Evaluation of the accuracy of the Fitbit Zip in clinical populations

by

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Declaration

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

Signed: Craig Farmer
Date: 11.12.2019

Summary of thesis

Demand for rehabilitation services is increasing with the ageing population. Financial pressures on the health system and allocation of scarce resources require efficient and innovative rehabilitation therapy to maximise gait and mobility function and achieve the patient goal of returning home. In recent years, many commercially available activity monitors have become available, and are increasingly popular in rehabilitation for monitoring patients' activity levels. These activity monitoring devices use accelerometer technology, and commonly attach to the patient's clothing, counting steps taken during walking. Accurate step count measurement in the rehabilitation setting is important to understand the association between physical activity and better health outcomes. Having accurate measurements of daily walking mobility and physical activity levels can then be utilised for motivational goal setting and exercise progression. Accurate therapist feedback on walking activity may assist in increasing physical activity dosage and in maximising walking potential. However, accuracy of commercially available activity monitors has been poor in people with altered gait parameters including slow gait speed, slower cadence and short step length. Recent research suggests that activity monitors are potentially more accurate when worn at the distal leg in rehabilitation patients, who walk more slowly than the general population.

There are two main parts to this thesis. The first part investigated the step count accuracy of a commonly used commercially available activity monitor, the Fitbit Zip, worn on the shoe in controlled conditions, compared to direct observation. The second part investigated the Fitbit Zip, worn in free-living conditions, compared to the ActivPAL activity monitor (commonly used in field research). Ninety sub-acute rehabilitation patients with a gait speed of 0.50 – 1.0m/s were recruited from the day rehabilitation service of a major rehabilitation hospital in South Australia. Diagnosis groups included neurological, orthopaedic, and other medical and surgical conditions. Overall accuracy, and the influence of environment was examined in indoor and outdoor conditions. High Fitbit accuracy was observed in controlled conditions, with the Fitbit undercounting steps. In contrast, the Fitbit counted more steps than the ActivPAL when worn in the free-living environment. The studies presented in this thesis identified slower gait speed as the main influencing variable on Fitbit accuracy in continuous walking in controlled conditions. Literature suggests that in free-living conditions, the interrupted patterns of step taking in activities of daily living appear to influence Fitbit accuracy. When combining outcomes from the studies, it appears that slower gait speed and other gait parameters that are more

prominent in the community conditions are associated with lower Fitbit accuracy, and the most distal Fitbit location on the forefoot of the shoe maximises step count detection.

Structure of thesis

The thesis is divided into five chapters. The first two chapters comprise the introduction and literature review. Chapters three and four each contain studies that are for submission for journal publication. Chapters three and four contain background, methods, result and discussion sections that are specific to each study. Chapter three investigated activity monitor accuracy in controlled walking conditions, while Chapter four investigated the activity monitor accuracy in free-living conditions. Chapter five is an overall discussion of the two studies.

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CHAPTER 1
INTRODUCTION

1.1 Introduction

Medical or surgical events including neurological, orthopaedic or other conditions can have a major effect on a person's mobility and functional ability. Rehabilitation aims to maximise function in activities of daily living through mobility improvements including gait pattern, speed and distance walked. Accurate measurement of current mobility is therefore important to patients and rehabilitation clinicians to enable assessment and progression of mobility during their rehabilitation journey. Recording the number of steps a patient takes in the action of walking can therefore assist to measure mobility and activity levels. Wearable technology studies have investigated step counting activity monitors' accuracy and provided guidance for use in the general population in controlled conditions. They have not investigated sub-acute rehabilitation patients with specific diagnoses at natural walking speeds in variable walking conditions and walking in the community.

The purpose of this thesis was to investigate the accuracy of a commonly used accelerometer in slow walking rehabilitation patients indoors, outdoors, at home and in the community.

1.2 Rehabilitation services

With Australia's ageing population [1] rehabilitation services will be in more demand. Admissions due to disability following stroke, hip fractures, and hip and knee arthroplasty are expected to increase greatly along with other medical diagnoses and conditions associated with ageing [1]. Life expectancy is increasing, as is the expectation to maintain activity levels as the population ages [2].

Disability is a wide ranging term defined by the World Health Organisation [3] as:

> *"An umbrella term, for impairments, activity limitations, and participation restrictions. An impairment is a problem in body function or structure; an activity limitation is a difficulty encountered by an individual executing a task or action; while a participation restriction is a problem experienced by an individual in involvement in life situations. Many people with disabilities experience a combination of impairment, activity limitation, and participation restriction".*

Rehabilitation services treat the disability restrictions of the patient, with the aim to return to previous mobility and function. To fully understand the challenges that come with an ageing population, this thesis will summarise the current position of Australian rehabilitation services with regards to health service demand, public health cost, rehabilitation service demand, and diagnosis impairment categories. This thesis will also examine length of hospital stay, discharge destination and functional outcome measures, which are reported to the Australasian Rehabilitation Outcomes Centre (AROC).

1.3 Rehabilitation service delivery and diagnosis

In South Australia, acute hospitals are the initial admission point for many of the patients who are transferred to a rehabilitation service. Rehabilitation services in the public health system triage their patients mostly from acute or sub-acute services, transferring to the most appropriate general or specialist rehabilitation service as per diagnosis, level of impairment, and function. The rehabilitation centre involved in this study was a general rehabilitation centre in the Southern Adelaide Local Health Network in Adelaide, South Australia, which admitted patients following neurological (mainly stroke), orthopaedic (mainly fractured neck of femur, and elective hip or knee arthroplasty) and other medical or surgical conditions. Other medical or surgical conditions may include patients with decreased mobility post cardiac, metabolic, vascular, pulmonary, or pain issues [4]. Inpatients are mainly referred from the major acute hospitals in Adelaide, while day rehabilitation patients mostly commence this service as an outpatient once discharged from inpatient rehabilitation. The continuing challenge for rehabilitation services is to improve patient outcomes, which are monitored by the Australasian Rehabilitation Outcomes Centres (AROC) [5], with rehabilitation service delivery and outcomes also audited against clinical guidelines such as the National Stroke Foundation [6]. Reports from AROC provide data on functional independence on admission and discharge, length of stay, and daily activity time with therapists. Evidence based practice such as the National Stroke Guidelines (2017) [6] includes the requirement to maximise patient opportunities for activity during therapy (dosage), functional goal setting, and where mobility is a limitation, to practice walking and repetitive gait training. Identifying ways to improve clinical and self-managed patient outcomes by monitoring and by providing feedback to the patient of physical activity, may see improvements in practicing, progressing and restoring gait and mobility function. Examination of the characteristics of diagnosis groups (neurological, orthopaedic and other conditions) will be reviewed in this thesis including impairment and activity restrictions, mobility and gait variables, and prognosis.

1.4 Physical activity levels in rehabilitation

Patients in rehabilitation are not achieving the daily recommended physical activity levels [7] and are at risk of muscle atrophy, loss of bone density and deconditioning [8]. Physical activity is defined by the World Health Organisation (WHO) as any bodily movement produced by skeletal muscles that requires energy expenditure [9].The WHO [9] has provided global recommendations on physical activity for health, based on different age groups, with those aged over 65 to undertake 150 minutes of moderate intensity activity each week. Patients are also not maximising opportunities to achieve the WHO modified recommendations to be as 'physically active as their abilities and conditions allow' [9]. Regular moderate intensity physical activity is associated with improved health outcomes [10].

WHO describes Physical Activity as having sub-categories of which exercise is one such category [9]. Exercise is defined by the WHO as "physical activity that is planned, structured, repetitive, and purposeful in the sense that the improvement or maintenance of one or more components of physical fitness is the objective". WHO also define other sub-categories; "Physical activity includes other activities which involve bodily movement and are done as part of playing, working, active transportation, house chores and recreational activities" [9].

Walking is the most common reported participation activity reported in surveys, (including leisure time activity) of those people who do achieve the guideline amounts of activity [11, 12]. Even at lower levels of physical activity intensity, older people may still maintain health outcomes [10]. Lower levels of physical activity may therefore include walking at a lower intensity than recommended. Walking is the most common personal mode of transportation and a requirement in many activities of daily living with walking being the single most important human movement to measure accurately and to promote physical activity [12]. Walking is also one component of maintaining an older adult's mobility [13], with mobility considered important to continuing active and independent lives [13]. Loss of mobility may occur when an older adult has physical impairments that impact on their walking, and/or when they can no longer drive a car [14]. Mobility is broadly defined as the 'ability to move oneself (e.g., by walking, by using assistive devices, or by using transportation) within community environments that expand from one's home, to the neighbourhood, and to regions beyond' [14]. Walking is traditionally measured by distance or time walked and can be either clinician or self-monitored. However, mobility limitations and activity levels may vary with diagnosis, including from the condition specific impairments to be explored further in this thesis. Measurement of walking when a patient is in the community or away from direct observation often relies on self-report of activity which can be unreliable [15]. Patients also have difficulty maintaining physical activity intensity when reliant on self-direction [16]. This highlights the importance of developing accurate objective methods to measure and improve walking by motivation through feedback of step count.

1.5 Activity monitors and accuracy

Remote clinical monitoring of patients at home and in the community is developing with technological advances. Wearable sensors have been used in recent years with potential to monitor and detect health condition changes [17]. These wearable devices are small and generally attach to the clothing or body. Some are able to assess physiological or biological data, while others can monitor mobility activity in the clinic or community [18]. More recently, commercially available step counting activity monitors have become popular in the community to measure walking, and in the healthy population activity monitors can be used successfully in the form of a watch, wristband, or device worn on the hip or in a pocket. Activity monitors with real-time step count feedback are also being used with therapist goal setting to increase levels of activity [19]. In slower walking rehabilitation patients, these devices are not accurately detecting steps [20], and recent research has sought to validate activity monitors and the variables that may influence device accuracy [21]. Activity monitors may improve the accuracy of mobility measures in rehabilitation patients, and consistent and reliable objective measures may prove preferable compared to current subjective reports by patients [15]. However, further investigations are required prior to validating the use of activity monitors, in particular when considering the influence of gait variability, anatomical location of wearing the devices, gait aid use, environment (clinic, home or community), and activities undertaken during mobility [19, 22].

1.6 Research objectives

In order to establish clinical, patient and researcher guidelines for the wearing of a commonly used activity monitor in patients undertaking rehabilitation, assessments of the accuracy of the Fitbit Zip will be investigated. The research objectives are:

- Investigate the accuracy of a commonly used commercially available activity monitor at counting steps in rehabilitation patients in controlled conditions, and in home and community environments.

- Investigate the influence of slow gait speed on the accuracy of the Fitbit.
- Determine if diagnosis by patient group (neurological, orthopaedic and other medical condition) influences accuracy of the Fitbit.

CHAPTER 2
LITERATURE REVIEW

2.1 Rehabilitation services

A primary aim of rehabilitation services is to assist restoration of mobility and function, thereby facilitating a return to the patient's usual living arrangements [6]. With the ageing population [23], immigration [24] and increasing life expectancy [2], there is growing demand on hospital admissions and subsequent rehabilitation services resulting in significant associated costs to the government and society [25]. For Australian's who are over the age of 65, the total health and aged care expenditure is expected to increase from $166 billion in 2015 to $320 billion over 20 years to 2035 [26]. Hospital system spending in Australia is significant being an estimated $66 billion in 2015-16 and increasing by 3.3% each year after adjusting for inflation [25]. Increased physical activity has been shown to improve function, whilst walking regularly indoors or outdoors may provide short-medium term protection against loss of mobility when function is already reduced [27]. The aim is for patients to recover quickly and gain functional independence as soon as possible. Rehabilitation of walking and functional mobility are therefore key components of a rehabilitation program, with the associated challenges being to motivate patients to increase their activity levels.

Mobility and physical activity are important in the rehabilitation journey on several levels. In the short-term it is imperative from a patient perspective to return to previous mobility while minimising disability and to return home [28]; while the health system receives economic benefits, with patients relying less on health system supports and carers [25]. Physical activity has general health benefits and is also important for preventing falls and on prevention and management of chronic diseases [29].

2.2 Ageing population

The Australian population is ageing, with a key contributor being the generation known as the Baby Boomers. This refers to people born between 1946 and 1966 who are now aged between 52 and 71 years [23]. Another contributing factor to the ageing population is the increase in life expectancy as a result of improved living conditions, nutrition, health education and medical improvements. A baby born in 2017 is expected to live to between 80.5 years for males and 84.6 years for females, an increase of 1.3 % in the past 10 years [2]. The number of older people, those aged 65 and over, is increasing and this trend will continue [30]. Australia's population is now approximately 25.1 million people [31], projected to increase to between 28.3 and 29.3 million people over the next 10 years. There is currently an estimated 3.8 million people over the age of 65, which is expected to almost double by 2042 to 6.5 million people [30]. Those over the age of 65 may be less independent and more likely to need assistance with activities of daily living [32]. The result is increased demand for rehabilitation and health services, and the need for patients to improve their health and mobility to efficiently move through their rehabilitation period.

2.3 Public health cost

With the ageing and increasing population growth, health system costs will increase to provide for the needs of the older people needing care. As people age, so does the increased prevalence of chronic disease and morbidity, with conditions such as heart disease, stroke and vascular diseases, diabetes, and cancer more prominent in the over 65 age group [33]. Falls are more prevalent in the older population, which can result in injury and fracture. In 2009/10 there was an estimated 84,000 admissions to hospital due to a fall [34]. For Australians who are over the age of 65, the total health and aged care expenditure is expected to increase from $166 billion in 2015, to $320 billion over 20 years [26]. Hospital system spending in Australia was an estimated $66 billion in 2015-16 and increasing by 3.3% each year after adjusting for inflation [25]. How services are funded, managed, delivered and assessed for quality is under constant discussion and review, including the use of innovative ways to provide rehabilitation services, therapy, and improve outcomes [25].

2.4 Health service demand

A health system is described by the WHO as 'all the activities whose primary purpose is to promote, restore and/or maintain health' [35]. Further, a good health system 'delivers quality services to all people, when and where they need them'. There are many health services within the health system in Australia, ranging from public to private; community based preventative services to primary health care; emergency services; acute hospitals; and rehabilitation services.

Older people use health services more than others in the population [25]. With the ageing population, demand for health services is increasing, particularly the use of public and private hospitals. An example is the 4.6% increase in total hospitalisations for all ages in the one year period from 2011-12, taking hospitalisations to almost 9.3 million [36]. People over the age of 65 accounted for 42% of all hospitalisations in 2016-17 [25]. Health system costs, and funding the rising health costs are major issues for Australia [34].

The ageing population represents a challenge on many levels, including the way interventions and services are delivered. One of the responses to this problem is ‘healthy ageing’, which encourages active and healthy lifestyles, and falls prevention strategies [34]. Other emerging strategies include the use of technology to supplement or provide services. E-health technologies that assist individuals in monitoring their own health have potential in modern health service provision. A study [37] found that 69% of United States adults monitored a health indicator including weight, diet or exercise activity, and 20% of these adults use a mobile phone or computer to do so. Activity monitor accelerometer devices fall into this category; commonly incorporating readout screens or mobile phone applications that provide feedback to individuals.

2.5 Rehabilitation service demand

Rehabilitation is provided by the private and public sector in Australia. The reasons for patient admission to a rehabilitation hospital can be described in terms of a principal diagnosis of injury or disease. In 2015, rehabilitation admissions in Australia comprised primary diagnoses of reconditioning (27%), orthopaedic fractures (22%) and stroke (16%) [25]. Rehabilitation hospital admissions in Australia have been increasing annually and since 2012 private hospital rehabilitation admissions have averaged 9.8% annual increases which appear mainly due to increased private health funding, with public hospitals remaining stable [25]. In 2016-17 there were 445,000 admissions for rehabilitation care in public and private hospitals with 79% occurring in private hospitals [25]. Although public hospital rehabilitation admissions were only 1.4% of all hospital admissions in 2016-17, they accounted for 6.3% of patient days spent in public hospitals [25]. In 2016-17 the provision of rehabilitation services in the private sector was heavily comprised of elective orthopaedic procedures such as hip and knee arthroplasties. Hip and knee arthroplasties are mostly non-complex, planned short-stay admissions therefore there was a significantly shorter overall rehabilitation average length of stay (3.9 days) in private hospitals, compared to 14.3 days in public hospitals [23]. This improved from 2010 when length of stay was 5.6 days in private hospitals and 18.1 in public hospitals. The longer length of stay in public hospital patients demonstrates the complexity of public rehabilitation admissions and need for innovative therapies to promote effective early recovery of function and to assist the growing rehabilitation demand by the elderly population with limitations on therapy resources.

2.6 Impairment categories and outcomes

The Australasian Rehabilitation Outcomes Centre (AROC) [38] is a benchmarking system aimed at improving clinical rehabilitation outcomes by providers in Australia and New Zealand. It provides information on admission demographics, on interventions and provides reports based on impairment groups and functional outcomes including the Functional Independence Measure (FIM), length of stay and activity levels while in rehabilitation.

The third most common impairment by admission to rehabilitation is neurological, comprised primarily of stroke and other neurological events [25]. There was an increase of 20% in patients admitted to rehabilitation following a stroke in 2017 [38]. The average length of stay for stroke was 27.2 days (2018) and 19.6 days for other neurological events [4]. Modern medical advances and associated models of care have led to increased stroke survivorship, but with residual mobility disability. The result is increasing rehabilitation demand by stroke patients as required under stroke models of care guidelines [6].

The orthopaedic group is the largest impairment group by rehabilitation admission and includes any orthopaedic fracture, as well as joint arthroplasty, primarily to the hip or knee [38]. The second largest group is described as “reconditioning”, with admission numbers doubling between 2006-2008; with patient average age of 79 and length of stay being 17.6 days [25]. The reconditioning group includes admission post-surgical or medical event, and those in this group often present with exacerbation of a chronic disease. Of interest, the reconditioning group was older than the average age of 74.7 years across all sub-acute rehabilitation patient admission impairment categories in 2015 [34]. This possibly demonstrates the impact of increased numbers of ageing people with chronic disease presenting as reconditioning patients to rehabilitation.

2.7 Main impairment categories

This section will provide background on the main presenting diagnosis groups seen in the study participants.

2.7.1 Neurological Diagnosis - stroke

Background

Stroke is a major health issue worldwide due to the high impact on mortality and morbidity and is a huge financial burden to the health system. In Australia in 2017 there were 475,000 people living following a stroke (2.9% of the population) and the number of stroke survivors is expected to increase to one million people by 2050 [39]. In 2015-16 there were approximately 37,300 acute hospital admissions with a diagnosis of stroke. The average acute hospital length of stay was 8 days, and those who then went to rehabilitation care (8500 people) stayed a further 26 days [40]. The majority of stroke survivors (65%) have a disability, or personal loss of independence and require assistance for activities of daily living [6, 40]. The overall estimated financial cost of stroke in Australia of $5 billion per year [40]. The high average rehabilitation length of stay indicates the substantial demand from this group for rehabilitation beds and the importance of improving their mobility and function as early as possible.

Stroke risk factors

Secondary stroke prevention and rehabilitation approaches are important in order to minimise the impact of this disease and maximise functional outcomes following a stroke. Potentially modifiable risk factors account for 90% of primary strokes [41]. Lack of regular moderate physical activity is the second highest risk factor for stroke behind hypertension [42]. Other risk factors include apolipoprotein, diet, high waist to hip ratio, current smoking status, high alcohol consumption, and diabetes mellitus [43]. Physical activity can have a secondary influence on some of these other risk factors by improving lipid and glucose metabolism, lowering blood pressure and improving endothelial function [44, 45]. Insufficient physical activity levels can lead to obesity, diabetes [46], and high cholesterol [45]. Not only are lower levels of physical activity a risk factor for stroke, but patients with pre-morbid low physical activity have been shown to have worse functional outcomes post stroke than a person who had higher pre-stroke activity levels [44]. The risk factor for stroke is higher following a primary stroke [47], therefore modification of risk factors including physical activity and the motivation to prevent further episodes is a high priority. Stroke patients who have pre-stroke habitual low physical activity levels are likely to need education and clinician support to incrementally increase their activity levels.

Post stroke physical activity

Physical activity, based on modelling data from the risk factors for primary stroke prevention studies, will reduce the risk of having a secondary stroke [48]. Specifically, the

American Heart Association recommends 20-60 minutes of medium to high intensity exercise for 3-7 days per week adapted for stroke survivors depending on their functional capacity which may require modification to 2-3 shorter sessions of 10-15 minutes [49, 50]. Walking is a mode of physical activity and is a common goal for stroke patients and improved physical activity is linked to improved walking and independence in activities of daily living [6]. Physical activity also has the potential to improve walking speed and endurance [51]. Stroke patients are not achieving the recommended physical activity levels required to reduce the risk of recurrent stroke and other health conditions, and to maximise functional recovery [52, 53]. In the hospital setting, almost half their day is spent inactive, with approximately one hour per day engaged in physiotherapy and another hour per day in occupational therapy [52]. Within physiotherapy sessions, less than half include activities such as standing and walking [52]. English et al [53] found that stroke survivors living in the community took less than half the amount of walking steps than aged matched (65 -75 years old) healthy participants. It may not be a realistic expectation for the step count of a patient post-stroke to match their healthy counterparts, however it is reasonable to target maximising their number of steps taken. Lower levels of overall physical activity indicates the need to increase incidental and organised walking to improve physical activity during stroke recovery [6].

***Post-stroke r*ehabilitation**

Exactly how early to commence rehabilitation for acute stroke patients has been the subject of much discussion and debate in recent years, with clinical guidelines changing as evidence is gathered. In 2015, in a review of 30 guidelines throughout the world, early mobilisation was recommended in 22 of the guidelines, however the detail of how early, how much, and what type of intervention was not commonly included [54]. Evidence of medical complications due to very early mobilisation (within the first 24 hours post stroke) [54] has resulted in the Australian Clinical Guidelines for Stroke Management (2017) [6] now recommending that mobilisation commence between 24 to 48 hours post stroke unless contraindicated. Mobilisation, tailored to the level of patient impairment, can then commence, with rehabilitation aiming to maximise walking ability.

Once patients are allowed to mobilise, the Australian Clinical Guidelines for Stroke Management [6] recommend:

- as much scheduled therapy (occupational therapy and physiotherapy) as possible (minimum of three hours a day including two hours of active task practice)

Furthermore, the guidelines state:

Stroke survivors should be encouraged to continue with active task practice outside of scheduled therapy sessions. This could include strategies such as:

- self-directed, independent practice;
- semi-supervised and assisted practice involving family/friends, as appropriate.

The above physical activity guidelines post stroke [6] highlight the importance of walking as a therapeutic activity (to improve walking by practicing walking) , as well as the importance of the measurement of the activity of walking, both in scheduled therapy and outside therapy. Repetitive functional walking task practice can improve walking distance and functional walking [55]. It also emphasises context for the patient in rehabilitation, as their rehabilitation journey moves from the inpatient setting to home. This changing context requires innovative and motivating methods to increase mobility and walking levels from the supervised and semi-supervised inpatient setting, through to less supervised settings at home and in the community with carers and family.

Specific physical activity interventions

Rehabilitation, using the clinical guidelines for stroke [6], has specific recommendations depending on the patient and therapist goals and can take place in any setting. The setting could include the acute hospital, stroke rehabilitation unit, supported home rehabilitation, outpatient service, ambulatory service, or any other form of rehabilitation ranging from formal services, community service, residential care, or informal rehabilitation at home. The clinical guidelines [6] include physical activity and goal setting recommendations that address the patient’s specific impairments (e.g. cardiorespiratory fitness, muscle weakness), mobility (e.g. walking in all environments) and function (activities of daily living). The level of the patient’s current function and hence what they practice as a physical activity therapy will change as improvements occur. For example, they could progress from being only able to sit, to then stand, and then commence walking. Patients and their therapists are therefore actively working to achieve their next short or long-term mobility goals throughout their rehabilitation period. Therapists being able to monitor walking and provide feedback may assist patient motivation to achieve these goals.

The specific recommendations in the physical activity section of the clinical guidelines for stroke [6] are interrelated, and lead to the ultimate goal of the patient being more active in their own community. The recommendation for cardiorespiratory fitness includes individually tailored exercise interventions shown to enhance activities of daily living [49], and the guideline encourages ongoing regular physical activity regardless of the patient's level of disability [6]. For activities of daily living, guidelines recommend targeting specific physical disabilities that impact on these activities [56], and home and community ambulation including the focus on walking in context [6]. Recommendations for muscle weakness include strength training [57], for which task-specific practice is recommended. Cardiorespiratory fitness, activities of daily living, and weakness have specific interventions that include the therapy of walking as part of the evidence based stroke guidelines that require therapists to monitor patient activity [6].

Walking post stroke

Difficulty with walking is common following a stroke [58]. Approximately 65% of patients admitted to hospital after stroke are reported to be unable to walk independently [59]. Therefore, a priority for patients and therapists is the goal of ambulating independently. The Clinical Guidelines for Stroke Management [6], (walking section) are designed so that interventions can be integrated with those detailed earlier for cardiorespiratory, activities of daily living, and weakness. For walking, the guidelines recommend:

- Stroke survivors with difficulty walking should be given the opportunity to undertake tailored repetitive practice of walking (or components of walking) as much as possible [55].

Specifically:

- 'Overall there is extensive evidence from many systematic reviews on interventions to improve walking. Reviews tend to focus on specific interventions such as task-specific overground training and on ways to deliver the interventions, such as circuit class training, treadmill training, electromechanically assisted training, and community-based ambulation training'.

From these recommendations, walking repetition is required to increase dosage of walking, and can be practiced by varying methods and environments. During rehabilitation, therapists' monitoring of patient step count in order to increase daily walking is important, particularly when the patient is at home or when the therapist is not able to directly observe their walking activity.

Goal setting

Goal setting brings together all components required for a patient to improve their function. Goal setting is an important recommendation in the Clinical Guidelines for Stroke Management [6]; goals should be well-defined, specific, challenging and should be reviewed and updated regularly [60]. Walking is a common goal for patients following a stroke, therefore the monitoring and progression of walking becomes a key component of their rehabilitation.

2.7.2 Orthopaedic - hip fracture

Background

Hip fractures are a major event in the lives of an increasing number of older people. Hip fractures are often the result of a patient having a fall, with the fracture commonly occurring in the proximal part of the femur [61]. There were 18,746 new hip fractures in Australia in 2015-16, an increase of 18% since 2006-07. Although this number has risen in line with the ageing population, the actual rate per capita had fallen by 9.5% after adjusting for age differences over that 10 year period [62]. This falling rate of hip fracture indicates success of falls and frailty intervention strategies, which includes attempts to increase physical activity levels [63].

Hip fractures have a large impact on a person's health and ability to be active in their usual activities, and are a growing cost to Australia's health system [64, 65]. The majority of hip fractures (99%) require surgical intervention, most commonly fixation or hemi-arthroplasty, requiring hospital admission and subsequent rehabilitation [62]. Patients will often change locations from an acute to a rehabilitation hospital as they progress through their rehabilitation program [66]. The average length of stay following a hip fracture in an acute hospital was 9 days in 2016 [62], and in rehabilitation an orthopaedic patients' length of stay was 20 days [4]. Many hip fracture patients will not regain sufficient function to return to their previous abode, with 10-20% requiring residential care following their hip fracture [28]. Longer term, a negative impact from hip fracture has been reported on wellbeing and quality of life, with individuals at a higher risk of re-fracture [66]. Those who were already in residential care are reported as having worse functional outcomes than those not previously in care [67]. The mortality impact is large; a study in 2017 demonstrated that people who had a hip fracture in Australia who were over the age of 65 were 3.5 times more likely to die within one year of their surgery than people who had not had a fracture [62]. In economic terms, hip fractures were estimated to cost about $1 billion in 2016 [68]. Hip fracture numbers are predicted to rise 35% by 2036 [69], with the prediction that hip fractures will cost $1.27 billion by 2022 [70]. The personal and economic importance of hip fracture prevention and management in Australia is clear, with physical activity having potential to reduce secondary fracture risk.

Hip fractures are often associated with the patient having another medical episode resulting in them being more likely to fall due to existing mobility and balance issues [61]. The most susceptible population group for hip fractures are older people. The fracture rate increases with age, and when age has been adjusted for, women are almost twice as likely to have a hip fracture than men [71]. Women are more likely to have a fracture from a fall due to reduced bone density from osteopenia or osteoporosis [72]. The fracture itself is caused by the impact from the fall combined with low bone density [62]. In 2015-16, 93% of new hip fractures were caused by falls, with comorbid conditions that may have contributed to their fall including hypotension, anaemias, delirium, type 2 diabetes and disorders of fluid, electrolyte and acid-base balance [62]. In theory, an integrated whole of health system approach addressing co-morbidities, bone density, and falls prevention strategies could further reduce rates of fractures, with physical activity playing a role in each area.

Falls prevention strategies

Major risk factors for having a fall also include poor balance and muscle weakness [71]. The ageing process itself reduces muscle strength and balance [62]. Exercise programs tailored to address balance and strength impairments, and community based interventions, reduce the risk of falls by approximately 30%, and the risk of resultant fracture from falls by 66% [63]. There is no clear evidence for walking as a falls prevention intervention in the healthy older population, although walking can improve mobility in older people who are already limited to walking less than 400 metres [73]. To reduce the chances of having a fracture during a fall, improvements in bone density are shown to respond to exercise that provides loading to the bones, including weight-bearing activity, aerobic activity, higher impact and resistance training in women [74]. Physical activity plays a key role in prevention of primary falls and is expected to reduce the risk factor in secondary falls.

Rehabilitation post hip fracture

The aim of rehabilitation for patients recovering from hip fracture is to improve their independence in movement and function, aiming for discharge to their usual residence. Rehabilitation patients often have complex pre-existing health conditions, which have been shown to impact on physical activity following hip fracture [75], further limiting their ability to walk. Prior to a fall, often the walking confidence of an older person in the community is reduced. Their mobility may have shown a decline in the recent months and years prior to the fall due to another health issue [76]. Turunen and colleagues [77] demonstrated that a year-long intervention including, among other interventions, guidance for safe walking, a progressive home exercise program, and physical activity counselling, significantly increased physical activity among patients following a hip fracture. Rehabilitation therefore needs to be tailored to the individual and progressively increased, considering comorbidities, confidence and their current condition.

Post-fracture physical activity

Low activity levels can remain for some time post hip fracture. Older people have difficulty with physical activity for up to two years post fracture, most pronounced in the early post-operative period [78]. In the months following a hip fracture, patients can therefore be less mobile walking indoors and outdoors [79], and lose significant function [29] due to fear, confidence, pain, other health issues, or reliance on others for transport if they are in the community [76]. A systematic review by Zusman et al [80] found that older adults following a hip fracture had excessive sedentary time and low levels of physical activity during rehabilitation. Resnick et al [75] found that at 2 months post hip fracture patients in the community undertook limited activity and only at low intensity, and older age and comorbidities also influenced activity levels. On the other hand, in a study [29] of rehabilitation patients following hip fracture, the potential influence of increased physical activity on rehabilitation outcomes was reported when the patients that were more active during their rehabilitation period also had better functional outcomes at 3 and 6 month time points. Further evidence of the benefits of earlier activity may be gathered through accurate step counting devices.

Hip fracture clinical care guidelines – activity

Hip fracture clinical care guidelines have been developed to ensure high quality care and management, from admission through to maximising the functional outcome for patients during their rehabilitation period. The Australian and New Zealand Guideline for Hip Fracture Care (ANZHFR 2014) [81] and the Hip Fracture Care Clinical Care Standard (ACSQHC 2016) [82] both highlight the importance of patients being active and mobilising. The key evidence-based requirements from these guidelines are to set mobility goals and to progress patient walking with consideration to the complexity of environment, incorporating indoors, outdoors, in the community, and in activities of daily living. These guidelines encourage therapists to promote, coach and motivate patient physical activity to maximise function.

2.7.3 Orthopaedic - joint arthroplasty

Background

Osteoarthritis is an end-stage degenerative joint disease associated with ageing where the most common and cost-effective intervention is elective joint replacement (arthroplasty) [83-85]. The prevalence of osteoarthritis in Australia is estimated to be 3.14 million by the year 2050, or around 11% of the total population [86], with total health expenditure for osteoarthritis already being at $2.3 billion in 2007 [86]. Hip or knee replacements are increasing as the population ages and osteoarthritis accounts for more than 80% of the arthroplasties [87].

Following primary arthroplasty, longer term outcomes are mostly favourable with generally improved function [87]. The functional gains are seen mostly in the first 6 months for hip arthroplasty and take up to 12 months for knee arthroplasty [87-89]. Knee arthroplasty outcomes in up to 30% of cases may not show improvement often due to pain, reduced range of motion and function [88]. Knee arthroplasties may require more sustained rehabilitation involvement from therapists.

Rehabilitation

Rehabilitation post hip and knee arthroplasty has a key focus on physiotherapy and exercise and is prominent in most models of care. Generally, the models of care encourage early mobilisation and activity with a functional and impairment-based goal. In South Australia, the SA Health Model of Care for Arthroplasty [90] requires patients to be mobilising within 12-18 hours of surgery.

Arthroplasty surgery and the inpatient hospital stay is often shorter than non-elective orthopaedic procedures due to the surgery being planned, with most patients expected to be discharged within 3-5 days in South Australia [90]. Patients who require longer inpatient stays or inpatient rehabilitation, often are previously very limited with their walking, older, and have other health conditions [91]. With the commencement of early rehabilitation, the patient’s abilities can be determined, and a discharge and rehabilitation plan arranged. Patients will mostly have rehabilitation in the community (outpatient clinics progressing to home based) after the first week, however this provides the challenge of maintaining patient motivation to be active away from the clinician.

There is evidence for exercise based interventions post arthroplasty [88, 92]. Most rehabilitation interventions include physical activity; activity during therapy and also accumulated in free living physical activity (during the whole day),and including walking and gait re-training components of patient mobility [88, 92, 93]. However, there is no clear evidence of whether low or high intensity, or home, inpatient, or clinic-based therapy is best. It is suggested further research is required to examine the patient variables to tailor delivery of therapy [88], which for some arthroplasty patients, may include remote monitoring and feedback from activity monitors.

Gait pattern

Spatiotemporal gait patterns post arthroplasty including stance time, shorter step length, lower cadence and slower gait speed, although shown to improve from rehabilitation and from pre-surgery, do not reach those of their age matched healthy adults, still evident at two years post-surgery [94, 95]. While neither gait pattern or gait speed returned to values seen in healthy populations, the improvements gained in walking following arthroplasty resulted in better subjective and functional scores [94].

Activity levels

Older adults with severe knee osteoarthritis awaiting total knee arthroplasty, and those who are within one year post-operative have more sedentary behaviour than the healthy aged match population [96]. Knee arthroplasty does not improve patient's pre-operative sedentary behaviour, although it can slightly improve the intensity of their free-living physical activity demonstrated by measurement of daily step counts post-surgery. When patients were walking, they worked at higher intensity by walking faster and taking more steps than pre-surgery [96]. A study by Peiris et al [97] found that sub-acute orthopaedic patients are mostly inactive during rehabilitation and are not achieving the recommended weekly activity guidelines for older adults. Increased walking, as measured by step count, was correlated with shorter length of stay and improved functional outcomes. Their study included patients who were admitted to rehabilitation for lower limb orthopaedic conditions including hip fracture, hip or knee arthroplasty, and demonstrated the importance of being active.

2.7.4 Other diagnoses – including reconditioning

Background

Apart from neurological and orthopaedic conditions, there are a variety of patients admitted to the rehabilitation units with other diagnoses [5]. These include diseases of ageing; exacerbation or progression of chronic disease; or other acute medical conditions leading to the patient becoming deconditioned and requiring rehabilitation [25]. Approximately 80% of patients in rehabilitation settings are aged over 60 and more likely to have health issues related to ageing. Many patients admitted with specific diagnoses will also have chronic conditions that may impact on their rehabilitation [33].

Common chronic conditions that present in rehabilitation include respiratory conditions, musculoskeletal conditions (including arthritis and back pain), diabetes, mental health conditions, cancer and cardiovascular disease (coronary heart disease) [98]. Chronic disease was involved in 37% of overall hospital admissions in 2015-16 as either the primary or secondary diagnosis [33]. The prevalence of chronic conditions including ischaemic heart disease, type 2 diabetes, obesity, and other circulatory systems diseases was lower among people who met the recommended physical activity recommendations [99]. As the ageing population increases, so do admissions of these patients to rehabilitation, and they often have complex presentations, with issues including pain, disability, psychological issues and previous poor health [100]. These issues require extra consideration by therapists when developing their physical activity program in rehabilitation.

2.8 Physical activity recommendations

2.8.1 Physical activity guidelines

The World Health Organisation (WHO) [9] has provided global recommendations on physical activity for health, based on different age groups.

Physical activity in the older adult (aged 65 years and above) is defined as skeletal muscle movement requiring energy expenditure, and includes ‘leisure time physical activity (for example: walking, dancing, gardening, hiking, swimming), transportation (for example walking or cycling), occupational (if the person is still working), household chores, play, games, sports or planned exercise, in the context of daily, family, and community activities’ (World Health Organisation) [9].

The WHO has provided physical activity recommendations in order to improve cardiorespiratory and muscular fitness, improve bone and functional health, and reduce the risk of non-communicable diseases, depression and cognitive decline. See text box 1:

Text Box 1

World Health Organisation Physical Activity Guidelines' – over age 65 years

1. Older adults should do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate and vigorous-intensity activity.
2. Aerobic activity should be performed in bouts of at least 10 minutes duration.
3. For additional health benefits, older adults should increase their moderate-intensity aerobic physical activity to 300 minutes per week or engage in 150 minutes of vigorous-intensity aerobic physical activity per week, or an equivalent combination of moderate and vigorous-intensity activity.
4. Older adults, with poor mobility, should perform physical activity to enhance balance and prevent falls on 3 or more days per week.
5. Muscle-strengthening activities, involving major muscle groups, should be done on 2 or more days a week.
6. When older adults cannot do the recommended amounts of physical activity due to health conditions, they should be as physically active as their abilities and conditions allow.

The above World Health Organisation Physical Activity Guidelines are for all individuals in the above 65 age group. Many adults in this age group will have specific health conditions and disabilities that may reduce their capacity to exercise to different degrees [9]. In this case the total of 150 minutes of exercise per week may need to be accumulated in a tailored fashion, including shorter bouts of exercise more often, and following medical advice for their specific medical condition [9]. Where patients are recovering from a new medical condition such as stroke, hip fracture, hip arthroplasty or other condition, they should be encouraged to be as active as their medical condition allows. Therapist assessment of levels of impairment, mobility, function and exercise tolerance may include pre-exercise screening [101], and mobility [102] and balance base-line outcome measures for safety [103], base-line goal setting, and re-assessment of mobility and physical activity gains.

Active ageing is terminology used in many countries and is seen as being the lifestyle of ageing healthily, aiming to reduce rates of chronic disease, and maintaining functional task abilities and independence to enjoy and participate in life [104, 105]. Active ageing includes behavioural and lifestyle recommendations in relation to smoking, alcohol and diet, however the most important determinant of active ageing is physical activity which can strongly influence quality of life by helping to maintain functional abilities [106]. Use of the ‘active’ terminology encourages a positive whole of lifestyle approach designed to motivate participation in physical activities and enjoy good health.

2.8.2 Sedentary behaviour

Patient sedentary behaviour occurs in rehabilitation settings [97]. Sedentary behaviour can result in poor outcomes for the older adult [107]. Sedentary behaviour is defined as physical activities that have low energy requirements, with these activities often taking place with minimal movement in a position of sitting, reclining or lying [107]. The poor outcomes associated with sedentary behaviour include all-cause mortality [108], reduced physical ability [109], reduced muscle mass and risk of sarcopenia [110], and the risk of having a fall [111]. The most sedentary age group is over 65 years of age who are spending 60-80% of their non-sleeping time in sedentary behaviour [112]. Sedentary behaviour prevalence increases with age in Australia [113]. Sedentary habits may be modifiable during an individual’s rehabilitation journey.

2.8.3 Physical activity/outcomes

There is an association between regular physical activity and better health outcomes [10]. In the wider population, physical activity leads to reduced disease burden, including risk factors such as obesity and high blood pressure. It can also reduce the risk of chronic disease conditions such as cardiovascular disease and type 2 diabetes, and has benefits on lipid levels, hypertension, and even improves cognition [114]. In older people, physical activity has been shown to reduce the age-related decline in function and can assist in maintaining muscle mass and strength in older adults. The relative risk of developing limitations of function or disability is reduced by 50% in people aged 65-85 years if physical activity is of moderate intensity [63]. The benefits of physical activity are evidenced for any age group.

The WHO guidelines [9], described earlier, provided physical activity examples, however walking is by far the most common physical activity reported, excluding household chores. In the older age group (over the age of 65) the three most common self-reported physical activities are recreational walking (62%), fitness/gym activities (26%) and swimming (12%) [11]. Even in the younger age group (18-64), walking was the most reported activity at

42% [11]. Walking is an activity most people can participate in, even if in a modified form, and a goal for patients in rehabilitation [6].

Recommended activity levels (WHO recommendations) [9] for age groups including older people are not being achieved [115]. In people over the age of 18, the proportion of people achieving the daily recommended activity levels reduced from 49% in 2007-08, to 44% in 2014-15. In those over the age of 65 in 2014-15, 75% of the population were estimated to not have achieved the recommended activity levels of 30 minutes per day for 5 days a week. In the 18-64 age group, an estimated 52% did not achieve the same recommended activity levels [11]. Rehabilitation patients are less likely to be able to maintain physical activity levels than the general older population [49].

2.8.4 Chronic disease

The risk of developing chronic disease is reduced by physical activity in older adults, but varies depending on age, cohort, and intensity. The estimated relative risk for all forms of stroke is reduced by 11-15% when moderate levels of physical activity are undertaken, and this improves to 19-22% with vigorous activity [115, 116]. Moderate intensity exercise can also reduce the risk for cardiovascular disease and Type 2 diabetes [114]. In the prevention of the development of Parkinson's Disease, those who have a physically active lifestyle have a reduced risk factor of between 20%-30%, while in those who already have the disease, the secondary intervention of exercise prescription still provides benefits in walking, balance and strength [115]. In older people without dementia, there is gathering evidence of improved cognitive function from the primary intervention of moderate physical activity, and for the improved health of people undertaking the secondary intervention of moderate physical activity in those that already have dementia [63]. In studies of people with Alzheimer's disease, there is improvement in physical function from the secondary intervention of moderate physical activity [117]. The American College of Sports Medicine [118] suggests that people with chronic disease should engage in regular physical activity as their abilities allow and should avoid inactivity.

2.8.5 Physical activity evidence when below recommended levels

There is some evidence that older people will still maintain the benefits of physical activity, even when not able to exercise at the recommended levels. At reduced daily physical activity of only 15 minutes duration, it is suggested that moderate activity may still be of benefit to health outcomes in community living older adults [10], although the improved benefits seem to increase in linear fashion with further physical activity [119]. In a study of adults aged 70-75, function as measured by activities of daily living was preserved at even lower than moderate intensity physical activity [63]. This finding may be particularly important as older adults with chronic disease and health conditions that limit their activity levels can gradually work their way back to health and mobility.

2.8.6 Enablers to physical activity

The hope of becoming healthier through activity is a motivator to patients walking and becoming more physically active [120]. Research has shown that patients will be more active within a therapy session with supervision, however will not be very active when reliance is on self-direction [16]. This was further shown in a randomised controlled trial where the addition of an extra therapy day (physiotherapy and occupational therapy) on a Saturday significantly increased physical activity levels, compared to the patients who did not have the extra Saturday therapy [121]. There is opportunity for clinicians to educate and engage the patient while building their confidence in supervised to semi-supervised conditions, progressing to self-monitoring of walking distance increases. This could also involve the family and carers supervising or walking with the patient, who could help provide positive feedback from activity monitor devices such as Fitbits that count their steps.

2.9 Walking as Physical Activity

2.9.1 Background

Walking is an activity that is usually a known skill, and can be undertaken almost anywhere without special facilities by most people with only a small risk of injury [122]. Walking can avoid some of the barriers that may be reasons for not participating in other forms of exercise, for example exercise that may require more planning, organisation or cost. Physical activity through gym activities and swimming, other activities popular with older people, both require facilities and equipment [11], or are cited as excuses for not exercising including ‘lack of time’ and ‘not (being) the sporty type’ [123]. One of the attractions of walking is that it can substitute as a form of transport within the community (particularly if unable to drive), and may be more sustainable if used this way than other exercise options [124].

2.9.2 Intensity of walking

The translation of the physical activity guidelines recommending moderate intensity daily activity into a step count walking guideline has been undertaken in one study. Marshall et al [125] found in controlled conditions (treadmill), a cadence of around 100 steps per minute intensity in younger people could be estimated to translate to moderate intensity exercise. To achieve the activity guidelines of 30 minutes moderate daily activity, a minimum of 3000 steps in a 30-minute period would be required, or if unable to sustain walking for that period, then shorter sessions of 10 or 15 minutes could be repeated until the 30-minute total is achieved. For some older people, continuous walking for exercise may be difficult to achieve due to disability or chronic conditions. The American College of Sports Medicine [118] suggest a health care professional be consulted about the types and amounts of activity appropriate for their abilities. Any incidental movement and walking during activities of daily living is important to avoid inactivity [118], even if not achieving the activity guideline minimums.

2.9.3 Walking in the home and community environment

The above-mentioned step count recommendation is for a purposeful step count while walking [125]. A person living in the community can accumulate steps in many ways and in context of their environment and activity or function. For example, incidental walking or sporadic movements will require small or variable steps of differing speed, length, and cadence. Cadence is a temporal parameter of gait and walking speed [72, 126]. When an individual is undertaking a ‘training walk’ or is supervised by a therapist, cadence is often physically observed and/or measured by step counting devices in controlled conditions However, when individuals are in free-living environments this is not practical. The development of technology is now allowing step count and cadence measures to be gathered in the community environment due to activity monitors that have time-stamping features [12]. Tudor-Locke et al [12] reviewed cadence when healthy individuals were walking naturally in community environments, including while shopping, walking on sidewalks, and walking for transport, and reported a mean of 115 steps/minute. This study was in healthy, and therefore faster walkers; however it demonstrates that at a mean cadence of 115 steps/minute, being ‘normal walkers’, the activity monitoring technology has the potential to measure step counts in the community and home environment [125].

2.9.4 Free-living step counts

Further exploration of step counts in the community, identified cadence and gait speed data and categorised walking patterns of daily living. Ayabe et al [127] found that older adults only occasionally achieved a cadence of >100 steps/minute during their day. Tudor-Locke [12] categorised step count per minute data to demonstrate walking patterns throughout a day with bands of 0 steps/minute (non-movement during wearing time), 1–19 (incidental movement), 20–39 (sporadic movement), 40–59 (purposeful steps), 60–79 (slow walking), 80–99 (medium walking), 100–119 (brisk walking) and 120+ steps/minute (all faster locomotion).

The conclusion in the Tudor-Locke study [12] of 3744 healthy adults followed for one day, was that they 'spent approximately 4.8 hours/day in non-movement during waking hours, ≅8.7 hours at 1–59 steps/minute, ≅16 minutes/day at cadences of 60–79 steps/minute, ≅8 minutes at 80–99 steps/minute, ≅5 minutes at 100–119 steps/minute and ≅2 minutes at 120+ steps/minute'. In the non-clinical, real–life context, gait speed and cadence are lower than in controlled clinical conditions. To report valid measures in controlled and free-living conditions, step counting devices should be accurate at all walking speeds and activities.

2.10 Activity monitors

2.10.1 General commercial

Activity monitors have increased in popularity in recent years with many commercially available wearable activity monitors now available [128, 129]. Previously activity monitors were mostly used for research purposes. Generally, the most frequently used commercially available monitors are accelerometers that detect activity. They vary in design and with the exact technology, and are small devices that are worn around the wrist or attached to clothing, commonly at the waist or pocket [19]. Activity monitors typically provide immediate feedback to the user with information on their activity [20] including step count, cadence, distance walked, and energy utilised via a digital display. Some also have added functionality including reports on sleep time, altitude gain in walking, time spent sitting, standing, walking, or running: while many are linked with the user's mobile phone and computers providing data breakdown or summary of hourly, daily and weekly activity that can subsequently be shared and used with others including therapists, fitness groups or coaches [19, 130]. Research designed activity monitors usually do not have any display for immediate feedback, are much more expensive, but have sophisticated software and data analysis available, and are able to be waterproofed [131, 132]. Commercially available activity monitor devices are primarily used by consumers with the aim of improving their health through increased activity. With the feature of real-time activity monitor information and feedback, they can be used independently or together with coaching or therapist goal setting to act as a motivator to achieve an increased level of activity [19].

2.10.2 Fitbit

One of the world's most widely used activity monitor manufacturer is Fitbit (Fitbit Inc, San Francisco, CA, USA) who have an approximate 20% market share for commercially available wearable devices [19]. In 2017 they had 25 million active users, with their first commercially available models released in 2011 being clip-on devices including the Classic, Zip and One models, followed in 2013 by models of wrist-worn monitors [133]. Fitbit activity monitors are now commonly used in the health services industry, with patients and their therapists being informed of step counts and activity by the real-time read out from the devices with a common goal to increase activity levels [19] . The physical activity measures provided from the devices can also assist researchers in understanding health promotion [19, 129]. The Fitbit was used in 171 clinical trials between 2011 and 2017, mostly to identify steps taken while walking as the main outcome measure [134].

Fitbit devices use a triaxial accelerometer to measure motion (acceleration) converted to step count data. The 3-dimensional motion data is analysed using proprietary algorithms to identify patterns of motion, which translates to activities including steps taken, distance walked, and calories used. Fitbit algorithms are set to detect accelerations triggered by motion most indicative of people walking [135]. This requires the stepping motion to meet the algorithm threshold in size and acceleration to be counted as a step [135]. The algorithm to count steps is therefore mostly reliant on normal gait motion.

The Fitbit Zip is the smallest (dimensions 35 x 28 x 10 mm) and most flexible in terms of body positioning and is not only used in research but also clinical practice; it is low cost, attaches easily, and has a readout screen. The manufacturer recommends wearing the Fitbit Zip in the shirt pocket, trouser pocket, belt, waistband, or attached to a bra. The number of steps taken is provided almost instantaneously to the user by tapping the screen on the device [135].

2.10.3 Fitbit validity - controlled conditions/normal gait speed

In a systematic review of Fitbit devices used in controlled conditions (continuous walking tracks), studies suggest that overall the devices are accurate to within a ±3% measurement error approximately half of the time [19]. In users walking at a normal pace (1.10m/s for healthy older adults 70-79 years) [136] the devices can be worn on the manufacturer recommended position at the waist, chest, or wrist if jogging [137], however, research has shown that generally the devices tended to under record the amount of steps counted compared to direct observation [19]. A systematic review showed that the overall mean step count accuracy across all walking speeds in controlled conditions was to underestimate the count by 9.3% [19]. The 9% error over all participant speeds highlighted the need to further research the influence of different gait speeds on the accuracy of the device.

Further research has shown that slower walkers cannot rely on accurate step counts when wearing Fitbit activity monitors in the recommended manufacturer position, or when wearing a watch with a built in accelerometer [19]. In a systematic review, at walking speeds of <0.80 m/s the mean measurement error overall was shown to be -24.1% when the device was worn in a variety of locations [19]. When slower walkers were examined, the device appeared to become less accurate as speed decreased [19, 22, 138], therefore requiring further investigation of the most accurate device location.

Findings from the studies at slower walking speeds have further defined the importance of anatomical location of the Fitbit device in order to increase accuracy of step counting [21, 22]. Activity monitor detection of body accelerations by stepping movements at slower walking speeds is more difficult due to less angular accelerations. At slower walking speeds, when the activity monitor is worn more distally on the leg the accelerations appeared to be higher than when worn on the hip at slower walking speeds [139]. Singh et al [22] found that at gait speeds below 0.80m/s the Fitbit accelerometer was not accurate at the hip or chest and required a more distal leg position at slower gait speeds. The Fitbit devices underestimated steps and when the gait speed was < 0.80m/s the Fitbit was more accurate when placed at the foot or ankle area than at the hip area [21, 22]. In a study of healthy older (>65 years) slow walkers (speed 0.30 - 0.90m/s) the Fitbit One positioned on the hip was less accurate at slower gait speeds [140], while another study found similar results with ankle-worn Fitbits down to a gait speed of 0.40m/s [20]. These two studies were conducted at a gait speed which was not natural to the participant, but artificially controlled using a metronome and floor markings. Fitbit accuracy below a gait speed of 0.40m/s was demonstrated to be unreliable worn in any position [21, 22].

2.10.4 Fitbit validity - in the community

Validation of activity monitors in community and household living becomes more difficult due to the lack of gold-standard comparison. Direct step count observation throughout longer periods in a user's living environment is not practical. Previous studies in free-living conditions have shown that mobility commonly does not involve continuous walking [12], and higher gait variability is expected in the community due to interrupted shorter walks [141]. Most of the research so far has examined device accuracy when walking in controlled supervised clinical environments [21, 22, 130]. Minimal research has been conducted on step count accuracy of activity monitors used by slow to very slow walkers in the free-living environment of community-based rehabilitation patients [142]. In healthy adults, step count accuracy of the Fitbit worn at the hip has been compared to other activity monitors, including the Actigraph, with excellent agreement (ICC = 0.94) in the free-living environment [137]. In a study of older subjects who have slower gait speed the Fitbit counted 25% less steps than the Actical accelerometer; however in this study participants wore the Fitbit on the hip, a location resulting in inaccurate step count measurements in slower walkers, as discussed earlier in this thesis, and it was compared to the Actical accelerometer which was positioned at the ankle [19].

In one of the only studies looking at the accuracy of the Fitbit in specific medical conditions, a small study in chronic stroke survivors walking in the community placed the Fitbit at the ankle, and found the device was within a 8% difference to the Actical accelerometer (also located at the ankle) when walking at gait speed above 0.60m/s [142]. As their study included only 12 participants, small sample size was a study limitation. There is a need for larger studies to validate Fitbit step counts in the free-living environment; in a range of other diagnostic groups and including comparisons to other well-regarded activity monitors such as the ActivPAL, which is commonly used in field-based research.

2.10.5 ActivPAL

The ActivPAL3 (PAL Technologies Ltd, Glasgow, UK) is a triaxial accelerometer device (size 2.4 x 4.3 x 0.5cm) and is placed on the anterior mid-thigh with adhesive tape. It uses proprietary analysis algorithms to determine stepping performance measures including steps taken, time spent walking, standing, and transitioning between positions [143]. It is a commonly used device in research to monitor and report physical activity, as it can be left on the patient 24/7 when covered with waterproof dressings. Moreover, data can be easily downloaded for analysis.

For healthy adults and children, the ActivPAL3 has been found to be valid and reliable in counting steps for speeds as slow as 0.67m/s [144, 145]. More recently, investigations have begun to closely review slower gait speed and validity of the ActivPAL devices. Stansfield et al [143] looked at slower gait (treadmill walking) in healthy adults to determine over 90% accuracy of the ActivPAL at or above 0.50m/s when compared to visual observation. Even though accuracy is still being investigated, currently the ActivPAL is one of the most widely used and considered one of the most appropriate and accurate commercially available devices for field-based research and for comparison to other activity monitor devices.

2.11 Gait variations

Gait parameters such as cadence, step length, use of walking aid, and gait variations due to age, disease, weakness or pain (such as in stroke or orthopaedic patients), are potential factors that influence the accuracy of activity monitoring devices, even when worn distally [20, 22]. Abnormal gait parameters can alter the movement pattern, kinematics, body motion and accelerations required to match the movement algorithms required by the device to trigger a step count. For example, the Fitbit may be less accurate in people with short shuffling steps, such as in a typical gait pattern of someone with Parkinson's disease [22].

It is important to assess spatial-temporal gait variations accurately in order to quantify the influence they have on activity monitor accuracy. Variations can be assessed in many ways, including using computerised systems, walkways and camera or physical observation [146, 147]. To improve reliability of physical gait observations, Lord et al [147] suggest a minimum data of 12 continuous steps are gathered from a controlled walk, however other studies recommend that up to 120 steps are required [148, 149]. Fatigue may influence the consistency of gait measures in patient populations and needs to be considered in gait assessment design [150]. Continuous walks present with less gait variability than interrupted shorter walks [141], however it's also known that individuals may have varying gait speed in different walking test protocols, particularly if walking is over a short distance and interrupted [146]. In controlled conditions a reliable measure of gait is important, however may not reflect the gait speed of an individual walking in free-living home or community activity.

2.11.1 Gait speed

Improvement in gait abilities, both gait speed and distance walked, are the main rehabilitation outcomes, and therefore goals, for patients and therapists [151, 152]. Slow gait velocity has associations with higher disability, early mortality and hospitalisation, while improving gait velocity improves independence in community mobility [153]. Gait parameters, including walking velocity and distance walked are predictors of an individuals' ability to return home and be able to walk in the community. A gait speed of 0.78m/s, and be able to walk a distance of approximately 367metres are indicators for being able to walk in the community [136]. Therefore a gait speed of >0.80m/s has been proposed as the predictor for community ambulating, and a gait speed of 0.4 - 0.8m/s has been associated with being able to independently undertake activities of daily living at home with limited community ambulation [154]. Increased gait speed (and distance) is a common goal for stroke and other patients during their rehabilitation program [58].

The gait speed of older patients in clinical settings has been documented as being slower than healthy aged matched adults. A systematic review of gait velocity in patients in acute, sub-acute rehabilitation and ambulatory rehabilitation settings estimated the speed of these patients to be a mean of 0.58m/s [155]. Further analysis showed that patients in acute care walked at 0.46m/s, sub-acute 0.53m/s, and in outpatient settings at 0.74m/s [155]. As documented earlier, older adults (70-79 years) in the healthy population are estimated to walk at approximately 1.10m/s [156]. Therefore, the mean gait speed for rehabilitation patients of between 0.53 – 0.74m/s is much slower than the healthy gait speeds seen in the community.

2.11.2 Stroke

Compared with healthy adults, patients following a stroke show slower gait speed, and increased spatial-temporal asymmetry [58]. Following a stroke, gait speed varies from 0.18 - 1.03m/s, depending on symptoms and time post stroke [58, 157]. Spatial (step length ratio) and temporal (single leg support time) asymmetries are reported in patients with moderate stroke and impact on gait speed [58]. These gait variations become factors in a person's ability to live at home and in the community.

2.11.3 Orthopaedic

Similarly, orthopaedic patients also present with slow gait velocity during rehabilitation, which can impact on function upon discharge. Following orthopaedic trauma, mean gait speed on discharge from a rehabilitation hospital has been shown to be 0.53 - 0.64m/s depending on their initial mobility [153]. In the same study, only 18% of the patients discharged were able to achieve the 0.80m/s community gait speed threshold for predicting ability to fully ambulate in the community [153, 158]. This highlights the requirement for continuing rehabilitation post discharge to improve gait speed and hence function.

2.12 Activity monitors in rehabilitation

The importance of walking is seen from the evidence in the literature and discussion points detailed earlier. Most patients in rehabilitation have mobility limitations, which continue to exist when their rehabilitation program moves to an outpatient service. The guidelines for rehabilitation care have a common theme of maximising the individual patient's therapy activity or dosage within their limitations. To progress a patient's walking as part of dosage, therapists regularly review with the patient and provide feedback with a view to increase activity and walking levels. Feedback is used as a motivator to continue walking and subsequently to improve mobility [159]. In a gym environment, the therapist can monitor and measure walking distance by direct observation. For example the distance walked to the gym, counting laps of the gym, repetitive gait practice, and task specific walking are common practices in rehabilitation to increase dosage [160, 161]. These interventions are also evidence based practices that are required by rehabilitation providers [6] .

Direct observation of number of steps taken require the therapist's full attention, and is not possible in a busy therapy gym, and even more difficult to monitor away from the gym [21]. When the patient is unsupervised and on the hospital ward, or at home, clinicians can only rely on patient self-report, or personal diaries recording the amount of walking and activity undertaken [162].

There are a variety of activity monitors on the market, and Fitbit activity monitors are becoming increasingly popular in the general consumer market as a method of counting and monitoring steps in younger and older populations [19]. They can be used in a patient's rehabilitation journey from inpatient through to more remotely monitored home-based interventions such as home rehabilitation and telehealth, allowing clinicians and researchers to monitor and measure activity levels, and encourage increased walking by review of actual steps and goal setting a new target [163, 164]. Further validation of Fitbit step count data collection is required in certain populations, considering environments and gait parameters.

2.13 Literature review summary

The increasing demand for rehabilitation services and the need to maximise patient activity levels, mobility, and function require innovative rehabilitation methods. Higher physical activity levels are linked to improved health, earlier rehabilitation recovery and secondary stroke prevention. New ways of achieving successful rehabilitation outcomes by using activity monitors such as the Fitbit Zip have the potential to motivate patients to achieve their walking goals. The accuracy of the Fitbit Zip in slow walking rehabilitation populations and the anatomical location of the device requires further investigation in controlled conditions, as well as in the home and community.

The specific research questions addressed in this thesis are:

- How accurate is the Fitbit Zip activity monitor at counting steps when the device is worn on the shoe in sub-acute rehabilitation patients in controlled conditions indoors and outdoors, compared to direct observation?
- How accurate is the Fitbit Zip at counting steps in free-living conditions compared to a research grade activity monitor, the ActivPAL?
- Does walking at community gait speed (>0.80m/s) or limited community gait speed (<0.80 m/s) influence the accuracy of the Fitbit?
- Does diagnosis by patient group (neurological, orthopaedic and other medical) influence the accuracy of the Fitbit?

CHAPTER 3
FITBIT ACCURACY IN CONTROLLED CONDITIONS

3.1 Background

Accurate step count measurement in the rehabilitation setting is important to understand the association between physical activity and better health outcomes [10]. Having accurate measurements of daily mobility and physical activity levels can then be utilised for motivational goal setting and exercise progression [165]. Accurate therapist feedback on walking activity may assist in increasing physical activity dosage and maximising walking potential [6, 90]. However, accuracy of commercially available step counters has been shown to be poor in people with altered gait parameters including slow gait speed, slower cadence, and short step length [20].

Patients in rehabilitation are not achieving the recommended regular physical activity levels [97, 102]. The World Health Organisation's physical activity guidelines provide minimum dosage recommendations for adults to maintain positive health outcomes [9]. In rehabilitation, health conditions typically affect mobility levels and the amount of exercise patients are physically able to complete. Modified WHO guidelines for older adults with health conditions are 'to be physically active as their abilities and conditions allow', while still aiming for the accumulation of 30 minutes of moderate intensity most days of the week [9]. Similarly, specific stroke guidelines [6] require physical activity, including walking, to be practiced as much as possible, while hip fracture clinical care standards [82] require goal orientated walking with increasing levels of speed and complexity during rehabilitation.

Walking is the most common physical activity in any age group [11]. Reduced walking ability is common in rehabilitation patients, who most commonly present with a slower walking speed than healthy adults [166]. Repetitive stepping practice, repetitive practice of gait, and repetitive task specific training is included in rehabilitation therapy sessions to provide a high dose of practice [6, 161]. Improvements of patients' gait speed and distance walked are positive indicators for discharge home, to live and manage in the community [136].

Measures of patient activity within a session, including walking and step count, are commonly monitored by therapists as reference points for progression [6]. Therapists regularly review activity levels and provide feedback to the patient, acting as a motivator to continue to increase walking activity and to improve their mobility [159]. The number of steps taken during therapy and non-therapy time can provide objective measures of repetitive training and other physical activity, including walking. Counting steps by direct observation requires the therapists full attention and is not practical in a busy environment, while gathering information on steps taken in non-therapy time by self-report methods may not be suitable due to subjectivity and lack of sensitivity [167]. In recent years, many commercially available activity monitors have become available, [20] and they have become increasingly popular in rehabilitation for activity monitoring and goal setting purposes [164].

The Fitbit activity monitor is commonly used in rehabilitation and widely used in research [134], and has been found to accurately count steps in healthy older adults [19, 137]. Studies have found that the accuracy of activity monitors in slower walkers requires further investigation and that gait parameters including speed, cadence, step length and the anatomical location of the activity monitor device influence accuracy [22, 138]. Older adults (70-79 years) in the population are estimated to walk at approximately 1.1m/s [156]. A gait speed of >0.80m/s has been proposed as the predictor for community ambulation, and a gait speed of 0.4 - 0.8m/s has been associated with independently undertaking activities of daily living at home with limited community ambulation [136, 154]. Singh et al [22] demonstrated that at gait speeds below 0.80m/s, the Fitbit accelerometer was not accurate at the manufacturer recommended position of hip or chest, however could provide accurate step counts when worn on a more distal foot position at gait speeds of between 0.5 to 0.8m/s. Similar outcomes were found in Fitbit step count accuracy examined when worn at the ankle in patients following a stroke [20] and in general rehabilitation patients [21]. Fitbit step count comparisons at comfortable gait speeds and walking indoors [21, 130] have been examined with the Fitbit worn at the ankle in the general clinical rehabilitation population. When step count in clinical groups have been studied [138, 140, 142], methodology has not included comfortable gait speed, or has not been compared to direct observation. The influence on Fitbit accuracy of specific clinical diagnosis, the influence when worn in outdoor environments, and the accuracy of the Fitbit when worn more distally on the shoe needs investigation.

The primary study aim was to assess accuracy of the Fitbit Zip activity monitor positioned on the shoe in controlled conditions, at comfortable walking speed compared to actual steps taken during a two-minute walk in both indoor and outdoor conditions in people receiving outpatient rehabilitation. Secondary aims were to assess if there were differences in the level of accuracy based on: (i) walking speed (community ambulation speed >0.80m/s or limited community ambulation speed <0.80m/s) [136], (ii) diagnostic reason for rehabilitation, or (iii) the use of a gait aid.

3.2 Methods

3.2.1 Participants

Participants were recruited from the outpatient Day Rehabilitation service at an Australian metropolitan hospital. Participants were screened from patient case notes and eligible for inclusion if they: (1) were admitted to rehabilitation following a recent hospital admission (within three months); (2) were able to walk for two minutes with or without a gait aid; (3) have a gait speed of 0.5m/s to <1.0m/s (taken from ten metre walk test in patient notes). The study protocol was approved by the local Ethics committee and all participants provided written informed consent before taking part in the study requirements.

3.2.2 Protocol

Participants attended the Hospital on a single occasion to walk a controlled indoor two-minute walk and outdoor two-minute walk. The order of the walks was randomised via a computer-generated program with a sealed sequenced opaque envelope prepared by an independent administrator. Each sequenced envelope was opened by the researcher prior to the intervention.

Each participant wore a Fitbit Zip activity monitor while completing the walks; the Fitbit Zip is commonly used in research and clinical practice and is low cost, attaches easily, and has a readout screen. The Fitbit Zip contains a triaxial accelerometer, uses proprietary algorithms to convert acceleration into step counts, and is designed to detect the motion patterns most indicative of walking. The manufacturer recommends wearing the Fitbit in the shirt pocket, trouser pocket, belt, waistband, or attached to a bra. The number of steps taken is provided almost instantaneously to the user by tapping the screen on the device [135].

Participants undertook the two controlled walks on walking tracks at a self-selected comfortable walking speed, following standardised instructions. Each study participant wore a Fitbit Zip positioned on the shoe of their unaffected or dominant leg, attached to the forefoot on the top of the shoe.

All participants completed a controlled continuous two-minute walk on an indoor 35-metre track and an outdoor 35-metre track. The indoor two-minute walk was selected to evaluate clinical indoor walking and was in a large hall with a flat oval track marked out on a vinyl floor. The outdoor two-minute walk track was in a paved purposefully built rehabilitation courtyard, and comprised even and uneven paving, slopes, ramps, a sharp turn and exposure to the elements of weather. Participants were transported in a wheelchair between all walks to avoid fatigue and used their usual walking aid.

Each two-minute walk was timed with a stopwatch and the walking distance was measured by counting the number of laps and with a measuring wheel. The assessor used a hand-held counter to observe and manually record the steps taken while walking beside the participant. A step was counted with each single foot lift or shuffle and foot movement to a different place. At the end of each walk, the Fitbit steps were recorded from the read out on the Fitbit device. Cadence and step length were averaged from distance/steps taken (manual count) over the two-minute walk.

3.3 Statistical Analysis

Recruitment of ninety participants allowed for an estimated thirty patients with neurological diagnosis, thirty with orthopaedic diagnosis, and thirty with other conditions, thus having the power to show significant difference in those clinical groups of Fitbit step count accuracy. Power calculations were based on the recruitment numbers in recent studies by Klassen [20] and Simpson [140]. Firstly, to assess if the Fitbit is accurate at recording steps during a two-minute walk, the number of steps recorded was compared to the actual number of steps taken using a paired sample t-test in each of the indoor and outdoor conditions. These were repeated for sub-group analysis based on if the participants were (i) community or limited community walkers determined by gait speed of > or < 0.80m/s, (ii) by diagnosis, and (iii) using a gait aid. For all comparison's alpha was set at 0.05.

Secondly, to assess the level of agreement between the Fitbit and the actual number of steps taken, percentage accuracy of the Fitbit was calculated using the formula ((Fitbit monitor count - actual count)/actual count) x 100. Criterion validity between the actual observed step count and Fitbit count was then examined by intraclass correlation coefficient (ICC) to examine (i) the reliability and (ii) the consistency of measure errors between the gold-standard direct observation and the Fitbit. Analyses of (i) absolute agreement and (ii) consistency was calculated with >0.75 being excellent, 0.60 - 0.74 good, and 0.40 - 0.59 fair.

Finally, to assess if the Fitbit is more accurate under different conditions, the level of accuracy was compared between (i) community and limited community walkers, (ii) diagnosis, and (iii) use of gait aid in each of the indoor and outdoor conditions. Independent t-tests were utilised to compare walking speed and gait aid use, and a one-way ANOVA with post-hoc pairwise comparison was used for diagnosis. For all comparison's alpha was set to 0.05.

3.4 Results

3.4.1 Participants

Ninety participants were recruited with eighty-eight included in the analysis (49% male, mean age 72.51 +/- 10.77, range 36-95 years). Two participants were excluded from analysis because of incomplete data due to recording errors. Twenty-eight (32%) participants had a neurological condition (stroke 14%, laminectomy 5%, plus other neurological conditions including Multiple sclerosis, Parkinson's disease, Guillain-barré syndrome), thirty-nine (44%) subjects had an orthopaedic condition (hip/knee arthroplasty 23% or hip fracture 8%), and the remainder were of other diagnosis including medical or surgical event. Fifty-nine (67%) participants used a walking aid for the study, mostly a walking stick or four-wheeled walker (Table 1).

All participants met the gait speed criteria when identified as suitable for the study based on the ten-metre walk test taken from patient notes. Based on the results of the two-minute walk tests, the indoor walking speed ranged from 0.48 to 1.25m/s (mean 0.81m/s), while outdoor walking speed ranged from 0.38 to 1.29m/s (mean 0.78m/s) (Table 2). Gait speed for limited community walkers (<0.80m/s) indoors (mean 0.67m/s) and outdoors (mean 0.63 m/s) was slower than community walkers (>0.80m/s) indoors or outdoors (both mean 1.0m/s) (Table 2). Cadence was higher indoors (mean 99.5 steps/m) than outdoors (mean 97.8 steps/m) and higher in the community walkers (indoors 107.4 steps/m, outdoors 105.2 steps/m) than limited community walkers (indoors 93.9 steps/m, outdoors 92.7 steps/m).

Table 1.

Participant characteristics Mean (SD; range) or n (%).

Characteristics	All	Diagnosis			Gait speed	
		Neurological	Orthopaedic	Other medical or surgical event	Limited community <0.80m/s	Community >0.80m/s
Number	88	28 (32)	39 (44)	21 (24)	52 (59)	36 (41)
Age, (years)	73 (11; 36-95)	69 (11;36-95)	73 (10;52-91)	76 (11;57-93)	73 (12;36-95)	72 (8;57-86)
Sex, male	43 (49)	17 (61)	13 (33)	14 (67)	25 (48)	18 (50)
Gait aid use Frame/w alker Walking stick Crutches	59 (67) 36 (61) 21 (36) 2 (3)	22 (78)	22 (55)	16 (76)	48 (92)	12 (33)

Table 2.

Spatiotemporal parameters

	Indoor mean (SD)	Outdoor mean (SD)
Gait speed		
All (metres/second)	0.81 (0.22)	0.78 (0.22)
Limited community Gait speed <0.80m/sec	0.67 (0.08)	0.63 (0.12)
Community Gait speed >0.80 m/sec	1.00 (0.13)	1.00 (0.15)
Distance walked		
All (metres)	97.1 (24)	93.3 (27)
Limited community <0.80m/sec	80.0 (10.0)	75.4 (14.0)
Community >0.80m/sec	121.8 (15.1)	119.3 (17.5)
Cadence		
All (steps per minute)	99.5 (12)	97.8 (13)
Limited community <0.80 m/sec	93.9 (11.4)	92.7 (13.3)
Community >0.80 m/sec	107.4 (8.3)	105.2 (8.9)

3.4.2 Comparison of Fitbit to direct observation

Table 3 presents the Fitbit step count and the direct observation manual step count for the two-minute walk indoor and outdoor test results. Step count difference was higher for the indoor test, in which the Fitbit presented with a mean step count of 17 (SD 21.2) steps lower than direct observation. This was slightly better when walking outdoors, with the Fitbit presenting a mean step count of 15.2 (SD 18.1) steps lower than direct observation. Neither indoor or outdoor step count differences were significant. There were also no significant differences when analysed for sub-group analysis based on if the participants were (i) community or limited community walkers, (ii) by diagnosis, and (iii) by use of a gait aid (Table 3). All Fitbit recordings undercounted steps compared to direct observations.

Table 3

Step Count - Fitbit v direct observation

	Fitbit step count (SD)	Observed step count (SD)	p-value
Indoor count	182 (30)	199 (24)	<0.001
Outdoor count	181 (28)	19 (26)	<0.001
Gait speed (limited community) <0.80m/sec			
Indoor	167 (26)	188 (23)	<0.001
Outdoor	166 (25)	186 (27)	<0.001
Gait speed (community) >0.80m/sec			
Indoor	204 (23)	215 (17)	0.001
Outdoor	201 (19)	210 (18)	<0.001
Diagnosis			
Neurological indoor	178 (24)	196 (23)	<0.001

	Fitbit step count (SD)	Observed step count (SD)	p-value
Neurological outdoor	176 (23)	194 (25)	<0.001
Orthopaedic indoor	184 (36)	203 (27)	<0.001
Orthopaedic outdoor	182 (35)	197 (30)	<0.001
Other diagnosis indoor	184 (28)	195 (20)	0.037
Other diagnosis outdoor	184 (21)	194 (22)	0.003
Gait aid use			
No gait aids indoor	202 (29)	216 (16)	0.004
No gait aids outdoor	201 (22)	213 (17)	<0.001
Gait aid used indoor	173 (27)	191 (23)	<0.001
Gait aid used outdoor	171 (26)	188 (26)	<0.001

3.4.3 Level of agreement and criterion validity

Table 4 displays the levels of agreement between the Fitbit and the actual number of steps taken and the results of the ICC analyses between the Fitbit and direct observation of step count. The Fitbit presented with a mean step count that was lower than direct observation indoors and outdoors and was also slightly less accurate indoors (90.1%) than outdoors (92.4%). There was excellent consistent agreement between Fitbit and direct observation for both indoor (ICC 0.825) and outdoor walks (ICC 0.877). Absolute agreement was good (ICC 0.742) for the indoor walk and excellent (ICC 0.809) for the outdoor walk. Sub-group analysis demonstrated excellent ICC consistent agreement for the outdoor walk at limited community (ICC 0.803) and at community gait speed (ICC 0.902), while the indoor walk was good at both speeds (ICC 0.739 and ICC 0.708). Sub-group analysis of absolute ICC agreement was excellent only for outdoor community walking speed (ICC 0.848) and good for all the other sub-groups.

Table 4.

Summary of percentage agreement of indoor and outdoor two-minute walk, walking speed observations, and intraclass correlations of step count between the Fitbit and direct observations.

		No	ICC Consistency (95% CI)	ICC Absolute (95% CI)	% agree (SD) a	Mean Absolute error (SD)b
Indoor	**All speeds**	88	0.825 (0.732-0.885)	0.742 (0.292-0.879)	91 (10)	18 (20)
	Limited community gait speed <0.80m/s	52	0.739(0.545-0.850)	0.600 (0.029-0.820)	89 (11)	21 (22)
	Community gait speed >0.80m/s	36	0.708 (0.427- 0.851)	0.645 (0.242-0.827)	94(7)	13 (15)
Outdoor	**All speeds**	88	0.877 (0.813-0.920)	0.809 (0.375-0.917)	92 (9)	15 (18)
	Limited community gait speed <0.80m/s	52	0.803 (0.657-0.887)	0.690 (0.076-0.868)	90 (10)	19(21)
	Community gait speed >0.80m/s	36	0.902 (0.809-0.950)	0.848 (0.431-0.942)	96 (5)	9 (11)

ICC: intraclass correlation, CI: confidence interval

a - The percentage agreement for the Fitbit compared with observed step count was calculated as: (Fitbit measures step count/observed step count) x 100.

b – Number of step difference (whole steps)

3.4.4 Accuracy under different conditions

For absolute and percent errors the level of error was significantly higher for limited community (<0.8m/s) walkers in both indoor and outdoor conditions (all $p<0.05$). Level of error was also significantly higher for community walkers (>0.80m/s) indoors when compared to community walkers outdoors ($p= 0.024$).

There was a significant weak negative relationship seen as participants walked slower the accuracy of the Fitbit reduced (a higher percentage error) when walking indoors ($r = -.251$, $p=0.018$), and outdoors ($r= -.322$, $p=.002$). Cadence was not significantly associated with step count accuracy in either the indoor or outdoor walks.

Post-hoc analysis showed that diagnosis (neurological, orthopaedic or other condition), walking distance, cadence, step length, and use of walking aid did not significantly affect Fitbit accuracy ($p >0.05$).

3.5 Discussion

In rehabilitation patients who walk at speeds between 0.38 - 1.29m/s in controlled conditions at their comfortable gait speed either indoors or outdoors, the accuracy of the Fitbit device worn on the shoe was high; consistently undercounting when compared to the manual count, with excellent consistent agreement. Subgroup analyses demonstrated that the Fitbit was more accurate in community walkers than in limited community walkers (>94% and >89% respectively). Patient condition (neurological, orthopaedic or other condition) did not affect Fitbit accuracy, nor did cadence or the use of a walking aid.

The Fitbit consistently underestimated step count compared to manual count, becoming increasingly inaccurate as walking speed reduced. These influences of gait speed are consistent with previous studies of indoor walking [20-22]. Treacy [21] had lower overall accuracy of 84% compared to this study of >90%, which can be explained by the lower mean gait speed of their study (0.42m/s compared to 0.79m/s), with almost half their participants' gait speed lower than 0.40m/s. The current study's participants' gait speed ranged from 0.38m/s-1.29m/s, with recruitment designed to exclude those speeds shown in research where the Fitbit was likely to be less accurate in counting steps (below 0.50m/s). The two-minute gait speed range varied from the recruitment criteria with some participants walking faster and some slower. Potential reasons for a faster or slower speed variation from time of recruitment to testing include natural improvement, influence of indoor or outdoor environment, or the extra endurance required with the longer two-minute walk. However, the recent Treacy study [21] indicates Fitbit accuracy down to 0.40m/s, which matches the gait speed of the participants of this study. The variation in gait speed from recruitment based on ten-metre walk test taken from patient notes to the observed gait speed over a two-minute walk may be considered more indicative of clinical practice when clinicians who are considering the use of the Fitbit may quickly screen suitability using the ten-metre walk test.

The Fitbit device was located on the forefoot in this study, with our previous work [22] indicating this position to be more accurate for slow walkers compared to the ankle position of most other studies using the distal leg location [20, 21]. The explanation is the forefoot location in slower walkers provides the most amplified leg movement position for each step, therefore allowing the accelerometer to record a step count. This is supported by Rueterbories [168], who found that magnitudes of lower limb angular accelerations reduce with gait velocity and cadence. They also found that with slower gait velocity and cadence, accelerations at the forefoot were largest, significantly more than the ankle and the thigh.

Overall, accuracy was slightly less precise indoors than outdoors, however this difference was not statistically significant. The difference may be explained by a higher stepping gait pattern required to ensure foot clearance on the uneven surface outdoors. Increased lower limb activity through hip flexion and ankle dorsi-flexion movement has been observed on inclined surfaces [169], which may result in more angular accelerations, and triggering the Fitbit step count and more accuracy outdoors.

A strength of this study was the large number of participants. Sample size within subgroups of neurological and orthopaedic populations were sufficient to validate the use of the Fitbit Zip for those patients, as well as in general rehabilitation patients. Enough numbers were also available within each gait speed group (n= 52 and 36) to determine accuracy by gait speed parameter. Gait speed was analysed at participants' comfortable gait speed and cadence, and was similar to that reported in other studies of stroke patients; walking speeds of 0.62 m/s, cadence of 85 steps per minute [58], and of orthopaedic patients 0.64m/s [153].

In clinical settings, therapists require trust in the consistency of step count information provided. The excellent ICC consistency agreement found between the Fitbit Zip and direct observation of step count indoors and outdoors should provide clinicians with confidence to rely on the Fitbit Zip as a consistent measure to enable feedback and comparison of patient day-to-day step count, and to aid in increasing patient motivation and walking activity. The ICC absolute agreements have relatively large 95% confidence intervals which may indicate the influence of other factors including gait parameters on the accuracy of the Fitbit, however for clinical use, the ICC consistency agreements are more important as a consistent feedback measure and the 95% confidence intervals are smaller.

An important outcome of this study is the fact that the Fitbit Zip could be used for all rehabilitation patients. Other studies investigated stroke [20, 142] without direct observation comparison, artificial walking speed, or were general rehabilitation patients [21] not analysed by subgroup. Potential differences in step count accuracy due to clinical group required further investigation as gait patterns can vary by diagnosis. For example in stroke [58] and orthopaedic patients [170] gait can be influenced by specific weakness, spasticity, pain or apprehension. This study was the first to validate the Fitbit Zip accuracy when walking naturally in clinical populations, with no significant difference observed between neurological, orthopaedic and other medical or surgical conditions. This study validated the positioning of the Fitbit Zip clipped on the shoe, whereas many other studies have required the Fitbit to be worn on the ankle [20, 136]. The shoe position is a practical location for the Fitbit Zip. It is potentially easier for the patient to access and may allow them to monitor their own step count from the read out on the device if desired.

This study is amongst the first to compare the accuracy of the Fitbit Zip device of participants walking slowly (community and limited community gait speed) at their natural speed in the rehabilitation setting. It is also the first study to determine the influence of diagnosis and gait parameters on the accuracy of the Fitbit Zip in controlled conditions indoors and outdoors. Based on the results of this study, the Fitbit Zip is a highly accurate step-counting device that can be worn by patients in a rehabilitation setting. Therapists and patients can rely on the Fitbit Zip step count data as an accurate measure to progress physical activity.

It is important to acknowledge this study's limitations. Although Fitbit Zip accuracy was assessed at the individuals comfortable gait speed, the conditions in this study were still in controlled, supervised conditions indoors and outdoors. The indoor and outdoor track was continuous, however in the home and community most activity is not continuous walking [12], with more gait variability from interrupted shorter walks [141]. Observations were from the same one observer counting the participant's steps which may be a limitation, however the consistency of step counting (relating to the definition of what is counted as a step) is likely to be higher than having multiple observers. Participant demographics show a variety of diagnoses, even within sub-group, and variety in time post hospital admission that may have influenced sub-group analysis. Activities of daily living, household tasks or community ambulation may require more incidental, shorter, shuffling steps difficult to accurately detect by activity monitors due to smaller leg accelerations [12]. Importantly, this study included shuffling steps in the step count, not just counting when the full foot cleared the ground. Direct observation of step counts throughout a 24-hour period in uncontrolled environments is not practical. Therefore, the second study of this thesis will investigate slow walking rehabilitation patients wearing the Fitbit Zip compared with another activity monitor in free-living home and community conditions.

3.6 Conclusion

Objective measurement of patient quantity of walking, activity levels, and dose of therapy is essential for accurate monitoring and provision of feedback, enabling progression of patient functional walking mobility. This study provides evidence that the Fitbit Zip accurately counts steps of patients in the sub-acute rehabilitation population, including stroke and orthopaedic patients, and can be worn in the practical position on the shoe.

CHAPTER 4
EVALUATION OF FITBIT ACCURACY IN FREE-LIVING CONDITIONS

4.1 Background

Following hospital discharge, free-living physical activity levels in rehabilitation patients are typically low [9, 53]. For older adults with physical activity and mobility limitations, the modified World Health Organisations' physical activity guidelines recommend 'to be as physically active as their abilities and conditions allow', while still aiming for accumulation of 30 minutes of moderate intensity most days of the week [9]. Walking is the most common physical activity [11], an important rehabilitation goal [171], and a main indicator of functional ambulation in the community [136]. Having accurate records of patients' walking mobility in the community can therefore assist therapists to set and adjust rehabilitation goals aimed at improving walking performance.

Rehabilitation patients commonly use a gait aid and walk slower than healthy aged matched adults [166]. To maximise patient walking abilities, rehabilitation should continue following hospital discharge [172]. Interventions to improve walking performance, involves repetitive task training addressing gait and functional walking mobility [6, 161]. Monitoring walking performance and step count can provide therapists with a reference point for progression [6]. In the clinic, therapists regularly review levels of walking activity by clinical observation. The provision of direct feedback on walking performance or step count can serve as a motivator for goal setting and increased walking activity [159, 165]. However, in the community, information on free-living physical activity relies mainly on self-report of walking and activities undertaken [167].

In recent years, various commercially available activity monitors have become available that hold step counting functions [20]. Depending on design, the activity monitor devices have immediate feedback features, allow remote monitoring, and have Bluetooth technology allowing pairing with a phone or computer. The activity monitors aimed at the commercial market have potential in rehabilitation as therapist and patient tools for monitoring and progressing walking mobility, while other models are more suited and widely used for research purposes. These are more expensive and allow more data analysis, but lack immediate feedback features [134]. The Fitbit activity monitor has been demonstrated to accurately detect steps in healthy older adults [19, 137], however the evidence on accuracy of the Fitbit in slower walkers is inconclusive. Gait parameters including speed and the anatomical location of the device influence accuracy [22, 138]. Recent studies in rehabilitation patients [21, 130], and unpublished evidence from chapter 3 of this thesis (Fitbit accuracy compared to direct observation), have demonstrated that wearing the Fitbit device distally at the ankle or shoe leads to increased step count accuracy in slow to very slow walkers (gait speed 0.40m/s – 1.0m/s).

Most of the research so far has examined device accuracy when walking in controlled supervised clinical environments [21, 22, 130]. Validation of accelerometer activity monitor devices in community and household living is compromised due to the lack of gold-standard comparison. The ActivPAL is an accelerometer-based activity monitor worn on the thigh, measuring periods in sitting, lying and upright [173], and is currently considered one of the most accurate step counters for field-based research. Minimal research has been conducted on step count accuracy of activity monitors used by slow to very slow walkers in the free-living environment of community-based rehabilitation patients [142].

The purpose of this study was to (i) determine the agreement between step count readings from the Fitbit Zip and the ActivPAL in community-based rehabilitation patients, and (ii) determine the influence of gait speed on this agreement.

4.2 Methods

Participants were recruited from the outpatient day rehabilitation service at an Australian metropolitan hospital. Participants were eligible for inclusion if they: (i) were admitted to rehabilitation following a recent hospital admission (within 3 months); (ii) were able to walk for two minutes with or without a gait aid; (iii) had a gait speed of 0.5m/s to <1.0m/s being very slow walkers (taken from ten metre walk test in patient clinical notes). The study protocol was approved by the local ethics committee and all participants provided written informed consent before taking part in the study requirements. The participants' characteristics were recorded including age, sex, primary diagnosis (divided into 3 groups; orthopaedic, neurological, or other condition) and use of gait aid. The 'neurological' diagnostic group included stroke and any other neurological condition, the 'orthopaedic' group included hip fracture, total hip or knee arthroplasty and any other orthopaedic condition and the 'other condition' included any other diagnosis that includes post medical or surgical event requiring rehabilitation. Gait speed measured in metres per second (m/s) and divided into 2 speeds – community ambulators (walking faster than 0.80m/s) and limited community ambulators (walking slower than 0.80m/s) [136].

Each participant wore two different activity monitors, the Fitbit Zip (Fitbit Inc, San Francisco, California) and the ActivPAL3 (Pal Technologies, Glasgow, Scotland), simultaneously for 24 hours in free-living conditions at home and in the community.

The Fitbit Zip contains a triaxial accelerometer, uses proprietary algorithms to convert acceleration into step counts, and is designed to detect motion patterns most indicative of walking. Feedback on the number of steps taken is provided almost instantaneously to the user by tapping the screen on the device [131]. The manufacturer recommends wearing the Fitbit in the shirt pocket, trouser pocket, belt, waistband or attached to a bra, however in slow walking individuals it has been shown to be more accurate when placed distally on the leg [20, 130]. Therefore, for the purpose of this study, the Fitbit Zip was worn on the shoe of the participant's unaffected or dominant leg, attached to the forefoot on the top of the shoe.

The ActivPAL3 is a triaxial accelerometer device (size 2.4 x 4.3 x 0.5cm) and was placed on the anterior mid-thigh of the unaffected or dominant leg with adhesive tape. It uses proprietary analysis algorithms to determine stepping performance measures including steps taken, time spent walking, standing, and transitioning between positions [143]. It is a commonly used device in research to monitor and report free-living physical activity, as it can be left on the patient 24/7 when covered with waterproof dressings.

Both the Fitbit and ActivPAL were configured on the same computer to ensure that the date and time stamp on each device was identical. Fitbit data was downloaded and processed through custom software which extracted step count at 60 second intervals. ActivPAL data was downloaded and extracted via the ActivPAL process and presentation v7.2.32 software in 15 second intervals, which was subsequently transformed into 60 second intervals. The two datasets were then matched by their time stamps and trimmed to include only the 12-hour period deemed most likely for patients to be dressed and active (8am-8pm), therefore excluding overnight and personal care periods when participants were unlikely to wear both devices simultaneously. A manual check was then conducted to ensure that both devices had recorded before being included for final analysis.

4.2.1 Statistical analysis

Power calculations based on studies by Klassen [8] and Simpson [13] suggested that recruitment of 30 participants per diagnostic group would adequately power the study to detect statistical significance, meaning the recruitment target for this study was a total of 90 participants.

To assess the accuracy of the Fitbit compared to the ActivPAL, the absolute actual error as well as percentage error between the Fitbit and ActivPAL step count was calculated as the difference between the Fitbit step count and the ActivPAL step count. Percentage accuracy of the Fitbit was calculated using the formula ((Fitbit monitor count - ActivPAL count)/ActivPAL count) x 100. Descriptive statistics were calculated, and Z-scores were assessed for normality of distribution. The Wilcoxon Sign rank Test was subsequently used to assess the actual and percentage accuracy of the Fitbit compared to the ActivPAL.

Criterion agreement between the Fitbit count and the ActivPAL count was examined by intraclass correlation coefficient (ICC) to examine the degree of association and reliability between the two measuring devices. Analyses of (i) absolute agreement and (ii) consistency was calculated with >0.75 being excellent, 0.60 – 0.74 good and 0.40 - 0.59 fair [14]. To assess systemic differences between the two devices a Bland-Altman plot was produced with limits of agreement set at two standard deviations either side of the mean. From the Bland-Altman plot, regression analysis of the difference of the mean actual error was calculated to determine any proportional bias at different walking speeds. To assess if results varied based on diagnosis or walking speed, sub-group analyses by Wilcoxon Signed Ranks Test were conducted with the participants divided into groups firstly based on diagnosis (neurological, orthopaedic, and other) and then into walking speed for community and limited community (>0.80m/s and <0.80m/s). For all tests, alpha was set to 0.05, and analysis was conducted using SPSS version 23 (IBM Corporation, Armonk, NY).

4.3 Results

A total of 90 participants were recruited and agreed to participation, and complete data sets were obtained from 84 of those participants. Data from six participants were excluded from final analysis due to missing data or recording errors (Fig 1). Participant demographics are presented in table 1.

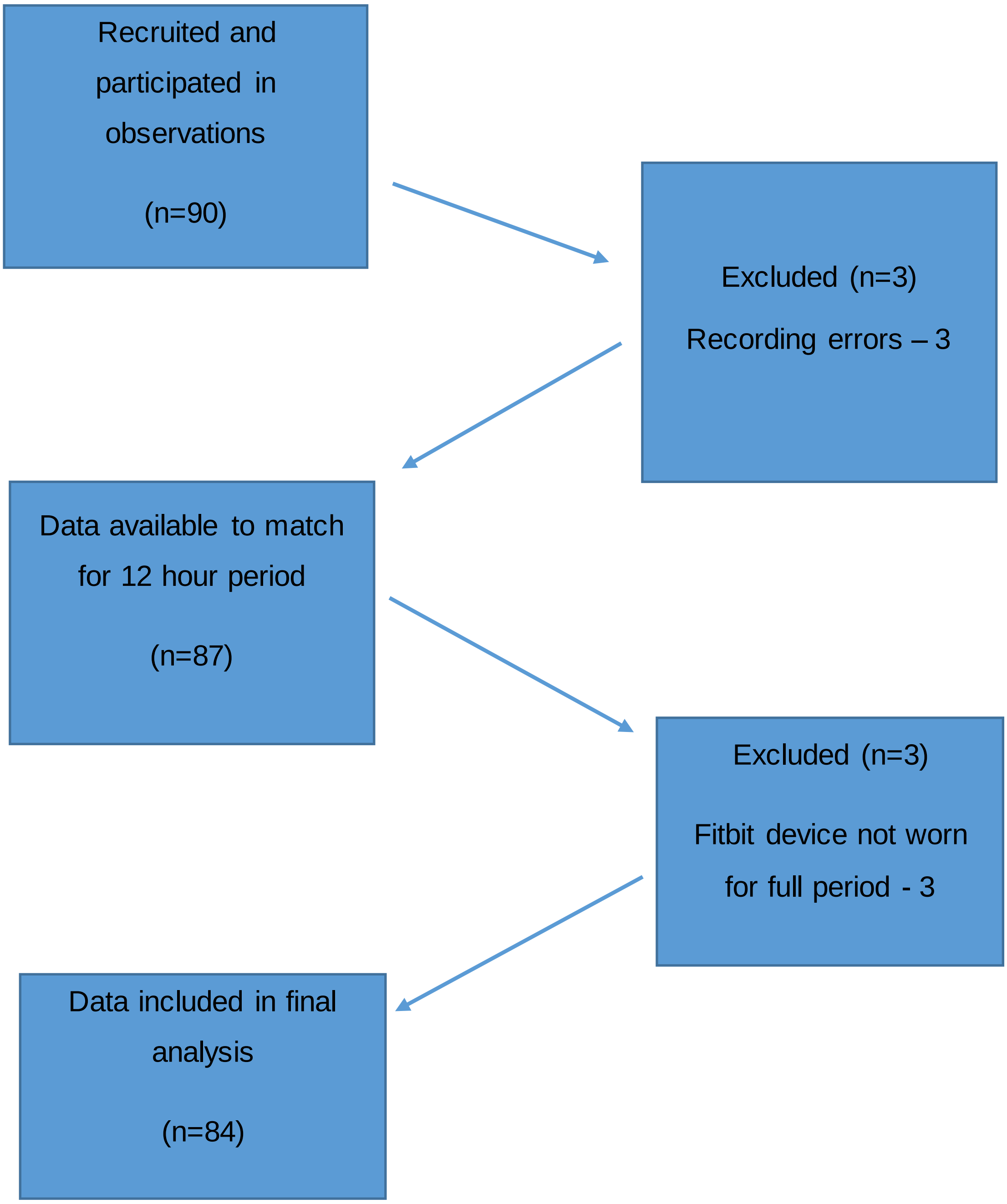
Table 1.

Participant characteristics

Characteristic	**Mean (SD; range)** **Or n (%)**
Number	84
Age, (years)	73 (11; 36-95)
Sex, male	43 (49%)
Gait speed (indoor 2-minute walk test)	0.81 (0.22: 0.48-1.25)
Walking aid use	59 (67%)
	Rollator frame/walker 36, w/stick 21, crutches 2
Diagnosis	
Neurological	27 (32%)
Orthopaedic	36 (43%)
Other post medical or surgical event	21 (24%)

For detailed demographics by subgroup including diagnosis and gait speed (limited community and community) refer to Chapter 3, Table 1 (Participant characteristics) and Table 2 (Spatiotemporal parameters).

Figure 1 – Recruitment and data collection exclusions flow chart



Accuracy of Fitbit

Overall, the Fitbit Zip step count was higher than the ActivPAL by a mean of 199.4 (SD 1055.6) steps, an over estimation of 11.0% (SD 48.0%), however this was not statistically significant (p=0.051), (Table 2). When analysed in subgroups, the Fitbit significantly over counted compared to the ActivPAL in the community walkers (> 0.80m/s) (p=0.002), but not the limited community walkers (< 0.80m/s) (p=0.772). When assessed based on diagnosis the Fitbit significantly over counted, compared to the ActivPAL, in the orthopaedic group (p=0.029), but not the neurological (p=0.631) or other diagnosis group (p=0.821). This however was not due to the orthopaedic group walking faster, as an assessment of walking speed based on group diagnosis showed no significant difference (p=0.681 indoors and p=0.389 outdoors).

Table 2.

Summary step count: actual and percentage accuracy, and intraclass correlations between Fitbit and ActivPAL

	12 hour Step count mean (SD)		Error of Fitbit compared to ActivPal		ICC (95%CI)	
Grouping	**Fitbit**	**ActivPal**	**Error (actual)**	**Error (percent)**	**Absolute**	**Consistency**
Diagnosis						
Ortho (n=36)	4957 (3350)	4611 (3195)	-345.4 (947.1)	-13.3(42.4)	.954(0.907, 0.977)	.958(0.920, 0.978)
Neuro (n=27)	3544 (2203)	3319 (2260)	-224.3 (981.8)	-16.2(65.7)	.902(0.799, 0.954)	.903(0.799, 0.955)
other (n=21)	3122 (2138)	3204 (2579)	82.9 (1295.7)	-0.60 (25.60)	.856(0.678, 0.939)	.850(0.668, 0.936)
Gait speed						
Limit community (n=50) (a)	2781 (1603)	2749 (1659)	-32.1 (877.2)	-9.3(59.2)	.858(0.762, 0.917)	.855(0.758, 0.915)
Community (n=34) (b)	5902 (3220)	5457 (3381)	-445.5 (1247.1)	-13.6(24.0)	.922(0.844, 0.961)	.929(0.862, 0.964)
all (n=84)	4044 (2831)	3845 (2821)	-199.4 (1055.6)	-11.0(48.0)	.929(0.892,0.953)	.930(0.894, 0.954)

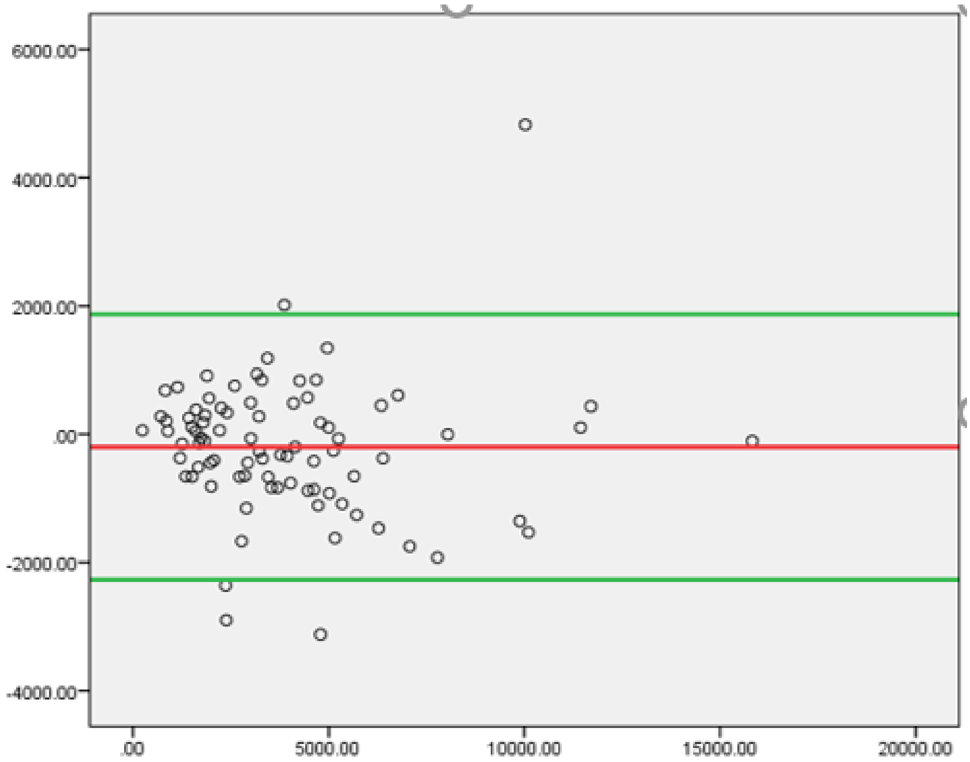
a: Limited community = <0.80m/s

b: Community = >0.80m/s

Table 2 displays the results of the ICC analysis of step counts between the Fitbit and ActivPAL. Overall, the Fitbit and ActivPAL showed excellent step count agreement for absolute average (ICC 0.929) and consistency average (ICC 0.930). Excellent agreement between the Fitbit and ActivPAL remained when ICC absolute and consistency average was analysed in subgroups of orthopaedic, neurological or other condition. When gait speed subgroups were analysed, excellent ICC agreement (absolute and consistency) was seen in both the community and limited community walking speed groups, however the within gait speed percentage agreement was higher in the community walking group than in the limited community walking group. The Bland-Altman plot is presented in figure 2. A comparison of the mean difference between the Fitbit and ActivPAL was not significant (p=0.087). A regression analysis of the difference between step count estimates was not significant, demonstrating no proportional bias (p=0.930), indicating the mean difference did not change at different walking speeds.

Figure 2 –Bland- Altman Plots of step count error of the Fitbit compared to ActivPAL

Actual difference - Fitbit and ActivPAL step count over 12 hour period.



Mean step count of Fitbit and ActivPAL – over 12 hour period

Bland-Altman plots comparing step counts over a 12-hour period: Comparison between the Fitbit and ActivPAL. Red line (middle) indicates the mean difference between the two measures, green lines (other 2 lines) indicate the limits of agreement (1.96 SDs of the mean difference).

4.4 Discussion

This study found that in slow walking rehabilitation patients monitored in a free-living environment, daily step counts, as measured by the Fitbit Zip device worn on the forefoot of the shoe, had excellent agreement to those recorded by the research grade ActivPAL device. Overall, the Fitbit counted more steps in the 12-hour period than the ActivPAL. Subgroup analysis demonstrated that, compared to the ActivPAL, the Fitbit counted significantly more steps in the community walking group (>0.80m/s), as well as in the orthopaedic group.

The results of this study demonstrated a high level of agreement and consistency compared to the ActivPAL. This agrees with the findings from chapter 3 presented in this thesis, of participants walking in controlled conditions, where the Fitbit showed a high level of accuracy and consistency with a manual step count during an indoor and outdoor two-minute walk with a Fitbit attached on the shoe. Although they have a high level of agreement, it is possible that both the ActivPAL and Fitbit under counted steps. It also validates the Fitbit device placement at the foot or distal leg found in this study in controlled conditions, and also in other studies [21, 130] of slower walking (0.40-1.0 m/s) rehabilitation patients in controlled conditions.

In the previous studies, the Fitbit undercounted the step count, and in this study, the Fitbit over counted compared to the ActivPAL. This variation may be explained by the comparator; the current study compared two activity monitoring devices, not to the gold-standard direct observation. The fact that the Fitbit counted more steps overall, and significantly more steps than the ActivPAL when walking at community walking speed, questions which device is most likely to be more accurate. In free-living conditions, most active movement does not involve continuous walking [12], therefore the Fitbit is expected to detect less steps in the free-living environment than observed in controlled conditions of chapter 3 of this thesis and other studies [21, 130]. Also, gait variability is higher with interrupted shorter walks [141]. Incidental, shuffling steps at slower speed result in gait parameters where the Fitbit becomes less accurate [22]. In this study, the Fitbit was worn on the dorsum forefoot section of the shoe, previously shown to potentially increase recording of steps compared to the ankle position [22]. This is explained by the larger angular accelerations provided by the foot action of dorsi-flexion during gait than at either the ankle or thigh [168], resulting in better Fitbit step count detection. While this is a benefit in slow walking populations, essentially amplifying the movement in each step, in faster walkers it potentially results in an over-estimation of step count. The ActivPAL device is recommended by the manufacturer to be worn on the thigh, the location used in this study. For reasons already mentioned, this more proximal location at the thigh may have resulted in the ActivPAL being less likely to record a step count than the Fitbit worn on the foot. The ActivPAL has recently been found to undercount steps compared to the Fitbit (One) and be less accurate when compared to direct observation in slow walking patients [21]. This suggests that in the current study the ActivPAL likely undercounted actual steps and the Fitbit step presented a more accurate count.

This study was large enough to determine that diagnosis played a role in the comparison between the devices; with the devices worn in the orthopaedic group showing a significant overcount in the Fitbit compared to the ActivPAL. This difference was not expected, as the gait speed, cadence, or use of gait aid of this group was not significantly different to other diagnostic groups (neurological or other diagnosis). Exact gait parameters causing step overcount in the orthopaedic group requires further investigation.

A main reason for using activity monitors, particularly during ongoing rehabilitation in the community, is for motivation [165]. The Fitbit can provide instant user feedback by screen display on the device. Clinicians and patients can also monitor step count using a web-based dash board or mobile phone summary reports of daily activity, which are stored long-term. Being able to use Fitbits during rehabilitation in the community, as motivation to improve activity levels may result in improved walking mobility, function and quality of life. Importantly, the accuracy of the Fitbit step count in this study compared to the ActivPAL did not change with the gait speed of the participants; the clinical implication being that the Fitbit can be reliably used at slow gait speeds ranging from 0.40- 1.0m/s. As such, clinicians may use Fitbits via remote services, like tele-rehabilitation, to encourage and monitor walking progression, resulting in health service cost savings and time savings through reduced travel by patients or clinicians.

This study has some limitations. Direct visual observation of step count would be the preferred comparison of accuracy of the Fitbit, however, is not practical in the community. At the time of study design, the ActivPAL, widely used in research, was considered the most suitable comparison device for the Fitbit, however, after data completion, recent research suggests that, in slow walkers, the accuracy of the ActivPAL is slightly lower than the Fitbit in controlled conditions [21]. As a comparator for this study the ActivPAL has positive attributes, including being widely used in research, software and data analysis capabilities, and being a durable and waterproof device [145]. The short data collection period of 12 hours (one daytime of activity), is not considered to impact on data collection. The wear period may be considered short compared to the 5-7 days the ActivPAL has been worn in other studies [174], however this study does not require this long period as it is not measuring time in lying, sitting, standing and transitions, or measuring time in different levels of activity intensity. The data collected in the 12 hours should be representative of most gait alterations from daily activity that could impact step count detection. Data from six participants was excluded, where three participants reported not wearing the Fitbit for the full data collection period.

The size of this study is a strength. A previous study with 12 stroke patients compared the Fitbit to a research-grade Actical device with good agreement [142]. The recruitment of 90 sub-acute rehabilitation patients allowed subgroup analysis, and therefore validation of the Fitbit activity monitor by diagnostic groups. The positioning of the Fitbit on the shoe is a practical position ideal for sustainable use compared to the ankle position used in many studies [20, 130]. The presented study findings demonstrating that the ActivPAL potentially undercounts steps in free-living conditions extend those by Treacy obtained in controlled conditions [21], and should be considered when using the ActivPAL device in field research involving slow community walkers.

4.5 Conclusion

This study is the first to compare the Fitbit activity monitor to the commonly used ActivPAL activity monitor worn in free-living conditions. It is the only study to examine and validate the use of the Fitbit device in neurological, orthopaedic and other general rehabilitation patients. The study results suggest that the Fitbit can be used by rehabilitation patients and their therapists in the community to count steps and potentially as a motivational tool to increase activity levels.

CHAPTER 5
DISCUSSION

5.1 Aims

This thesis comprised two parts, with the main aim of part 1 (Chapter 3) to assess the accuracy of the Fitbit Zip activity monitor when worn on the shoe in slow walking rehabilitation patients under controlled conditions indoors and outdoors, where step count was examined compared to direct observation. Part 2 (Chapter 4), aimed to further assess accuracy of the Fitbit Zip worn in free-living community conditions, with the Fitbit Zip being compared to the ActivPAL activity monitoring device, a device commonly used in research. The overall thesis aims also included analysis of participant gait speed and the influence of gait speed on comparative accuracy of the Fitbit, examined at limited community ambulation (<0.80m/s) and community ambulation (>0.80m/s) speeds. The final common aim was to explore if diagnosis influenced Fitbit step count accuracy, examined by three sub-groups comprised of neurological, orthopaedic and other medical conditions.

5.2 Summary of outcomes

In controlled conditions, we found that the Fitbit undercounted steps compared to direct observation overall, being accurate to within 9%. In free-living conditions, the Fitbit Zip overcounted by an average 11% compared to the ActivPAL. When gait speed was examined by sub-group in controlled conditions, the accuracy of the Fitbit in the limited community group was significantly lower compared to the community walking speed group. In free-living conditions, in the limited community speed group, the Fitbit had a higher percentage agreement to the ActivPAL than in the community speed group.

The studies were large enough (n=88, n=84) with sub-groups powered to demonstrate diagnosis validity for neurological, orthopaedic and other rehabilitation patients. In controlled conditions, the accuracy of the Fitbit was not influenced by diagnosis compared to the manual count. In free-living conditions, although over counting of steps was seen in all diagnosis groups, the Fitbit only counted significantly more steps than the ActivPAL in the orthopaedic group.

There has been growing research validating step count accuracy of commonly used activity monitors in a range of populations including healthy older adults [126, 156]. However, the need for further investigation of activity monitors in slower walking rehabilitation populations has been identified in developing research [127, 157-159]. This study was able to implement some of these recommendations for further research including participants being clinical patients walking at slow natural speeds, walking indoors and outdoors.

5.3 Gait speed overall – indoors, outdoors and free-living

In controlled conditions, with participants walking at their comfortable gait speed indoors and outdoors, the accuracy of the Fitbit device, worn on the shoe, was found to be high at all gait speeds compared to direct observation. The Fitbit step count was slightly less precise indoors than outdoors, however this difference was not statistically significant. The Fitbit undercounted steps compared to the gold-standard direct observation. The undercount may be explained by reduced leg movement in the slower walking population, not eliciting the Fitbit to record a step count [22, 168]. The results on Fitbit accuracy presented in this thesis are comparable to the results of previous studies generally demonstrating undercounting of the Fitbit in controlled conditions with similar gait speed demographics [20-22, 130]. The undercount of up to 11% is considered acceptable in the clinical situation due to consistency of the undercount and the clinician can adjust the patient goals for step count accordingly. In the free-living environment, daily step counts measured by the Fitbit Zip device worn on the shoe at all speeds had excellent agreement to those recorded by the research grade ActivPAL activity monitor device. The Fitbit overcounted steps in the 12-hour period compared to the ActivPAL. The difference may be explained by the study results of Treacy et al [21], with their research showing the Fitbit is more accurate than the ActivPAL device at slower gait speeds. At all gait speeds <1.2m/s their study indicated the Fitbit was more accurate (counting more steps) than the ActivPAL, with the ActivPAL becoming less accurate in slower walkers. The gait speeds in the presented study are similar to those examined in the Treacy study [21], however device location and walking conditions were different. Another recent study, reviewing free-living stroke patients (Hui et al) [142], found the Fitbit to have a higher relative error associated with slower walking speed when compared to an Actical device, another research grade activity monitor. The gait speeds in their study were similar to those of this study, however, the comparator and device location were different and will be discussed later

5.4 Gait speed – community and limited community

When the accuracy of the Fitbit was assessed in gait speed sub-groups, the Fitbit was more accurate in the community walkers than the limited community walkers in controlled conditions, indoors and outdoors, compared to direct observation. The Fitbit undercounted in the controlled community and limited community walking groups, however by contrast it counted more steps in free-living conditions in both gait speed groups compared to the ActivPAL.

To analyse the influence of gait speed on device accuracy, we dichotomised the participants into subgroup speeds based on previous research considered important for community living; (i) >0.80m/s being a predictor for ability to ambulate in the community; (ii) < 0.80m/s being the predictor for limited ability to ambulate in the community (i.e. mainly household walking) [136]. Earlier studies have used gait speeds within this range [20, 22] and with the same matching thresholds [21, 130]. Step count, in controlled conditions, although more inaccurate when worn by the limited community walking group was still accurate to 11%, compared to 6% in the community walking group, a significant difference. As described previously, slow gait speed influences the ability of activity monitors to detect step counts. The triaxial accelerometers of activity monitors used in this study have algorithms set for normal patterns of walking which rely on detecting angular accelerations. The lower accuracy associated with slower gait speed can be explained by the reduced angular accelerations seen in the leg as walking speed decreases [168], and the reduced leg swing speed influencing step count accuracy [21]. The findings of reduced accuracy in controlled conditions in the limited community walking group are comparable with other studies [20-22, 130]. However, this study undercounted steps in both groups, while Treacy et al [21] appeared to find very slight over counting compared to manual observation in their limited community walking group compared to observation by GAITRite electronic walkway. This difference in outcome may be due to the data collection method in this study gathered over a two-minute walk, which may be a more reliable measure for step count [148, 149] than the approximate five metre walkway used by the GAITRite in their study.

When examining gait speed of free-living participants, in the community walkers the Fitbit recorded significantly more step counts in comparison to the ActivPAL, while this was not the case in the limited community walkers. Direct comparison of the step count results between the two parts of the thesis (controlled condition walkers to free-living participants) is not possible due to the different study designs: the comparator in controlled conditions was the gold-standard direct observation, whereas in free-living conditions this was the ActivPAL. While the undercount of the Fitbit in controlled conditions is confirmed, in contrast, the overcount of the Fitbit compared to the ActivPAL found in free-living conditions requires further discussion considering evidence from this study and other literature, to determine the relative accuracy of both the Fitbit and ActivPAL. In the recent study by Treacy et al [21], the ActivPAL was found to undercount steps compared to the Fitbit (One), and to be less accurate when compared to direct observation in slow walking patients [21]. Their gait speeds groupings matched those of this study's community and limited community gait speeds, however the controlled conditions of their study contrasted to the free-living conditions of this study. These findings by Treacy et al [21] may indicate the potential for the Fitbit to also be more accurate than the ActivPAL in the free-living conditions of this presented study.

In free-living conditions, Hui et al [142] compared the Fitbit to the Actical activity monitor, also a research orientated device. In their study the Fitbit undercounted steps compared to the Actical by 8% when walking at speeds faster than 0.58m/s, however the Fitbit overcounted by 27% at walking speeds below 0.58m/s. In this study the Fitbit overcounted steps compared to ActivPAL at both speed groups. However, comparisons between the two studies are limited by the different devices used, the different set point for gait speed group breakdowns (in this study gait speed was set at <0.80 m/s and > 0.80m/s), and the different anatomical location, with both devices in their study at the ankle position. Most literature on device accuracy is from studies in controlled conditions, while walking in free-living conditions is more likely to involve varying gait parameters that may explain the differences seen in this study.

5.5 Gait variability with environment

Gait variability may explain the results when examining step count variance in controlled conditions indoors and outdoors (undercounted) and compared to free-living conditions (over counted compared to ActivPAL). Gait observed in the controlled conditions study exhibited mostly predictable continuous walking, however without direct gait measurements or observation in the free-living participants, there is no objective walking pattern data, and can only rely on literature to provide information on gait variations that may be more unpredictable in the community. Although the outdoor conditions in the controlled study environment followed a walking track, components of environmental conditions seen in the home and community were included, including uneven paving, sharp turns, slopes and narrow walkways. Informal gait observations by the therapist collecting the data included more variability in gait patterns outdoor than indoor, with participants adjusting step length for the changing track surface with short shuffling steps.

Analysis of gait parameters between the device worn outdoors and the device worn indoors showed, non-significant, reduced step length, speed, step count and slower cadence in those walking outdoors. Previous studies in free-living conditions have shown that walking mobility commonly does not involve continuous walking [12], and higher gait variability is expected in the community due to interrupted shorter walks [141]. Activities of daily living including kitchen tasks require smaller steps due to change of direction and confined spaces [175]. The resulting interrupted walks [141, 175] with gait variations including short, shuffling steps [22] at slower gait speed [21, 130] potentially decrease step count accuracy [175]. With regards to device positioning it should be taken into account that lower limb angular accelerations reduce with cadence [168] , a finding reinforced in the Fitbit study by Singh et al [22]. Analysis of walking patterns over the course of a day has shown that in healthy adults most daily activity (approximately 9 hours) occurs with a cadence of 1-59 steps/minute, as incidental movement, sporadic movement or purposeful steps [12], and that only thirty minutes a day was activity with a cadence higher than 60 steps/minute. Therefore, with this type of gait variability the Fitbit is expected to be less accurate in free-living conditions than either in the indoor or outdoor controlled conditions. Even though the Fitbit counted more steps compared to the ActivPAL device, when considering the evidence from these other studies, the Fitbit is likely to be undercounting actual steps, but to be more accurate than the ActivPAL in free-living conditions.

5.6 Device location

In this study the Fitbit was worn on the forefoot section of the shoe, a location previously shown to potentially increase accuracy of step count compared to other distal leg positions [22]. Other studies have demonstrated that in the ankle location the Fitbit accurately counts steps in stroke patients at artificial slow gait speeds [20], with high agreement compared to another activity monitor device (Stepwatch activity monitor) [130], and in general rehabilitation patients [21]. However in the study by Singh et al [22], we compared multiple distal leg positions and found the forefoot on the shoe (dorsum of foot) to be the most accurate position at gait speeds down to 0.40m/s. The Singh et al [22] study was related preliminary research leading up to the work presented in this thesis, conducted in healthy participants, walking at a gait speed which was not their comfortable gait speed. It is the only study to have compared the accuracy of a single activity monitor, in this case the Fitbit Zip, by multi-position comparison at the ankle, lateral top side of shoe, and forefoot of the shoe. The forefoot shoe Fitbit location was found to be the most accurate in the slower walkers. The potential for increased step count accuracy at the forefoot location in slower walkers due to amplified leg movement is supported by Rueterbories et al [168]. They also found that the magnitude of lower limb angular accelerations reduce with gait velocity and cadence, and that with slower gait velocity and cadence, accelerations at the forefoot were largest, significantly more than at the ankle and the thigh, due to the forefoot being the body part having the largest angular acceleration in slow walkers [168]. In slow walkers, the accelerometer algorithm is therefore expected to be more likely to record a step count when the Fitbit is positioned on the forefoot than when the device is positioned at the ankle or thigh. At gait speeds greater than 1.0m/s, the Fitbit positioned in the same location may overcount steps, as it will potentially detect angular accelerations not matching step patterns. The results in this controlled study, which positioned the device on the forefoot of the shoe confirmed those of Singh [22]. It is the first to investigate the combination of the foot position, a clinical population and walking at comfortable gait speeds including outdoors, and this study also confirmed the potential for Fitbit accuracy in free-living conditions.

The ActivPAL device is recommended by the manufacturer to be worn on the thigh, the location used in this study. For similar reasons detailed in the previous paragraph, this more proximal thigh location may have resulted in the ActivPAL being less likely to record a step count than the Fitbit which was worn on the foot. The different device placements may influence the discrepancy in steps recorded between the two devices.

5.7 Device type

The model of Fitbit in this study was the Fitbit Zip, chosen for its features of having a clip for attachment, a display screen for immediate step count feedback, being able to link and upload data to a mobile phone or computer for remote monitoring, affordability, being a consumer targeted device, and having software capabilities for data analysis. Previous investigation of activity monitors in slower walking rehabilitation populations [22, 173, 176, 177] has included a variety of activity monitors. Some activity monitors such as the Stepwatch activity monitor [132], ActivPAL and Actical are designed for research and do not provide immediate feedback, are more expensive, but have more comprehensive data analysis software. The Stepwatch activity monitor [175] is considered the gold-standard in terms of step count accuracy, however is very expensive which prohibited its use in this study as a comparison device for the Fitbit Zip in free-living conditions. For the study design in free-living conditions, the ActivPAL was selected, a device widely used in research and regarded as accurate [144, 145]. Only since commencement of this study has research indicated the Fitbit may be more accurate than the ActivPAL in slower walkers [21]. Even so, the research grade features of the ActivPAL, including data analysis, ability to tape the device to the individual, and waterproofing to allow 24-hour wear time, were essential to this study. The Fitbit family of activity monitors are consumer devices including wrist worn and clip on models, and in recent years the clip on Fitbit models have become more prominent in research of step count accuracy in slower walkers [20-22, 130]. The Fitbit One [20, 21, 130] and Fitbit Zip [22], although different devices, are similarly designed to attach by clip and measure step count by proprietary algorithm. Both models have triaxial accelerometer technology with the underlying algorithms developed based on the recommended anatomical positioning of the Fitbit, gait speed, and gait patterns most common in the healthy population. The algorithm for step count detection of angular accelerations for both models is expected to be the same, therefore making no difference in sensitivity to step count.

5.8 Demographics

The Fitbit has been previously validated in healthy participants [137], and this study is amongst the first to assess accuracy in clinical populations. This study included neurological (mainly stroke), orthopaedic (mainly hip fracture and hip and knee arthroplasty) and patients of other diagnosis in the sub-acute phase of rehabilitation in outpatient settings. Another recent study [21] also included clinical populations, however the participants were general rehabilitation patients, and from an inpatient setting. The recruitment from the outpatient setting allowed us to firstly observe the participants' step count accuracy wearing the Fitbit in controlled conditions, and then secondly compare the same participants continuing to wear the Fitbit in the community in free-living conditions. Patients in the study by Treacy et al [21] were slightly older (mean 80 years of age, compared to 73) than participants in the current study, which may be explained by the higher percentage of orthopaedic participants, and in particular high proportion of potentially younger elective total hip and knee arthroplasty patients, commonly seen in outpatient settings.

Actual gait speed observed in the two-minute walk of this study was different to the 10-metre indoor walk test gait speed results taken from patient records and used as an inclusion criterion. This may reflect the variation and progression expected in a clinical population. The gait speed eligibility criterion was 0.50m – 1.0m/s, and gait speed of all participants was within this range on recruitment, based on data collected from patient records. However, gait speed measured from the two-minute time walk observations ranged from 0.38 – 1.29 m/s. Participants' gait speed may have increased or decreased with potential reasons including; the extra endurance required for a two-minute walk test; progression of walking ability since the original 10-metre walk test; variance in walking due to the indoor or outdoor environment, or due to less gait variability seen in longer walks [141]. Fifty-nine percent of participants in this study were categorised as limited community walkers. The gait speed range was reflective of gait speeds reported in clinical rehabilitation patients elsewhere; of any diagnosis (0.58m/s) [155], stroke 0.18-1.03m/s [58, 157], and orthopaedic 0.53 to 0.64m/s [153]. Unlike a recent study [21] in which gait speed of participants was very slow (mean .42, SD 0.22; 0.04-1.17), with almost 50% of their participants walking slower than 0.40m/s (with resulting inaccuracy of step counts below 0.40m/s), this study focussed on gait speeds above the level which we have previously shown the Fitbit to not record any steps [22].

5.9 Limitations

This study had some limitations. The participants' gait speed varied slightly from recruitment with changes in gait speed from time of recruitment until time of data collection, with some participants walking faster and some slower. These changes may be due to natural variations in walking or changes in functional ability between the 10-metre walk test and participation in the study. However, having a slightly slower gait speed (0.38m/s) than our original criteria of minimum gait speed of 0.50m/s agreed with the gait speed of 0.40m/s found in a recent study by Treacy et al [21] where the Fitbit appeared to be accurate.

In the controlled conditions of this study, participants' gait speed was assessed over a two-minute walk at their natural speed. Although not analysing gait speed by a pressure sensor walkway such as using GAITRite software analysis [178], gait speed data was collected over a longer distance. The GAITRite analyser [178] measures temporal spatial parameters of gait via an electronic 4.88 metre walkway mat. The two-minute walk observations of gait parameters allowed participants to take more steps for data analysis, a minimum of 101 steps being recommended [148, 149], to improve the reliability of step count data. The participants took an average of 199 steps (SD 24; 134-248) walking indoors during the two-minute walk. Further reasoning for the two-minute walk observations compared to a GAITRite is the purposeful continuous walking, which may be more indicative of the type of training walk undertaken by a rehabilitation patient and providing more clinical validation for step count measurement of this type of activity.

In free-living conditions, it is acknowledged there are unknown activity types, environments and the gait parameters associated with those activities. An example of changing gait parameters depending on the activity and environment is demonstrated by stroke patients' gait speed reducing from 0.70m/s in the controlled clinic to 0.60m/s in a shopping mall, while cadence varies from 88 steps/minute in a controlled clinic, 82 steps/minute on a footpath, and 80 steps/minute in the shopping mall [166]. Other examples include kitchen activities and home walking, which include shorter step length and short bouts of steps where gait speed and total number of steps will be lower [175]. This will influence the accuracy of the Fitbit activity monitor device.

In free-living conditions, direct visual observation of step count would be the preferred comparison to determine the accuracy of the Fitbit, however this is not practical throughout a whole day in the community. The ActivPAL was selected at study design as the activity monitor for comparison due to being widely used in field research and the most suitable for wearing the device over a 24 hour period when considering device accuracy, cost, and features including having research grade software and data analysis capacity; being a durable and waterproof capable device; and being available to use from within our research group [145]. However, since commencement of this study, research has indicated the ActivPAL has slightly lower accuracy than the Fitbit in counting steps in slow walkers [21]. An alternative comparison option is the Stepwatch activity monitor (Orthocare Innovations, Oklahoma City, Oklahoma) [132]. At the time of this study design, the ActivPAL device was considered the most appropriate comparator available, with the Stepwatch activity monitor not considered due to being very expensive.

Although data was collected over only one day (period of 12 hours of wake time) in free-living conditions, this period of data collection is considered enough to capture the main activities of daily living and associated stepping. The wear period may be considered short compared to the 5-7 days the ActivPAL has been worn in other studies [174], however this study does not require this long period as it is not measuring time in lying, sitting, standing and transitions, or measuring time in different levels of activity intensity. Therefore, the step count data collected should include steps taken during different activities and the opportunity to measure step count in altered gait patterns and speed associated with these activities.

5.10 Future research directions

The outcomes from the step count analysis in controlled conditions within this thesis may assist clinicians and researchers on the use of the Fitbit Zip for counting steps based on gait speed, diagnosis and gait parameters in controlled purposeful walking conditions indoors and outdoors. In free-living conditions, the results have provided important findings when compared to another activity monitor. There are several studies which may be undertaken to potentially analyse gait parameters in more detail and add to the findings of the work presented in this thesis. The future research directions will be discussed with reference to the Fitbit step count in controlled environments indoors and outdoors and in free-living conditions.

In controlled walking conditions, step length, cadence and gait speed data were gathered. A future study could examine spatial and temporal gait variations. Temporal (single leg support time) asymmetries are reported in patients with moderate stroke and impact on gait speed [58], while abnormalities including asymmetries of gait are also shown to be present in the orthopaedic rehabilitation population [94, 95]. To thoroughly examine the influence of gait variations on Fitbit accuracy, the GAITRite analyser [178] could be used in a similarly designed study in controlled conditions in the future. The GAITRite has the advantage of providing additional data on duration of step and stance phase, and leg swing velocity during gait that may explain difference in device accuracy in free-living conditions, in particular, the differences seen in the step count of the Fitbit compared to ActivPAL in the orthopaedic group. Investigations by Treacy et al [21] found that duration of step and stance phase did not have a strong influence on the accuracy of the Fitbit in slow rehabilitation patients, although velocity in the swing phase of the leg did affect accuracy. However in contrast to the study in this thesis, the Treacy study [21] did not examine the more distal forefoot shoe location of the Fitbit.

In free-living conditions, the actual number of steps taken by the participant is not known. Gait parameters in free-living conditions are expected to vary from the gait parameters and step count seen in controlled environments. Further investigation of Fitbit step count accuracy is required in a variety of different environments and activities commonly seen in the home and community. This would require step count to be assessed by either direct observation or video analysis based on walking in a range of environments, such as within the house, in the garden, down the street, and in a shopping centre. Common activities may be observed in a similar fashion, beginning with simulation of activities of daily living including bathroom, kitchen and household tasks including cleaning, and progressing to clinical rehabilitation participants. The GAITRite or similar sensor mat and data analyser may be an option to examine step counts if some of these activities of daily living tasks are able to take place on a sensor mat. Although not the gold standard that direct observation provides, the Stepwatch activity monitor may be the next best option. It has been used in step counting of tasks commonly undertaken including kitchen activities, rising from a chair, and home walking, and was found, by video analysis, to be 96% accurate [175]. While the Fitbit (One) has been shown to be accurate to within 7% of the Stepwatch activity monitor at similar gait speeds to the controlled walking participants in this study, this was not in free-living activities [130]. The Stepwatch activity monitor has some limitations, such as being a very expensive research device and not having an immediate display feedback option. However, the device does conveniently attach to the ankle area and has comprehensive software and data analysis features. In the free-living conditions of this current study, data was collected during one day of 12 consecutive waking hours. Future research could extend this period to 3-4 days (12 waking hours daily) to ensure that more activities of daily living are included in the investigation [142]. To strengthen findings future research could also compare the Fitbit and ActivPAL activity monitor step counts by direct observation firstly in controlled conditions then follow the same participants, comparing the activity monitors in non-observed free-living conditions.

5.11 Conclusion

Hospital and health system key performance indicators are closely monitored and analysed [179]. At the clinical and rehabilitation setting level, reporting of patient activity levels, functional and walking mobility gains, and monitoring of patient length of stay in rehabilitation is required [5]. Demand for rehabilitation services are increasing with the ageing population, placing increased pressure on rehabilitation centres to achieve good functional outcomes, to reduce length of hospital stay, and returning patients to normal activities as soon as possible, thereby reducing care service needs. Maximising patient activity during their rehabilitation period is therefore important, with walking being the most common goal for rehabilitation patients and therapists.

The accuracy of relatively new methods of monitoring patient activity levels, particularly step counts when walking, were examined in this thesis. Activity monitors are increasingly being used in the clinical population and a commonly used consumer device is the Fitbit. First, the accuracy of the Fitbit Zip was observed and confirmed in rehabilitation patients walking in controlled conditions indoors and outdoors at gait speeds as low as 0.40m/s. Upon further analysis at the two walking speeds used to determine community ambulation (>0.80m/s) or limited community ambulation (<0.80m/s), the Fitbit was found to be accurate. Second, the Fitbit Zip was compared to a research-based device, the ActivPAL with excellent agreement in step count when worn in free-living conditions in the community. The study results suggest that neurological, orthopaedic or patients admitted for other medical conditions can use the Fitbit with accurate step counts.

Future studies should consider the findings of potential gait variability in free-living conditions, including the shorter step length, duration of step bouts and reduced gait speed, and the highlighted need for further research in this area to clarify validity of the Fitbit Zip in activities of daily living and walking in other environments commonly occurring in the community.

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APPENDIX A: SOUTHERN ADELAIDE CLINICAL HUMAN RESEARCH ETHICS COMMITTEE CERTIFICATE OF APPROVAL

Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Final approval for ethics application

You are reminded that this letter constitutes **ethical** approval only. **Ethics approval is one aspect of the research governance process.**
You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form has been authorised by the Chief Executive or delegate of each site.

07 March 2017

Dr Maayken Van Den Berg
Rehabilitation Aged and Extended Care
C Block
Repatriation General Hospital
DAW PARK SA 5041

Dear Dr Van Den Berg

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this application which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research.*

Application Number: OFR # 32.17 - HREC/17/SAC/60

Title: Accuracy of the fitbit activity monitor in sub-acute rehabilitation patients with different walking speeds and gait patterns

Chief investigator: Dr Maayken Van Den Berg

Approval Period: 07 March 2017 to 07 March 2020

Public health sites approved under this application: Repatriation General Hospital

The below documents have been reviewed and approved:

- Low and Negligible Risk Research form AU/15/21FB28 dated 20 February 2017
- Participant Information Sheet/Consent Form v3 dated 06 March 2017
- Letter of Support from A/Prof Craig Whitehead, Director, Division of Rehabilitation, Aged Care and Allied Health dated 16 December 2016

TERMS AND CONDITIONS OF ETHICAL APPROVAL
As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval only covers the science and ethics component of the application. A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).

4. To immediately report to SAC HREC anything that may change the ethical or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.

Kind Regards

A/Professor Bernadette Richards
Chair, SAC HREC

APPENDIX B: CLIENT PARTICIPANT INFORMATION FORM

Government of South Australia
SA Health

Flinders UNIVERSITY

Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Title	Accuracy of the fitbit activity monitor in rehabilitation participants
Protocol Number	*32.17*
Coordinating Principal Investigator/ Principal Investigator	*Dr Maayken Van den berg*
Associate Investigator(s)	*Craig Farmer* *Dr Chris Barr*
Location	*Repatriation General Hospital*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project; "*Accuracy of the fitbit activity monitor in rehabilitation patients*". This is because you are currently participating in a rehabilitation program at Repatriation General Hospital which includes walking activity.

The fitbit is a device that tracks the steps you take during the day. Accuracy of activity monitors such as fitbits are of significant importance as they are used in rehabilitation to motivate, monitor, and increase physical activity levels to assist patients return to their normal function. Slow walking speeds may impact on the measurement accuracy of the fitbit.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the research 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 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 the research that is 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?

The aim is to determine the accuracy of the fitbit activity monitor in counting steps at different walking speeds including indoors, outdoors and in daily function at home or in the community during rehabilitation. There are currently no guidelines for clinicians around the use of the fitbit. The information gained from this study will help to develop recommendations to guide therapists, researchers and patients on the use and accuracy of the fitbit in hospital and community rehabilitation.

The results of this research will be used by the study investigator Craig Farmer to obtain a Masters degree.

This research has been initiated by Maayken Van den berg

3 What does participation in this research involve?

If you are willing to participate you will sign a consent form.

You will be asked to complete 2 walking tests: one indoors two-minute walk, at your own comfortable walking speed, and one outdoors two-minute walk at your own walking speed. During the indoor walk you will walk over a special mat which provides us with information about your walking pattern. You will be wearing a fitbit activity monitor during both indoor and outdoor walking tests. This session will last for approximately 45 minutes.

You will then be asked to continue to wear the fitbit activity monitor along with a second activity monitor (named activPAL) for comparison at home for one full day. You will be asked to return the activity monitors when you next attend at the Hospital for rehabilitation.

You will not be required for any further follow up.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.
There are no costs associated with participating in this research project, nor will you be paid.

4 What do I have to do?

You will be asked to attend the Repatriation General Hospital for approximately 45 minutes. You will wear a fitbit activity monitor attached to your shoe. You will then be asked to walk once indoors for two minutes, and once outdoors for two minutes. You will then be asked to continue to wear the fitbit activity monitor (attached to your shoe) along with an activPAL activity monitor (attached to your thigh) at home for one full day (the next day). You will be asked to return the activity monitors when you next attend at the Hospital for rehabilitation.

You will not be required for any further follow up. You should undertake all your normal activities.

5 Other relevant information about the research project

We will recruit approximately 90 patients receiving day rehabilitation services for this study. The project will be completed by September 2017.

This research project follows up a similar but smaller project that did not include community rehabilitation patients.

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.

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 or Flinders University.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital.

8 What are the possible benefits of taking part?

There will be no clear benefit to you, however the information from this project will provide some information as to whether these activity monitors are useful during rehabilitation in a clinical and community setting.

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

There are minimal risks involved in the study. We ask you two walk twice for 2 minutes. If you feel tired you can rest at any time. The study will be conducted in the grounds of the Repatriation General Hospital; in the unlikely event of injury suitable medical attention will be provided.

13 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the 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.

14 What happens when the research project ends?

At completion of the project you are not required to do anything else. If you would like a copy of the results you can request a copy from the researchers.

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 researchers 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 information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Data files will be managed using unique identification numbers for each participant and no personal information will be made available to other researchers or third parties. Personnel with access to the non-identifiable data include the investigators. Upon completion of the study all information will be retained for 15 years in accordance with NHMRC guidelines. All personal data will be stored securely in a locked filing cabinet in the Department of Rehabilitation, Aged and Extended Care and there will be password protected access for computer data storage.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Publication of the results will be sought in peer-reviewed scientific journals.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research 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 project and for the future research described in Section 16 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.

18 Who is organising and funding the research?

This research project is being conducted by Dr Maayken van den Berg, Department of Rehabilitation & Aged Care, and is being funded by Flinders University.

No member of the research team will receive a personal financial benefit from the participant's involvement in this research project (other than their ordinary wages).

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 the Southern Adelaide Local Health Network.

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

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project, you can contact the principal researcher Dr Maayken van den Berg on 8275 1297 or 0422060264.

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	Villis Marshall
Position	Director, Office for Research
Telephone	8204 6453
Email	Health.SALHNofficeforresearch@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	Damian Creaser
Telephone	8204 6453
Email	Health.SALHNofficeforresearch@sa.gov.au

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

Position	Research Governance Officer
Telephone	8204 6139
Email	Health.SALHNofficeforresearch@sa.gov.au

Consent Form - *Adult providing own consent*

Title	Accuracy of the fitbit activity monitor in rehabilitation participants
Protocol Number	*32.17*
Coordinating Principal Investigator/ Principal Investigator	*Dr Maayken Van den Berg*
Associate Investigator(s)	*Craig Farmer* *Dr Chris Barr*
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 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 project 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 ______________________

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness to informed consent is required*

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.

Declaration by Study Doctor/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 Doctor/ 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.

Form for Withdrawal of Participation - *Adult providing own consent*

It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary.

Title	Accuracy of the fitbit activity monitor in rehabilitation participants
Protocol Number	*32.17*
Coordinating Principal Investigator/ Principal Investigator	*Dr Maayken Van den Berg*
Associate Investigator(s)	*Craig Farmer* *Dr Chris Barr*
Location	*Repatriation General Hospital*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *Flinders University*.

Name of Participant (please print) ______________________________

Signature ______________________ Date ______________________

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) ______________________________

Signature ______________________ Date ______________________

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

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