using fitted models of the data in order to examine the patterns of individual change within each group (Sahafi et al., 2016). In addition to the main analysis, exploratory analyses were conducted on sub-populations such as hip versus knee patients, and BMI categories with the aim to explore options for future research.

The reporting of this trial complies with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for conducting RCTs to assess non-pharmacological treatments (Moher et al., 2010).

4.12 Summary

This chapter presented details about the study's design which was intended to provide high quality data to measure the effectiveness of the Flinders Program based self-management support intervention tailored for obese people with osteoarthritis awaiting hip or knee replacement surgery. The outcome data collected included the domains of improvement in HRQoL and weight loss. No changes were made to the design and methods after the trial commencement.

5. RESULTS OF THE RANDOMISED CONTROLLED TRIAL

5.1 Introduction

This chapter presents the findings of the randomised controlled trial described in the previous chapter. First, preliminary results are presented including demographic characteristics and baseline data of participants in both the intervention and control groups. The flow chart of participant recruitment is shown as recommended by the CONSORT guidelines (Moher et al., 2010). The baseline characteristics for each study group, after randomisation, are also presented in tabular form. Reporting the preliminary findings is important as it ensures the external validity of the main findings.

For each primary and secondary outcome, intervention effects for both groups, and the difference between groups, are provided. The uncertainty of the estimates is recognised by using 95% confidence intervals (CIs).

Findings from the exploratory analyses are then presented. The effects of the BMI categories, time of surgery and self-management competency on the primary outcomes are individually presented. The differences in the outcomes between hip and knee replacement patients are also evaluated. Subsequently, the effects of gender and socio-demographic status on the primary outcomes and weight loss are presented. There were no adverse events in this study to report.

5.2 Preliminary results

5.2.1 Participant recruitment

The flow of participants through each stage of the study is shown in Figure 7. Participants were recruited from a total of 218 patients on the hip or knee replacement waiting list over an 8-month period from July 2015 to February 2016. The most common reason for study exclusion was residential distance from the hospital and lack of easy access to transport arrangements ($n = 27$). A total of 95 participants were recruited and randomised into the groups using stratified blocked

randomisation, as described in Chapter 4. As a result, 48 participants were allocated to the intervention group, and 47 participants to the control group. Table 7 shows the distribution of participants among groups with the stratification variables of gender and BMI groups.

Table 7: Distribution of participants using stratified blocked randomisation

		Control group n = 47	Intervention group n = 48
Female		29 (61.7%)	29 (60.4%)
Male		18 (38.3%)	19 (39.6%)
BMI		37.7 (4.9)	36.8 (4. 6)
BMI group	BMI (35-40)	21 (44.7)	20 (41.6)
	BMI 40 or above	10 (21.3)	11 (22.9)

Data are mean (standard deviation [SD]) or n (%).

Abbreviations: BMI = body mass index.

Baseline measurements were taken from all 95 enrolled participants before randomisation. Two of the 95 participants dropped out of the study due to their unwillingness to attend the study's follow-ups. They were both allocated to the intervention group and did not attend the first session of the intervention program. They were both male and morbidly obese (BMIs of 52.8 and 47.7).

The mean follow-up time for the first follow-up was 25.4 weeks (standard deviation [SD] = 6.30) ranging from three weeks to 37 weeks. The mean follow-up time for the final follow-up was 42.9 weeks (SD = 7.1) ranging from 25 weeks to 60 weeks. This wide range of follow-up visits was due to the variation in the times of surgery commonly experienced in everyday health services, for instance when patients were scheduled for surgery, and the availability of surgeons to perform these procedures. This, and the fact that the first follow-up visits were done before surgery with the second follow-up visit four months after, caused the wide range of follow-up visits. Twenty-six participants (26) in each of the intervention and control groups had their operation at some point after the first follow-up and before the second follow-up. This balance between the two groups ensured the results could not be affected by the time of surgery. This, however is tested in section 5.5.3.

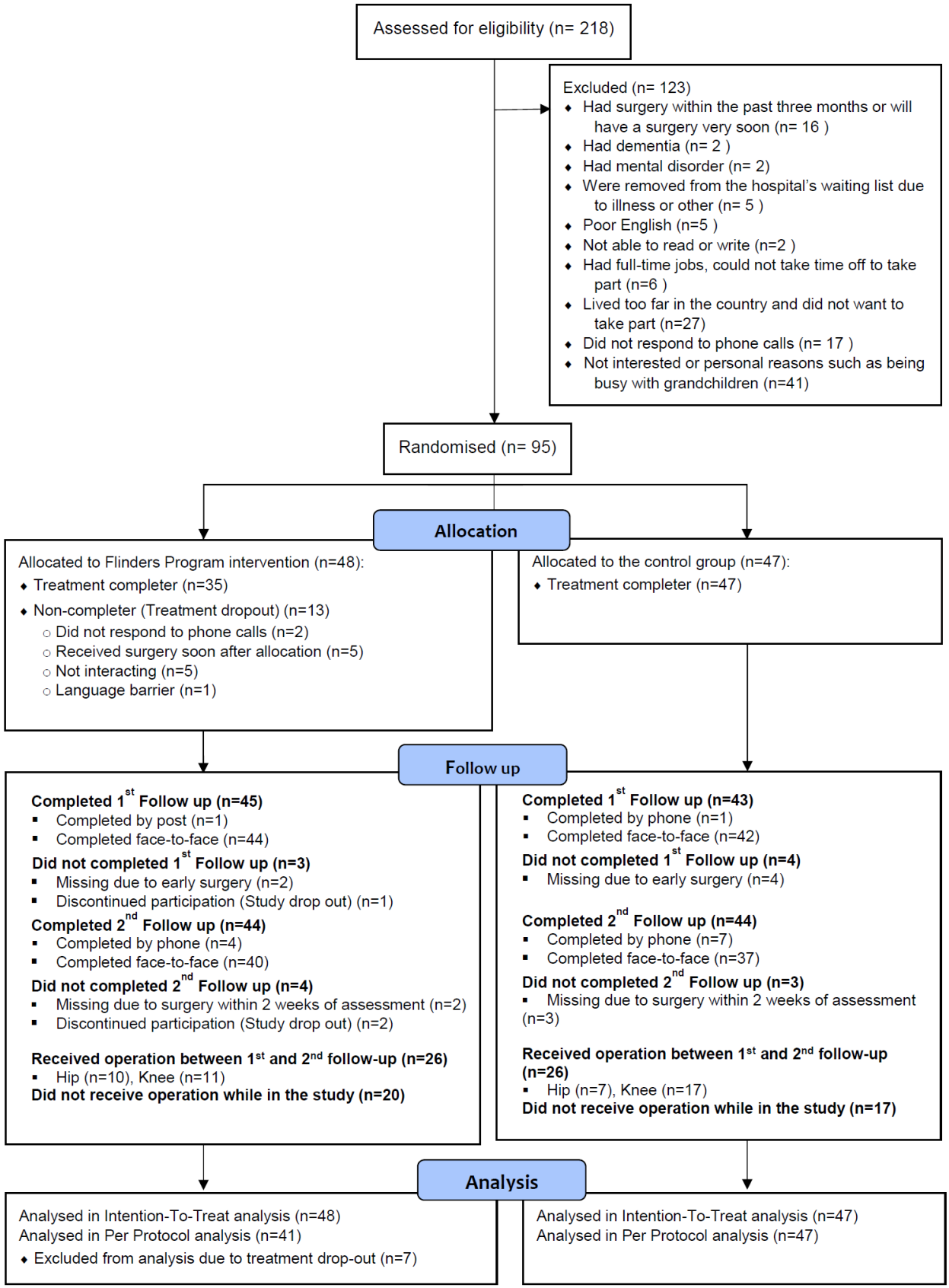


Figure 7: Participant flow

5.2.2 Baseline characteristics

The baseline socio-demographic and clinical characteristics for participants ($n = 95$) are presented for each group in Table 8. The baseline characteristics appear to be balanced between the control and intervention groups. The use of stratified blocked randomisation ensures balance in the known confounders; therefore, modelling any statistical tests for baseline differences are illogical (Moher et al., 2010).

The mean age of participants in the control group was 68.5 (SD = 8.2) years ranging from 46 to 85 years. The mean age of participants in the intervention group was 67.2 (SD = 9.0) years ranging from 48 to 83 years. Most participants in both control and intervention groups were female: the 29 females in each group comprised 61.7% and 60.4% of the participants in the control and intervention groups, respectively. Over half of the participants in both groups lived with their partner, while more than a quarter lived alone. A large majority of participants in both groups were retired or unemployed, with 85.1% in the control group and 81.2% in the intervention group. About 64% of participants in both groups had completed secondary school.

The mean BMI of participants in the control group was 37.7 (SD = 4.9) ranging from 30.3 to 52.4, and the mean BMI of participants in the intervention group was 36.8 (SD = 4.6) ranging from 30 to 52.8. Of the total 95 participants, 65 were allocated to knee replacement surgery ($n = 33$ [70.2%] in the control group and $n = 32$ [66.7%] in the intervention group) compared to 30 participants allocated to hip replacement surgery ($n = 14$ [29.8%] in the control group and $n = 16$ [33.3%] in the intervention group). The total SF-36 physical score was similar for both groups, with 31.7 (SD = 7.2) for the control group and 31.5 (SD = 6.3) for the intervention group, both considerably lower than the South Australian population norm of 53.6 (Marin et al., 2009). The mean SF-36 mental score was 47.2 (SD = 12.4) for the control group and 44.2 (SD = 12.6) for the intervention group (the SF-36 mental score is 48.8 for the South Australian population norm).

Table 8: Baseline characteristics

	Control group (n = 47)	**Intervention group (n = 48)**
Socio-demographic data		
Age (years)	68.5 (8.2)	67.25 (9.0)
Female	29 (61.7%)	29 (60.4%)
Living arrangement		
Living alone	17 (36.2%)	15 (31.2%)
Living with partner	25 (53.2%)	29 (60.4%)
Living with children	3 (6.4%)	2 (4.2%)
Other	2 (4.3%)	2 (4.2%)
Work status		
Retired/unemployed	40 (85.1%)	39 (81.2%)
Full-time job	3 (6.4%)	4 (8.3%)
Part-time job	4 (8.5%)	5 (10.4%)
Qualification		
Primary school	5 (10.6%)	3 (6.2%)
Secondary school	30 (63.8%)	31 (64.6%)
Undergraduate	4 (8.5%)	6 (12.5%)
Postgraduate	3 (6.4%)	4 (8.3%)
Other	5 (10.6%)	4 (8.3%)
Clinical characteristics		
BMI	37.7 (4.4)	36.8 (4.6)
WC	119.1 (14.0)	118.3 (12.1)
WHtR	0.7 (0.1)	0.7 (0.1)
%BF	40.8 (5.1)	40.7 (5.3)
SF-36		
Physical function	29.7 (6.8)	29.5 (7.2)
Physical role	34.7 (8.5)	32.6 (7.5)
Bodily pain	32.1 (5.6)	30.8 (6.3)
General health perception	46.8 (11.2)	44.4 (9.9)
Total physical score	31.7 (7.2)	31.5 (6.3)
Vitality	40.1 (10.6)	39.7 (8.5)
Social role	36.5 (13.4)	37.6 (12.8)
Emotional role	41.1 (12.6)	36.2 (13.1)
Mental health	47.3 (11.7)	44.1 (10.4)
Total mental score	47.2 (12.4)	44.2 (12.6)
OAKHQoL		
Physical activity	35.5 (16.6)	32.1 (19.1)
Mental health	59.8 (24.0)	50.6 (26.4)
Pain	28.5 (19.5)	25.8 (22.5)
Social support	67.8 (24.6)	68.2 (20.5)
Social activity	62.6 (27.6)	55.8 (24.4)
Professional activities	61.7 (34.9)	41.7 (33.6)
Spouse relations	58.5 (33.1)	43.2 (36.9)
Sexual activity	54.8 (41.9)	38.3 (38.5)
Self-management (PIH)	77.8 (13.9)	78.1 (10.5)
Knowledge	13.7 (2.3)	12.8 (3.5)
Partnership	29.8 (4.4)	30.2 (2.7)
Symptom recognition & management	13.9 (2.4)	13.8 (12.9)
Coping	22.3 (6.8)	21.5 (6.8)

Data are mean (standard deviation [SD]), or n (%).
Abbreviations: BMI = body mass index; WC = waist circumference; WHtR = waist-to-height ratio; %BF =percentage body fat.

5.2.3 Implementation of interventions

No treatment non-completers were in the control group as they all received usual care. However, 14.6% (7/48) participants were classified as treatment non-completers in the intervention group having received less than one-third of the intervention (three or less intervention phone calls). This included two females and three males who did not continue the intervention after attending the first session, and two males who did not attend the first session. Table 9 presents their BMI, the number of phone calls where contact was made and the reason why they did not complete the intervention.

Table 9: Characteristics of treatment drop-out participants

	Gender	BMI	Number of phone call follow-ups	Reason for not completing treatment
1	Male	52.8	0	Did not answer phone calls and did not attend the first session (eventually dropped out of the study)
2	Male	47.7	0	
3	Male	36.5	0	Language barrier
4	Male	32.4	0	Not interacting, difficult to reach or engage
5	Female	39.4	0	
6	Male	36.8	2	
7	Female	40.2	3	

5.3 Main results

5.3.1 Primary outcomes

The primary research question tested in this study was: does the self-management support program plus treatment as usual improve the HRQoL (measured by SF-36 and OAKHQoL) in patients with obesity and osteoarthritis awaiting joint replacement surgery of the hip or knee compared to the existing clinical pathway (usual care) for the management of patients with obesity and osteoarthritis?

As SF-36 and OAKHQoL measure HRQoL from a generic and disease-specific perspective and complement each other, they are considered co-jointly through each stage of analysis. Before estimating the intervention effects, SF-36 and OAKHQoL scores were examined at the individual levels.

5.3.1.1 Observed data

SF-36:

The plots of observed individual profiles for SF-36 physical and mental scores by treatment group are shown in Figure 8 and Figure 9, respectively. On these plots, each dot represents one participant's score at a particular time point. The red lines show the mean South Australian population norm for each score. A substantial difference can be seen at the participant level in both baseline scores (at 0 weeks) and the rate of responses over time.

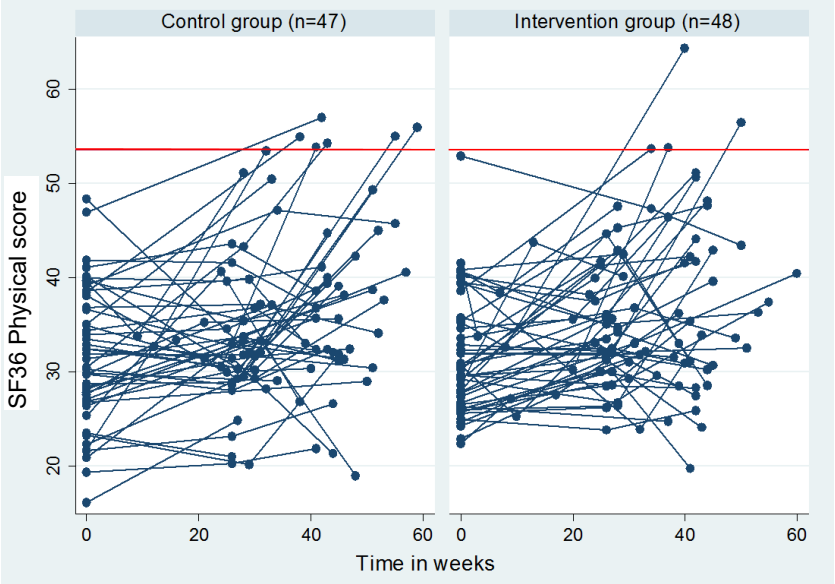


Figure 8: Individual response profiles for SF-36 total physical score

Higher SF-36 scores indicate better quality of life.

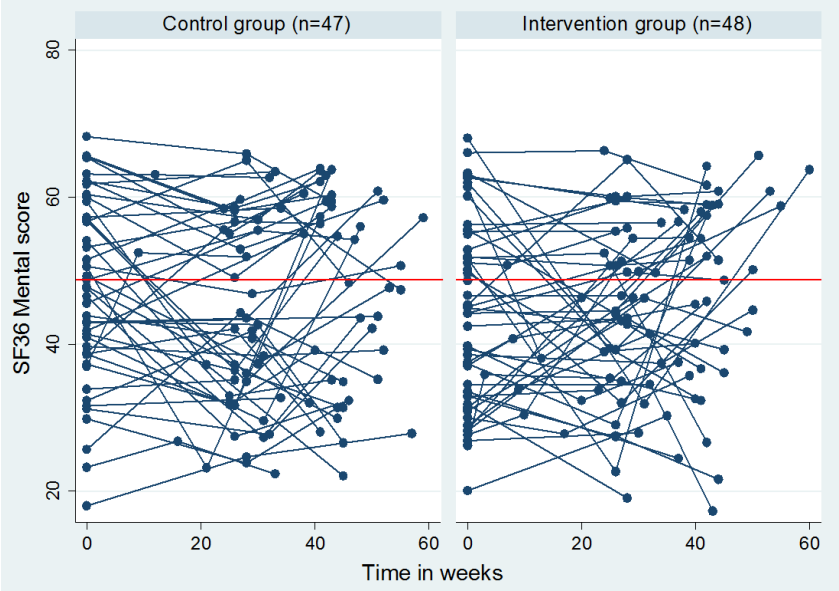


Figure 9: Individual response profiles for SF-36 total mental score

Higher SF-36 scores indicate better quality of life.

The observed SF-36 mean physical and mental scores by treatment group and visit time are demonstrated in Figure 10 and Figure 11, respectively. The mean scores in both control and intervention (Flinders Program) groups appear to increase (improve) and have a similar trend to the individual profiles in Figure 8 and Figure 9. From the observed data, the mean physical score for the intervention (Flinders Program) group seems to have a greater improvement at six months compared to that of the control group, with the opposite pattern seen between the two groups at 10 months.

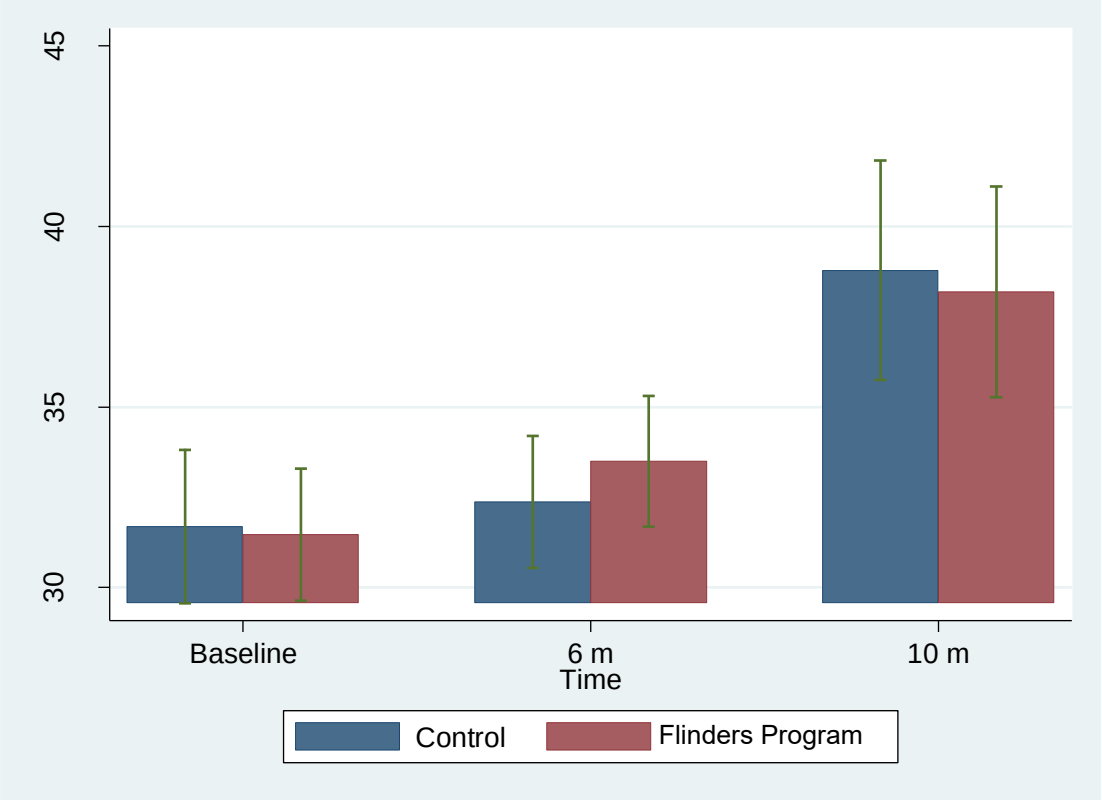


Figure 10: Observed mean SF-36 physical scores by treatment group and visit time

Higher SF-36 scores indicate better quality of life; m = months

From the observed data, the mean mental scores of both groups seem to decline over the first six months and then improve at the 10-month point. The mean mental score of the intervention (Flinders Program) group started considerably lower (poorer) than that of the control group, but it appeared to have a higher improvement at both 6-month and 10-month points compared to the control group.

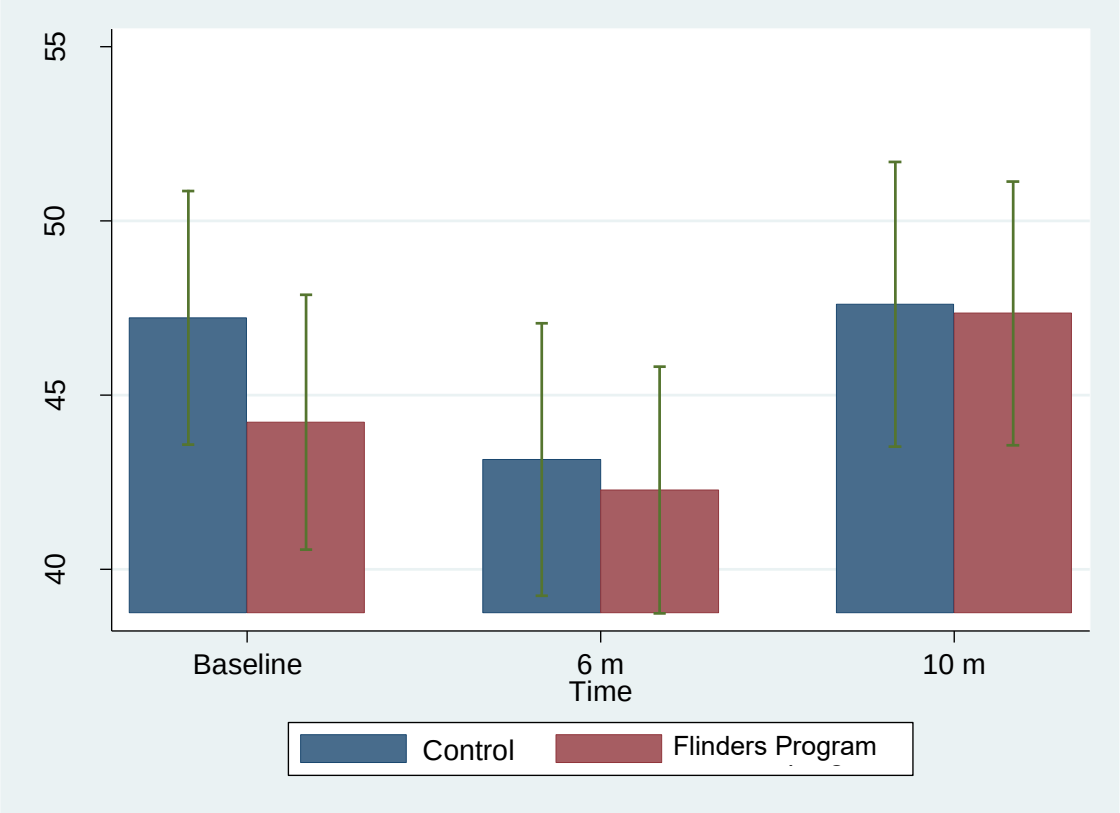


Figure 11: Observed mean SF-36 mental scores by treatment group and visit time

Higher SF-36 scores indicate better quality of life; m = month

OAKHQoL:

The plots of observed individual profiles for OAKHQoL scores by treatment group are shown in Figure 12. On these plots, each dot represents one participant's score at a particular time point. A substantial difference can be seen at the participant level in both baseline scores (at 0 weeks) and the rate of responses over time.

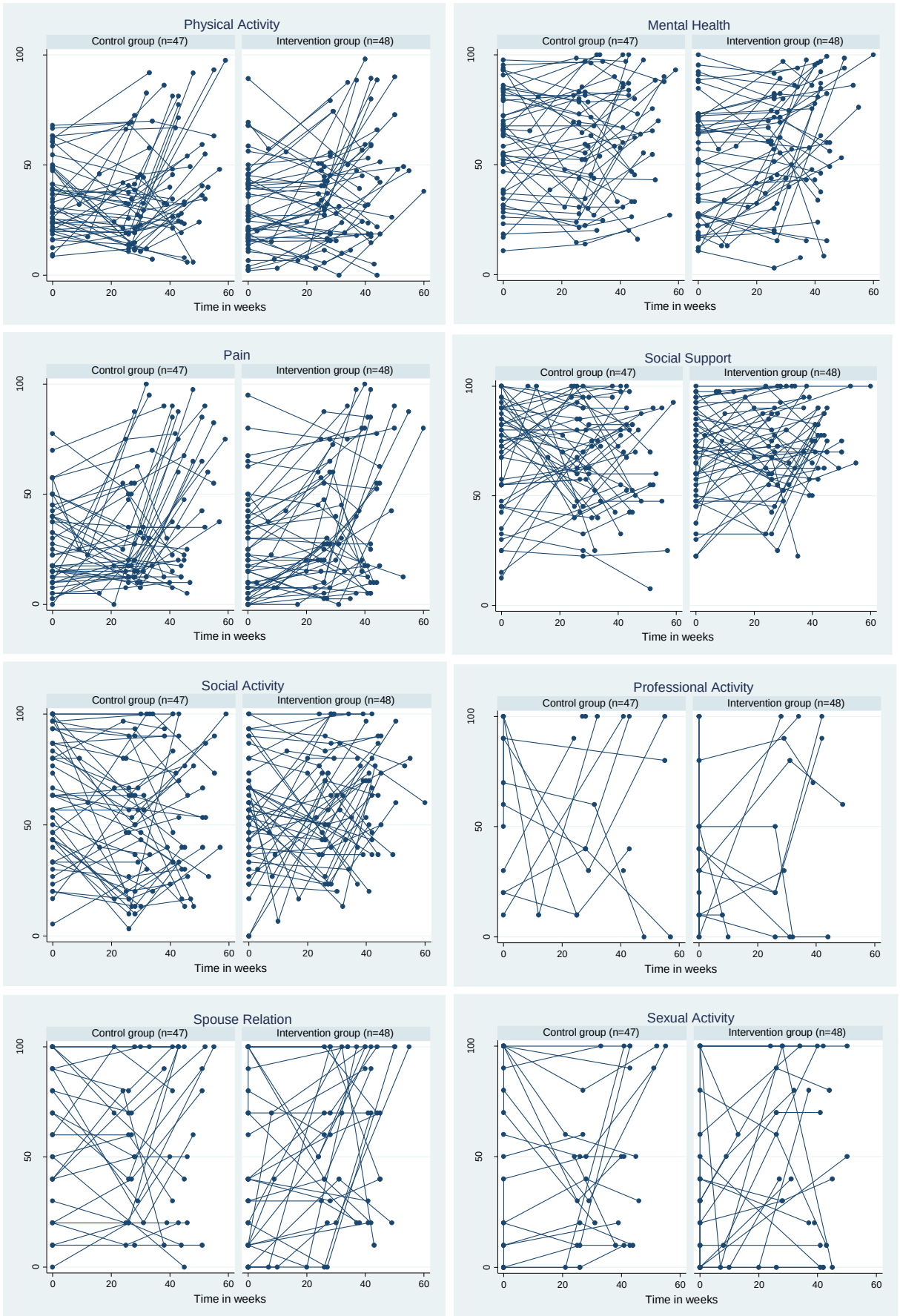


Figure 12: Individual response profiles for OAKHQoL scores

Higher OAKHQoL scores indicate better quality of life.

The observed mean OAKHQoL scores by treatment group and visit time are shown in Figure 13. The mean scores in both control and intervention (Flinders Program) groups appear to have a similar trend to the individual profiles in Figure 12. From the observed data, physical activity, social activity and professional activity scores of both groups seem to decline over the first six months and then improve at the 10-month point. The intervention (Flinders Program) group appears to increase (improve) in scores of mental health, pain, spouse relations and sexual activity across time, whereas the control group seems to have a decline in these scores over the first six months and then an improvement at 10 months. The social support score appears to improve in the intervention group across time, while it seems to slightly improve at six months for the control group and then declines at 10 months.

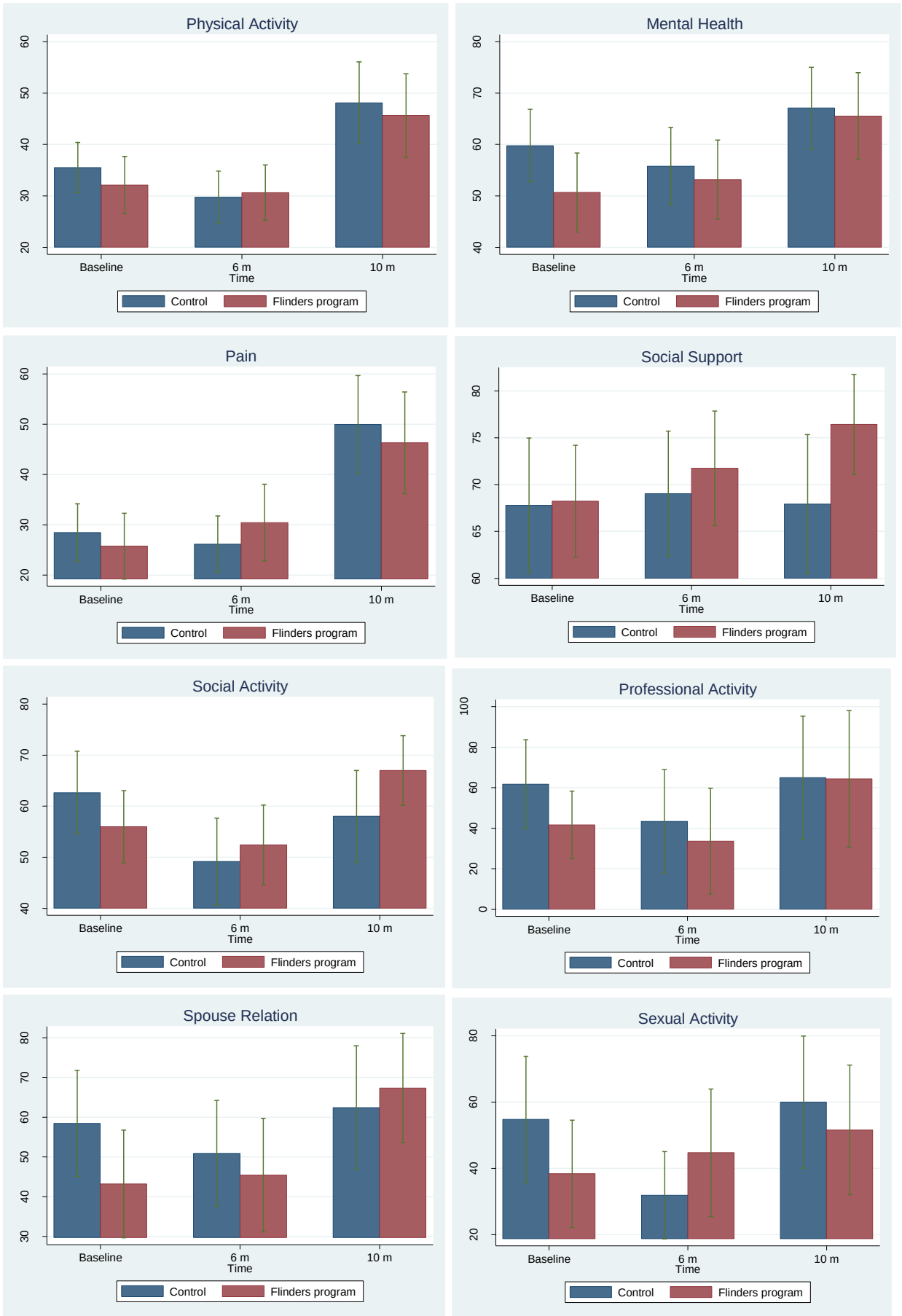


Figure 13: Observed mean OAKHQoL scores by treatment group and visit time

Higher OAKHQoL scores indicate better quality of life; m = month

5.3.1.2 Missing data

The patterns of missing primary outcomes (SF-36 and OAKHQoL) for both control and intervention groups are presented in this section. The patterns of missing SF-36 data for both groups are shown in Table 10. For all participants in both groups, SF-36 data were available on at least one follow-up time point. Overall, 6-month (follow-up 1) data points were missing for six participants, and 10-month (follow-up 2) data points were missing for five participants. One participant in the control group filled out the SF-36 questionnaire incompletely at the 1st follow-up time point and, despite having some SF-36 domain scores, was therefore considered to be missing SF-36 data. The same was the case for one participant in the intervention group at the 2nd follow-up time point. All other missing data occasions occurred when participants received surgery before six months due to cancellations by other patients and the availability of study participants, as well as hospital staff forgetting to notify the PhD candidate (LS) regarding the time of surgery. Subsequently, it seems plausible to consider the missing data to be missing at random (MAR). The pattern of missing data was consistent for both groups and for follow-up time points.

Table 10: Missing data frequency and pattern for SF-36 outcome by group

	Frequency	%	Baseline	Follow-up 1	Follow-up 2
Control group n=47	0	0	X		
	4	9		X	
	3	6			X
	0	0		X	X
Intervention group n=48	0	0	X		
	2	4		X	
	2	4			X
	0	0		X	X

X represents missing data for the specified visit

The patterns of missing data for OAKHQoL for both groups are shown in Table 11. For all

participants in both groups, most OAKHQoL domains were available on at least one follow-up time point. Two participants in the control group who completed their follow-up 2 questionnaires on the phone could not answer more questions and, therefore, had missing OAKHQoL data. This was also the case for two participants in the intervention group at follow-up 1 and three participants in the intervention group at follow-up 2. The pattern of missing data was consistent for both groups and for follow-up time points.

Table 11: Missing data frequency for OAKHQoL outcome by group

	Frequency	%	Baseline	Follow-up 1	Follow-up 2
Control group n=47	0	0	X		
	3	6		X	
	5	11			X
	0	0		X	X
Intervention group n=48	0	0	X		
	4	8		X	
	4	8			X
	0	0		X	X

X represents missing data for the specified visit

The domains of professional activity, spouse relations and sexual activity of OAKHQoL were missing for many participants due to a large number of participants being retired and having lost their partners. Table 12 shows the frequency of missing data for these domains of OAKHQoL for both control and intervention groups. The numbers in the table represent 'Not Applicable' as well as missing data.

Table 12: Missing data frequency for optional OAKHQoL domains by group

		Baseline	Follow-up 1	Follow-up 2
Control group n=47	Professional activity	35, 74%	38, 81%	37, 79%
	Spouse relations	21, 45%	25, 53%	22, 47%
	Sexual activity	26, 55%	31, 66%	30, 64%
Intervention group n=48	Professional activity	30, 62%	36, 75%	39, 81%
	Spouse relations	17, 35%	23, 48%	20, 42%
	Sexual activity	24, 50%	30, 62%	27, 56%

The first numbers represent the number of participants with missing data at the specified visit.

5.3.1.3 Intention-to-treat analysis

The primary outcome measures for SF-36 and OAKHQoL were analysed based on the intention-to-treat (ITT) principle. Due to considerable variation in intra-individual and inter-individual changes in these measures across the study intervention and follow-up, a mixed-effects modelling approach was considered justified to provide analysis of repeated measures of data at each time point to determine changes across the time periods. Fixed effects included the treatment group, time points at the baseline (0 weeks), first follow-up (24 weeks) and second follow-up (40 weeks), and interaction between groups and visit times. The model included both random intercept and random slope terms at the individual level, and used an independent covariance structure and a quadratic term for time, as described in Section 4.11. A likelihood ratio test comparing this model with both the fixed-effects ordinary linear regression and the linear mixed-effects model showed a significantly better fit ($p < 0.05$).

SF-36:

The first primary outcome measure was the HRQoL measure of SF-36, comprising scores in eight domains which are summarised as total physical and total mental scores. The model was run for both total SF-36 physical and mental scores. In total, 271 observations were recorded for the 95 participants, with each participant having an average of 2.9 (range of 1–3) completed assessments.

Changes in these scores for the control and intervention groups and between groups at baseline, 6-month and 10-month follow-ups are provided in Table 13.

Table 13: Changes in primary outcome between control and intervention groups at baseline, 6-month and 10-month points

	Baseline				6 months				10 months			
	Unadjusted Estimate (Standard error [SE])		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value
	Control N=47	Intervention N=48			Control N=47	Intervention N=48			Control N=47	Intervention N=48		
SF-36 total physical	31.1 (1.1)	31.1 (0.1)	-0.3 (-2.7 – 2.7)	0.980	34.5 (0.9)	34.7 (0.9)	0.4 (-2.2–2.9)	0.778	36.7 (1.1)	37.1 (1.2)	0.6 (-2.6–3.9)	0.707
SF-36 total mental	47.2 (1.8)	44.1 (1.7)	-3.4 (-8.2 – 1.5)	0.175	44.0 (1.9)	42.2 (1.7)	-1.1 (-5.3–3.1)	0.617	45.5 (1.7)	46.0 (1.6)	0.4 (-4.2–5.1)	0.850

The main intervention effects for SF-36 are presented in Table 14. A mixed-effects model with linear time fitted the best with the SF-36 physical score across time within groups. There were significant improvements in the SF36 physical score within both groups across time ($p < 0.001$ for both the intervention and control groups). However, there were no significant differences between the two groups in SF36 physical score across time ($p = 0.712$). There were significant improvements in SF-36 mental scores within both groups across time ($p = 0.010$ for the intervention group and $p = 0.033$ for the control group) and although there was a greater improvement in the SF-36 mental score in the intervention group compared to the control group across time, it was not statistically significant at 5% α-level ($p = 0.094$). Also, there were no significant differences in the 6-month (i.e. before surgery) SF-36 physical ($p = 0.442$) and mental ($p = 0.398$) scores between the two groups.

Table 14: Main intervention effect for SF-36 total scores within and between groups across time

SF-36	Within-group		Between-group
	Control group n = 47	Intervention group n = 48	
Total physical score	$p < 0.001$	$p < 0.001$	$p = 0.712$
Total mental score	$p = 0.033$	$p = 0.010$	$p = 0.094$

To further interpret this analysis, the post-estimation marginal effects of responses for total physical and mental outcomes, with time at fixed values of 0 week, and at 24 and 40 weeks were obtained, as shown in Figure 14. These figures corresponded with the observed mean scores in Figure 10 and Figure 11.

The SF-36 physical score increased across time for both groups, reflecting improvements for both groups from the baseline. There is a downward trend of the SF-36 mental score for both groups from baseline to the 6-month follow-up reflecting the deteriorating mental score, but then an increase from the 6-month follow-up to the 10-month follow-up, indicating mental score improvements.

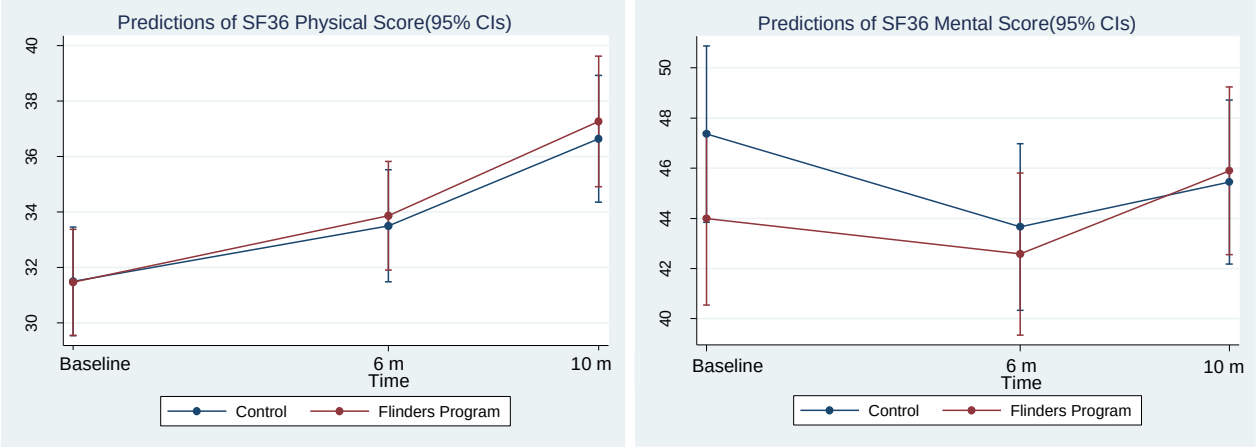


Figure 14: Predictions of SF-36 physical and mental scores (95% CIs)

Higher SF-36 scores indicate better quality of life

As SF-36 quantifies the HRQoL in eight domains, mixed modelling was then used to analyse all SF-36 domains in more detail. Changes in domain scores within control and intervention groups and between groups at baseline, and at 6-month and 10-month follow-ups are provided in Table 15.

Table 15: Changes in SF-36 domains between control and intervention groups at baseline, 6-month and 10-month points

SF-36 scores of domains	Baseline				6 month				10 month			
	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value
	Control N=47	Intervention N=48			Control N=47	Intervention N=48			Control N=47	Intervention N=48		
Physical function	29.6 (1.1)	28.5 (1.0)	-0.3 (-3.1–2.6)	0.858	28.8 (1.2)	31.8 (0.9)	0.8 (-1.8 – 3.3)	0.563	32.9 (1.2)	34.0 (1.2)	1.43 (-1.92 – 4.79)	0.402
Physical role	34.2 (1.2)	32.1 (1.1)	-2.1 (-5.3 – 1.1)	0.194	36.9 (1.0)	35.9 (0.8)	-0.9 (-3.4 – 1.7)	0.516	38.6 (1.2)	38.4 (1.2)	-0.02 (-3.31 – 3.27)	0.990
Bodily pain	31.4 (0.9)	30.1 (1.0)	-1.4 (-4.0 – 1.2)	0.283	34.3 (0.9)	34.0 (0.9)	-0.1 (-2.5 – 2.4)	0.949	36.3 (1.3)	36.9 (1.2)	0.82 (-2.60 – 4.23)	0.639
General health	46.5 (1.5)	44.5 (1.4)	-2.1 (-6.1 – 2.0)	0.320	47.4 (1.4)	46.0 (1.3)	-1.4 (-5.1 – 2.3)	0.468	48.0 (1.4)	47.1 (1.4)	-0.92 (-4.87 – 3.04)	0.650
Vitality	39.5 (1.6)	39.0 (1.2)	-0.6 (-4.4 – 3.2)	0.748	42.2 (1.4)	41.3 (1.0)	-0.7 (-4.2 – 2.7)	0.671	44.0 (1.6)	42.8 (1.2)	-0.83 (-4.85 – 3.18)	0.683
Social role	36.4 (1.9)	37.4 (1.8)	1.4 (-3.6 – 6.4)	0.593	33.9 (1.9)	37.2 (1.8)	2.6 (-1.6 – 6.9)	0.228	36.9 (1.8)	40.4 (1.6)	3.46 (-1.33 – 8.26)	0.157
Emotional role	41.1 (1.8)	36.0 (1.7)	-5.4 (-10.2 - -0.6)	0.027	38.0 (1.8)	35.7 (1.7)	-1.5 (-5.5 – 2.5)	0.460	40.5 (1.6)	41.6 (1.6)	1.08 (-3.49 – 5.64)	0.643
Mental health	47.3 (1.7)	43.9 (1.5)	-3.4 (-7.8 – 0.9)	0.118	44.2 (1.8)	42.1 (1.6)	-2.0 (-6.0 – 2.0)	0.332	45.6 (1.8)	44.7 (1.6)	-0.99 (-5.70 – 3.71)	0.680

Intervention effects for the SF-36 domains are presented in Table 16. There were significant improvements in all SF-36 domains within the intervention group across time. There were also significant improvements in SF-36 domains within the control group across time, except for general health ($p = 0.163$).

The intervention group had a significantly greater improvement in emotional role score across time compared with the control group ($p = 0.009$). Within group analyses showed a medium effect size ($d = 0.61$) baseline to 10-month follow up for the intervention group. There were no significant differences between the two groups in other SF-36 domains.

Table 16: Intervention effects for SF-36 domains across time

SF-36 domains	Within-group		Between-group
	Control group n = 47	Intervention group n = 48	
Physical function	$p < 0.001$	$p < 0.001$	$p = 0.374$
Physical role	$p < 0.001$	$p < 0.001$	$p = 0.307$
Bodily pain	$p < 0.001$	$p < 0.001$	$p = 0.264$
General health	$p = 0.163$	$p = 0.020$	$p = 0.460$
Vitality	$p = 0.001$	$p = 0.006$	$p = 0.914$
Social role	$p = 0.009$	$p = 0.027$	$p = 0.396$
Emotional role	$p = 0.016$	$p = 0.005$	$p = \mathbf{0.009}$
Mental health	$p = 0.024$	$p = 0.038$	$p = 0.282$

To further interpret this analysis, the post-estimation marginal effects of responses for SF-36 domains, with time at fixed values of 0 week, and 24 and 40 weeks were obtained (Appendix F). The trend for social role, emotional role and mental health scores in both groups was downward from baseline to the 6-month follow-up and then upward to the 10-month follow-up. There was a better overall improvement for the intervention group in those scores compared with the control group, although the improvement was only significant for the emotional role ($p = 0.009$).

OAKHQoL:

The second primary outcome measure of HRQoL was OAKHQoL which comprises scores in the eight domains of physical activity, mental health, pain, social support, social activity, professional activity, spouse relations and sexual activity. To analyse the treatment effects on the OAKHQoL scores, mixed-effects modelling was used.

In total, 266 observations were reported for 95 participants with an average of 2.8 completed assessments for each participant (range 1–3). Changes in these scores for within groups and between groups at the baseline, and 6-month and 10-month follow-ups are provided in Table 17. The mental health score in the control group was significantly higher than in the intervention group at baseline ($p = 0.043$). This difference became insignificant at the 6-month and 10-month follow-ups ($p = 0.456$ and $p = 0.834$, respectively). The difference in the professional activity score between the two groups was quite large at the baseline ($p = 0.065$), then became less at the 6-month follow-up ($p = 0.330$), and then highly insignificant at the 10-month follow-up ($p = 0.913$). This was due to the greater improvement of this score in the intervention group across time compared with the control group; however, the difference between the two groups across time was not significant ($p = 0.326$).

Table 17: Changes in OAKHQoL between control and intervention groups at baseline, 6-month and 10-month points

OAKHQoL domains	Baseline				6 month				10 month			
	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value
	Control	Intervention			Control	Intervention			Control	Intervention		
Physical activity	35.3 (2.6)	29.9 (2.8)	-3.2 (-10.4 – 4.0)	0.387	31.9 (2.9)	36.9 (2.7)	-0.97 (-8.15 – 6.21)	0.792	41.8 (3.2)	41.4 (3.4)	-0.51 (-8.94 – 0.97)	0.916
Mental health	59.7 (3.5)	48.5 (3.6)	-10.1 (-19.8 - -0.3)	0.043	57.4 (3.6)	57.1 (3.3)	-3.39 (-12.31 - -5.52)	0.456	62.2 (3.5)	62.8 (3.7)	1.07 (-8.90 – 11.03)	0.834
Pain	25.0 (3.4)	23.8 (3.4)	-1.7 (-10.7 – 7.4)	0.719	35.3 (2.7)	35.3 (3.2)	0.51 (-7.58 – 8.59)	0.902	42.2 (3.2)	42.9 (4.1)	1.95 (-8.24 – 12.15)	0.707
Social support	68.4 (3.3)	68.5 (2.7)	-0.0 (-8.7 – 8.2)	0.999	68.2 (2.7)	72.8 (2.2)	4.71 (-2.23 – 11.65)	0.184	68.1 (3.1)	75.6 (2.6)	7.85 (-0.14 – 15.83)	0.054
Social activity	62.6 (4.1)	53.5 (3.3)	-7.3 (-17.4 – 2.8)	0.158	51.4 (4.1)	59.0 (2.5)	2.81 (-5.62 – 11.25)	0.513	53.6 (3.8)	63.7 (3.2)	9.54 (-0.22 – 19.31)	0.055
Professional activity	58.9 (9.6)	36.3 (8.2)	-22.4 (-46.3 – 1.4)	0.065	57.6 (6.8)	48.2 (8.0)	-10.02 (-30.16 – 10.12)	0.330	56.8 (9.4)	56.2 (10.4)	-1.74 (-33.05 – 29.57)	0.913
Spouse relations	59.1 (6.4)	40.5 (5.9)	-16.2 (-33.2 – 0.8)	0.062	51.2 (6.6)	53.8 (4.6)	-4.00 (-17.82 – 9.82)	0.571	59.6 (6.1)	62.8 (5.9)	4.13 (-12.13 – 20.40)	0.618
Sexual activity	54.4 (7.6)	35.4 (7.2)	-14.9 (-35.6 – 5.8)	0.159	36.5 (8.1)	43.6 (5.9)	-7.28 (-24.61 – 10.04)	0.410	51.9 (7.4)	49.1 (7.6)	-2.20 (-23.32 – 18.92)	0.838

The main intervention effects on OAKHQoL outcomes are presented in Table 18. There were significant improvements in pain, physical activity, mental health, social activity and spouse relations scores within both groups across time ($p < 0.05$). There was a significant improvement in social support within the intervention group across time ($p = 0.016$), but not in the control group.

The improvement of the OAKHQoL mental health and social activity scores was significantly greater in the intervention group (with a medium effect size $d = 0.56$ and $d = 0.50$, respectively baseline to 10-month follow up) than in the control group ($p = 0.012$ and $p = 0.002$, respectively). The analysis also showed a significantly greater improvement of the OAKHQoL spouse relations score in the intervention group with a medium effect size baseline to 10-month follow up ($d = 0.67$) compared to the control group ($p = 0.032$); however, it is worth mentioning that the total number of observations for this score was 154 for 59 of the participants. There were no significant differences in other OAKHQoL domains between the two groups across time.

Table 18: Main intervention effects for OAKHQoL domains within and between groups across time

OAKHQoL domains	Within-group		Between-group
	Control group n = 47	Intervention group n = 48	
Physical activity	$p < 0.001$	$p = 0.001$	$p = 0.458$
Mental health	$p = 0.041$	$p < 0.001$	$p = \mathbf{0.012}$
Pain	$p < 0.001$	$p < 0.001$	$p = 0.525$
Social support	$p = 0.913$	$p = 0.016$	$p = 0.070$
Social activity	$p = 0.089$	$p = 0.027$	$p = \mathbf{0.002}$
Professional activity	$p = 0.880$	$p = 0.065$	$p = 0.326$
Spouse relations	$p = 0.044$	$p = 0.003$	$p = \mathbf{0.032}$
Sexual activity	$p = 0.002$	$p = 0.136$	$p = 0.302$

For further interpretation of the analysis, the post-estimation marginal effects of responses for OAKHQoL domains, with time at fixed values of 0 week, and 24 and 40 weeks were obtained, as shown in Figure 15. The statistically significant improvement of mental health, social activity and

spouse relations scores in the intervention group compared to those of the control group can be seen in the plots. The trends of social support and professional activity scores reflect an overall improvement of these scores in the intervention group, while these scores deteriorate for the control group across time. The marginal effects of physical activity, pain and sexual activity scores show a constant or slightly deteriorating trend from baseline to the 6-month follow-up and then an improvement to the 10-month follow-up, and are similar with a slightly better trend for the intervention group compared to the control group.

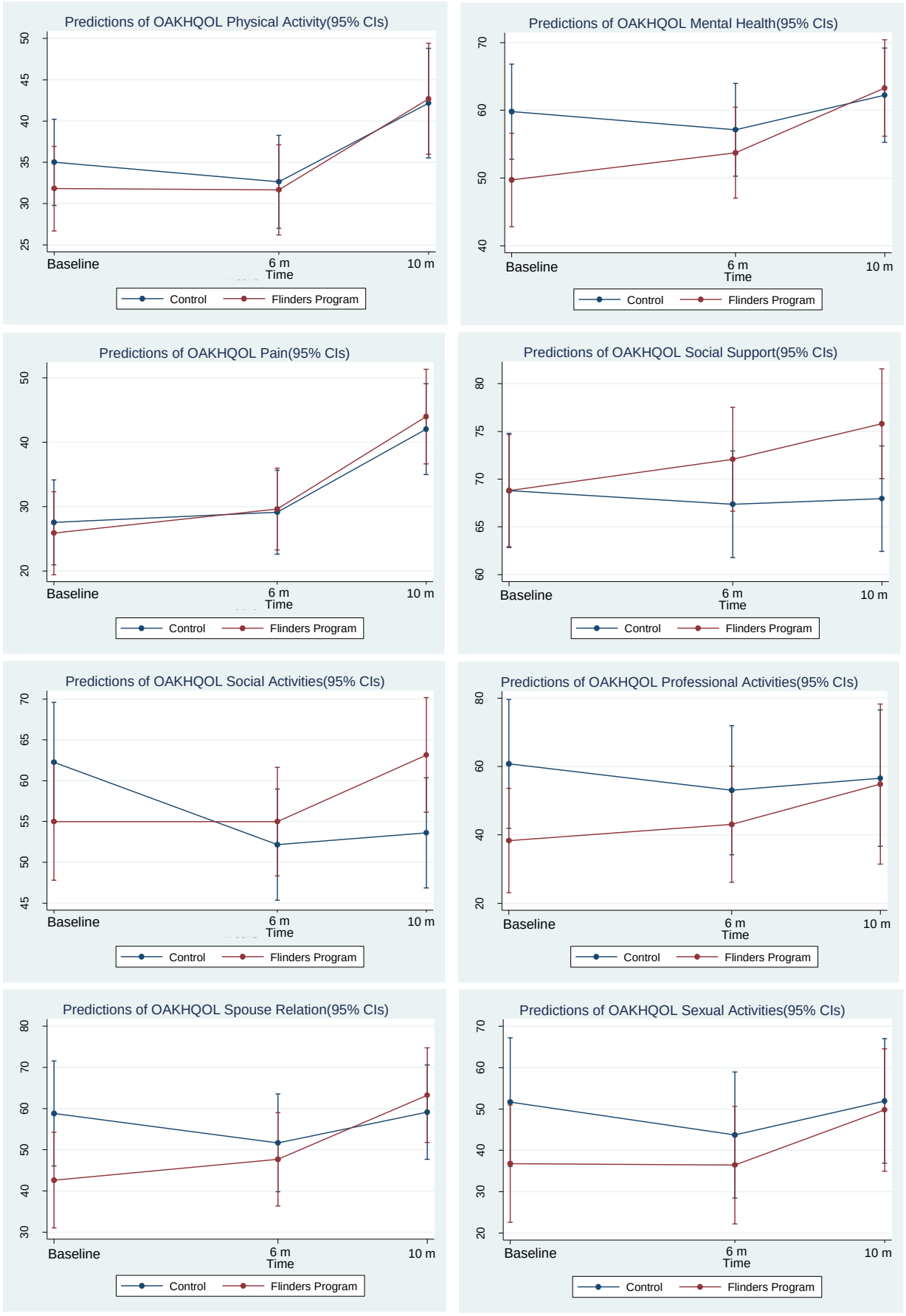


Figure 15: Predictions of OAKHQoL domains (95% CIs)

Higher OAKHQoL scores indicate better quality of life

5.3.2 Secondary outcomes

The frequency of missing secondary outcomes of obesity and self-management competency in the control and intervention groups are presented in Table 19 and Table 20. There were more cases of missing obesity outcomes of body mass index (BMI), waist circumference (WC) and waist-to-height ratio (WHtR) than in the questionnaires, as some participants were willing to answer the questions over the phone, but were not available to attend a visit session where the obesity outcomes could be measured. More participants were missing percentage body fat (%BF) outcomes than other obesity outcomes, as some were not eligible to be measured by the device due to heart problems.

Table 19: Missing data frequency for secondary outcomes in the control group

	Baseline	Follow-up 1	Follow-up 2
BMI, WC, WHtR	0	4	10
%BF	1	8	13
PIH	0	3	6

Numbers represent the number of participants with missing data at the specified visit.

Abbreviations: BMI = body mass index; WC = waist circumference; WHtR = waist-to-height ratio; %BF = percentage body fat; PIH = Partners in Health.

Table 20: Missing data frequency for secondary outcomes in the intervention group

	Baseline	Follow-up 1	Follow-up 2
BMI, WC, WHtR	0	5	8
BF%	3	8	13
PIH	0	4	4

Numbers represent the number of participants with missing data at the specified visit.

Abbreviations: BMI = body mass index; WC = waist circumference; WHtR = waist-to-height ratio; %BF = percentage body fat; PIH = Partners in Health.

5.3.2.1 Obesity

Mixed-effects modelling was used to analyse the intervention effects on obesity outcomes (i.e. BMI, WC, WHtR and %BF). There was a total of 255 observations of BMI, WC and WHtR for 95 participants with an average of 2.7 completed assessments per participant (range 1–3), and there was a total of 236 observations of %BF for 95 participants with an average of 2.5 completed assessments per participant (range 1–3). Changes in these outcomes for within groups and between

groups at the baseline, and 6-month and 10-month follow-ups are provided in Table 21.

Table 21: Changes in obesity outcomes between control and intervention groups at baseline, 6-month and 10-month points

Obesity scores	Baseline				6 months				10 months			
	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value
	Control	Intervention			Control	Intervention			Control	Intervention		
BMI	37.7 (0.7)	36.8 (0.6)	-0.9 (-2.8 – 1.0)	0.337	37.3 (0.7)	36.2 (0.7)	-1.05 (-2.99 – 0.90)	0.292	37.4 (0.8)	36.3 (0.7)	-1.1 (-3.1 – 0.9)	0.280
WC	119.1 (2.1)	118.2 (1.7)	-0.9 (-6.2 – 4.3)	0.728	117.5 (2.1)	115.8 (1.8)	-1.73 (-7.03 – 3.58)	0.523	116.5 (2.1)	114.2 (1.8)	-2.2 (-7.7 – 3.2)	0.421
WHtR	0.7 (0.01)	0.7 (0.01)	0.01 (-0.02 – 0.03)	0.729	0.7 (0.01)	0.7 (0.01)	-0.01 (-0.3 – 0.02)	0.582	0.7 (0.01)	0.7 (0.01)	-0.02 (-0.05 – 0.01)	0.283
%BF	40.9 (0.7)	40.4 (0.8)	-0.4 (-2.5 – 1.7)	0.701	41.1 (0.7)	41.0 (0.8)	-0.41 (-2.48 – 1.66)	0.701	41.3 (0.7)	40.8 (0.8)	-0.4 (-2.5 – 1.7)	0.716

Abbreviations: BMI = body mass index; WC = waist circumference; WHtR = waist-to-height ratio; %BF = percentage body fat.

The main intervention effects for obesity outcomes are presented in Table 22. There were significant improvements in the BMI and WC within the control group across time ($p = 0.023$ and $p < 0.001$, respectively) and within the intervention group across time ($p \leq 0.001$). There were also significant improvements in WHtR within the intervention group ($p = 0.001$), but not within the control group ($p = 0.240$). There were no significant differences in the BMI and WC between the control and intervention groups ($p = 0.506$ and $p = 0.213$, respectively). The WHtR outcome of obesity showed a significantly greater improvement in the intervention group compared with the control group ($p = 0.034$). The percentage body fat outcome was similar between the two groups over time with a slight increase ($p = 0.956$).

Table 22: Main intervention effects for obesity outcomes across time

Obesity outcomes	Within-group		Between-group
	Control group n = 47	Intervention group n = 48	
BMI	$p = 0.023$	$p = 0.001$	$p = 0.506$
WC	$p < 0.001$	$p < 0.001$	$p = 0.213$
WHtR	$p = 0.240$	$p = 0.001$	$p = \mathbf{0.034}$
%BF	$p = 0.324$	$p = 0.171$	$p = 0.956$

Abbreviations: BMI = body mass index; WC = waist circumference; WHtR = waist-to-height ratio; %BF = percentage body fat.

Figure 16 shows mean the waist-to-height ratio (WHtR) by treatment across time. The significant improvements in WHtR in the intervention group versus the control group can be observed.

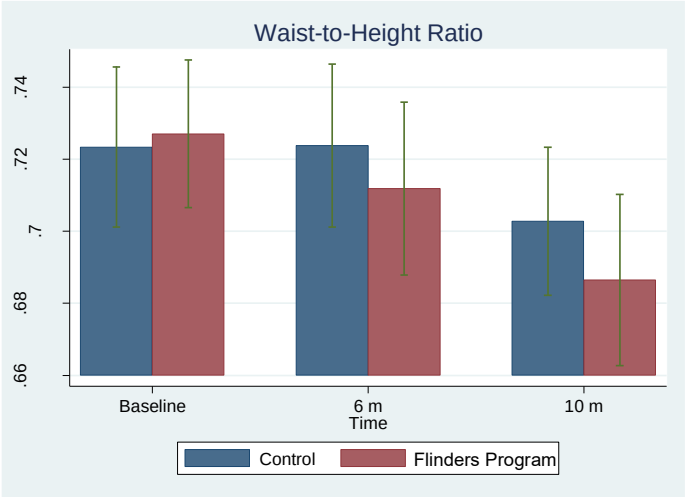


Figure 16: Mean waist-to-height ratio score by treatment group and visit time

Similar trends were shown in the BMI, WC and %BF for both intervention and control groups in the post-estimation marginal effects of responses for obesity outcomes (Appendix G).

***Weight loss in various BMI categories*:**

When comparing weight loss within each BMI category (Table 23), there was a significantly greater weight loss (BMI reduction) in severely obese participants in the intervention group compared to those in the control group ($p = 0.028$). Also, morbidly obese participants in the intervention group had a significantly greater weight loss compared to those in the control group ($p = 0.005$). However, weight loss (BMI reduction) among obese participants in the intervention group was significantly poorer than those in the control group ($p = 0.030$).

Table 23: Weight loss within various BMI categories between groups

	Obese	Severely obese	Morbidly obese
BMI	$p = 0.030$ (in favour of the control group)	$p = 0.028$ (in favour of the intervention group)	$p = 0.005$ (in favour of the intervention group)

Figure 17 shows the mean BMI of participants with various scales of obesity in the two groups (intervention and control) across time.

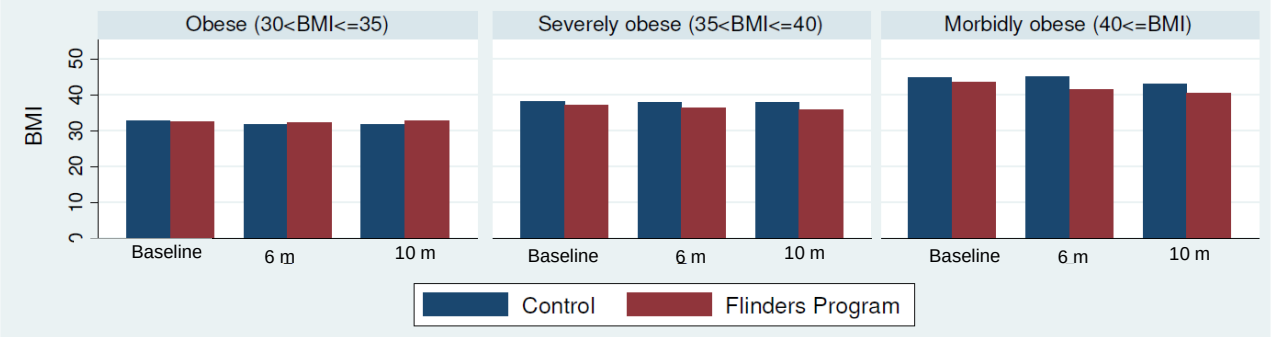


Figure 17: Mean BMI by treatment group and obesity category across time

5.3.2.2 Self-management competency

Finally, self-management competency was measured using the PIH questionnaire. To detect intervention effects on the PIH scale between the control and intervention groups, mixed-effects modelling was used. In total, 265 observations were recorded for 95 participants with an average of 2.8 completed assessments per participant (range 1–3). Changes in the PIH total score and subscale scores for within groups and between groups at baseline, and 6-month and 10-month follow-ups are provided in Table 24.

Table 24: Changes in Partners in Health (PIH) outcomes between control and intervention groups at baseline, 6-month and 10-month points

	Baseline				6 month				10 month			
	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value
	Control	Intervention			Control	Intervention			Control	Intervention		
Total PIH	78.2 (1.6)	78.3 (1.3)	0.2 (-3.8 – 4.2)	0.922	80.3 (1.3)	81.6 (1.2)	1.2 (-2.2 – 4.7)	0.479	81.7 (1.5)	83.7 (1.3)	1.9 (-2.0 – 5.8)	0.335
Knowledge	13.7 (0.3)	13.0 (0.4)	-0.6 (-1.7-0.4)	0.218	13.8 (0.3)	13.8 (0.4)	-0.1 (-0.9-0.9)	0.980	13.9 (0.3)	14.3 (0.4)	0.4 (-0.6 – 1.4)	0.415
Partnership in treatment	30.0 (0.5)	30.3 (0.4)	0.2 (-0.9-1.4)	0.668	30.2 (0.3)	30.4 (0.3)	0.03 (-0.8 – 0.9)	0.942	30.4 (0.4)	30.3 (0.4)	-0.1 (-1.2 – 1.0)	0.835
Recognition & management of symptoms	14.1 (0.3)	13.9 (0.3)	-0.1 (-0.1 – 0.7)	0.720	14.5 (0.2)	14.4 (0.2)	-0.1 (-0.8 – 0.5)	0.687	14.7 (0.3)	14.7 (0.3)	-0.1 (-0.9 – 0.7)	0.757
Coping	22.2 (1.0)	21.4 (0.9)	-0.8 (-3.4 – 1.8)	0.534	22.5 (0.9)	23.3 (0.8)	0.9 (-1.4 – 3.2)	0.438	22.6 (0.9)	24.6 (0.9)	2.1 (-0.4 – 4.6)	0.108

The main intervention effects for self-management competency (measured by the PIH scale and its subscales) are presented in Table 25. Participants within both control and intervention groups achieved a significant improvement in total PIH scores ($p = 0.039$ and $p < 0.001$, respectively); however this improvement was not significantly different between the two groups ($p = 0.408$). The mixed-effects modelling was then run for the PIH subscales. There was a significant improvement in the symptom recognition and management score within both groups across time ($p = 0.040$ for the intervention group and $p = 0.038$ for the control group), but this improvement was not significantly different between the two groups ($p = 0.952$). Knowledge and coping scores significantly improved within the intervention group ($p < 0.001$), but not in the control group ($p = 0.508$ for knowledge and $p = 0.614$ for coping). As a result, there were significantly greater improvements in knowledge and coping scores in the intervention group compared to the control group ($p = 0.030$ and $p = 0.014$, respectively). There were no significant differences in partnership scores between the intervention and control groups ($p = 0.597$).

Table 25: Main intervention effects for self-management competency across time

Self-management outcomes	Within-group		Between-group
	Control group n = 47	Intervention group n = 48	
Total PIH	$p = 0.039$	$p < 0.001$	$p = 0.408$
Knowledge	$p = 0.508$	$p < 0.001$	$p = \mathbf{0.030}$
Partnership in treatment	$p = 0.515$	$p = 0.928$	$p = 0.597$
Symptom recognition and management	$p = 0.038$	$p = 0.040$	$p = 0.952$
Coping	$p = 0.614$	$p < 0.001$	$p = \mathbf{0.014}$

Figure 18 shows the mean knowledge and coping scores by group and visit time.

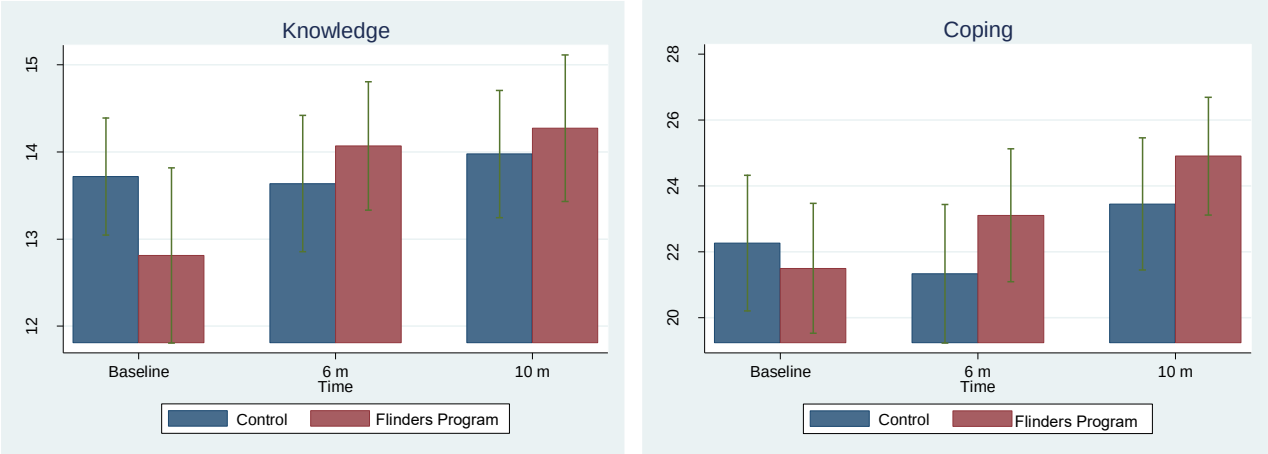


Figure 18: Mean knowledge and coping scores by group across time

To further interpret this analysis, the post-estimation marginal effects of responses for the PIH scale outcome and its subscales, with time at fixed values of 0 week, and 24 and 40 weeks were obtained (Appendix H). There was an upward trend of PIH score for both intervention and control groups, reflecting an improvement of self-management competency across time. Recognition and management of symptoms had very similar trends in both the intervention and control groups.

5.4 Per protocol analysis

For the primary outcomes of SF-36 and OAKHQoL, a per protocol (PP) analysis was conducted on the subset of participants who completed the allocated intervention. In total, seven (7) treatment non-completers were in the intervention group, whereas all participants in the control group completed their treatment as they all received usual care.

As this analysis was conducted on a subset of the randomised participants and the data set was now observational, the prognostics of randomisation were potentially lost and the baseline characteristics were not necessarily balanced. Therefore, statistical tests were performed to check if any differences occurred in participants between groups at the baseline, as can be seen in Table 26. No statistically significant differences were found between PP participants of the intervention and control groups at baseline.

Table 26: Baseline characteristics between control and intervention groups in per protocol analysis

	Control (n = 47)	**Intervention (n = 41)**	***p*-value**
Socio-demographic data			
Age (years)	68.5 (8.2)	67.6 (8.7)	0.612
Female	29 (61.7)	27 (65.8)	0.686
Living arrangement			
Living alone	17 (36.2)	14 (34.1)	
Living with partner	25 (53.2)	23 (56.1)	0.983
Living with children	3 (6.38)	2 (4.9)	
Other	2 (4.3)	2 (4.9)	
Work status			
Retired/unemployed	40 (85.1)	34 (82.9)	0.823
Full-time job	3 (6.4)	2 (4.9)	
Part-time job	4 (8.5)	5 (12.2)	
Qualification			
Primary school	5 (10.6)	2 (4.9)	
Secondary school	30 (63.8)	27 (65.8)	0.862
Undergraduate	4 (8.5)	4 (9.8)	
Postgraduate	3 (6.4)	4 (9.8)	
Other	5 (10.6)	4 (9.8)	
Clinical characteristics			
BMI	37.7 (4.9)	36.2 (3.7)	0.096
WC	119.1 (14.0)	116.3 (10.2)	0.277
WHtR	0.7 (0.8)	0.7 (0.1)	0.674
%BF	40.8 (5.1)	40.9 (5.3)	0.980
SF-36			
Physical function	29.7 (6.8)	28.9 (6.5)	0.594
Physical role	34.7 (8.5)	32.5 (7.0)	0.175
Bodily pain	32.1 (5.6)	30.9 (5.3)	0.291
General health perception	46.8 (11.2)	45.1 (10.2)	0.445
Total physical score	31.7 (7.2)	31.3 (5.5)	0.794
Vitality	40.1 (10.6)	39.9 (8.6)	0.913
Social role	36.5 (13.4)	37.9 (13.9)	0.632
Emotional role	41.1 (12.6)	36.8 (13.0)	0.117
Mental health	47.3 (11.7)	43.8 (11.0)	0.164
Total mental score	47.2 (12.4)	44.6 (13.0)	0.338
OAKHQoL			
Physical activity	35.5 (16.6)	31.4 (18.3)	0.271
Mental health	59.8 (24.0)	51.1 (26.6)	0.112
Pain	28.5 (19.5)	25.7 (20.9)	0.529
Social support	67.8 (24.6)	67.6 (21.8)	0.967
Social activity	62.6 (27.6)	55.8 (24.6)	0.222
Professional activity	61.7 (34.9)	42.5 (35.3)	0.165
Spouse relations	58.5 (33.1)	42.4 (38.5)	0.116
Sexual activity	54.8 (41.9)	36.3 (40.3)	0.165
Self-management (PIH)	77.8 (13.9)	78.3 (10.1)	0.846
Knowledge	13.7 (2.3)	13.0 (3.2)	0.211
Partnership	29.8 (4.4)	30.1 (2.9)	0.732
Symptom recognition & management	13.9 (2.4)	14.2 (2.4)	0.497
Coping	22.3 (6.8)	21.2 (6.7)	0.487

Abbreviations: BMI = body mass index; WC = waist circumference; WHtR =waist-to-height ratio; %BF = percentage body fat.

In total, 47 PP participants were in the control group and 41 PP participants were in the intervention group. In order to detect the intervention effects on primary outcomes between the control and PP intervention groups, mixed-effects modelling was used. Changes of outcomes from the PP analysis are shown in Table 27.

Table 27: Per protocol analysis results

	Baseline				6 month				10 month			
	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value	Unadjusted Estimate (SE)		Estimated between-group difference (95% CI)	*p*-value
	Control n = 47	Intervention n = 41			Control n = 47	Intervention n = 41			Control n = 47	Intervention n = 41		
SF-36 Physical	31.1 (1.1)	30.9 (0.9)	-0.2 (-2.9 – 2.5)	0.877	34.5 (0.9)	35.2 (0.9)	0.8 (-1.8 – 3.3)	0.552	36.7 (1.1)	38.0 (1.2)	1.4 (-1.9 – 4.8)	0.402
SF-36 Mental	47.2 (1.8)	44.5 (1.8)	-3.0 (-8.0 – 2.0)	0.242	44.0 (1.9)	43.4 (1.8)	0.1 (-4.3 – 4.4)	0.976	45.5 (1.7)	47.6 (1.7)	2.1 (-2.7 – 6.92	0.392
SF-36 Physical activity	29.6 (1.0)	27.9 (1.1)	-0.8 (-3.7 – 2.0)	0.572	28.8 (1.2)	31.8 (0.9)	0.9 (-1.7 – 3.5)	0.516	32.9 (1.2)	34.5 (1.2)	2.0 (-1.5 – 5.4)	0.262
SF-36 Physical role	34.2 (1.2)	31.8 (1.1)	-2.4 (-5.6 – 0.9)	0.151	36.9 (1.0)	36.4 (0.9)	-0.3 (-3.0 – 2.3)	0.795	38.6 (1.2)	39.4 (37.0)	1.0 (-2.4 – 4.4)	0.560
SF-36 Bodily pain	31.4 (0.9)	30.1 (1.0)	-1.4 (-3.9 – 1.2)	0.294	34.3 (0.9)	34.6 (0.8)	0.6 (-1.9 – 3.0)	0.645	36.3 (1.3)	37.7 (1.2)	1.9 (-1.6 – 5.3)	0.293
SF-36 General health	46.5 (1.5)	45.2 (1.5)	-1.4 (-5.6 – 2.8)	0.523	47.4 (1.4)	47.2 (1.4)	-0.2 (-4.0 – 3.7)	0.926	48.0 (1.4)	48.6 (1.5)	0.6 (-3.5 – 4.7)	0.770
SF-36 Vitality	39.5 (1.6)	39.1 (1.3)	-0.4 (-4.4 – 3.6)	0.841	42.2 (1.4)	42.2 (1.1)	0.2 (-3.4 – 3.8)	0.918	44.0 (1.6)	44.2 (1.3)	0.6 (-3.5 – 4.7)	0.778
SF-36 Social role	36.4 (1.9)	37.0 (1.8)	1.7 (-3.5 – 6.9)	0.529	33.9 (1.9)	40.1 (1.5)	3.9 (-0.5 – 8.3)	0.084	36.9 (1.8)	42.1 (1.7)	5.4 (0.4 – 10.3)	0.034
SF-36 Emotional role	41.1 (1.8)	35.3 (1.8)	-4.8 (-9.7 – 0.04)	0.052	38.0 (1.8)	39.5 (1.4)	-0.7 (-4.7 – 3.3)	0.728	40.5 (1.6)	42.3 (1.7)	2.0 (-2.6 – 6.6)	0.390
SF-36 Mental health	47.3 (1.7)	42.8 (1.6)	-3.8 (-8.3 – 0.8)	0.104	44.2 (1.8)	44.8 (1.4)	-1.1 (-5.3 – 3.0)	0.590	45.6 (1.8)	46.1 (1.6)	0.6 (-4.1 – 5.4)	0.795
OAKHQoL Physical activity	35.3 (2.6)	28.9 (2.9)	-4.1 (-11.5 – 3.3)	0.283	31.9 (2.9)	37.7 (2.9)	-0.1 (-7.5 – 7.4)	0.989	41.8 (3.2)	43.5 (3.7)	2.6 (-7.2– 12.5)	0.602
OAKHQoL Mental health	59.7 (3.5)	48.3 (3.8)	-10.1 (-20.1 – 0.04)	0.049	57.4 (3.6)	58.1 (3.4)	-2.2 (-11.3 – 7.0)	0.640	62.2 (3.5)	64.7 (3.8)	3.1 (-7.1 – 13.3)	0.552
OAKHQoL Pain	25.0 (3.4)	23.3 (3.5)	-2.1 (-11.2 – 7.1)	0.656	35.3 (2.7)	36.5 (3.3)	1.9 (-6.3 – 10.1)	0.653	42.2 (3.7)	45.3 (4.3)	4.5 (-6.0 – 15.1)	0.401
OAKHQoL Social support	68.4 (3.3)	68.3 (3.0)	-0.2 (-9.0 – 8.5)	0.960	68.2 (2.7)	72.8 (2.5)	4.7 (-2.7– 11.6)	0.304	68.1 (3.1)	75.9 (2.9)	7.5 (-1.1 – 16.2)	0.087
OAKHQoL Social activity	62.6 (4.1)	53.3 (3.5)	-4.7 (-15.7 – 6.3)	0.400	51.4 (4.1)	60.9 (2.7)	4.7 (-4.6 – 12.1)	0.211	53.6 (3.8)	66.0 (3.4)	8.0 (-0.5 – 16.5)	0.064
OAKHQoL Professional activity	58.9 (9.6)	38.1 (8.9)	-21.9 (-46.7 – 3.0)	0.085	57.6 (6.8)	51.3 (8.6)	-7.4 (-27.8 – 13.0)	0.476	56.8 (9.4)	60.2 (10.9)	2.2 (-28.9 – 33.3)	0.889
OAKHQoL Spouse relations	59.1 (6.4)	38.7 (6.5)	-17.8 (-35.6 – 0.3)	0.050	51.2 (6.6)	54.3 (5.1)	-3.0 (-17.7 – 12.7)	0.690	59.6 (6.0)	64.6 (6.4)	6.9 (-10.2 – 23.9)	0.755
OAKHQoL Sexual activity	54.4 (7.6)	33.2 (8.0)	-17.1 (-38.9 – 4.8)	0.125	36.5 (8.1)	45.1 (6.5)	-5.1 (-23.4 – 13.1)	0.581	51.9 (7.4)	53.0 (8.5)	2.8 (-19.7 – 25.3)	0.806

The findings for the intervention effects of PP analysis are presented in Table 28. Statistically significant improvements were found in primary outcomes within the control group across time, except for SF-36 general health, OAKHQoL social support and OAKHQoL professional activity ($p = 0.163$, $p = 0.913$ and $p = 0.880$, respectively). Per protocol (PP) participants within the intervention group achieved significant improvements in all primary outcomes across time.

Table 28: Intervention effects' findings of per protocol analysis

	Within-group		Between-group
	Control group n = 47	Intervention group n = 41	
SF-36			
SF-36 total physical score	$p < 0.001$	$p < 0.001$	$p = 0.372$
SF-36 total mental score	$p = 0.033$	$p = 0.017$	$\mathbf{p = 0.030}$
Physical function	$p < 0.001$	$p < 0.001$	$p = 0.160$
Physical role	$p < 0.001$	$p < 0.001$	$p = 0.109$
Bodily pain	$p < 0.001$	$p < 0.001$	$p = 0.121$
General health perception	$p = 0.163$	$p = 0.002$	$p = 0.210$
Vitality	$p = 0.001$	$p < 0.001$	$p = 0.612$
Social role	$p = 0.009$	$p = 0.012$	$p = 0.150$
Emotional role	$p = 0.016$	$p = 0.001$	$\mathbf{p = 0.008}$
Mental health	$p = 0.024$	$p = 0.039$	$\mathbf{p = 0.047}$
OAKHQoL			
Physical activity	$p < 0.001$	$p < 0.001$	$p = 0.199$
Mental health	$p = 0.041$	$p < 0.001$	$\mathbf{p = 0.004}$
Pain	$p < 0.001$	$p < 0.001$	$p = 0.268$
Social support	$p = 0.913$	$p = 0.017$	$p = 0.071$
Social activity	$p = 0.089$	$p = 0.002$	$\mathbf{p < 0.001}$
Professional activity	$p = 0.880$	$p = 0.044$	$p = 0.253$
Spouse relations	$p = 0.044$	$p = 0.001$	$\mathbf{p = 0.010}$
Sexual activity	$p = 0.002$	$p = 0.064$	$p = 0.132$

No significant differences were found in improvements in the SF-36 total physical scores between the PP participants in the control and intervention groups across time ($p = 0.372$). However, significantly greater improvements were found in the SF-36 total mental score among PP participants in the intervention group compared to those in the control group ($p = 0.030$).

Significantly greater improvements were also found in SF-36 emotional role and mental health scores of the PP participants in the intervention group compared to the PP participants in the control group ($p = 0.008$ and $p = 0.047$, respectively). With regard to OAKHQoL scores, significantly greater improvements were found in mental health, social activity and spouse relations scores among PP participants in the intervention group compared to those in the control group ($p = 0.004$, $p < 0.001$ and $p = 0.010$, respectively).

5.5 Exploratory subgroup analyses

Secondary post-hoc analyses were conducted to evaluate the impact of other factors on improvements in the primary outcomes and on weight loss in both control and intervention groups.

5.5.1 Effect of PIH on primary outcomes

In order to evaluate the impact of PIH scores at baseline on the primary outcomes, mixed-effects modelling was used. The findings are presented in Table 29.

Table 29: Was baseline PIH a predictor of primary outcomes improvements and BMI reduction between groups

Outcomes	**Was PIH a significant predictor factor of greater improvements between groups?**
SF-36 total physical score	$p = 0.077$
SF-36 total mental score	$p < 0.001$
Physical function	$p = 0.001$
Physical role	$p = 0.003$
Bodily pain	$p = 0.101$
General health perception	$p = 0.001$
Vitality	$p = 0.006$
Social role	$p = 0.004$
Emotional role	$p < 0.001$
Mental health	$p < 0.001$
Physical activity	$p = 0.003$
Mental health	$p < 0.001$
Pain	$p = 0.244$
Social support	$p = 0.003$
Social activity	$p = 0.003$
Professional activity	$p = 0.016$
Spouse relations	$p = 0.006$
Sexual activity	$p = 0.012$
BMI	$p = 0.004$

The PIH score at baseline was a significant predictor factor of greater improvements in SF-36 mental score and in its domains: vitality, social role, emotional role and mental health ($p \leq 0.006$). However, a higher PIH score at baseline was not a significant predictor factor of greater improvements in the SF-36 physical score at 5% α-level ($p = 0.077$). The main reason was that the PIH score did not reach statistical significance as a predictor of improvements in the SF-36 bodily pain domain ($p = 0.101$). Other SF-36 physical domains comprising general health, physical function and physical role were significantly improved with higher PIH scores at baseline ($p \leq 0.003$).

The PIH score at baseline was also a significant predictor variable of greater improvements in all OAKHQoL domains ($p \leq 0.003$), except for the pain domain ($p = 0.244$).

Higher PIH scores were also significant predictors of lower BMI scores ($p = 0.004$).

5.5.2 Effect of BMI categories on primary outcomes

The study used mixed-effects modelling to evaluate the impact of BMI categories on improvements in primary outcomes between the control and intervention groups (3-way interaction). The BMI categories were obese ($30 \leq BMI < 35$), severely obese ($35 \leq BMI < 40$) and morbidly obese ($BMI \geq 40$). The findings are presented in Table 30.

Table 30: Effect of BMI categories on improvements of primary outcomes between groups

	Obese	Severely obese	Morbidly obese
SF-36			
Total physical score	$p = 0.330$	$p = 0.733$	$p = \mathbf{0.045}$
Total mental score	$p = 0.418$	$p = 0.757$	$p = 0.994$
OAKHQoL			
Physical activity	$p = 0.785$	$p = 0.786$	$p = 0.164$
Mental health	$p = 0.500$	$p = 0.263$	$p = 0.689$
Pain	$p = 0.766$	$p = 0.733$	$p = 0.661$
Social support	$p = 0.074$	$p = 0.390$	$p = 0.419$
Social activity	$p = \mathbf{0.004}$	$p = 0.168$	$p = 0.408$
Professional activity	$p = 0.072$	$p = 0.868$	$p = 0.611$
Spouse relations	$p = 0.413$	$p = 0.490$	$p = 0.753$
Sexual activity	$p = 0.827$	$p = 0.136$	$p = 0.730$

No significant differences were found in improvements in the SF-36 physical score or SF-36 mental score between obese and severely obese participants in the control and intervention groups ($p = 0.330$ and $p = 0.733$, respectively). However, a significantly greater improvement in the SF-36 physical score was found for morbidly obese participants in the intervention group in comparison to those in the control group ($p = 0.045$). The three BMI categories (obese, severely obese and morbidly obese) had no significant impact on changes in the SF-36 mental scores ($p = 0.418, p = 757$ and $p = 0.994$, respectively).

No significant differences in OAKHQoL scores were found between severely obese and morbidly obese participants in the control and intervention groups. Obese participants in the intervention group had significantly greater improvements in the OAKHQoL social activity score compared to those in the control group ($p = 0.004$).

5.5.3 Effect of surgery on primary outcomes

Time of surgery was categorised into two groups: ‘late surgery’ being those who did not receive surgery before the final follow-up and those who received surgery less than 10 weeks prior to the

final follow-up; and 'on-time surgery' being those who received surgery 10 weeks or more prior to the final follow-up. The 10-week cut-off was chosen because although different from person to person, it takes about that time to recover from surgery (Greengard and Carey, 2017). The aim of this categorisation was to distinguish participants who had recovered from the operation from those who either had not had an operation or had not fully recovered from it. In order to evaluate the impact of the time of surgery on the improvements of primary outcomes between the control and intervention groups, mixed-effects modelling was conducted. The findings are presented in Table 31.

A significantly greater improvement in SF-36 physical scores was found in 'on-time surgery' participants compared to 'late surgery' participants within both groups ($p = 0.040$ and $p = 0.001$, respectively). Improvements in physical function ($p = 0.011$) and physical role ($p = 0.004$) scores were significantly greater among 'on-time surgery' participants compared to 'late surgery' participants within the intervention group, but this was not found within the control group.

Table 31: Effects of surgery time on changes in primary outcomes across time

	On-time surgery versus late surgery		On-time surgery	Late surgery
	Within Control group (n = 47)	Within Intervention group (n = 48)	Between-group	
SF-36				
Total physical score	$p = \mathbf{0.040}$	$p = \mathbf{0.001}$	$p = 0.484$	$p = 0.617$
Total mental score	$p = 0.601$	$p = 0.537$	$p = 0.899$	$p = 0.553$
Physical function	$p = 0.076$	$p = \mathbf{0.011}$	$p = 0.594$	$p = 0.658$
Physical role	$p = 0.058$	$p = \mathbf{0.004}$	$p = 0.515$	$p = 0.884$
Bodily pain	$p = \mathbf{0.006}$	$p = \mathbf{0.015}$	$p = 0.945$	$p = 0.247$
General health	$p = 0.749$	$p = 0.202$	$p = 0.316$	$p = 0.573$
Vitality	$p = \mathbf{0.048}$	$p = \mathbf{0.019}$	$p = 0.798$	$p = 0.743$
Social role	$p = 0.503$	$p = 0.140$	$p = 0.563$	$p = 0.979$
Emotional role	$p = 0.719$	$p = 0.748$	$p = 0.668$	$p = \mathbf{0.048}$
Mental health	$p = 0.317$	$p = 0.069$	$p = 0.561$	$p = 0.978$
OAKHQoL				
Physical activity	$p = \mathbf{0.025}$	$p = \mathbf{0.002}$	$p = 0.746$	$p = 0.824$
Mental health	$p = 0.699$	$p = \mathbf{0.033}$	$p = 0.192$	$p = 0.656$
Pain	$p = \mathbf{0.006}$	$p = \mathbf{0.025}$	$p = 0.876$	$p = 0.803$
Social support	$p = 0.847$	$p = 0.574$	$p = 0.663$	$p = 0.206$
Social activity	$p = \mathbf{0.010}$	$p = 0.220$	$p = 0.385$	$p = \mathbf{0.016}$
Professional activity	$p = 0.388$	$p = 0.097$	$p = 0.881$	$p = 0.488$
Spouse relations	$p = 0.373$	$p = 0.083$	$p = 0.443$	$p = 0.338$
Sexual activity	$p = 0.562$	$p = 0.426$	$p = 0.949$	$p = 0.456$

Bodily pain was improved in ‘on-time surgery’ participants more significantly than in ‘late surgery’ participants within both the control group ($p = 0.006$) and the intervention group ($p = 0.015$). Among the SF-36 mental domains, only the vitality score had a significantly greater improvement among ‘on-time surgery’ participants compared to ‘late-surgery’ participants within both groups ($p = 0.048$ within the control group and $p = 0.019$ within the intervention group). No significant differences were found in improvements in any SF-36 domains between ‘on-time surgery’ participants of the two groups across time. A significantly greater improvement was found in emotional role scores of ‘late-surgery’ participants in the intervention group compared to those in the control group ($p = 0.048$), but not in other domains.

The OAKHQoL physical activity and pain scores both improved significantly, with this greater in the 'on-time surgery' participants compared to the 'late-surgery' participants within both the control group ($p = 0.025$ and $p = 0.006$, respectively) and intervention group ($p = 0.002$ and $p = 0.025$, respectively). The 'on-time surgery' participants had an improved mental health score that was significantly greater within the intervention group ($p = 0.033$), but not within the control group ($p = 0.699$). The social activity score had a greater improvement among 'on-time surgery' participants compared to 'late surgery' participants within the control group ($p = 0.010$); however, no significant differences were found in the improvement of social activity scores between 'on-time surgery' and 'late surgery' participants within the intervention group ($p = 0.022$). None of the improvements in the OAKHQoL scores were significantly different in the 'on-time surgery' participants between the two groups. 'Late surgery' participants in the intervention group had significantly greater improvement in the social activity score than those in the control group ($p = 0.016$), but not in the other OAKHQoL scores.

5.5.4 Difference of hip or knee replacement on primary outcomes

Mixed-effects modelling was used to evaluate the differences between the primary outcomes of hip and knee replacement patients across time. The findings are presented in Table 32. No significant differences were found in improvements in any SF-36 or OAKHQoL scores between knee and hip replacement participants within the control group. Within the intervention group, hip replacement patients received significantly greater improvements in most physical scores including SF-36 physical function ($p = 0.001$), SF-36 physical role ($p = 0.009$), SF-36 pain ($p = 0.019$) and SF-36 total physical ($p = 0.003$) as well as OAKHQoL physical activity ($p < 0.001$) and OAKHQoL pain ($p < 0.001$) compared with knee replacement patients. The SF-36 vitality and social role scores as well as the OAKHQoL mental health score also improved significantly greater in hip replacement patients than in knee replacement patients within the intervention group ($p = 0.036$, $p = 0.033$ and $p = 0.008$, respectively).

For between-group differences, a greater improvement was found in SF-36 total physical scores in hip replacement patients of the intervention group compared to those in the control group, but this difference was not statistically significant at 5% α-level ($p = 0.080$). A significantly greater improvement was found in SF-36 physical function scores in hip replacement patients of the intervention group compared to those in the control group ($p = 0.042$), but not in knee replacement patients ($p = 0.556$). No significant differences were found in other SF-36 scores between hip or knee replacement patients of the two groups. The OAKHQoL physical activity and pain scores improved significantly more in hip replacement patients of the intervention group compared to those in the control group ($p = 0.028$ and $p = 0.011$, respectively), but not in knee replacement patients. Knee replacement patients in the intervention group received a significantly greater improvement in the OAKHQoL social activity score compared to those in the control group ($p = 0.023$).

Table 32: Hip replacement versus knee replacement participants and primary outcomes

	Hip versus Knee		Hip	Knee
	Within Control group (n = 47)	Within Intervention group (n = 48)	Between-group	
SF-36				
Total physical score	$p = 0.660$	$p = \mathbf{0.003}$	$p = 0.080$	$p = 0.350$
Total mental score	$p = 0.971$	$p = 0.299$	$p = 0.465$	$p = 0.477$
Physical function	$p = 0.659$	$p = \mathbf{0.001}$	$p = \mathbf{0.042}$	$p = 0.556$
Physical role	$p = 0.994$	$p = \mathbf{0.009}$	$p = 0.066$	$p = 0.708$
Bodily pain	$p = 0.656$	$p = \mathbf{0.019}$	$p = 0.199$	$p = 0.906$
General health perception	$p = 0.912$	$p = 0.389$	$p = 0.520$	$p = 0.920$
Vitality	$p = 0.532$	$p = \mathbf{0.036}$	$p = 0.328$	$p = 0.355$
Social role	$p = 0.567$	$p = \mathbf{0.033}$	$p = 0.253$	$p = 0.897$
Emotional role	$p = 0.929$	$p = 0.074$	$p = 0.213$	$p = 0.182$
Mental health	$p = 0.750$	$p = 0.554$	$p = 0.552$	$p = 0.721$
OAKHQoL				
Physical activity	$p = 0.347$	$p < \mathbf{0.001}$	$p = \mathbf{0.028}$	$p = 0.382$
Mental health	$p = 0.478$	$p = \mathbf{0.008}$	$p = 0.144$	$p = 0.237$
Pain	$p = 0.892$	$p < \mathbf{0.001}$	$p = \mathbf{0.011}$	$p = 0.270$
Social support	$p = 0.871$	$p = 0.322$	$p = 0.589$	$p = 0.073$
Social activity	$p = 0.496$	$p = 0.702$	$p = 0.512$	$p = \mathbf{0.023}$
Professional activity	$p = 0.898$	$p = 0.625$	$p = 0.906$	$p = 0.436$
Spouse relations	$p = 0.488$	$p = 0.203$	$p = 0.451$	$p = 0.113$
Sexual activity	$p = 0.799$	$p = 0.456$	$p = 0.529$	$p = 0.454$

5.5.5 Effect of socio-demographic status on primary outcomes and weight loss

The primary outcomes were similar for female and male participants over time ($p = 0.830$ for the SF-36 physical score and $p = 0.913$ for the SF-36 mental score). No significant differences were found in changes in primary outcomes or weight loss across genders, living arrangements, education levels and employment status in the control and intervention groups.

6. QUALITATIVE INTERVIEWS

6.1 Introduction

To address the primary research hypothesis 'At 10-month follow-up, there will be a statistically significant difference in health-related quality of life of obese osteoarthritis patients awaiting hip or knee replacement surgery who receive the Flinders Program versus treatment as usual', the results from the randomised controlled trial (RCT) were presented in Chapter 5. The findings indicated that receiving the intervention program significantly improved the emotional, mental and social aspects of HRQoL, but not the physical aspects especially pain, and no significant differences between the intervention and control groups in physical and mental SF36. Furthermore, there was evidence to support benefits of the intervention program to improving self-management knowledge and coping skills, and also reducing body weight for severely and morbidly obese participants. Perhaps then, seeking what the participants had to say about their experiences with the self-management support program would further enhance the understanding of intervention effects.

In recent years the use of qualitative interviews alongside clinical trials has become more prevalent in order to supplement trial findings and help interpret theory for use in everyday health care practice (Grant et al., 2013). Qualitative interviews are especially useful for evaluating complex interventions such as our intervention program where there are several components, for example the Flinders Program's Partners in Health Scale (PIH), Cue and Response Interview, Problem and Goals assessment, and care plan, in addition to the other lifestyle elements of weight loss and exercise. Because the evaluation of such complex interventions is difficult, the use of qualitative data may help enhance, interpret and explain findings of the quantitative study to help further understand in what way and for whom the intervention succeeded (Campbell et al., 2000). This could then provide a basis for modification of the intervention of its delivery and inform future research.

In this study, the qualitative interviews attempted to view the trial from the experiences and

perceptions of a sub-group of participants and analyse the effectiveness, or otherwise, of the intervention program. This would add to the chronic condition self-management literature as to date, no qualitative study alongside an RCT to investigate a self-management support program in obese patients with osteoarthritis has been reported. Therefore, the objective of the qualitative interviews was to support and extend findings from the main RCT investigating the self-management support program for obese patients with osteoarthritis awaiting hip or knee replacement surgery. The research question for this qualitative study was "What were the intervention participants' experiences and perceptions of the program?"

6.2 Methods

6.2.1 Interviewer

Interviews were conducted by the PhD candidate (LS) at the location of the trial (Repatriation General Hospital [RGH], Adelaide). She has a degree in Computer Engineering and a Masters in Mechatronics Engineering, and experience in teaching and research with a multidisciplinary team including a psychiatrist, orthopaedic surgeon, nurse and biostatistician during her studies prior to conducting these interviews. As the interviews occurred after completion of study intervention and follow-up assessments, the participant and interviewer had already met two or three times before the interview, depending on the number of assessments the participant had attended. At the beginning of the interview, consent to participate in the interview was obtained. Participants were also told about the role of the interviewer as a PhD candidate.

6.2.2 Participants

To conduct qualitative interviews, convenience sampling was used. At the end of the first follow-up, each participant was asked whether they would be interested in being contacted to participate in an interview after the second follow-up. A total of 39 participants said they would be interested. At the end of the follow-ups, when the allocation of the participants was released to the PhD candidate, it became clear that 21 of these participants were allocated to the control group. The interviewer then

contacted the remaining 18 participants in the Flinders Program group by telephone and invited them to participate in a face-to-face interview at the location of the trial at a time convenient to them. Of the 18 participants, 13 initially agreed to be interviewed but then one participant declined on the day of the interview due to geographical distance and lack of available transport. The reasons for not taking part in the interview included work commitments (two participants), a limited understanding of English (one participant), and two participants could not remember details of the intervention and therefore felt that their participation would not make any meaningful contribution to the study. The characteristics of the interviewees are presented in Table 33.

Table 33: Characteristics of interview participants

Participant	Gender	Surgical site	Age (years)	BMI (kg/m^2)	Employment	Highest level of education	Living arrangement
PAR01	Female	Knee	80	32	Retired	Secondary school	With partner
PAR02	Male	Knee	74	32.7	Retired	Undergraduate	With friend
PAR03	Female	Hip	78	35.2	Retired	Postgraduate	Alone
PAR04	Female	Hip	81	39.3	Retired	Secondary school	With children
PAR05	Female	Hip	70	41.5	Retired	Secondary school	With partner
PAR06	Female	Knee	58	35.8	Part-time	Secondary school	Alone
PAR07	Female	Hip	74	33.5	Retired	Secondary school	Alone
PAR08	Female	Knee	66	39	Retired	Secondary school	With partner
PAR09	Male	Knee	73	35.3	Retired	Secondary school	With partner
PAR10	Female	Hip	56	35.2	Retired	Undergraduate	With partner
PAR11	Female	Knee	72	35.8	Retired	Secondary school	With partner
PAR12	Female	Knee	69	36.6	Retired	Secondary school	With partner

6.2.3 Interviews

One-on-one interviews were conducted at the location of the trial (Repatriation General Hospital [RGH], Adelaide) in the presence of only the interviewer and the participant in November and December 2016. The average duration of the interviews ranged from 20 minutes to approximately one hour, and all were audio recorded.

The interviews were semi-structured. Each interview started with a grand tour open-ended question

'Tell me about your experiences with the self-management support program you received.' Other open-ended questions that were used to guide the interviews included 'motivators and barriers towards the program', and 'other potential programs in the past'. Probes were then used to further explore participants' experiences. These questions were not introduced to the participant, so they could talk openly about their personal experiences. No repeat interviews were carried out.

6.2.4 Method for qualitative analysis

The methodological orientation to underpin this study was a thematic approach to explore the explicit meanings of what each participant had to say about the self-management support program (Braun and Clarke, 2006). This approach was chosen to enable the flexible interpretation of participants' broader experiences and perceptions relative to the testable hypotheses and main findings of RCT data. Through the theoretical freedom of thematic analysis (Braun and Clarke, 2006), a number of themes could be explored in relation to the specific area of interest of trial hypotheses, for example: 'Was the delivery of the self-management support program to obese osteoarthritis patients awaiting hip or knee replacement surgery associated with improvements in health-related quality of life?' The interview data would provide an opportunity to support and extend trial findings of both primary and secondary hypotheses and to theorise the significance of the patterns of data in relation to previous literature.

6.2.5 Data analysis

The interviews were transcribed verbatim by the PhD candidate (LS) facilitated by NVivo software (QSR International Pty Ltd. Version 11, 2017). The transcribing process enabled LS to become more familiar with interview data and to retain as much meaning as possible in converting spoken sounds (Lapadat and Lindsay, 2018). The transcript was then checked against the original audio recording, and then read again in an active way searching for patterns, taking notes of key points and marking ideas for coding. NVivo software (QSR International Pty Ltd. Version 11, 2017) was then used to facilitate the analysis of data. Codes were identified from the responses to the grand

tour open-ended question. Then, using mind-maps and by moving back and forward between the codes and transcripts, codes were sorted into potential themes. Next, different codes were combined to form overarching themes, and their relationship with sub-themes were considered. Those themes and sub-themes were then refined by reading all the collated extracts for each theme and subtheme in order to reflect the meanings evident in the data as a whole.

To enhance transparency, the findings from interviews were reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines, which comprises a 32-item checklist in three domains: (1) research team and reflexivity; (2) study design; and (3) analysis and findings (Tong et al., 2007). Supporting quotations from different participants were reported to add to the study's transparency.

6.3 Findings

The themes comprised evident features of the Flinders Program (categorised into positive overall evaluation, identifying problems, non-judgemental, goal setting, and follow-up phone calls); benefits (categorised into information, motivation, talking to someone, helpful in losing weight, and mental help); barriers (categorised into unclear process, lack of social support, lack of motivation and pain); and comparison to other weight loss programs. Participants' experiences are presented below as quotations with participant identifiers. The name Kerry (pseudonym) is used for the nurse who delivered the intervention program.

6.3.1 Evident features of the Flinders Program

Specific features of the Flinders Program came up in the responses of the participants to the open-ended questions regarding their experiences of the program. As these references were irrespective of the benefits gained from participating in the program, they were assigned to this theme as opposed to benefits or barriers.

6.3.1.1 Positive overall evaluation

All interviewees reported a positive overall evaluation, although with varying degrees of

satisfaction. Some participants described how knowing someone at the hospital with whom to be in contact was a positive experience.

> *I thought it was a very good program; my doctor never gave a lot of thought; he sent me here with my hip, you know, and then Kerry [the nurse who delivered the intervention program] had a lot with this and that ...* (PAR04)

> *It was nice knowing somebody was going to call and let me know what was going on, because she was here … and I wasn't getting anxious or upset about not having heard from anybody.* (PAR10)

At the far end of the positive spectrum, one interviewee was very satisfied with the program, calling it a life-changing experience.

> *My marriage was on the line; my relationship with my children was on the line … I was this fish swimming in the water, really lost, and somebody threw me a life line, and that's how I see it, and it has saved our family and saved our marriage … It's been life changing.* (PAR08)

6.3.1.2 Identifying problems

A number of participants mentioned that before participating in the program, even though they knew there was a problem, but they were so focused on the pain and discomfort they were experiencing that they could not think of the underlying issues and their own roles. Some interviewees identified their problems at the first session. For example:

> *At the very first meeting, I found out if we are overweight, it would be in our best interest to shed as much as we could, because both the anaesthetist and the surgeon prefer to have [people with] less weight on the operating table than very overweight people, for our own health*. (PAR11)

Some other interviewees identified the underlying problem preventing the achievement of their goals throughout the program, even though they had good self-management capacity from the start.

> *She helped me get on track to lose weight, and you know to keep a diary of how much food was going into my mouth, finding out where I was going wrong … she said for a whole week, itemise every time you eat … I was very surprised [to find out] how much sugar I was taking on board.* (PAR08)

> *I actually hadn't thought about going on an anti-inflammatory [medication]*. (PAR10)

6.3.1.3 Non-judgemental

One characteristic which was mentioned by many interviewees was the non-critical and non-judgemental approach of the Flinders Program. The fact that the nurse delivering the intervention program was listening to what they had to say made the participants feel more comfortable. This was one of the aims of the program to create an atmosphere where participants do not feel pressured and therefore are hopefully able to focus on their goal with a more relaxed mindset.

> *She wasn't at all critical of me for not losing what I had to achieve; … so I wouldn't become depressed about it or you know trying to keep my spirit up … to know that Kerry understood my situation.* (PAR02)
>
> *Not trying to pressure me to lose weight. Just asking gentle questions and checking.* (PAR05)
>
> *She was very approachable ... She said she understood, you know, getting to be our age, how difficult it is to lose weight.* (PAR08)
>
> *The most important thing was the reassurance … when you go through so many ordeals with your health, at this age of your life, it's really very distressing, when you [have] got experienced people who have witnessed and taken care of other people in the same situation, then it's so reassuring to have people that say 'ah. at this stage you can expect this'.* (PAR03)

6.3.1.4 Goal setting

Some participants remembered the personal goals they set at the first session to be important.

> *It was to lose a bit of weight, and to do a bit more exercise*. (PAR12)
>
> *The goal was to work on the fitness level, and to maintain, keep with exercises that she had been giving to me. It was a booklet that I got when I first came in and had the exercises I had to do before the operation, and there's a list of exercises to do after the operation*. (PAR09)
>
> *Basically, the goal was to stay positive until the operation, and to try and keep as healthy as I possibly could*. (PAR10)

However, a few interviewees were not very sure about their goal, or did not remember it.

> *She used to ring me up to see how I was going, … I just did a little bit of exercise, that sort of thing.* (PAR04)
>
> *She was ringing to talk about how I was feeling*. (PAR07)

6.3.1.5 Follow-up phone calls

Follow-up phone calls were mentioned by the majority of interviewees. As these phone calls formed most of the contact they had with the nurse who was delivering the intervention program, interviewees had more to say about them.

Some participants did not find the follow-up phone calls very clear or effective.

> *It was just the case that she was asking me how I was feeling, just to keep [on] doing the best I could with the walking and diet, that was basically it.* (PAR12)
>
> *It was every fortnight for a while and then I didn't hear anything from her and then she was looking after grandchildren and she lost track of all the phone calls, and then a couple of phone calls after that and then nothing*. (PAR09)

Although it seemed like the phone calls were detailed enough and proceeding as planned, one interviewee (PAR04) thought that she expected more. This may be due to this participant not being clear about what to expect from the self-management support program, as was quoted previously.

> *In a way I found them a bit helpful, but not as helpful as I thought they should've been … I expected more.* (PAR04)

Another interviewee (PAR02) was satisfied with the phone calls, although from what he mentioned, they were not about detailed actions towards his goal.

> *I looked forward to her phone calls every fortnight; I had a chat with her, you know, talk a bit about what was happening at Repat … usually I had some sort of question; was very good.* (PAR02)

Two of the interviewees mentioned that they were not informed that the program was ending, and that they never received a final phone call.

> *Last time she rang, she said I'll ring you in a couple of weeks, but she hasn't, and I haven't heard anything. I thought whether she thought I was a waste of time, I don't know.* (PAR09)
>
> *She phoned up one time: she said, 'I'll ring you back maybe in about 6 weeks' time'. I never heard of her after…. It made me feel that I was useless, that I wasn't contributing anything. So, she must have thought what's the point in calling me?* (PAR01)

In these cases, the follow-up of the intervention program was not delivered as intended.

6.3.2 Benefits of the self-management support program

A number of interview participants talked about the benefits they received from the intervention program. Reported benefits could generally be categorised into the following groups: information, motivation, having someone to talk to, helpful in losing weight, and mental help.

6.3.2.1 Information

Most interview participants found the intervention program helpful in terms of the information they received. One interviewee (PAR11) mentioned information sheets that she received from the nurse delivering the program on '*what people with type 2 diabetes should and should not be eating*'. Another interviewee was happy with the information she received about the potential sources of caring and help from the community.

> *You felt the welcome information from people caring and find out how you're coping, so yeah, the feedback was very, very good and encouraging, the whole thing like, to say, well, you'll be able to do this, or what to expect, and do you have someone to help you, or put you into programs with other people in carers or charities, can [help] with the housework and gardening, that sort of thing, so it put you in a system that you wouldn't probably [have] know[n] the information [about] on your own.* (PAR03)

A few interviewees mentioned their satisfaction with the time they could spend talking to a health care provider, in contrast to visits to their GP who '*doesn't like to talk much*'.

> *I did learn quite a few things ... about the process ... in the operation, the risks and, you know, various alternatives*. (PAR02)

A few interviewees benefited from the intervention program in terms of information regarding pain management.

> *In particular, she suggested that I went on an anti-inflammatory [medication] which [the] doctor hadn't put me on, which actually improved things considerably in the last couple of months ... [I] actually talk to Kerry fortnightly; every time we talked ... she was like 'have you tried this?' ... she always had suggestions [on] what to do and things which actually helped considerably. Things that the doctor hadn't even thought of suggesting.* (PAR10)
>
> *I always had a good relationship with my GP but he was extremely impressed with the fact that when a particular anti-inflammatory [medication] for example, was not working, she said to go back to the GP, go back to the toolbox as she called it,*

and seek another form of medication. (PAR11)

These extracts support the findings from the RCT in terms of significantly greater improvements in the PIH knowledge subscale among the participants in the intervention group compared to those in the control group (Section 5.3.2.2).

6.3.2.2 Motivation

Some interviewees thought the self-management support program gave them the motivation to cope better with the problems and to perform the tasks towards their goals.

> *I found it very helpful, personally, because it kept me motivated, someone checking up to see how I was doing. For me, it worked well. It has also motivated me even now.* (PAR05)
>
> *I think it's up to the individual: honestly, with me, it was something I've been trying out for years; when I was asked whether I'd like to go on this study, I thought here we go, another program ... but when I spoke with Kerry, I came out and said to my husband, I'm gonna lose weight this time.* (PAR08)

These extracts support the findings from the RCT regarding greater improvements in the PIH coping subscale for participants in the intervention group compared to those in the control group.

6.3.2.3 Talking to someone

All interview participants mentioned having someone to talk to as a benefit they experienced while participating in the intervention program. This shows the importance of sharing stories and talking to a health care provider even when it is not a long chat.

> *It was nice knowing somebody [was] ringing me and asking me how I was, and if I was handling it ok, hmm: I did like that, somebody else type of thing, somebody other than the family sort of cared a little bit about me ... did make me feel a little bit better in myself.* (PAR12)
>
> *I just thought it was good that somebody was there in the background, speaking from a professional point of view and support[ing] you in that respect.* (PAR07)
>
> *I thoroughly enjoyed talking to her throughout the whole thing; it was really good, and nice knowing that there was someone that I could actually talk to, other than just my doctor, who as much as I like him, he doesn't actually talk much.* (PAR10)

6.3.2.4 Helpful in losing weight

Some interviewees mentioned that the self-management support program helped them to lose weight or at least to feel they are on the right track to lose weight.

A few interviewees described achieving successful weight loss.

> *I lost well over 12 kg. I know I can do much more now … it was a good start-off, so I know I can do it on my own.* (PAR05)
>
> *My main goal was weight loss and a bit of exercise. I did lose 4 kilos*. (PAR06)

Another interviewee (PAR08) was very satisfied with her weight loss achievement, and thought it '*revolutionised her whole outlook*' and that her whole life had '*just turned around*'.

> *I think the whole program has made me look at how much junk food we were consuming, and it hasn't only helped me, but it's helped my husband, because he's come on board with me too.* (PAR08)

She also believed that the positive impact of the program on her weight loss was going to be a long-term effect.

However, a few participants did not think they received the benefit of weight loss. One interviewee (PAR12) said that she did not achieve any weight loss

> *because I wasn't mobile enough, I think that was the problem, and I just wasn't eating like I should've been*.

One interviewee (PAR02) stated that:

> '*I didn't actually make [as] much progress on losing weight as I had hoped I would. I lost a bit of weight, but I didn't really achieve a great deal*'.

6.3.2.5 Emotional support

The majority of interview participants stated to have received some sort of mental help through participating in the intervention program.

> *I thought it was very helpful emotionally … it did help me to have a better attitude throughout that waiting period.* (PAR02)
>
> *I used to be depressed … [had] very poor self-image … but now I have my sense of humour back… I've got my old self back* (PAR08)

This interviewee mentioned that the program helped save her relationship with her husband.

> *We've got our sense of humour back … we've been married now for 40 years … we were contemplating ending it, because I wasn't in a good place ... It has saved my marriage.* (PAR08)

These extracts support the findings from the RCT in terms of greater improvements in mental health and emotional role among participants in the intervention group compared to those in the control group.

6.3.3 Barriers to the self-management support program

Interview participants also talked about the barriers they experienced to achieving benefits from the self-management support program.

6.3.3.1 Unclear process

For some interviewees, the process of the intervention program was not very clear. Some participants appeared unable to follow through the steps of the program, or did not fully comprehend the form and details of the program.

> *It was good … but I didn't feel I contributed much to it because I didn't know exactly what I was expected [to do] or what I should say.* (PAR01)
>
> *I think more information should be given to the person. I think the program should be more clear.* (PAR04)
>
> *I think if there was perhaps a written-down program that you might be able to, you know; at this time, you'll expect to have done this, or expect to have spoken about that, and just a bit of [an] outline of what you could expect, and if something was missed you could say what about so and so?* (PAR07)

Another interviewee thought that the person delivering the program could be clearer and more proactive in terms of asking the questions rather than waiting for the participant to ask them. Even though she was satisfied with the program, she thought that her satisfaction was due to her nursing qualifications and being active in asking the right questions herself.

> *I think a lot of people who aren't quite as educated wouldn't know what questions to ask. So I think in some respects it might be beneficial for other people if those questions were actually asked of them rather than them having to ask the questions.* (PAR10)

6.3.3.2 Lack of social support

A few interviewees felt that the main barrier they experienced was the lack of social support. For example, one interviewee found it difficult that her friends did not understand and accommodate her new choice of diet.

> *When I went out to people's, when you're invited for dinner, they just didn't comprehend that I would go for the steamed vegetables instead of the baked potatoes if they had a BBQ, and so I would go for the baked potato and I wouldn't put any butter on that, and that's another thing too.* (PAR08)

6.3.3.3 Lack of motivation

Lack of motivation was another barrier that a few interview participants experienced. One interviewee (PAR12) mentioned her '*mindset'* as the barrier and that she '*wasn't motivated whatsoever*'. Another interviewee appeared to have been unable to find a way to change his lifestyle.

> *Not much joy in life these days other than eating, so I didn't get really prepared to be tough on myself about my food as much as I had hoped I would.* (PAR02)

6.3.3.4 Pain

Some interviewees found pain to be the main barrier to the tasks they wanted to perform to achieve their goals.

> *I couldn't do what I wanted to do; I was getting angry with myself ... I just wanted to [be] able to carry on normally, like play with the grandchildren and go shopping ... So I don't think really anything could have got through to me. I wasn't as mobile as I wanted to be.* (PAR12)
>
> *Wife and I used to walk, on a daily basis, several kilometres a day, and the weight was coming off, but knees started [to get worse]. I was fine until the knee decided to [be] worn out and I just couldn't maintain [it].* (PAR09)

6.3.4 Comparison to other weight loss programs

Some interview participants compared the intervention program with other weight loss programs they had experienced in the past.

One interviewee found that weight loss programs that sent food to her were more helpful for her.

> *I was doing Light 'n Easy. I did lose a lot of weight, but I stopped it … I think the difference was that with Light 'n' Easy the meals were already made; I didn't have to bother and work anything out, whereas with this program I was having to do it myself, and I was a bit lazy at the time … I don't like cooking.* (PAR12)

Another interviewee thought that he could not stay on a diet for a long time. He also did not lose weight on the intervention program.

> *I've been on [the] Jenny Craig program years and years ago, and some chemist program a few years ago as well, which was moderately successful for a while, but I sort of went off them and I slipped back, you know… being sick of being on a diet so eventually got off it.* (PAR02)

Two interviewees felt that the intervention program's approach was different in a positive way, and they were both able to achieve weight loss with its help.

> *Weight Watchers tend to humiliate you if you haven't lost weight, whereas Kerry was like you might be better next week, that's OK, and how are you going? How are you managing it? And if I hadn't, she wouldn't, you know, tell me off*. (PAR05)

> *Weight Watchers, Jenny Craig, then I tried the cabbage soup diet, you name it. Weight Watchers, I had to go and buy all the stuff, and I didn't like their food anyway. Jenny Craig was the same … I persevered with that for about a month … and I kept saying to them, I love my rice … and they told me, no, you gotta buy this food, but I found with Kerry, she said OK you like your rice, cut down on the oil, don't have a big serve … and I didn't have to go and change my pantry.* (PAR08)

6.4 Discussion

Studies have shown a small effect size in improving health-related quality of life in people with chronic conditions such as osteoarthritis gained by self-management support programs (Bennell et al., 2016, Coleman et al., 2012, Hurley et al., 2007, Lorig et al., 2005, Nelson et al., 2014). When conditions such as obesity are added to the situation, self-management becomes even further challenging and such support programs seem more essential. The randomised controlled trial presented in this thesis provided a quantitative method to evaluate the effectiveness of a Flinders Program based self-management support intervention in order to improve the health-related quality of life in obese osteoarthritis patients awaiting hip or knee replacement. The qualitative interviews in this chapter provided an insight into the perceptions of a sub-group of obese osteoarthritis patients who participated in the self-management support program, and to capture the depth of their

experiences. Michie et al. (2011) developed a framework for designing interventions that use behaviour change techniques. In this system, capability, opportunity, and motivation interact to generate behaviour that in turn influences these components. The findings of the qualitative interviews are discussed in this framework.

It was intended for the self-management support program to help participants understand the underlying problems and condition management options, and set realistic and measurable goals. The findings of the interviews showed that the majority of interviewees could identify their problems either at the first session with the nurse delivering the program, or throughout the program, and accordingly set goals with the help of the intervention program. These findings were similar to the findings of another qualitative study exploring experience of receiving the Flinders Program for six months in people with chronic conditions such as osteoarthritis in New Zealand (Roy et al., 2011). In their study, Roy et al. (2011) found that goal setting facilitated by the Flinders Program provided focus and a concrete aim for the participants. However, there were a few participants in our study who did not remember their goals clearly. This could be because the goals they set at the first session were not SMART (specific, measurable, action-oriented, realistic and timely), and therefore difficult to follow. This could be a concern for intervention delivery, as the health provider who delivers the intervention has the responsibility to guide the participant to define a SMART goal. However, this could also be related to the participant's recall, given the interview occurred almost a year after the first session of the Flinders Program.

Self-management support programs are also expected to provide information regarding choices of chronic condition management as well as information resources that participants may continue using to inform themselves with updated knowledge about their ongoing chronic condition (Wagner et al., 2001). The majority of interviewees in our study described learning pain coping skills as one of the biggest benefits of participating in the intervention program.

In telephone-based self-management support programs such as the one used in our study, the majority of contacts between the participant and the health care provider occurs on the phone. Our

data showed all participants found the follow-up phone calls to be motivating and something to look forward to. The latter even applied to participants who failed to remember/set goals. Talking to someone was the most reported advantage of participating in the program. In fact, all interviewees mentioned 'talking to someone' or 'being listened to' as a benefit of the intervention program. This finding was in line with the findings of Roy et al. (2011)'s study. Another qualitative study explored experience of Peer-Reinforced Self-Management Strategies - a peer support pain management program - in male veterans with chronic musculoskeletal pain in the US after 4 months of intervention. Similarly, they found 'somebody to talk to' and the social connections to be the most important reported benefit of the intervention (Matthias et al., 2016).

Our data showed that most interviewees believed to have achieved some level of mental help from participating in the intervention program. This could be due to having access to more information and condition management options, and finding themselves moving towards a goal, while having someone to talk to and sharing the setbacks they might encounter throughout the program, which altogether can make a challenging task less intimidating.

Our data also showed that some participants believed one of the barriers to the Flinders Program to be the unclear process as they had difficulties following various steps of the program, from identifying the problems to setting goals and taking steps towards achieving goals. This could inform improvement in delivering the intervention program.

Strengths and limitations

One strength of this study was that the PhD candidate (LS) conducted the interviews as well as transcribing them. This helped with gaining a deeper understanding of the data and accordingly with coding.

One limitation was that the interviews were conducted on completion of the randomised controlled trial, which was some months after the intervention program had ended for the participants. This was in order to keep the PhD candidate who conducted the interviews blinded to the group

allocations. The time gap could introduce a recall bias on the participants' side. Another limitation was that there was no second investigator double checking interview transcribing and there was no second coder. Also, interviewing participants who did not complete the program would assist in better understanding the barriers of the program. This is a further limitation.

Based on these limitations, and the fact that qualitative interviews did provide an understanding of participants' perception, a qualitative study using grounded theory to reach saturation is recommended to ensure generalisability of the results.

6.5 Summary

The interviews in this chapter provided a more in-depth perspective of experiences and perceptions of participating in the Flinders Program based self-management support program and extended the key findings of the randomised controlled trial (RCT). All interviewees gained some benefits from the intervention, and reported outcomes ranging from '*just having someone to talk to*' to a life-changing experience, with these outcomes being beneficial in achieving weight loss as well as improvements in mental health, spouse relations, knowledge and pain management.

In addition, the findings showed that occasional communication issues and perceived ambiguity for some participants were deficiencies in delivering the intervention program, which could be reasons for not producing better outcomes. However, this study presented a real-world implementation of the Flinders Program, in which the above-mentioned issues would be possible. This chapter highlighted areas in which delivery of the Flinders Program in real-world conditions could be further improved.

7. DISCUSSION AND CONCLUSIONS

7.1 Introduction

This is the first study internationally to test the efficacy of a clinician telephone-delivered model of chronic condition self-management support applied to obese patients on a hip or knee replacement waiting list. The study was conducted in three phases.

Phase 1 involved a review of the literature on self-management support and HRQoL from hip or knee replacements in obese osteoarthritis patients which showed that a new trial was justified. In addition, Phase 1 included a literature review of self-management support programs and the proposed intervention for obese people with advanced hip or knee osteoarthritis waiting for joint replacement surgery was explained.

Phase 2 consisted of a randomised controlled trial (RCT) that was conducted to evaluate the effectiveness of the self-management support program on HRQoL outcomes in this cohort of patients.

Finally, Phase 3 involved qualitative interviews on a subgroup of participants in the intervention program about their personal perceptions and experiences throughout the intervention.

7.2 Summary of main findings

The testable hypotheses in this study were as the following:

Hypothesis 1: At 10-month follow-up, there will be a statistically significant difference in health-related quality of life of obese osteoarthritis patients awaiting hip or knee replacement surgery who receive the Flinders Program versus treatment as usual.

Hypothesis 2: At 10-month follow-up, there will be a statistically significant difference in (1) weight loss and (2) self-management competency in obese osteoarthritis patients awaiting hip or knee replacement surgery who receive the Flinders Program versus treatment as usual.

Using the intention-to-treat (ITT) analysis of the 95 participants (47 control, 48 intervention), our

data showed that the Flinders Program showed no significant effect on the generic HRQoL measure SF36 physical and mental components, however was more effective in improving mental health, social activity and spouse relations measured by the osteoarthritis specific HRQoL measure OAKHQOL. The osteoarthritis specific effect was supported by the per protocol analysis which also showed significant differences in SF36 mental component improvements in the Flinders Program group compared to the usual care. A medium effect size was found for emotional role measured by the generic SF-36 instrument, and mental health, social activity and spouse relations measured by the disease-specific OAKHQoL instrument in the self-management support group, but not in the usual care group. These findings support the first hypothesis.

Contrary to the part one of our second hypothesis, the intervention program was not associated with an increased weight loss, although the waist-to-height ratio (WHtR) outcome showed a significantly greater improvement in the intervention group than in the control group. A novel finding was the significantly more successful weight loss (measured by BMI) in severely and morbidly obese participants in the intervention group compared to those in the control group. However, this trend was the opposite among obese participants. Findings of this study also showed significantly greater improvements in knowledge and coping skills with the intervention program, which supports part two of the second hypothesis.

The secondary post-hoc exploratory analyses for the primary outcomes showed some novel findings. The intervention program conferred a significantly greater total physical improvement (measured by SF-36) than the usual care in morbidly obese participants. Furthermore, the intervention program offered a greater physical improvement and pain reduction than the usual care in hip replacement patients, but not in knee replacement patients. The intervention program however provided a greater social improvement to the knee replacement patients than the control group.

7.3 Discussion

Assessing the effectiveness of the intervention by using a pragmatic approach, the findings were based on intention-to-treat (ITT) analysis. We measured the primary outcome health-related quality of life using both generic SF-36 and osteoarthritis-specific OAKHQoL. Our results showed that the self-management support program helped participants to achieve significantly greater emotional improvements (measured by SF-36) than those in the control group. A medium effect size (Cohen's $d = 0.61$) was found for this outcome baseline to 10-month follow up. The findings from the interviews support this finding. Most participants in the qualitative interviews mentioned mental and emotional improvements resulting from participation in the intervention program. This finding was comparable to the results of Helminen et al. (2015)'s study in Finland. In their RCT, Helminen et al. (2015) showed that significantly greater emotional improvements measured by the generic SF-36 were achieved from a self-management support program supervised by a psychologist and a physiotherapist. In a similar study in Hong Kong (Kwok et al., 2016), the ASMP self-management support program was shown to be associated with significantly greater improvements in SF-36 physical and pain, but not mental health after three months. One interpretation of the differences in results could be that participants in Kwok et al. (2016)'s study were determined as having knee osteoarthritis based on self-reports and not diagnostic investigations. Therefore it could be that their osteoarthritis was not at an advanced stage, and a six-week self-management support program could help them to control the physical impacts of their condition. Having a different cultural background could be an explanation for the different results in mental quality of life. Our data showed no significant differences in pain reduction between the participants in the intervention program compared to the control group. This is comparable to the results of O'Brien et al. (2018)'s recent randomised controlled trial in NSW, Australia that showed no statistically significant differences in pain reduction between over-weight and obese knee osteoarthritis patients who received a telephone-based weight loss support compared to usual care.

Our data showed that participants in the intervention group achieved significantly greater improvements in mental health, social activity and spouse relations measured by OAKHQoL with a medium effect size baseline to 10-month follow-up (Cohen's d =0.56, 0.50 and 0.67, respectively) as well as knowledge and coping skills across time than those in the control group. Many of the interviewees confirmed this finding when they indicated that the empathy and the feeling of being understood that they found in the intervention program were mentally helpful. Before this study, no RCT had evaluated the impacts of self-management support on HRQoL, as measured by OAKHQoL. One interpretation of the differences in our findings in terms of SF-36 outcomes versus OAKHQoL outcomes could be the form of the questions in these two questionnaires. For example, to determine the SF-36 social role score, participants were asked *'to what extent [has] their physical health or emotional problems … interfered with their normal social activities with family, friends, neighbours or groups'*. Due to its broad implications, various personal factors affected participants' responses to this question. A number of participants said they did not have friends or that they were not close to their family or that the term 'normal social activities' reminded them of how different it had been in the past. These factors affected their responses to this question. On the other hand, the social OAKHQoL activity score asked participants to rate how often they *'get out of the house as much as they like'* and how often they *'entertain at home as much as they like'*. These simple and direct questions meant that the participants' responses were not contaminated by above factors. Comparing the results of the SF-36 and the OAKHQoL questionnaires suggests that using the generic SF-36 questionnaire alone might underestimate some intervention effects in obese people with advanced osteoarthritis. Two other trials studied the effectiveness of a self-management support program in advanced hip or knee osteoarthritis patients awaiting joint replacement. Crotty et al. (2009) conducted an RCT to evaluate the efficacy of the Flinders Program for hip or knee osteoarthritis patients on a waiting list for arthroplasty, and found no significant differences in health-related quality of life measured by the generic AQoL instrument. In another trial, Ackerman et al. (2012) evaluated the impacts of the ASMP self-management support program on health-

related quality of life, again measured by the generic AQoL instrument, and found no significant differences in quality of life improvements between their control and intervention groups. One interpretation of the difference between the results of these studies and our findings could be the use of generic instruments alone to measure HRQoL which could be insensitive to the changes in this cohort of patients. Furthermore, Ackerman et al. (2012)'s study did not reach the sample size, and even among recruited participants there was a large difference in receiving the intended intervention between the two groups as many participants in the intervention group could not attend six weekly sessions of the ASMP program, due to physical limitations. We expected this in our study, as people with advanced hip or knee osteoarthritis on a joint replacement waiting list could be very limited in terms of traveling, and therefore designed our intervention program with only one face-to-face session, followed by telephone-based follow ups. For example, Bennell et al. (2016) evaluated the effectiveness of a pain coping and exercise self-management support program which involved attending 10 face-to-face sessions, and found significantly improved physical function and mental (measured by AQoL), but not pain in knee osteoarthritis patients who were not waiting for surgery, and therefore were not highly debilitated.

Pain is the one aspect of HRQoL that is shown not to improve significantly through self-management support programs in advanced hip or knee osteoarthritis patients; however pain coping skills can provide patients with strategies to better accept and tolerate pain. Our data showed that the intervention group significantly improved knowledge and coping skills. This finding was also in line with the findings of the interviews. Most interviewees indicated that the intervention program helped them to better cope with issues caused by osteoarthritis and that they had gained a better level of knowledge about their condition and its management.

Another trial studied only knee osteoarthritis patients who were scheduled for joint replacement. This was an RCT in Perth, Australia, by Coleman et al. (2012) where the generic SF-36 instrument was used to evaluate the effectiveness of the OAK self-management program on quality of life, and

showed that participants in the self-management program group achieved significantly greater improvements in all SF-36 domains except for physical function and pain compared to the control group at the 6-month point of receiving the program. Participants in our intervention group only achieved significantly greater improvements in emotional domain of SF-36 than the control group. One explanation for this difference is that participants in Coleman et al. (2012)'s trial were not obese. It is known that obesity can introduce further limitations on people's life style (Giuli et al., 2014). There are a limited number of studies investigating health-related quality of life in obese osteoarthritis patients. Ravaud et al. (2009) investigated the effects of a self-management support program on quality of life in obese knee osteoarthritis patients in France. At 12 months, they found no significant differences in physical or mental improvements (measured by SF-12) between the two groups. The reason for the different results could be the fact that the self-management support program in Ravaud et al. (2009)'s study did not involve pain coping skills which is essential in chronic condition management.

We found a significant improvement in SF36 emotional role, OAKHQoL mental health, social activity and spouse relations with a medium effect size in the self-management support group. This is comparable to the findings of Battersby et al. (2013)'s study in terms of a medium effect size in improvements of anger among Vitenam veterans who received the Flinders Program. These results suggest that the Flinders Program benefits are meaningful from a practical or clinical perspective, at least for constructs related to psychosocial wellbeing. This finding is plausible or coherent with previous research in self-management. For example, in patients with arthritis, numerous studies that measured psychological wellbeing reported benefits. These include improved coping and emotional stabilization (Leibing et al., 1999), depression (Sharpe et al., 2001), and social functioning (Evers et al., 2002).

The primary outcome in this study is HRQoL measured by SF36 (in two summary components) and OAKHQOL (in 8 subscales). It is a concern that in certain situations, multiple testing could lead to

finding significant differences by chance. Even though adjusting for multiple testing reduces the chance of making a type I error (introducing ineffective treatments), at the same time increases the chance of making a type II error (the chance that effective treatments are not discovered) (Feise, 2002). Therefore, the consequences of both Type I and Type II errors need to be considered. As mentioned in Chapter 4, in the case of our study the consequences of making a Type II error is perhaps more costly in terms of health benefits. Moreover, reducing the alpha level and maintaining the beta level means increasing the sample size and thereby increasing the cost of the study (Feise, 2002), which would make the study impossible. We are currently at an early stage of testing the Flinders Program in this study's population of interest, and therefore the findings of this study will inform a future larger RCT. Finally, our primary outcome HRQoL has multiple manifestations. Because no manifestation dominates, it is not helpful to select one primary endpoint. In such cases, use of a composite endpoint is valuable in testing multiple endpoints (Feise, 2002).

For the second hypothesis, our data showed no significant differences in weight loss between the two groups, although participants in the intervention group were significantly more successful in reducing the waist-to-height ratio (WHtR) than those in the control group. This finding was different to the results of a pilot RCT that investigated the impacts of a 4-session weight loss intervention at 12 months in patients receiving hip or knee replacements. In their pilot study, Simmance et al. (2014) showed that a dietitian-led intervention program helped obese osteoarthritis patients awaiting total joint replacement to achieve a greater weight loss than the control group. The difference in results could be because the main aim of Simmance et al.'s study was weight loss, and was led by a dietitian. It has been shown that WHtR is a better screening tool than waist circumference (WC) and BMI in detecting cardio-metabolic risk factors such as diabetes and heart diseases (Ashwell et al., 2012). No studies have yet compared the efficiency of these obesity instruments in hip or knee joint replacement patients, but it may be that WHtR is a better screening tool than WC and BMI also in detecting risk factors in hip or knee osteoarthritis patients. In that

case, our self-management support intervention would be beneficial for such patients in terms of effective obesity reduction too. Our anticipation was that this obesity reduction would be detected by the percentage body fat (%BF) measure, but %BF measure was similar between the two groups over time with a slight increase in both groups. One possible explanation for this unexpected result could be the variability in hydration level in participants which is known to influence the %BF measure, or potential calibration issues.

A prominent finding of our study was the significantly more successful weight loss (measured by BMI) in severely and morbidly obese participants in the intervention group compared to those in the control group. This finding was similar to the findings of a retrospective cohort study in the US conducted by Rohrer et al. (2010) which showed that severely and morbidly obese individuals achieved a significantly greater weight loss with the help of a telephone coaching program compared to others who did not participate in the program. However, participants in (Rohrer et al., 2010)'s study were not limited by advanced hip or knee osteoarthritis. This is an important finding, because severely and morbidly obese patients are shown to face more complications and less physical improvements after joint replacement surgery (Amin et al., 2006, Foster et al., 2015, Nuñez et al., 2011, Waters, 2014).

Morbidly obese participants in our intervention group also reported a significantly greater total physical improvement (measured by SF-36) than those in the control group. A reason for this finding could be that morbidly obese individuals face further limitations than those who are obese or severely obese, and therefore can further benefit from the knowledge and self-management skills they gain from self-management support programs. This shows the important role of such interventions in the care for morbidly obese patients while waiting for surgery.

A per protocol (PP) analysis was conducted to evaluate the effectiveness of the intervention in a near-perfect scenario. This analysis showed that participants who completed their program within the intervention group received significant improvements in all primary outcomes across time. This

difference shows that adherence to a self-management support program or the lack thereof can highly influence the intervention effects.

Secondary post-hoc exploratory analyses were conducted to evaluate the impact of other factors on the improvements in primary outcomes and on weight loss in both control and intervention groups. One of the findings was that self-management competency (measured by PIH) at baseline was a significant predictor factor of more successful weight loss and greater improvements in all domains of health-related quality of life, except for pain. This was also reflected in the qualitative interviews where pain was mentioned as one of the main barriers. This finding was comparable to the findings of a previous RCT conducted by Battersby et al. (2015) in Adelaide, Australia, to evaluate the Flinders Program in terms of improving self-management in people with various chronic conditions, where a significant association between baseline PIH and mental SF-12 was found, but not with physical SF-12 including pain.

In all, 55% of the participants in each group received surgery at some point between the first and second follow-ups. When considering the impact of the time of surgery in exploratory analyses, those who received surgery and recovered from it before the end of the study irrespective of which group they were allocated to showed greater improvements in physical scores and pain than those who did not received surgery. This was to be expected, as joint replacement surgery is the ultimate treatment for advanced hip or knee osteoarthritis (Skou et al., 2015). The intervention program further helped those who received surgery to achieve a greater improved mental health compared to those who did not received surgery. The intervention program was also more effective in providing greater social improvement to those who did not receive surgery than the usual care. The reason for this could be that the intervention program was socially beneficial for all participants regardless of whether they received surgery. This was reflected in both the results of the RCT and the interviews.

On the other hand, when broken down by hip and knee, hip replacement patients who participated in the intervention program had significantly greater improvements in mental and physical

components including pain compared with knee replacement patients. An explanation for this finding is the longer recovery time for knee replacement surgery compared to hip replacement surgery (Martin, 2003, Pelt, 2015). Therefore, hip replacement patients could benefit more in terms of the physical aspects when they received self-management support.

Finally, similar characteristics were found in our study participants to those in a comparable study conducted by Dowsey et al. (2010) in Melbourne, Australia, in which SF-12 was used to compare clinical and functional outcomes of hip replacement between obese and non-obese osteoarthritis patients. A similar age group (67.9 years versus 68.9 years) and a similar ratio of female participants (61.1% versus 60.7%) were found to those in our study compared to Dowsey et al. (2010)'s. The baseline mean BMI of participants in this trial was 37.3, with participants slightly more obese than those in Dowsey et al. (2010) study with a mean BMI of 35. The SF-36 total physical score was similar for both groups in our trial, with 31.7 (SD=7.23) for the control group and 31.46 (SD=6.3) for the intervention group, both considerably lower than the South Australian population norm of 53.6. The baseline mean score of the SF-36 total physical score in Baker et al. (2013) retrospective study in the UK where WOMAC and SF-36 were used to assess the influence of obesity on health and function three years after total knee replacement was 26.8 for obese participants and 25.7 for severely and morbidly obese participants, which were comparable to the mean scores in our study. The mean SF-36 mental score was 47.2 (12.4) for the control group and 44.2 (12.6) for the intervention group. This score is comparable to the SF-36 mental score in Baker et al. (2013) study with 47.1 for obese patients and 42.0 for severely and morbidly obese patients. The general population of South Australia has a SF-36 mental score of 48.8.

7.4 Strengths and limitations of the study

One of the strengths of our study was the generalisability of the findings to population of people undergoing hip or knee arthroplasty. Participants in our study were of similar age group, gender ratio, and baseline BMI and quality of life to those in similar studies.

Another strength of this study was that it reached the expected study power, and therefore increased the generalisability of the findings. Due to the broad inclusion criteria for participating in this study, many participants had co-occurring conditions, such as diabetes or depression, with this increasing the external validity of the findings.

Another strength was the RCT design and having a control group. Our study is also the first in this area of research to use mixed-effects modelling for data analysis. This was a strength of the study as mixed-effects modelling handles the effects of individual trajectory changes on the final outcome better than other statistical methods.

Follow-ups for the intervention program in this study were all telephone-based. Mohr et al. (2012) in their RCT in the U.S. examined whether telephone-based cognitive behavioural therapy reduces attrition in treating depression among primary care patients, found that the telephone-based program improves adherence compared with face-to-face delivery. Given this, and the fact that most participants in our study lived far from the study location and had travel difficulties due to their physical condition, the form of follow-ups provided a strength to the study by increasing participation as participants did not need to travel to the study location.

The performance of telephone-based follow-ups requires a significantly shorter time from clinicians, and therefore, this form of follow-ups have the potential to make the intervention efficient and cost-effective. Radcliff et al. (2012) in their 1-year prospective randomised controlled clinical trial, compared the costs of telephone versus face-to-face weight loss program for 50 years or older adult from rural areas in the U.S., and found that the telephone-based format had a lower cost. This could be a further strength of this study; however, a large RCT to evaluate the cost-effectiveness of telephone-based self-management program in Australia is required.

In accordance with the ITT principle, the PhD candidate used her best efforts to attain follow-up assessments from all participants regardless of their adherence to the study protocol. Strategies to

improve follow-up response rates included asking the questions on the telephone or posting the questionnaires along with stamped envelopes for return. These attempts to collect follow-up data minimised occurrences of missing data and increased the strength of the study.

There were some limitations in this thesis. Limitations of the section on literature review of self-management support programs in people with osteoarthritis included lack of a second reviewer which reduces the strength of the review, and the fact that only two databases were searched. One of the RCT limitations was that outcome data were collected from self-report questionnaires. In this form of data collection, participants may provide responses that are expected rather than actual. This however is balanced by both intervention and control participants providing data by self-report questionnaires. Also, participants were enrolled from a single hospital in South Australia and only one nurse delivered the self-management support program. This could be a limitation in terms of broader generalisability. Another limitation was the lack of a formal fidelity assessment for the delivery of the self-management program to inform the implementation of the self-management support program. The results from the qualitative component also showed this limitation. A further limitation was the lack of an economic analysis of adopting the self-management support program for obese osteoarthritis patients awaiting a hip or knee replacement. Patients on a waiting list for joint replacement are at the most severe end of the arthritis spectrum. Their capacity to improve QoL without an operation, particularly in a 6-month or 10-month time frame, can be limited, especially as they have the expectation that they will receive surgery and might not be ready to make lifestyle changes. Therefore, not having long-term follow-ups nor having a large sample size are other limitations to this study. The exploratory analyses showed that timely surgery had a significant impact on the primary outcome, but the inclusion of any post-randomisation variables (e.g. time of surgery) in the primary analysis would lead to biased estimates due to a disruption in prognostics of randomisation. Therefore, the primary analysis was conducted using a simple, unadjusted model in concordance with the pre-specified sample size calculation and analysis plan.

This could be a limitation of exploratory analyses.

7.5 Clinical implications

Based on this study's findings, the preliminary evidence is that our self-management support intervention program could be a beneficial adjunct to patient care, specifically in providing improvements in mental health, coping and knowledge in obese patients with advanced hip or knee osteoarthritis, and in weight loss for severely and morbidly obese patients. Improved knowledge and coping through receiving the intervention program were also found to improve the physical quality of life. Therefore, we recommend this intervention to joint replacement programs at hospitals and clinics for obese osteoarthritis patients awaiting hip or knee replacement surgery. Another important clinical finding of our study is that the intervention can be useful for this cohort of patients irrespective of when the surgery occurs.

One issue arising from implementing this program in hospitals and clinics is the time that health care providers need to spend in providing the support. However, the first one-on-one session takes approximately an hour while the telephone-based follow-ups altogether take between 1 and 1.5 hours for each patient over six months. Also, the intervention program could be provided completely by telephone so that even people who live remotely could access the service. The implementation of this program can be improved by regular supervision of senior educators of clinicians who deliver the program. This can be further informed through an extensive process evaluation.

Our results from the per protocol analysis showed that mental health improved when participants adhered to the program. This highlights the importance of strategies to increase adherence. Examples of these strategies that are recommended include tailoring the program to individuals' needs and preferences, goal setting and reinforcing the agreed goals, helping individuals to find social support, and relapse prevention.

7.6 Conclusions

This study contributes to the knowledge of self-management support for obese patients with osteoarthritis who are waiting for hip or knee replacement surgery. The main results of this research specifically demonstrated that:

1. Participants who receive the self-management support intervention program while waiting for hip or knee replacement experience mental, emotional and social benefits.
2. Severely and morbidly obese participants who receive the self-management support intervention program achieve more successful weight loss.
3. Morbidly obese participants who receive the self-management support intervention program achieve greater physical improvements than morbidly obese participants who do not.
4. Participants who receive the self-management support intervention program improve their knowledge and coping skills.
5. High self-management competency is associated with greater health-related quality of life (HRQoL) in all domains.

7.7 Recommendations for future research

Several directions for future research stem from this study:

1. A large RCT is recommended to evaluate the cost-effectiveness of a telephone-based Flinders Program, and to test whether the results of this small RCT can be replicated, so a practical intervention for clinics and hospitals could be offered.
2. Most behavioural and self-management intervention effects fade with time. Therefore, an RCT is recommended for evaluation of the long-term intervention effects with extended follow-ups.
3. This study showed that morbidly obese patients achieved physical benefits from the intervention program. Further study is recommended to recruit only morbidly obese patients to confirm this finding.

4. This study showed that the self-management support intervention program was associated with significant reduction in waist to height ratio (WHtR), but not in WC and BMI. Other studies have shown that WHtR is more effective in detecting risk factors in diabetes and cardiovascular disease. A longitudinal study is recommended to compare the efficiency of these three obesity measures in detecting risk factors in hip or knee joint replacement patients.

APPENDICES

Appendix A. Ethics and Amendment Approval

FLINDERS MEDICAL CENTRE

Government of South Australia
Southern Adelaide Health Service

02 April 2015

Professor Jegan Krishnan
Department of Orthopaedics
Flinders Medical Centre
BEDFORD PARK SA 5042

Dear Professor Krishnan

HREC reference number: HREC/14/SAC/414 (401.14)
SSA reference number: SSA/15/SAC/40
Project title: A randomised controlled trial of evaluating the impacts of the Flinders self-management support program on health related quality of life outcomes of total knee or hip replacement for obese osteoarthritis patients.
Ethics approval: 18 November 2014 - 18 November 2017

RE: Site Specific Assessment Review

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to commence at the following site: Repatriation General Hospital

- Site Specific Assessment form
- CV for Professor Jegan Krishnan
- SAC HREC approval letter dated 18 November 2014
- Participant information sheet/consent form v2 dated September 2014
- Data collection sheet v2
- Letter of invitation – no date
- SF-36 questionnaire

HREC reviewed documents listed on the approval letter dated 18 November 2014 from the SAC HREC are accepted as part of the site authorisation.

Should you have any queries about the consideration of your Site Specific Assessment form, please contact Bev Stewart-Campbell on 08 8204 4507.

Flinders Medical Centre
The Flats G5 – Rooms 3 and 4
Flinders Drive, Bedford Park SA 5042
T: 08 8204 6453
F: 08 8204 4586
E:Research.ethics @health.sa.gov.au

The SSA reference number should be quoted in any correspondence about this matter.

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.

Yours sincerely

Bev Stewart-Campbell
Research Governance Officer
Southern Adelaide Clinical Human Research Ethics Committee

Southern Adelaide Clinical Human Research Ethics Committee

Government of South Australia
Southern Adelaide Health Service

11 June 2015

Dear Professor Jegan Krishnan

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: 401.14

Title: A randomised controlled trial of evaluating the impacts of the self-management support Flinders Program on health related quality of life of obese osteoarthritis patients on a knee or hip replacement waiting list

Chief Investigator: Professor Jegan Krishnan

Approved public heath sites: Repatriation General Hospital

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 8 April 2015
- SAC HREC General Research Application form v4 dated 2 June 2015 (tracked)
- Letter of Invitation v2 dated 8 April 2015 (tracked)

This amendment approval does not alter the current SAC HREC approval period for the study: 18 November 2017

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

Appendix B. Consent form

Consent Form - *Adult providing own consent*

Title	A randomised controlled trial evaluating the impacts of the self-management based Flinders Program on Health Related Quality of Life outcomes of Total Knee or Hip Replacement osteoarthritis patients.
Short Title	Impacts of Self-Management on Health Related Quality of Life of joint replacement patients
Coordinating Principal Investigator/ Principal Investigator	Prof. Jegan Krishnan
Associate Investigator(s)	Ms. Ladan Sahafi Prof. Malcolm Battersby Dr. Melanie Harris Mr. Donald Bramwell
Location	Repatriation General hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Repatriation General hospital – Orthopaedic Department clinics concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Researcher/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Researcher/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Name of Study Researcher/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning the research project.

Note: All parties signing the consent section must date their own signature.

Appendix C. Patient Information Sheet

Government of South Australia
SA Health

Flinders UNIVERSITY

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Repatriation General Hospital – Orthopaedic Department clinics

Title	A randomised controlled trial evaluating the impacts of the self-management support Flinders Program on Health Related Quality of Life of osteoarthritis patients on a knee or hip replacement waiting list.
Short Title	Impacts of the self-management support Flinders Program on Health Related Quality of Life of osteoarthritis patients on a knee or hip replacement waiting list
Coordinating Principal Investigator/ Principal Investigator	Prof. Jegan Krishnan
Associate Investigator(s)	Ms. Ladan Sahafi Prof. Malcolm Battersby Dr. Melanie Harris Mr. Donald Bramwell
Location	Repatriation General Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, because you have been assessed for a knee or hip replacement. This research project is testing a new method of helping people to self-manage their health including diet and daily activities before an operation.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

In this study, we evaluate the impacts of self-management support on health related quality of life, such as physical and psychological health and also social and mental well-being. This study may be able to improve outcomes of knee or hip replacement surgery, and may also help osteoarthritis patients to lose weight and achieve good outcomes from the operation.

The results of this research will be used by the study researcher Ladan Sahafi to obtain a postgraduate higher degree (PhD) degree.

3 What does participation in this research involve?

If you choose to participate in this study,
1- A consent form will be signed by you and the study researcher.
2- You will be randomly allocated to one of the two groups:
Group A – will receive the usual care,
Group B – will receive the usual care as well as a self-management support.
3- You allow us to look through your clinical information.
4- You attend Repatriation General hospital – Orthopaedic Department clinics on three occasions to be measured for your height, weight, waist circumference and hip circumference, and also to fill out three questionnaires which will take about 40 minutes. On these three occasions (your first appointment, and two follow-ups at 6 months and 10 months after your first appointment) your whole-body fat percent will also be measured. This measurement will take about 6 minutes when you will be asked to lie down on a bed and eight small sticky electrodes of the size of your thumb will be located on your feet, ankles, hands and wrists, on both sides. A small electric current will be sent through the electrodes to measure the water and fat percentage in your body. There is absolutely no pain, discomfort or risk involved with this test. There is no need for extra insurance regarding this test.
You are encouraged to attend all three appointments to complete the study, but if you are unable to attend your follow-up appointments, the questionnaires will be sent out to you.
5- If you get allocated to group B, you will receive the Flinders self-management support program which will require you to attend an extra session in the beginning of the study for an interview which will take about one hour, and you will also receive follow-ups by phone or face-to-face every 2 to 4 weeks for six months. You might also need to visit a dietician and go to a gym upon a mutual agreement in the first interview.

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). There is a 50% chance you will be allocated to either group.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study investigators or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All care required as part of the research project will be provided to you free of charge.

This study will be at the time of your regular visits to the hospital. Otherwise, you may be reimbursed for any reasonable travel, parking and other expenses associated with the research project visit.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

No medications or activities would restrict you from participating in this study.

5 Other relevant information about the research project

There will be about 196 participants in this study, with 98 participants in group A and 98 participants in group B. This study will be conducted in Australia in one hospital. Based on the outcomes of this study, similar treatments might be applied to other hospitals. This is a collaborative study between Orthopaedics Department and Flinders Human Behaviour and Health Research Unit of Flinders University.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. However, we would greatly appreciate you taking part.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Repatriation General hospital – Orthopaedic Department clinics.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment for your joint. Your joint replacement surgery is irrespective of your participation in this study.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include losing weight and improved health related quality of life, and less complications after your operation.

9 What are the possible risks and disadvantages of taking part?

This study does not involve any medical treatments, and therefore there are no physical side effects. It is expected that there will be no harm from participating in this study. You might feel a pain in your joint while doing exercises you are encouraged to do in this study.

If you become upset or distressed as a result of your participation in the research, the study researcher will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

This study does not involve collection of samples.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the study investigators will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the study researcher will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, the study researcher might consider it to be in your best interests to withdraw you from the research project. If this happens, she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

There are no restrictions on using other treatments during this study.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study researcher and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly if the study researcher is unable to continue the study for unexpected personal reasons. Even then, both departments would take over and ensure the completion of the project.

15 What happens when the research project ends?

When this research ends, you may or may not be able to receive the self-management support program used in this study, depending on whether the hospitals decide to adapt their treatments. When this research project ends however you will be informed about its outcomes via mail or face-to-face.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study researcher and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your data sheets and questionnaires will be kept under lock and key in Repatriation General hospital - Orthopaedic Department clinics. Only the study researcher and qualified staff will have access to it. No information that could lead to your identification will be released.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities, the institution relevant to this Participant Information Sheet, Repatriation General hospital – Orthopaedic Department clinics, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forms. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. No information that could lead to your identification will be released.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the unlikely event of loss or injury, the parties involved in this research project have agreed to follow MA compensation guidelines which will made available on request.

18 Who is organising and funding the research?

This research project is being conducted by Prof. Jegan Krishnan and orthopaedic department.

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of *Flinders Medical Centre*.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

If you would like any further information concerning this project, you can contact the study researcher Ms. Ladan Sahafi on 0423892015 or any of the following people:

Clinical contact person

Name	Prof. Jegan Krishnan
Position	Head of orthopaedic department and the principal investigator
Telephone	(08) 8204 4289
Email	Jegan.krishnan@flinders.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Mr. Donald Bramwell
Position	Co-investigator
Telephone	(08) 8204 4673
Email	Donald.bramwell@health.sa.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Southern Adelaide Clinical Human Research Ethics Committee
HREC Executive Officer	Petrina Kasperski
Telephone	(08) 8204 6453
Email	Petrina.kasperski@health.sa.gov.au

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Bev Stewart Campbell
Position	Research Governance Officer
Telephone	8204 4507
Email	Bev.stewart-campbell@health.sa.gov.au

Appendix D. Invitation letter

Government of South Australia
SA Health

Flinders UNIVERSITY

Name: to be inserted

Address: to be inserted

INVITATION TO TAKE PART IN A STUDY

(Date to be inserted)

Dear (name of patient to be inserted)

Re: *Impacts of the self-management support Flinders Program on Health Related Quality of Life of osteoarthritis patients on a knee or hip replacement waiting list*

I am writing to notify you of the above study taking place in Repatriation General hospital – Orthopaedic Department clinics. The purpose of this study is to evaluate impacts of self-management on health related quality of life for joint replacement patients. All used techniques are well established, none of it is new or experimental. This study aims to improve the quality of life for patients.

The study has been approved by the Southern Adelaide Human Research Ethics Committee. You are invited to participate in this project because you have been assessed for a knee or hip replacement. Please read the Information Sheet provided. Ladan, one of the investigators will contact you by phone in a week to ask if you are interested in participating.
If you choose to take part, you will sign a consent form and then be randomly allocated to one of two groups:

- Group A) will receive the usual care.
- Group B) will receive the usual care as well as the Flinders self-management support program.

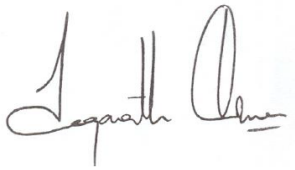
You will be required to attend three more follow up appointments than usual, and in addition we will ask you to fill out some questionnaires.

Any personal details that you provide will be treated confidentially. Your participation in this study is voluntary, and you may withdraw at any stage. Participation or non-participation will not prejudice any of your medical treatments or entitlements or have any impact on the time you wait for your joint replacement.

Thank you very much for assisting with this study. If you would like more information, please contact Ms. Ladan Sahafi on 0423892015.

Yours sincerely,

Professor Jegan Krishnan
Head of Orthopaedic department



Version 2, 8th April 2015

Flinders University

Orthopaedic Surgery AND
Flinders Human Behaviour & Health Research Unit

Mobile: 0423 892 015
Email: ladan.sahafi@flinders.edu.au

Project: Impacts of the self-management support Flinders Program on Health Related Quality of Life of osteoarthritis patients on a knee or hip replacement waiting list

Participant Questionnaire

Participant Number:

_____100_____

Participant Questionnaire

Thank you for your participation in this research study.

Please complete this participant questionnaire in blue or black pen. The questionnaire includes some questions that are quite similar, but your answer to each individual question is very important. Please answer each question even if you answered a similar one earlier.

If you have any questions about the study or the questionnaire please ask.

Your privacy

This information will not be seen or used by anyone except the research team. Your information will not be given to any other person without your permission. All personal information will be coded without names and stored in the Repatriation General Hospital – Orthopaedic clinic under lock and key for as long as you are receiving support from the clinic. After that it will be destroyed. Data on computers will be password protected. Project outcomes will be published in the conference papers and journals but any publications arising from the study will not contain any personal identifying information. Under privacy rules you are entitled to request a copy of your personal information.

Your Questionnaire

This questionnaire contains four sections. We would like you to complete all four sections.

1. The first section asks you about your date of birth, gender and living arrangement.
2. The second section asks for your view of the current quality of your life and in the past four weeks.
3. The third section asks about how your osteoarthritis is influencing your life.
4. The last section asks about how you are going now.

Date Questionnaire Completed: _ _ / _ _ / _ _

Demographics

Date of birth: __ / __ / ____

Gender: □ Female □ Male

Living arrangement:

□ Alone

□ With partner

□ With children

□ Other, Please specify: _____

Work status / occupation:

□ Unemployed/retired

□ Full-time job – (state type of occupation): _____

□ Part time job – (state type of occupation): _____

Qualification:

□ Primary School □ Secondary School

□ Undergraduate □ Honours

□ Postgraduate □ Other, Please specify:

_____

Your health and well-being

This questionnaire asks you for your views about your health.

For each of the following questions, please mark an ☒ in the **one** box that best describes your answer.

These questions are about your health now and your current daily activities.

1- In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

2- Compared to <u>one year ago</u>, how would you rate your health in general now? Would you say it is:

Much better than one year ago	Somewhat better than one year ago	About the same as one year ago	Somewhat worse than one year ago	Much worse than one year ago
☐	☐	☐	☐	☐

The following questions are about activities that you might do during a typical day. Please answer if your health now limits you a lot, limits you a little, or does not limit you at all, in these activities

3a- First, vigorous activities, such as running, lifting heavy objects, participating in strenuous sports. Does your health now limit you a lot, limit you a little, or not limit you at all?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3b- What about moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3c- And what about lifting or carrying groceries?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3d- Climbing several flights of stairs?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3e- Climbing one flight of stairs?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3f- Bending, kneeling or stooping?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3g- Walking more than one kilometre?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3h- Walking half a kilometre?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3i- Walking 100 metres?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3j- Bathing or dressing yourself?

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

The next four questions ask about your physical health and your daily activities during the past four weeks.

4a- During the past four weeks, have you had to cut down on the amount of time you spent on work or other regular daily activities as a result of your physical health?

Yes	No
☐	☐

4b- During the past four weeks, have you accomplished less than you would like as a result of your physical health?

Yes	No
☐	☐

4c- During the past four weeks, were you limited in the kind of work or other activities you do, as a result of your physical health?

Yes	No
☐	☐

4d- During the past four weeks, have you had any difficulty performing the work or other activities you do, for example, it took extra effort?

Yes	No
☐	☐

The following questions ask about your emotions and your daily activities during **the past four weeks**.

5a- Have you cut down the amount of time you spent on work or other regular daily activities as a result of any emotional problems, such as feeling depressed or anxious?

Yes ☐ No ☐

5b- Have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?

Yes ☐ No ☐

5c- Did you not do work or other regular daily activities as carefully as usual as a result of any emotional problems, such as feeling depressed or anxious?

Yes ☐ No ☐

6- To what extent has your physical health or emotional problems interfered with your social activities like visiting friends or relatives?

Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely ☐

7- How much did pain interfere with your normal work, including both work outside the home and housework? Did it interfere:

Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely ☐

8- How much bodily pain have you had during the past four weeks? Have you had:

None ☐ Very mild ☐ Mild ☐ Moderate ☐ Very severe ☐

The following questions are about how you feel and how things have been with you in the past four weeks. Please choose the one answer that comes closest to the way you have been feeling.

9a- How much of the time during the past four weeks did you feel full of life? Would you say all of the time, most of the time, a good bit of the time, some of the time, a little of the time or none of the time?

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 ☐

How much of the time during **the past four weeks** have you:

9b- been a very nervous person?

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
☐	☐	☐	☐	☐	☐

9c- felt so down in the dumps that nothing could cheer you up?

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
☐	☐	☐	☐	☐	☐

9d- felt calm and peaceful?

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
☐	☐	☐	☐	☐	☐

9e- had a lot of energy?

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
☐	☐	☐	☐	☐	☐

How much of the time during **the past four weeks** have you:

9f- felt down?

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
☐	☐	☐	☐	☐	☐

9g- felt worn out?

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
☐	☐	☐	☐	☐	☐

9h- been a happy person?

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
☐	☐	☐	☐	☐	☐

9i- felt tired?

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
☐	☐	☐	☐	☐	☐

10- During the past four weeks, how much of the time has your physical health and emotional problems interfered with your social activities like visiting friends and relatives?

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
☐	☐	☐	☐	☐	☐

The next questions are a list of statements. After each one, please answer if it is definitely true, mostly true, mostly false, or definitely false. If you are not sure, just answer 'don't know'.

11a- "I seem to get sick a little easier than other people".

Definitely true	Mostly true	Don't know	Mostly false	Definitely false
☐	☐	☐	☐	☐

11b- "I am as healthy as anybody I know".

Definitely true	Mostly true	Don't know	Mostly false	Definitely false
☐	☐	☐	☐	☐

11c- "I expect my health to get worse".

Definitely true	Mostly true	Don't know	Mostly false	Definitely false
☐	☐	☐	☐	☐

11d- "My health is excellent".

Definitely true	Mostly true	Don't know	Mostly false	Definitely false
☐	☐	☐	☐	☐

This is the end of the section about your general health and well-being.

How should you complete this part of the questionnaire?

Please circle the number on the scale that most likely matches your response for each of the questions. The scale will look like this:

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

OR THIS

1 2 3 4 5 6 7 8 9 10

Never All the time

OR THIS

1 2 3 4 5 6 7 8 9 10

Not at all Very much agree

Impact of Osteoarthritis on the Quality of Your Life

1. I have difficulty walking

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

2. I have difficulty bending down or straightening up

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

3. I have difficulty carrying heavy things

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

4. I have difficulty going down stairs

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

5. I have difficulty climbing stairs

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

6. I have difficulty taking a bath

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

7. I have difficulty getting dressed (socks, tights, shoes etc)

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

8. I have difficulty cutting my toe-nails

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

9. I have difficulty getting going again after staying in the same position for a long time

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

10. I have difficulty getting in and out of a car

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

11. I have difficulty using public transport (bus, train, ...)

I don't use public transport □→ Go to question 12

I use public transport □

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

12. I have difficulty doing my job

I do not work □→ Go to question 13

I do work □

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

13. I have to pace myself

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

14. I take more time to do things

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

15. My spirits are low because of the pain

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

16. I worry about being dependent on others

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

17. I worry about being disabled

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

18. I feel embarrassed when people look at me

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

19. I am anxious

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

20. I am depressed

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

21. I feel my family life is being affected

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

22. I feel my relationship with my partner is being affected

Not Applicable □→Go to question 23

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

23. I feel my sexual relationship is being affected

No sexual activity in the last four weeks □→Go to question 24

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

24. I have difficulty staying in the same position for a long time (sitting, standing, not moving etc)

1 2 3 4 5 6 7 8 9 10

Never All the time

25. I need a walking stick/cane or crutches to walk

1 2 3 4 5 6 7 8 9 10

Never All the time

26. I have pain (describe frequency)

1 2 3 4 5 6 7 8 9 10

Never All the time

27. I have pain (describe intensity)

1 2 3 4 5 6 7 8 9 10

Not at all Unbearable

28. I need help for things like housework and shopping etc.

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

29. I feel older than my age

1 2 3 4 5 6 7 8 9 10

Not at all Very much agree

30. I am able to plan projects for the long term

1 2 3 4 5 6 7 8 9 10

Not at all Very much agree

31. I get out of the house as much as I like

1 2 3 4 5 6 7 8 9 10

Not at all Very much agree

32. I entertain at home as much as I like

1 2 3 4 5 6 7 8 9 10

Not at all Very much agree

33. I have difficulty getting to sleep or getting back to slee because of pain

1 2 3 4 5 6 7 8 9 10

Never All the time

34. I wake up because of pain

1 2 3 4 5 6 7 8 9 10

Never All the time

35. I wonder what will become of me

1 2 3 4 5 6 7 8 9 10

Never All the time

36. I am irritable or aggressive

1 2 3 4 5 6 7 8 9 10

Never All the time

37. I feel I annoy those close to me

1 2 3 4 5 6 7 8 9 10

Never All the time

38. I am worried about the side effects of my treatment

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

39. I can talk to others about the difficulties I have due to my arthritis as much as I like

1 2 3 4 5 6 7 8 9 10

Not at all Very much agree

40. I feel others understand the difficulties I have due to my arthritis

1 2 3 4 5 6 7 8 9 10

Not at all Very much agree

41. I am embarrassed to ask for help if I need it

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

42. I feel supported by people close to me (partner, family, etc)

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

43. I feel supported by those around me (friends, neighbours, colleagues, etc)

1 2 3 4 5 6 7 8 9 10

Not at all A great deal

This is the end of the section for impact of Osteoarthritis on the quality of your life.

Your Partners in Health

1. Overall, what I know about my health condition(s) is:

0 1 2 3 4 5 6 7 8

Very little — Something — A lot

2. Overall, what I know about the treatment, including medications of my health condition(s) is:

0 1 2 3 4 5 6 7 8

Very little — Something — A lot

3. I take medications or carry out the treatments asked by my doctor or health worker:

0 1 2 3 4 5 6 7 8

Never — Sometimes — Always

4. I share in decisions made about my health condition(s) with my doctor or health worker:

0 1 2 3 4 5 6 7 8

Never — Sometimes — Always

5. I am able to deal with health professionals to get the services I need that fit with my culture, values and beliefs:

0 1 2 3 4 5 6 7 8

Never — Sometimes — Always

6. I attend appointments as asked by my doctor or health worker:

0 1 2 3 4 5 6 7 8

Never — Sometimes — Always

7. I keep track of my symptoms and early warning signs (e.g. blood sugar levels, peak flow, weight, shortness of breath, pain, sleep problems, mood):

0 1 2 3 4 5 6 7 8

Never — Sometimes — Always

8. I take action when my early warning signs and symptoms get worse:

0 1 2 3 4 5 6 7 8

Never — Sometimes — Always

9. I manage the effect of my health condition(s) on *my physical activity* (i.e. walking, household tasks):

0 1 2 3 4 5 6 7 8

Not very well — Fairly well — Very well

10. I manage the effect of my health condition(s) on *how I feel* (i.e. my emotions and spiritual wellbeing):

0	1	2	3	4	5	6	7	8
Not very well				Fairly well				Very well

11. I manage the effect of my health condition(s) on *my social life* (i.e. how I mix with other people):

0	1	2	3	4	5	6	7	8
Not very well				Fairly well				Very well

12. Overall, I manage to live a healthy life (e.g. no smoking, moderate alcohol, healthy food, regular physical activity, manage stress):

0	1	2	3	4	5	6	7	8
Not very well				Fairly well				Very well

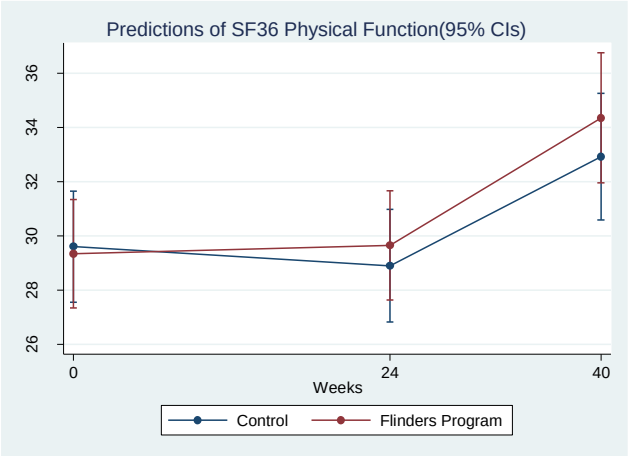
Thank you for completing this questionnaire!

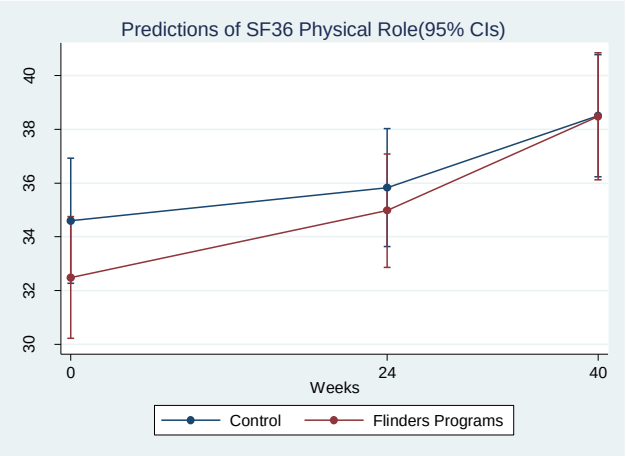
Appendix F. Post-estimation marginal effects for SF-36 domains

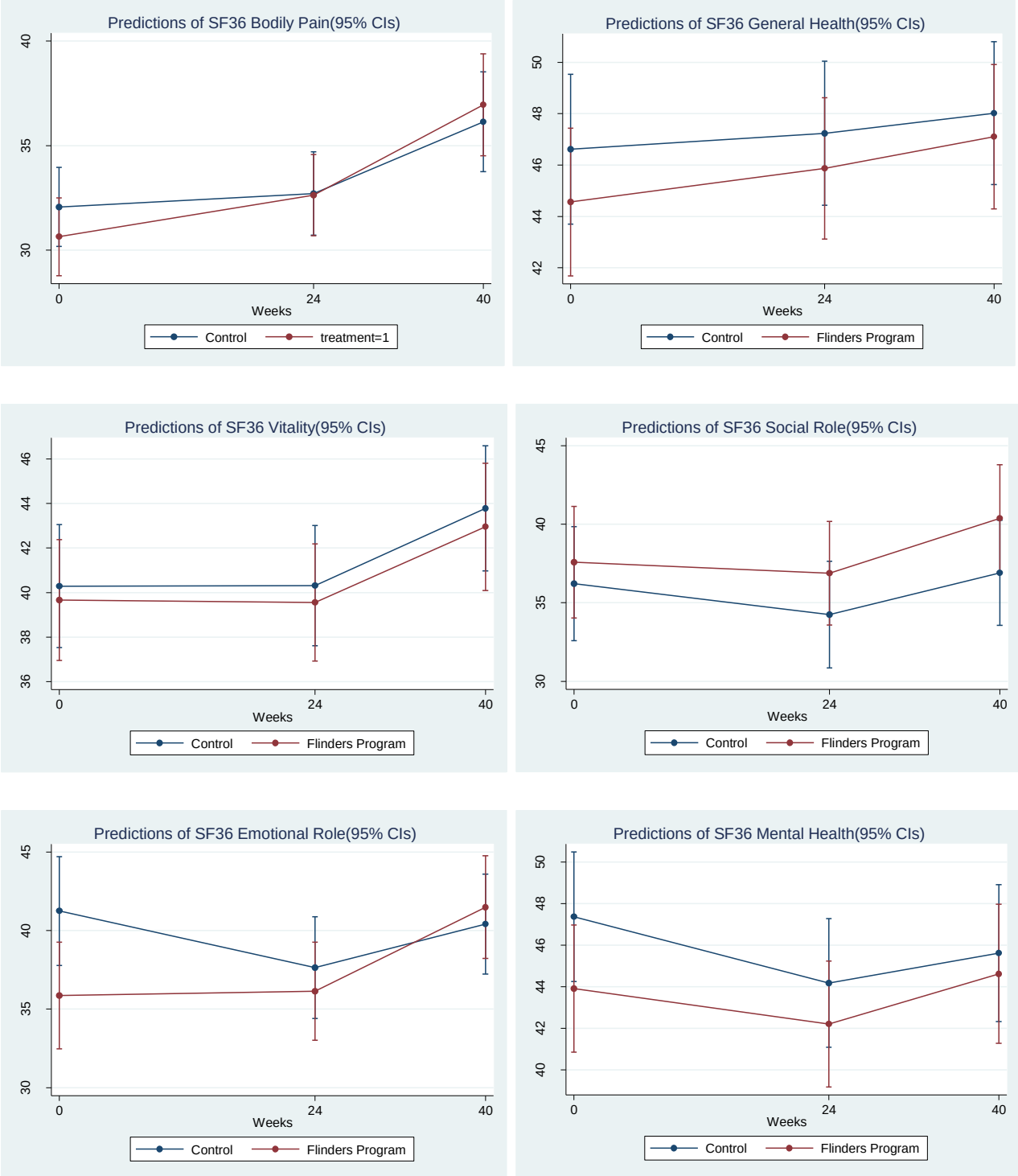
To further interpret the analysis of SF-36 subdomains, the post-estimation marginal effects of responses to the SF-36 domains, with time at fixed values of 0, 24 and 40 weeks, were obtained and are shown in Higher SF-36 scores indicate improvement

Figure 19.

An overall improvement was observed in the scores for physical function, physical role, bodily pain, general health and vitality for both intervention and control groups across time. The trends for vitality and general health scores in the two groups were similar. The participants in the intervention group appear to have greater improvements in physical function, physical role and bodily pain scores than those in the control group across time; however, these improvements were not statistically significant ($p = 0.374$, $p = 0.307$, and $p = 0.264$, respectively). The trends for social role, emotional role and mental health scores in both groups were downward from baseline to the 6-month follow-up and then upward to the 10-month follow-up. A better overall improvement was observed for the intervention group in these scores compared to those for the control group, although the improvement was only significant for emotional role.







Higher SF-36 scores indicate improvement

Figure 19: Predictions of SF-36 domains (95% CIs)

Appendix G. Post-estimation marginal effects for obesity outcomes

To further interpret the analysis of obesity outcomes, the post-estimation marginal effects of responses to obesity outcomes, with time at the fixed values of 0, 24 and 40 weeks, were obtained and are shown in Figure 20. The trends of BMI, WC and %BF are similar for both intervention and control groups. A faster reduction was found in the WHtR ratio in the intervention group compared to that for the control group.

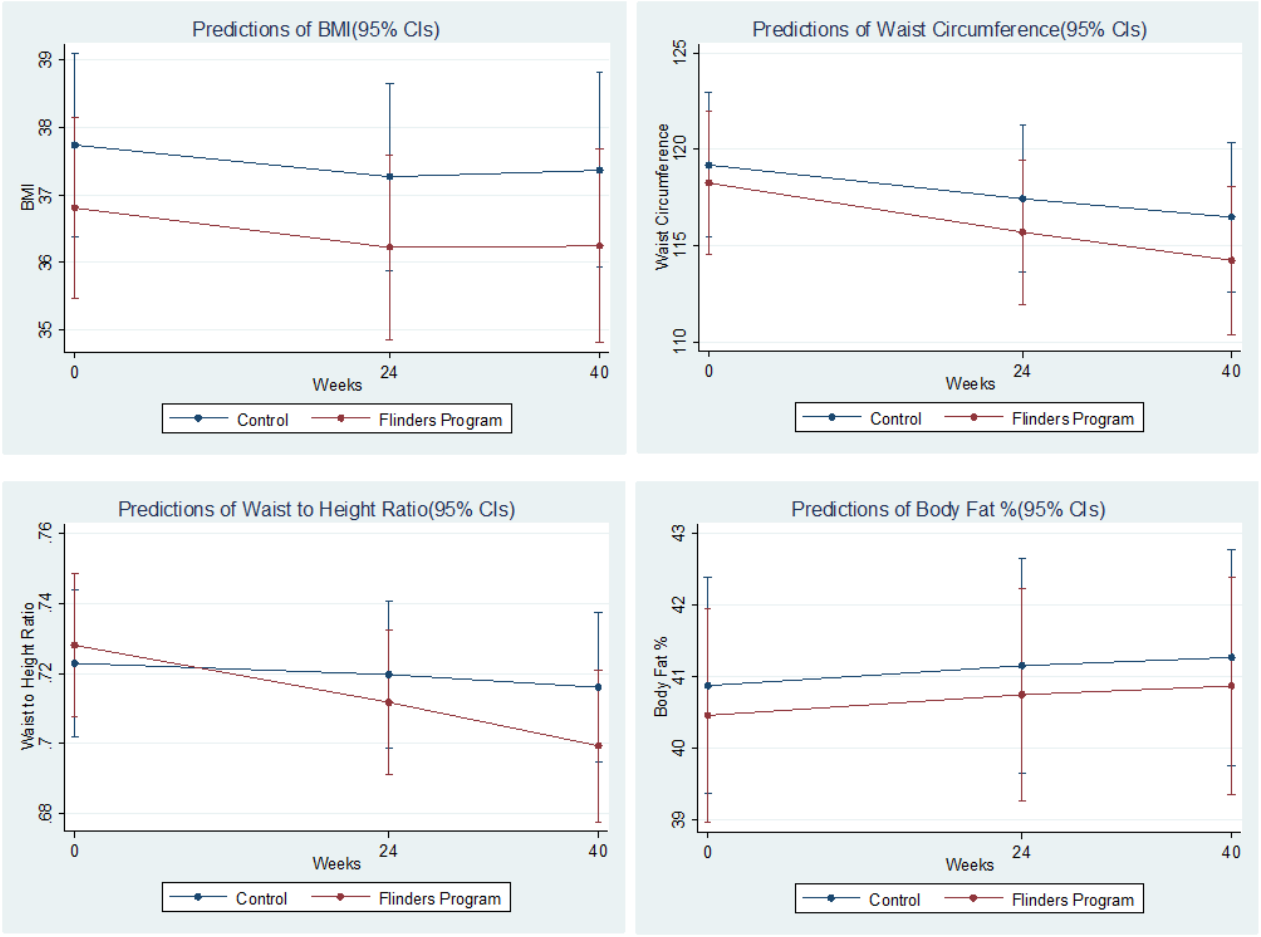
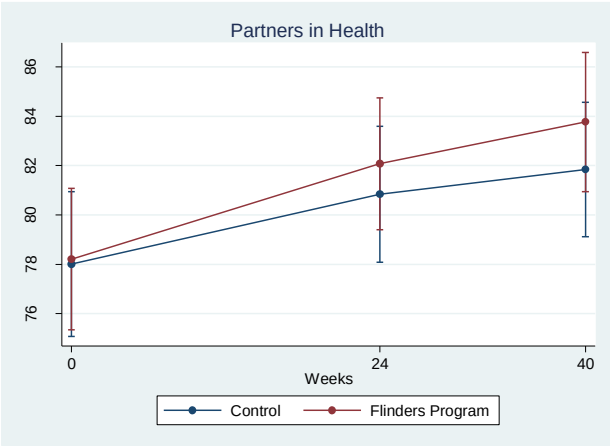
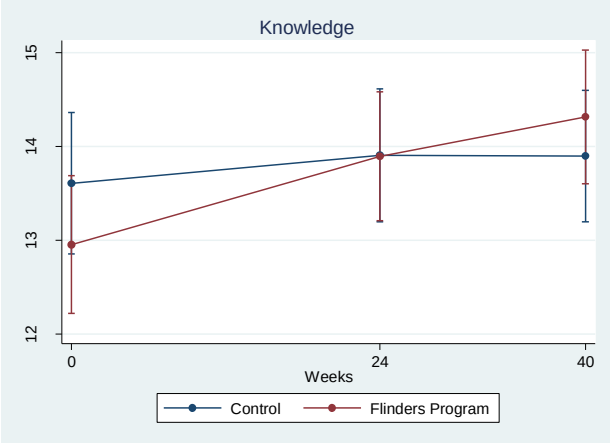


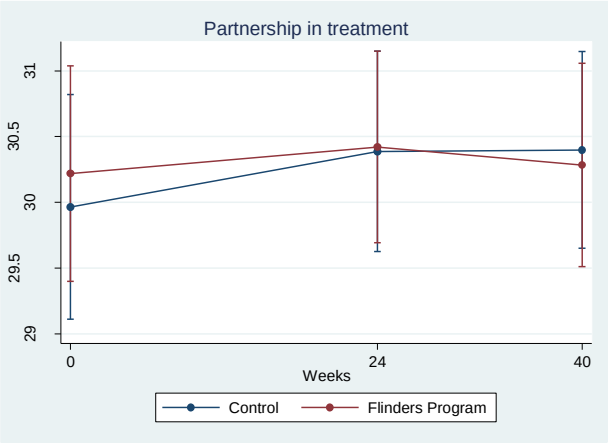
Figure 20: Prediction of obesity outcomes (95% CIs)

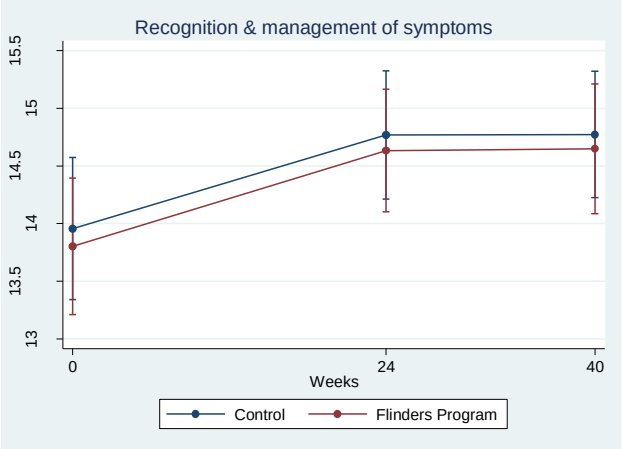
Appendix H. Post-estimation marginal effects for Partners in Health outcomes

To further interpret the analysis of Partners in Health (PIH) scores and subscales, the post-estimation marginal effects of responses to the PIH outcomes and their subscales, with time at fixed values of 0, 24 and 40 weeks, were obtained and are shown in Figure 21. An upward trend in the PIH score for both intervention and control groups reflected an improvement of self-management competency across time. The marginal effect is higher for the intervention group than it is for the control group at 6-month and 10-month follow-ups, indicating a greater improvement of self-management competency in the intervention group than in the control group. The greater improvement of knowledge and coping in the intervention group compared to the finding for the control group can be seen in these graphs. Recognition and the management of symptoms have very similar trends in both intervention and control groups. The overall trend in the partnership in treatment scale is poorer in the intervention group than it is in the control group.









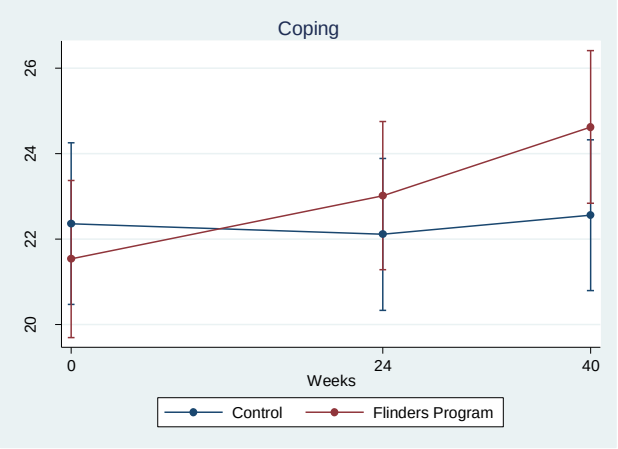


Figure 21: Prediction of secondary outcomes of Partners in Health (95% CIs)

Higher PIH scores indicate improvement

Appendix I. Interview schedule

1 – Re-gaining rapport – make them feel comfortable talking to you.

2 – Tell the interviewee the interview is going to be recorded, and start by getting a verbal and recorded consent.

3 – Start with the grand tour open-ended question ‘Tell me about your experiences with the Flinders Program’.

4 – Don’t interrupt the interviewee.

5 – When the interviewee stops, use a probe depending on how they have answered the question, so they continue.

6 – Did you get a response for all guiding questions?

7 – Thank her/him for participating in the interview.

Probes:

Detail-oriented Probes: ‘When did it start?’, ‘Whom did you talk about it?’, ‘How did you feel about it?’.

Elaboration Probes: ‘Could you tell me more about that?’, ‘Could you give me an example?’, ‘

Clarification Probes: ‘What do you mean by ….?’

Echo Probe: Repeat the last thing the interviewee said and ask to continue.

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