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A randomised controlled trial to measure the effects of an augmented prescribed exercise programme (APEP) for frail older medical patients in the acute hospital setting

Ruth McCullagh

A thesis submitted to the National University of Ireland, Cork, for the degree of Doctor of Philosophy in the School of Medicine

October 2017

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ABSTRACT

Older adults experience prolonged hospital stays and are at risk of functional decline following hospitalization. The aim of this thesis was to measure the effectiveness of additional exercises on length of stay, physical performance and quality of life for frail older medical inpatients.

The thesis was divided into three phases in order to (1) identify a suitable and accurate motion sensor to measure walking in hospital, (2) measure walking in hospital, and (3) measure the effectiveness of an augmented prescribed exercise programme for frail older medical inpatients in the acute setting (Randomised Controlled Trial).

Phase 1 consisted of a scholarly review and a validation study. The scholarly review was conducted to identify an accurate accelerometer to measure walking in frail inpatients. While no motion sensor had been validated, two accelerometers and three pedometers showed promise of accuracy. A validation study was then completed on three of these sensors (n=32). While two showed poor accuracy, the third showed acceptable accuracy.

In Phase 2, the accelerometer was used to measure the association between walking (step-count) and (1) length of stay, (2) physical performance and (3) potential influencers of walking (n=154). A crude association existed between walking and physical performance. However, the association was lost when the model was adjusted for physical performance at baseline. A crude association also existed between walking and length of stay and this remained when adjusted for many potential confounding variables. Every 50% more walking was associated with a 6% shorter length of stay. Better physical performance on admission predicted more walking by 15% while assigned bed-rest and tethering treatments were associated with less walking by 70% and 30% respectively.

In Phase 3, the effectiveness of an augmented prescribed exercise programme was measured (n=190). The primary outcome measure was length of stay. Until discharge, twice daily exercise sessions were delivered; strengthening and balance exercises to the intervention group, and stretching and relaxation exercises to the control group. At discharge, one third of patients were transferred to sub-acute care. The intervention group experienced less hospital days and there was a 30% reduction in length of stay in those who had been discharged directly home, however, the model (with only 58% of the power-calculated number of observations) failed to reach significant significance (n=128), (HR 1.3 (CI 0.90-1.87) p=0.1). Benefits in physical performance at discharge (β 0.88 (CI 0.2-1.57) p=0.01) and quality of life at follow-up (β 0.28 (CI 0.91-0.47) p=0.004 were detected. Less negative events (pooled falls, prolonged hospital stays, deaths and admissions to long-term care) occurred in the intervention group (OR 0.42 (0.2-0.92) p=0.03, *post hoc analysis*).

The results of this thesis showed that older medical patients are inactive in hospital, and this inactivity is associated with length of stay. The additional exercises improved physical performance and quality of life. Its effect on length of stay remains inconclusive.

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GLOSSARY OF ABBREVIATIONS

6-CIT: Six-Item Cognitive Impairment Test

ActivPAL3: AP3

APEP: Augmented Prescribed Exercise Programme

CIRS-G: Cumulative Illness Rating Scale – Geriatrics

EQ-5D-5L: EuroQol 5-Domain 5-Level Scale

FES-I: Falls Efficacy Scale International

IRQ: Interquartile Ranges

ICC: Intra-Class Correlation

METS: Metabolic Equivalents

M/sec: Metres Per Second

N-EADL: Nottingham Extended Activities of Daily Living Scale

PA: Physical Activity

%: Percentage

PI: Principal Investigator

STEP: Piezo Step MV

RA: Research Assistant

RPT: Research Physiotherapist

SAM: Stepwatch Activity Monitor

SHARE-FI: Survey of Health, Aging and Retirement in Europe Frailty Instrument

SPPB: Short Physical Performance Battery

DC: Measurement taken at discharge

FU: Measurement taken at follow up

LOS: Length of Stay

DECLARATION

This is to certify that the work I am submitting is my own and has not been submitted for another degree, either at University College Cork or elsewhere. All external references and sources are clearly acknowledged and identified within the contents. I have read and understood the regulations of University College Cork concerning plagiarism.

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Ruth McCullagh

1 Background and Introduction

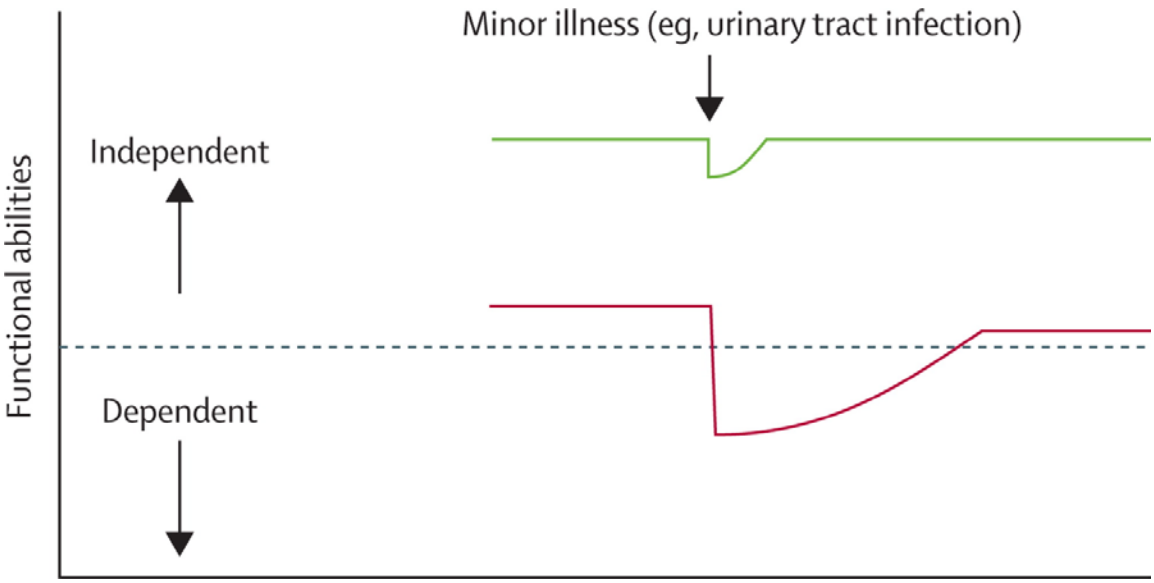
1.1 Introduction

The number of older adults living in Ireland is increasing significantly, with those aged 65 years and older estimated to almost double to around one million people by 2031. The greatest proportional increase will be in those aged 85 and over[1]. In the 75 years and older group, 49% and 51% of males and females respectively report some or severe limitation in usual activities due to health problems[1].

Patients aged 65 and over occupy over 50% of all acute hospital beds[2] and experience prolonged hospital stays, whilst those aged 85 years and over experience an average length of stay of 14 days [2]. Frail adults are potentially more at risk of these negative outcomes, with a slower recovery rate and a poorer chance of returning to premorbid independence (Figure 1.1)[3].

1.2 Frailty, co-morbidity, and disability

Frailty has been described as a state of high vulnerability for adverse health, and results in muscle wasting, loss of endurance and mobility, slow performance and weight loss[4]. Rates are reported to be between 55% in adults aged 65 years, and 96% in adults aged 90 years and over. The onset of frailty predicts a 3-year progression or incidence of both mobility and functional decline[5].



Legend: The green line represents a fit elderly adult, whilst the red line represents a frail elderly adult. The fit elderly patient recovers quickly to premorbid independence, while the frail adult recovers slower and without full recovery of independence (Clegg et al. [3])

Figure 1.1: Frailty and acute illness

Fried et al. [6] has stated that although frailty, co-morbidity and disability are each independently associated with increased healthcare utilisation, they also have a negative aggregate effect on recovery (Figure 1.2). Inactivity, leading to muscle weakness has been identified as a major determinant in the onset of frailty, and exercise has been found to prevent or slow down this decline[6]. Therefore, it is reasonable to assume that inactivity in hospital will have detrimental effects on recovery of independence.

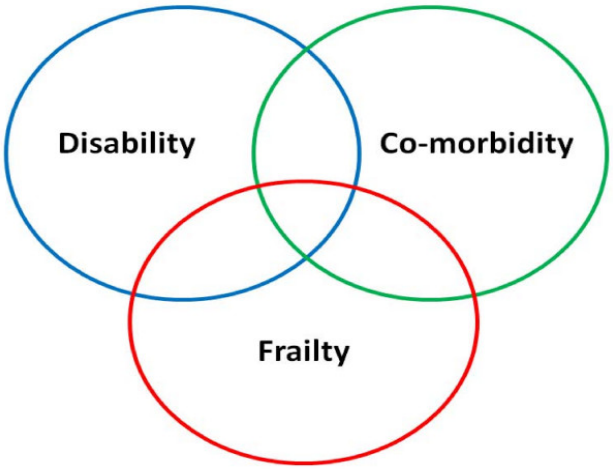


Figure 1.2: Frailty, co-morbidity and disability

Evidence has shown that about one third of patients aged 65 and over lose functional independence following an acute hospital admission [7, 8]. Recently, this has been characterised as a post hospital syndrome – an acquired, transient period of vulnerability [9]. Covinsky et al. [7] described the outcomes of this vulnerability to include loss of independence, with a higher risk of readmission, falls and institutionalisation.

The determinants of these negative outcomes can be described as either modifiable or non-modifiable. Traditionally, clinicians have focused their treatment on the presenting complaint and haven't considered the interventions in hospital as the overarching cause of functional decline. However, more recently, there has been a call to reduce interventions in hospital which may contribute to functional decline, such as fasting for examinations and limited physical activity[10], and to limit additional stresses patients experience, such as poor sleep and altered nutrition[9] . It is reasonable to assume that most patients use walking as their main form of PA in hospital, especially in the acute setting (with minimal

rehabilitation equipment available). Therefore, this review will focus on the evidence that limited walking in hospital exists, and that lack of walking, exercise or PA are key determinants in negative outcomes.

1.3 Limited walking in hospital

In an effort to measure walking activity in hospital, researchers have used self-report [11], direct observation [12], accelerometers measuring time spent in the upright position (suggesting but not proving that the wearer is walking rather than simply standing), [13, 14] and step-count [15, 16]. All results indicated that medical patients walked very little in hospital. Zisberg et al. [11] found that 35% of ambulatory patients (n=525) did not leave their room to walk. Similarly, Kuys et al. [12] observed that patients (n=102) spent 88% of their day in their room. Brown et al. [13] observed only 27% of patients (n=46) walking in the hospital hallways. The studies using accelerometers reflect similar results. Pedersen et al. [14] found that ambulatory patients (n=46) spent only one hour per day standing/walking. Fisher et al. [16] reported that patients (n=239) walked an average of 740 steps, while Ostir et al. [15] reported a range from 478 steps on the first full day of hospitalisation, to 847 steps on the last (n= 224). It is estimated that 600 steps equated to approximately twelve minutes of walking in older slower walkers[17]. Therefore, using a variety of methods to measure walking, the results all indicate that inpatients are very inactive.

1.4 The association between in-hospital walking and length of stay

Observational studies have measured the association between walking and health outcomes in this cohort. Shadmi, Zisberg [18] found that patients who walked outside of their room daily (rather than just around

their room) tended to stay in hospital 1.5 days less. Fisher et al. [16] found those patients who increased their step-count from their first to their second day in hospital by 200 steps, tended to stay in hospital for 2 days less. Both these studies show the importance of in-hospital walking as a marker of reduced stay; in that more walking was associated with a shorter hospital stay, but it does not prove that walking caused the reduced length of stay, rather than other factors.

However, gaps in our knowledge still remain. Firstly, these studies were not European and currently, no data describing walking activity in hospitals in Ireland or the United Kingdom exists. Secondly, Fisher et al. [19] found that a considerable increase between the first and second day of walking is associated with a shorter length of stay; however, only 32 of the 162 patients increased their walking activity to that level. Therefore, these questions remains; is it possible to identify those patients on admission who *will* be least active in hospital, can the association between adverse events and limited activity in hospital (ie. step-count) be explored further, and finally, is there an effective way to prevent this from happening? Objective measurements of walking using motion sensors could be more accurate [19] and less burdensome for staff than direct observation when examining these questions [18].

1.5 The association between in-hospital walking and physical performance

To date, no study exists measuring the association between walking activity and physical performance (ie, the persons' ability to balance, stand and walk). However, a few studies have examined the relationship between in-hospital low mobility and functional independence (ie, the ability to complete tasks such as feeding, dressing, washing etc.). Zisberg et al. [11] found that patients (n=525) who reported not walking outside

their room had nearly four times greater risk of declining in activities of daily living independence and nearly three times greater risk of declining in instrumental daily activities during their hospital stay. Brown et al. [20] found similarly that patients (n=498) who walked infrequently and with assistance in hospital, had 2.5 times greater risk of losing functional independence than independent frequent walkers.

Both of these reported the association between mobility and functional independence, rather than walking activity and physical performance. They both relied on patient and nursing reports, which are known to be erroneous. However, they both found that low mobility is associated with functional loss. Whether simple walking is associated with physical performance at discharge, remains unclear.

1.6 The effectiveness of exercise interventions to improve healthcare utilisation and patient outcomes

Good balance, strength and walking skill are required to walk confidently and safely therefore, can hospital-based exercise programmes addressing these impairments, make a difference? Two recent meta-analyses present the effectiveness and feasibility of additional exercises for acute geriatric patients [21, 22]. They examined the effectiveness of a multidisciplinary programmes (which included a geriatrician, nurses, social worker, occupational therapist and physiotherapist) with an additional exercise intervention, or usual care with an additional exercise intervention. One trial measured the effectiveness of usual care with a hospital mobility (i.e. walking only) programme.

1.6.1 Multidisciplinary interventions including an exercise component

Many studies have found improvements in physical performance, functional independence and healthcare utilisation with a multidisciplinary programmes including an exercise programme [23-28]. While most reported similar costs to usual care, with one reporting a reduced cost [27], they require a considerable change in practice to set up and implement, especially in an acute hospital where many older medical patients are under the care of a medical physician, rather than a geriatrician. Therefore, examining the effectiveness of a simple and easy to implement, exercise intervention, is indicated.

1.6.2 Additional Exercise Programmes only interventions

Six studies measured the effectiveness of additional exercises [29-33]. Three studies examined the effectiveness of exercises only delivered while in hospital [30, 31, 29], while one other study had a slightly different intervention; the exercise programme began in hospital and continued at home with nurse-led support [32].

Courtney et al. [32] examined the effectiveness of a physiotherapy-prescribed exercise programme that was supported in the hospital and continued at home with nurse-led support (n=124). They found that the intervention reduced readmission rates (47% in the control group versus 22% in the intervention group) and improved patients' self-reported quality of life for the subsequent 6 months. Patients were recruited if they were able to walk independently and if they were living independently in the community, suggesting that very few would be categorised as frail.

de Morton et al. [30] found that twice daily exercise interventions in older inpatients (n=236) did not affect activity limitation, adverse events or healthcare utilisation. To prescribe the exercises, the physiotherapist chose the most suitable programme from a selection of four: lying, sitting, standing and stairs programmes, which were primarily strengthening and mobility exercises. The programme was then further tailored for each patient. The programme was delivered by an allied health assistant. Suggested reasons for the limited effectiveness were short average lengths of stay (five days in the intervention and six in the control group) and the use of the Timed Up and Go, where 27% of patients were unable to stand independently (and therefore, a baseline score was unattainable) on admission. Interestingly, 47% of patients were independently mobile.

Jones et al. [31] using a similar exercise programme for older inpatients (n=160), found an improvement on length of stay and functional performance. Further analysis revealed that it was most effective for patients with poorer physical performance. It is also important to note that the exercise intervention was continued from the acute into the sub-acute setting; whereas, in all the other studies, the intervention was provided in the acute setting only.

Siebens et al. [29] found that an additional exercise programme for older inpatients (n=300), delivered in the hospital and supported by telephone for one month post-discharge, improved functional performance one month post-discharge only. The exercise programme consisted of stretching and strengthening, completed while sitting and with no additional weights, and mobility exercise. They found that it had no effect on length of stay, and only 19% of patients reported continuing the exercises independently at home. Once again, 55% were independently mobile on admission. The authors' reasons for the limited effectiveness was the limited intensity of the exercise intervention.

And finally, a small pilot study was completed in the Mercy University Hospital, when 40 patients were allocated to either the exercise group (usual care augmented with twice-daily exercise sessions) or the control group (usual care only). At discharge, the intervention group had better physical performance and self-reported quality of life, with a median reduction of 2 days length of stay [34].

While it is clear that exercise and mobility are important, there are a number of factors which may have contributed to the limited evidence of effectiveness. Issues the authors reported included using the Timed Up and Go test as an outcome measures, inclusion of patients who were independently mobile and the intensity of the exercise programme. These suggest that frailer patients are most at risk, the exercise intensity should be both challenging, and safe, and the outcome score should not require patients to stand up independently on admission.

1.6.3 Hospital Mobility Programme

Brown et al. [35] measured the effectiveness of a mobility programme in hospital on functional ability and mobility at discharge and at one month follow-up. Patients (n=110), aged 65 years and older, were independently mobile (with or without a walking aid, two weeks before admission). The mobility programme consisted of twice daily sessions to assist patients to walk, as well as a behavioural intervention strategy to increase the patients' independent mobility. Both were delivered by a research assistant. The intervention group had a longer median hospital stay (3.6 days versus 4.6 days) but this was not significant and the programme had little effect on functional ability. However, after discharge, patients in the control group had lost their community mobility, while the intervention group maintained their levels.

1.6.4 Conclusions from the literature

The research has shown that walking is important while in hospital, however, three questions still remain unanswered. Firstly, how active are older medical inpatients in the acute hospital setting in Ireland? Secondly, which patient group that are affected negatively by limited walking in hospital? And finally, do additional exercises for the identified patient-group improve health outcomes in the acute setting?

1.7 The aim and objectives of the thesis

The overall aim of the thesis was to measure the effectiveness of an augmented prescribed exercise programme on patients' physical performance, healthcare utilisation and quality of life in frail older medical in-patients.

The objectives were

- To identify an accurate motion sensor to objectively measure walking activity in frail older people in hospital
- To identify those patients on admission who are least likely to walk in hospital
- To measure the association between walking and negative health outcomes, namely, prolonged length of stay and poor physical performance
- To identify modifiable influencers to patients' walking in hospital
- To measure the effectiveness of an augmented prescribed exercise programme on hospital utilisation (length of stay and readmission rates)
- To measure the effectiveness of an augmented prescribed exercise programme, physical performance and quality of life at discharge and at three months following discharge

1.8 Introduction to the project structure

In order to examine these questions, the project was divided into three main phases (Figure 1.3). With limited rehabilitation equipment in the acute hospital, the most accessible form of physical activity for patients is walking. In order to explore the relationships between walking activity in hospital and health outcomes, a valid and feasible method of measuring walking was required. It was anticipated that the patients' self-report would be unreliable, as up to 30% of older medical patients experience delirium on admission to hospital[36], and nurse-reported walking activity would not be feasible as the acute wards are simply too busy. Therefore, the aim of the first phase was to identify a suitable accurate motion sensor for hospital use (Figure 1.3, Phase 1). Firstly a scholarly review was conducted (Chapter 2) which showed that two motion sensors had been validated to measure time spent in the upright position (suggesting time spent walking) but none had been validated to measure absolute step-count (which could be more clinically meaningful). It was thought that step-count may possible give clinicians a clearer indication of patients' recovery of independent walking, rather than time-spent-upright. Therefore, a validation study of motion sensors was indicated. The review highlighted three motion sensors that were most promising for use older inpatients. These were then tested (Chapter 3), and one showed reasonable accuracy, meaning that it was possible to objectively measure walking activity in hospital.

The aim of the second phase of the study was to explore the relationships between objective walking activity, patient presentation and negative health outcomes (Figure1.3, Phase 2). This information would not only inform healthcare but also identify the patients who would may benefit most from the exercise intervention. An observation study of walking activity in 154 older medical patients was completed. Firstly, the association between walking activity and (1) length of stay and (2) physical performance at the end of the study was measured (Chapter 5). Secondly,

we measured the relationship between walking and day to day in-hospital events; in other words, what influences walking activity. (Chapter 6).

Once the characteristics of patients most at risk to negative outcomes were identified, Phase 3 aimed to measure the effects of additional exercises during hospitalisation on health-related outcomes, including length of stay (primary outcome measure) and physical performance, quality of life and readmission rates for the three months following discharge (Figure 1.3, Phase 3). An augmented prescribed exercise programme protocol was designed (Chapter 8) and the trial was completed (n=190). The results of the trial are presented (Chapter 9) and are discussed in relation to the project as a whole (Chapter 10).

Most of the results of the thesis have been published, so this thesis takes the form of a Publication-based thesis. The text of each paper, published or prepared for submission, is presented in a chapter, along with additional supporting text as needed. The published papers are also presented in the appendices. Many of the assessment tools were used repeatedly for each paper/study and copies of these tools are also presented in Appendix A.

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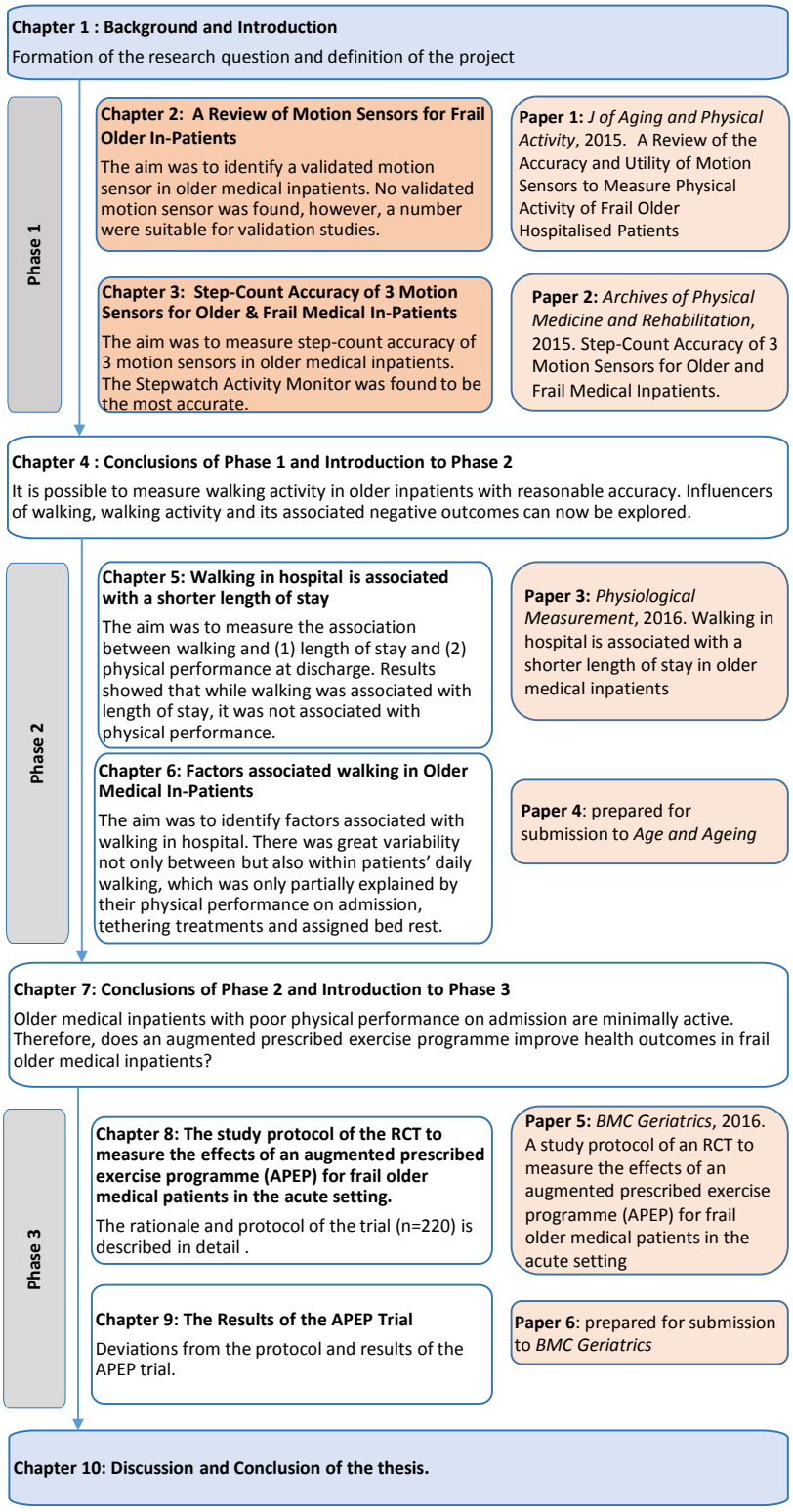


Figure 1.3: Flow diagram of the project: Introduction to Phases 1 (in orange), 2 and 3

2 A Review of Motion Sensors for Frail Older In-Patients

2.1 Background to the Review Study

This review was the first part of the thesis completed. The research project came about as it was thought that older medical patients were inactive in hospital. However, in order to examine the level of physical activity and its relationship with the health outcomes, it must be measured accurately. The hospital wards are busy, and many patients are confused or disorientated when in hospital. Hence, an objective form of measuring physical activity seemed to be the most appropriate.

Many accelerometers exist. They are waist, hip, thigh or ankle worn, with their measurements of physical activity expressed in different formats; energy expenditure, metabolic equivalents, time-spent-upright and step-count. It was unclear which accelerometer would be the most feasible and accurate in this patient group, and which output would be the most relevant for the thesis. Therefore, a review was conducted to inform us of the important factors when choosing an accelerometer and to identify one which would be accurate in this patient group. As walking is the most common form of physical activity in the acute hospital setting, it was the main focus of the review.

It was decided to complete a scholarly review rather than a systematic review for two reasons. Firstly, limited evidence existed on motion sensors in older and frail populations. Hence, a scholarly review allowed me the scope to review papers of varying quality, to gather as much information as possible. Secondly, the main aim of the thesis was to measure the effectiveness of the APEP intervention. A systematic review would have demanded a more detailed and in depth review, when time and resources were limited.

A number of people helped me to complete this review. Dr Christina Dillon, a PhD student in the Department of Epidemiology and Public Health, UCC gave me invaluable insight into accelerometry by helping me to understand the concept of measuring physical activity and assisted me in the scientific writing of this report. I completed the initial database search and excluded those papers that did not fit the research criteria. Dr Noeleen Brady and I independently extracted the data and discrepancies were resolved by Dr Suzanne Timmons. I was the chief author of the paper, assisted by Dr Noeleen Brady, Dr Suzanne Timmons and Prof Frances Horgan. The paper was published in *Journal of Aging and Physical Activity* and the PDF version is attached in Appendix B.

2.2 Summary

The purpose of this review was to examine the utility and accuracy of commercially-available motion sensors to measure step-count and time-spent-upright in frail older hospitalised patients. A database search (CINAHL and PubMed, 2004-2014) and a further hand search of papers' references yielded 24 validation studies meeting the inclusion criteria. Fifteen motion sensors (eight pedometers, six accelerometers and one sensor systems) have been tested in older adults. Only three have been tested in hospitalised patients; two of which detected postures and postural changes accurately but none estimated step-count accurately. Only one motion sensor remained accurate at speeds typical of frail older hospitalised patients but has yet to be tested in this cohort. Time-spent-upright can be accurately measured in the hospital, but further validation studies are required to determine which, if any, motion sensor can accurately measure step-count.

Keywords: Aged, frail, hospitalised, physical activity, step count, postures and postural changes

2.3 Introduction

In the United States, the United Kingdom and the Republic of Ireland, patients aged 65 years and over occupy most acute hospital beds and account for the longest length of stay (30 days or more) [37-39]. Frailty, described as a geriatric syndrome with reduced capacity of the individual to resist stress [4] includes characteristics of slow mobility, low physical activity (PA) and energy levels [5]. Acute illness, medical treatments such as intravenous or oxygen therapy, and the hospital environment can reduce or prevent mobility [40]. Low PA in older hospitalised patients has been associated with functional decline, prolonged length of stay and higher re-admission rates [8, 20], and walking-aid-users on admission are the least active in hospital [41]. However, exercise programmes have shown positive benefits in frail patients [31, 42], and may help preserve independence and quality of life when discharged home [43].

PA is a complex, multidimensional behaviour defined as bodily movement [44] produced by skeletal muscles, requiring energy expenditure [45]. Both patients and staff have been found to overestimate PA [46]. Accurate and precise measurement of PA in frail older patients could help to motivate them to increase activity [47, 48], and measure recovery of functional activity [41]. Self-reported measures of PA are feasible and cost-efficient, but also time-consuming and possibly invalid with the high prevalence of delirium in this group [36], while by-proxy reports burdens staff and carers. Direct observation may be possible for research, but it is costly and inefficient for clinical purposes. Therefore, motion sensors would appear to have a role in hospital care. But motion sensors can be time-consuming to attach to the patient [49], or may need to be removed for showering, or to check for skin irritation, or their outputs may not be clinically relevant. The sensor must be precise, accurate and feasible for clinical use.

Many large public health studies have successfully used motion sensors in community-dwellers [50, 51]. Pedometers are readily affordable, easy to

apply, and their unit of measurement (step-count) can be interpreted easily. They detect the vertical displacement of the person's hip during the gait cycle, thus counting each step. But, steps are not time-stamped, and may be falsely counted during incidental leg movements [52]. Most importantly, studies have found undercounting of slow, short steps [53-56], the most prevalent gait pattern in frail older inpatients [57].

Accelerometers measure body movement in terms of acceleration and are worn at the waist, wrist, ankle or thigh. Outputs include proprietary activity counts, step counts, inclination indicators or raw acceleration data. Activity counts are dimensionless, non-interpretable units which are converted into PA intensity levels and/or energy expenditure (EE). PA intensity is categorised as sedentary, light, moderate and vigorous [58]. Older inpatients spend most time in sedentary or light PA, and as thresholds between these levels are difficult to discriminate [59, 60], the subtle but highly important change from sitting (sedentary) to standing and walking (light) can be missed. The alternative conversion is to EE, which requires Resting Metabolic Rate (RMR) to be determined. The use of a single RMR value for all individuals has become an acceptable practice [61]. However, RMR can vary greatly in the oldest-older adults, especially with frailty and chronic illness [62], acute infection and altered dietary intake in hospitals [63], indicating that EE is not an acceptable option. Alternatively, step-count and postures and postural changes are clinically meaningful measurements indicating progression to functional independence. Time-stamped recordings can indicate the duration of patients' activity and functional fitness.

Motion sensors have undergone testing in older community-dwellers, but testing is limited in frail older inpatients. Older inpatients stand and walk less [49] and walk slower than older community-dwellers (0.46 m/sec and 1.27 m/sec respectively) [49, 57]. Furthermore, many are walking-aid-users, reducing walking speed to less than 0.41m/sec [64], emphasising

the need for validation studies and appraisal of motion sensors in this population.

This review study was conducted to identify those sensors which had either been validated or showed most promise for use in frail older hospitalised patients. We reviewed the limited literature on the step-count and posture and postural changes detection accuracy of commercially-available motion sensors and we discuss their application and utility. Accelerometers can be expensive, making validation and clinical studies costly. Therefore, researchers need to justify their choice of sensors. This paper provides a comprehensive summary of published validation studies which may help clinicians and researchers to select the best device for their area of interest.

2.4 Methods

2.4.1 Database Search

Validation or accuracy reports of step-count or posture and postural changes in the older adult population were specifically of interest. The main themes that were included in the strategy were developed from clinical experience and MeSH was used to develop the search terms. As the technology has advanced greatly recently, the dates were limited to the previous 10 years (2004). Due to the anticipated small number of studies, a review was conducted to assess all studies found in the review process, irrespective of the size/quality of the study. A quality review tool (CASP Diagnostic Checklist) was not used as meta-analysis was not performed, and we aimed to include as many papers as possible. However, the criterion standard in all studies was explicit and unambiguous (such as video-recordings or direct observations of walking). A search of PubMed, Cumulative Index to Nursing and Allied Health

Literature (CINAHL) was conducted using relevant keywords including aged, frail, elderly, measurement of physical activity, accelerometers, pedometers and motion sensors. All validation or accuracy studies which included a group of patients aged 65 and over were included. Outputs such as physical activity classification, falls or upper limb validation were excluded.

Full details of the search strategy are as follows: The **search terms** used were: aged OR aged 80 and over OR frail OR elderly AND patients OR residential care OR rehabilitation OR nursing care AND accelerometer OR accelerometry OR motion sensors OR measurement of physical activity OR measured physical activity OR physical activity measurement monitor(s) OR pedometry OR pedometer(s) OR step-count OR raw acceleration OR counts OR energy expenditure OR posture OR positions AND activity OR walking OR physical activity OR activity levels OR mobility OR energy expenditure AND validation OR validity OR criterion validation OR accuracy OR agreement. The **filters** used were: Publication date: 10 years range, Species: Human, Language: English; Ages: Ages 65+ (last search completed, February 2015).The e**ligibility criteria** were: a group or subgroup included of participants aged 65 and over, objective measurement of PA, a validation / accuracy study. The **exclusion criteria** were: participants aged 64 years and less only, review papers, participants for palliative care, validation of upper extremity measurement, validation of moderate/vigorous category of physical activity, validation of energy expenditure measurement, falls detection and inclusion of critically-ill patients.

Figure 2.1 illustrates the literature search process. The titles and abstracts were screened by RMcC. Following further searches performed through review of article citations, and removal of duplicates, 24 articles were found which validated the measurement of step-count and accurate detection of body postures and postural changes in the target population. The data was independently extracted by two assessors (RMcC, NB) and

discrepancies were resolved by a third independent reviewer (ST). We focused our data extraction and report on the following measurements: study size, age, medical condition, walking speed and study setting, task duration and complexity, use of walking aids, criterion measurement and accuracy and applicability of the motion sensors (see Table 2.1).

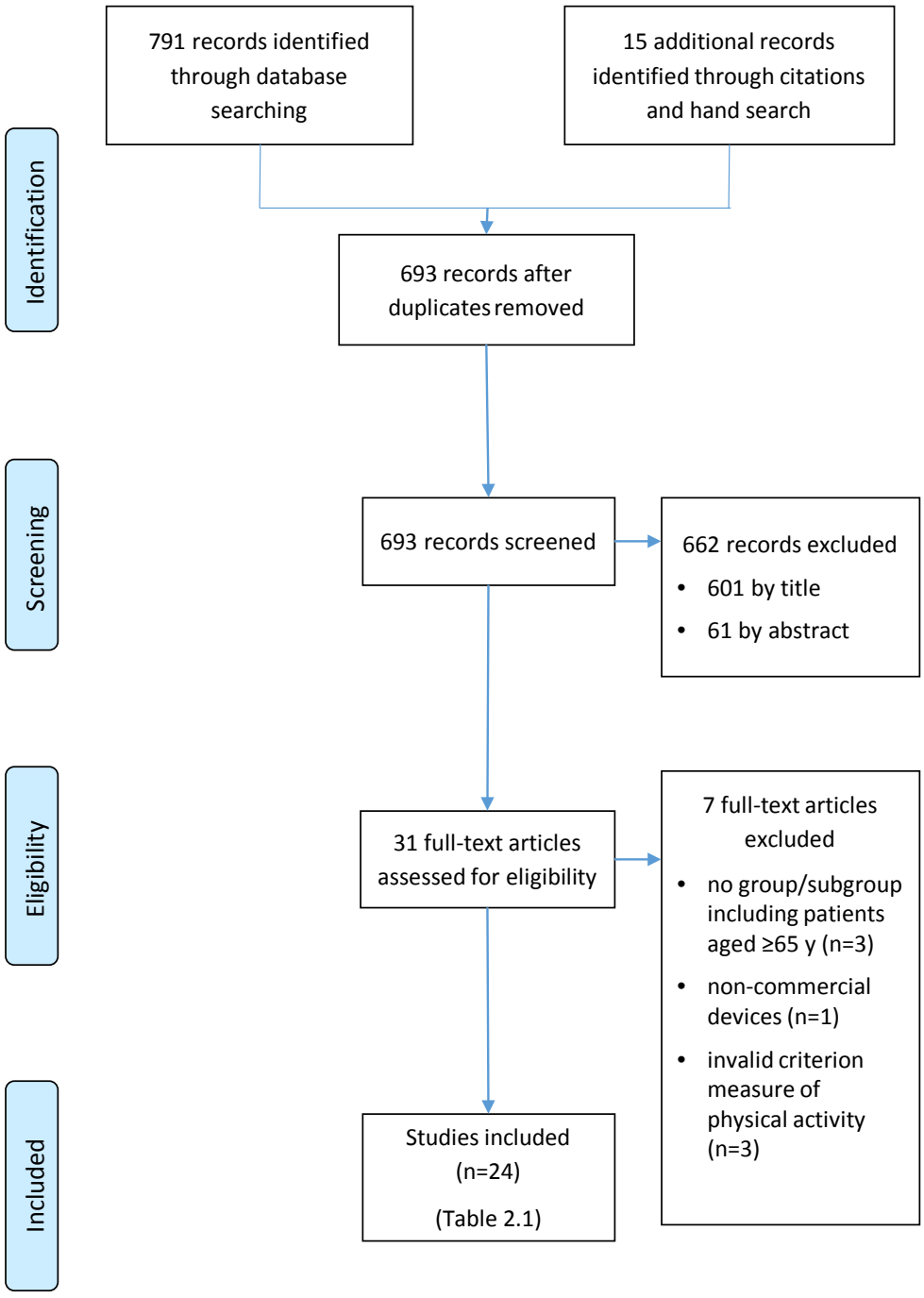


Figure 2.1: Flow diagram of the review process

2.4.2 Findings

Twenty four studies were included in the review, many of which validated more than one motion sensor. In total, six pedometers, eight accelerometers and one shoe-based sensor were validated in an older adult sample, with ages ranging between 56 and 88 years. Sixteen were laboratory trials, four were free-living trials and four were mixed. Seven studies used direct observation as the criterion measurement, eleven used video-recording and four used other validated measurement tools. Eight studies were conducted in the United States, four in the Netherlands, three in Canada, two in New Zealand and Brazil, and one in Australia, Scotland, Norway, Belgium and Switzerland.

Although the accuracy of many devices have been tested on community-dwelling adults, only three studies included hospitalised patients [13, 65, 57], (n=47, n=50 and n=38, respectively), and two included long-term care patients [66, 67], (n=28 and n=22, respectively). Sixteen studies validated step-count accuracy, six validated postures and postural change detection and two validated both step-count and postures and postural changes.

2.4.2.1 Pedometer Validation Studies

Eight studies, validating eight pedometers were reviewed. Studies included a stroke inpatient group [65], (n=50), a long-term care resident group [66], (n=52), and the remaining studies included community-dwellers. The accuracy of the Omron HJ113E [65], (n=50), Omron HJ-720ITC [68, 69], (n=49 and n=97 respectively), Yamax DW-200 [66], (n=52), Yamax SW-200 [70-72], (n=52, n=30 and n=35, respectively), Yamax PW610 [73], (n=30), Kenz Lifecorder [68], (n=49), Digiwalker SW701 [74], (n=60) and SC Step MX [72], (n=35) were tested. Each study used its own definition of accuracy such as percentage error,

significant differences in percentage error or Pearson correlation. Therefore, each study's own definition has been used to report accuracy. Results showed that the Omron HJ-720ITC was accurate at speeds greater than 0.64m/sec [69] and the SC Step MX was also accurate at speeds of 0.8 m/sec [72]. The remaining pedometers were less accurate at these slow speeds. The Omron HJ113-E generally did not detect any steps at speeds less than 0.5/sec, all three Yamax pedometers, (the DW-200, the SW-200 and the PW 610) were less accurate at walking speeds less than 1.0 m/sec [66, 70, 72]. Interestingly, Vanroy et al. [71] found the step-count of SW200 correlated well with video recorded steps in stroke patients (n=15) if worn at the knee. When stroke patients walked as slowly as 0.42m/sec, it remained moderately accurate (r=0.69). This is the only study we found which tested any device's accuracy when knee-worn. Finally, the Digiwalker SW701 and the Kenz Lifecorder lost accuracy below walking speeds of 1.33 m/sec [68, 74]. Therefore, although the Omron HJ-720ITC, the Yamax SW-200 at the knee and the SC Step MX were not tested in older hospitalised patients, it appears that these pedometers show the most accuracy at walking speeds less than or equal to 0.8 m/sec, the typical speed of a walking-aid-user [72] and thus, they show promise for hospital use.

2.4.2.2 Accelerometer Validation Studies

The remaining 15 studies validated accelerometers. Two studies included medical hospitalised patients [75, 57], (n=38 and n=47 respectively), one included patients in long-term residential care [67](n=22), while the remainder included community-dwellers.

2.4.2.2.1 Accurate posture and position changes detection.

Six accelerometers' ability to detect postures and positions was tested: the AugmenTec, [75] (n=47); the DynaPort [76], (n=20); the DynaPort Minimod [77, 76], (n=37 and n=20, respectively); the DynaPort MoveMonitor [78, 67], (n=27 and n=22, respectively); the SmartShoe [79], (n=12); the Activity Monitor (VitaPort 3) [80], (n=11) and the ActivPAL [57], (n=38).

The AugmenTec and the ActivPAL have been tested in older medical hospitalised patients. The AugmenTec uses a sensor at the ankle and thigh, and was tested using direct observation as the criterion measurement. Results showed that the levels of agreement between AugmenTec and the direct observation of lying, sitting, standing/walking were excellent (median κ=0.92) [75]. The ActivPAL, worn on the thigh, uses an in-built inclinometer to detect upright positions. Its accuracy was compared to video-recordings in older medical patients and community-dwellers with a hip fracture that had occurred three months previously [57]. The ActivPAL showed near perfect accuracy in detecting lying/sitting and standing/walking.

The remaining four accelerometers were tested in community-dwellers. The SmartShoe system uses an accelerometer which is clipped onto the side of the shoe, and five force sensitive resistors embedded in a flexible insole. It was validated in a small group (n=12) of community-dwellers with chronic stroke. Results showed that it detected sitting, standing, walking with over 95% accurate identification of all postures, and measured step-count with less than one step error [79]. The results indicate excellent accuracy, however this study size was small, and the SmartShoe requires a small cut at the back of the shoe (for the device to be attached), and hospital patients frequently alternate between shoes and slippers, limiting its feasibility.

The Activity Monitor (VitaPort 3) was validated in community-dwellers with Parkinson's Disease (PD) [80]. Using video recordings as the criterion measurement, the patients completed tasks in both a fixed and random order. Results showed good correlations between the Activity Monitor and the video, but showed less accuracy for tasks lasting less than five seconds. The system uses three sensors attached at both thighs and the sternum and is not waterproof, which would affect compliance in the hospital setting.

Three DynaPort motion sensors were tested in community-dwellers with chronic obstructive pulmonary disease (COPD) [76], peripheral arterial disease (PAD) [78], Parkinson's disease (PD) [77] and long-term care octogenarians [67]. These sensors are worn at the base of the spine, between the iliac crests. The DynaPort and DynaPort Minimod were tested in COPD patients in an outpatient setting and video recordings were used as the criterion measurement. No patient used a walking-aid and the average walking speed was 0.8m/sec. Results showed that both the DynaPort and DynaPort Minimod were 97% accurate in detecting postures and postural changes in COPD patients [76]. The DynaPort MoveMonitor showed poorer accuracy when tested in patients with PAD [78] and in octogenarians. Its detection of standing was poor in patients with PAD (Intraclass Correlation Coefficient, ICC 46%) [78], and in octogenarians (24.7% error) [67]. Interestingly, it accurately detected sitting in patients with PAD (ICC>97%) [78], but not in octogenarians (22.3% error) [67]. The reason for this is unclear but suggests that sitting to standing, an important postural change, may not be recorded accurately, especially in a frail older group. It is not possible to compare results across different patient groups but in general, the AugmenTec and ActivPAL accurately detected postures and postural changes in hospitalised patients, and the SmartShoe, DynaPort and DynaPort Minimod were accurate for community-dwellers. But the DynaPort MoveMonitor neither accurately detected sitting (in community-dwellers or long-term care residents), nor standing (in long-term care residents). Therefore, the SmartShoe and DynaPort Minimod

have proven accuracy in community-dwellers and show promise for hospitalised patients, but the DynaPort MoveMonitor may not be sufficiently accurate for this group.

2.4.2.2.2 Accurate step-count measurement.

Fourteen studies measured the step-count accuracy of accelerometers [81, 82, 70, 79, 74, 76, 83-86, 57, 71, 72, 87] in an older adult sample.

Using the default filter (DF), the Actigraph GT3X+ was found to undercount steps of older adult community-dwellers [88]. Therefore, a low-frequency-extension (LFX) filter option was introduced, specifically designed to detect low force movements and slower walking speeds. Step-count accuracy of the DF and the LFX filter were compared to the research standard pedometer NL-1000 in 15 older community-dwellers for seven days [81]. The absolute percentage difference between the DF and pedometer measurements was 16%. The LFX filter estimated almost double the number of actual steps not only during low-intensity movements, but also during high-intensity movements. The authors concluded that step-count measured by GT3X+ using the DF and the LFX filter cannot be compared accurately to the pedometer [81]. Another study using video footage as the gold standard, found that the absolute percentage error of the GT3X+ varied between 6.7% and 7.6% for non-walking-aid users (n=13) and between 51% and 52% for walking-aid-users in healthy older community-dwellers [72] (n=22). Walking-aid-users walked considerably slower at 0.8m/sec compared to non-walking-aid-users at 1.2m/sec. While these studies are relatively small, their results are similar, questioning the usefulness of the Actigraph GT3X+ in frail older hospital patients.

The ActiHealth accelerometer is attached to the shoe and its accuracy has been tested in community-dwelling men with COPD (n=46) and healthy

older males (n=15). Results showed that it detected steps well with 86% accuracy in the COPD group, but its accuracy deteriorated at walking speeds less than 0.9 m/sec[84].

The step-count accuracy of the Dynaport Minimod [76], (n=10) and the Dynaport Micromod [70], (n=32) have been tested for community-dwellers with COPD [76] with PD[70]. Both studied the step-count accuracy for short walks of 30 and 15 metres respectively in a hospital laboratory setting. No participant used a walking frame. The step-count of only one participant, who walked slower than the others (0.7m/sec versus 0.8m/sec) was underestimated [76]. These results do not validate their use for frail or hospitalised patients; the participants walked faster and none of them used a walking aid.

Only two studies have tested the accuracy of ActivPAL's step-count; one for community-dwellers with COPD [82], (n=20), the other for older hospitalised patients[57], (n=38). Both studies compared step-count to direct observation or video footage and were conducted in hospital settings (outpatients and inpatients). Results showed an undercount of steps with slower walkers. For COPD patients, ActivPAL's ability to detect steps reduced with slower speeds: it underestimated an average of four steps per minute when walking at a speed of 0.76 m/sec, compared to an average of seven steps per minute when walking at a speed of 0.56 m/sec. Similarly, Taraldsen et al. [57] also found that older hospitalised patients' walking speed was slow at an average speed of 0.46m/sec. They found that the ActivPAL's accuracy lessened with walking speeds less than 0.47m/sec, with an absolute percentage error of 40.3% for slower walkers and of 29.1% for faster walkers.

The SenseWear Armband (SWA) has been found to accurately measure energy expenditure in older community-dwellers, but not step-count [74, 76, 83]. The studies compared its recorded step-count to video recordings for community-dwellers with COPD [74, 76], (n=43, n=10, respectively)

and in patients with stroke [83, 71], (n=12, n=15 respectively). Most of these studies were small but all indicate inaccurate step-count measurement. The SWA underestimated step-count by an average of 42% and 50%[76]. Results were similar in stroke patients with the ICC<0.35 [83], and ICC >0.6 [71]. This error occurred at any walking speed, but was especially apparent for walking speeds less than 0.62m/sec [83]. The authors gave the plausible explanation that the SWA is worn on the arm as opposed to other devices at the hip or leg, potentially making it less sensitive to steps [74].

The accuracy of the Stepwatch Activity Monitor (SAM) has been measured for patients with COPD [82](n=20), chronic stroke [85] (n=25), older adults using a cane[87] (n=16), and PD and Multiple Sclerosis (MS) [86] (n=20). Overall, it appears that its accuracy is not affected by walking speed. All participants were community-dwellers. Ng et al. [82] found its step-count accuracy for patients with COPD to be within two steps per minute and this was not affected by either slow walking speed or the use of a walking frame. Mudge et al. [85] measured its accuracy against direct observation and three-dimensional gait analysis in patients with chronic stroke. The median walking speed of the participants was 0.50 m/sec. Attaching the SAM to the non-paretic ankle, they reported a -1.1% error, but this error increased to -4.9% when worn on the paretic limb. The SAM's accuracy has been measured in cane-users when attached to the participants' leg, attached to their cane, and over different surfaces such as grass, pavement, stairs and carpet. Although walking speed was not reported, self-selected walking speed using a cane has been previously reported as 0.41 m/sec (95% CI 0.38-0.44) [64]. When the SAM was attached to the participants' leg, overall accuracy was reported at 93.4%, with poorest accuracy on stair-climbing at 85.9%. Accuracy deteriorated over all surfaces when attached to the cane, with the average accuracy at 84.7% [87]. Schmidt et al. [86] found very strong correlations (r>0.99) between step-count and strides measured by the GaitMat II for older patients with PD and MS (n=20); however the study size was small and the patients'

walking speed was not reported. Therefore, while some of these studies were small, it appears that the SAM's accuracy is unaffected by walking speed or walking-aid use, and therefore, shows promise for frail older patients.

2.5 Discussion

There were three main findings from this review. Firstly, postures and postural changes can be measured accurately for older adults in all settings. Secondly, although step-count has been measured accurately for older community-dwellers, it has not been accurately measured for frail older adults in hospital or institutional care. Step-count accuracy of many motion sensors deteriorates when walking speeds reduce to approximately 1.0 to 0.8 m/sec [66, 70, 74, 84, 73, 72], which is considerably faster than the typical speed of hospitalised, frail older adults (0.5m/sec) [57]. This suggests that many motion sensors are invalid for step-count measurement in frail hospitalised patients. Thirdly, the SAM appears to be the only motion sensor that accurately measures step-count for slow walkers, but it has yet to be validated for frail older hospitalised patients.

Postures and postural changes can be accurately measured in frail older medical patients by the AugmenTec and the ActivPAL. The DynaPort and the DynaPort Minimod showed good accuracy in community-dwellers with COPD, but they have not been tested in frail patients. The results from the DynaPort MoveMonitor are inconclusive. Its detection of sitting and standing appears poor, especially in the older-old. The SmartShoe shows excellent accuracy in a small community-based study, but its feasibility for hospital use is limited. Accurate objective measurements of time spent in standing/walking have been used in studies [14, 49]. While this information

characterises the duration and patterns of activity, step-count would be a better indication of the patients' activity level and physical recovery.

The review found that most accelerometers tested for older adults accurately detected steps in community-dwellers but this accuracy deteriorated when walking was slower than 0.5m/sec [82, 57, 72]. The only step-count accuracy study in frail older hospitalised patients [57], found that the ActivPAL did not measure step-count accurately. Although the SWA has been found accurate in measuring energy expenditure, it did not measure step-count accurately at any walking speed [74, 76]. Alternatively, there is strong evidence that the SAM appears the most sensitive for slower walkers [85, 82] and for cane-users [87]. One reason for the considerable difference might be related to their position on the body. While the SWA is worn on the arm, the Stepwatch Activity Monitor (SAM) is attached to the ankle. This may affect their sensitivity to the trajectories of the foot while stepping. It may also explain its loss of accuracy when cane-mounted or when worn on the paretic limb. Another reason may be that the sensitivity of the SAM must be adjusted specifically to each participant; the patient's height and walking pattern are required to set its sensitivity before use, thus potentially improving accuracy.

Older patients tend to be inactive in hospital and institutional care settings [66, 16]. There are many reasons for this inactivity, such as lack of encouragement to exercise and lack of knowledge of hospital layout [41]. More walking in hospital may help preserve independence and quality of life in this vulnerable group [43]. Time-stamped step-count would provide a meaningful measurement of activity. Furthermore, it would inform clinicians, nurses and therapists of the progression of recovery - whether each patient is able to remain active for longer bursts over time and the daily patterns - whether patients need more encouragement during periods of prolonged rest. Physical performance and ability is fundamental to regaining independence, planning for discharge home and improving

quality of life. Future research should aim to identify an accurate, precise and feasible motion sensor in frail older patients.

2.5.1 Limitations

This review was limited to the last ten years and to the English language. It did not include technologies in motion capture including gyroscope and magnetometer devices, or combination devices. Hand searching was limited to citations from retrieved articles and did not include conference proceedings. We did not contact experts or ask for unpublished work which may have allowed reporting bias and selective outcome reporting to influence our findings. Therefore, some research in this field may have been missed. However, we did contact the manufacturers of two accelerometers (SAM; Orthocare Innovations and ActivPAL and ActivPAL3; PalTechnologies) and one pedometer (Piezo StepMV; StepCount) to check whether they were aware of any other relevant studies.

2.6 Conclusion

This review provides a comprehensive summary of the published validation studies of motion sensors in older adults. The DynaPort, DynaPort Minimod and the Smartshoe, have shown accurate detection of postures and postural changes in community-dwellers but have not been validated for use in frail hospitalised patients. The AugmenTec and ActivPAL, have been shown to detect postures and postural changes in older hospitalised patients, but not step-count.

Eleven motion sensors showed good step-count accuracy in older community-dwellers walking at speeds greater than approximately 1.0m/sec (Actigraph GT3X+, ActivHealth, ActivPAL, Digiwalker SW710, DynaPort Micromod, DynaPort Minimod, Omron, SAM, SmartShoe, Yamax PW610 and Yamax SW-200). However, to date, no motion sensor has shown step-count accuracy in frail hospitalised patients. Step-count accuracy appears to depend greatly on walking speed. Many of these patients walk slower than 0.5m/sec, the speed at which arm, waist and thigh mounted accelerometers appear to lose their accuracy. Three pedometers, the Omron HJ-720ITC, the SC Step MX and the Yamax SW-200 (worn at the knee) have been found accurate in older adults who walk slower than 0.8 m/sec. Their relative in-expense justifies a validation study of their accuracy in the hospital setting and may provide a cheap alternative to accelerometers. The SAM also showed promise as it does not appear to be affected by walking speed, and patients' walking is time-stamped, allowing the bouts of walking to be examined. However, this also has to be tested in the hospital setting.

To conclude, postures and postural changes can be accurately measured in frail older hospitalised patients. A motion sensor to measure time-stamped step-count has yet to be identified for this cohort. This activity information would inform clinicians of physical recovery from illness and patients' ability to progress their rehabilitation and retain independence at home. Therefore, further validation studies of accelerometers and pedometers which accurately estimate steps of slower, older community-dwellers should be completed in frail hospitalised patients.

Table 2.1: Studies included in the review (all reported walking speeds have been converted to metres per second (m/sec))

Authors **Condition, Dwelling (sample size), Age**	**Physical Activity Observed** **Criterion Measurement**	**Devices** **(Outputs)**	**Results**
Barreira et al. (2013) Healthy CD (n=15) Men: 73±9 years Women: 67±4 years	Free-living activity (7 days) NL-1000 pedometer (research standard)	ActiGraph GT3X+ accelerometer • default filter, (DF) • light filter (LFX) **(step-count)**	DF: -7.4% error (769 steps/day) LFX: 121.9% error (8140 steps/day)
Brown et al. (2008) Medical IP (n=47) male 73±6.5 years	lying, sitting, standing/walking Direct observation	AugmenTec wireless monitor **(posture classification)**	Concordance (median κ=0.92) between posture classification and observation Standing/walking, sitting, lying (r>0.90) Unable to detect walking periods

Carroll et al. (2012) Stroke IP (n=50) 72.4 ±12.3 years	6MWT and short walk Video recordings	Pedometer × 3 (Omron HJ113-E) 1 around neck & 1 at each hip **(step-count)**	20% could not use pedometers without assistance. Steps virtually undetected at w/s <0.5m/sec Steps undercounted at w/s >0.5m/sec
Cyarto et al. (2004) Healthy CD (n=28) 70.6±5.5 years NHR (n=26) 79.4±8.2 years	Various self-paced walks (13m) Direct observation	Yamax pedometer (DW 200) **(step-count)**	Healthy: -25% error (0.95m/sec) to -7% error (1.61m/sec) NHR: error -74% error (0.42m/sec) to -46% (0.8m/sec)
Dijkstra et al. (2008) Healthy CD (n=20) 68.5±7.4 years PD CD (n=32)	Various self-paced walks; various distances; while doing secondary tasks. Video recordings	DynaPort Micromod **(step-count)** Yamax (SW-200) pedometer **(step-count)**	DynaPort: -7.4% error in healthy adults; -6.9% error in PD Yamax: -6.8% error in healthy adults; -11.1% error in PD Accuracy decreased with trajectories <5m

67.3±6.6 years Excl. pts using w/aids			
Dijkstra et al. (2010) PD CD (n=32); (n=5) 67.3±6.6 years; 76±3 years	ADLs in movement lab (n=32); at home (n=5) Video recordings	DynaPort Minimod accelerometer **(posture classification, step-count)**	Lying and walking most accurately detected (81.7% to 99.9%) Poor accuracy for slow or shuffled walking Short periods of sitting hard to identify
Dondzila et al. (2012) Healthy CD (n=49) 65.4±6.9 years	Treadmill walk (0.9-1.8m/sec) Overground various self-paced walks Direct observation	Omron pedometer (OM) **(step-count)** Kenz Lifecorder EX (LC) pedometer **(step-count)**	OM: mean error step-count, -12.4 to 4.5 LC: mean error step-count -64.5 to -3.2 Both OM and LC increasingly accurate as walking speed increased
Fokkenrood et al. (2014) Peripheral Arterial Disease CD (n=27) 67±10 years	Free living hospital visit Video recordings	DynaPort MoveMonitor **(posture classification, step-count)**	Gait speed not reported Accurate for lying, sitting, walking (all >90%); moderate for standing (46%); shuffling virtually undetectable (18%)

Fulk et al. (2012) Chronic stroke CD (n=12) 62.1±8.2 years	Sitting, standing, walking and step-count Video recordings	SmartShoe – shoe based sensor system **(posture classification and step-count)**	>95% accuracy for sitting, standing, walking Step-count mean difference <1
Furlanetto et al. (2010) COPD CD (n=30) 67±8 years Healthy CD (n=30) 68±7 years	Treadmill walking at various set speeds Video recordings	Digiwalker SW701 (pedometer) **(step-count)** SenseWear Armband (multisensor) **(step-count)**	High speed (1.33±0.2m/sec): pedometer accurately measured step-count; poor step-count accuracy with multisensor Slow speeds (0.3±0.1m/sec & 0.8±0.1,/sec): multisensor & pedometer underestimated step-count
Jehn et al. (2011) Chronic heart failure CD (n=97) 60.7±13.4 years	Free and treadmill walk (40-80 m/min) (n=10) 6MWT (n=97) Direct observation	Omron HJ-720ITC **(step-count)**	Speeds <0.64m/sec, significant % error Self-paced 6MWT, significant % error at distances <400 m

Langer et al. (2009) COPD CD (n=10) 65±8 years Healthy CD (n=10) 65±9 years	Sitting, standing, walking. Video recordings	DynaPort, DynaPort Minimod & Sensewear Pro Armband (SWA) **(step-count, posture classification)**	Minimod: mean step-count accuracy (-43 steps); less accurate for slow walker (<0.7 m/sec) SWA: mean step-count accuracy (-486 steps) 97% of postures accurately detected by DynaPort and DynaPort Minimod
Manns & Haennel (2012) Stroke CD (n=12) 64.2±10.4	6MWT × 2 over 25m StepWatch Activity Monitor (SAM)	SenseWear Pro (SWA) armband **(step-count)**	SWA and SAM step-count agreement poor (ICC<0.35); particularly at speeds less than 0.62m/sec
Moy et al (2008) Healthy CD males (n=15) 56±12 years COPD CD males (n=46) 71±9 years	Walk 244m at self-selected speed Direct observation	ActiHealth accelerometer **(step-count)**	Healthy: step-count accuracy 98% COPD: step-count accuracy 86% Accuracy decreased at speeds less than 0.98m/sec

Mudge et al. (2007) Physical disability post stroke CD (n=25) Med 69 years	8m indoor walk; outdoor walk over various surfaces 3D Gait Analysis (gait lab) and footswitches (outdoor walks)	SAM **(step-count)**	Step-count accuracy 95% % error increased when attached to the paretic limb; indoors (-2.6% vs -7.3%), outdoors (-1.3% vs -4.2%)
Ng et al. (2012) COPD CD (n=20) 73±9 years	4 walks (5 mins) with and without rollator Direct observation	Stepwatch Activity Monitor (SAM) **(step-count)** ActivPAL **(step-count)**	SAM: Mdiff 2 steps/min; unaffected by speed or aid use ActivPAL: Mdiff 7 steps/min; worsened with slower walking <0.56m/sec; unaffected by aid use
Sant'Anna et al. (2012) COPD CD (n=30) 67±7 years	Walk × 2 (slow, fast) Circuits × 3 (set tasks) Video recordings	Yamax Power Walker (PW) (610) (pedometer combined accelerometry) **(step-count)**	Correlations of step-count: slow walking (1.05m/sec; r=0.79); fast walking (1.3m/sec; r=0.95)

Schmidt et al. (2011) PD CD (n=11) 66.8 years MS CD (n=9) 55.9 years	Self-selected walks over GaitMat II GaitMat II	SAM **(step-count)**	Correlation: PD (r=1.0), MS (r=0.99)
Taraldsen et al. (2011) Medical IP (n=38) 79.7±7.3 years	Set tasks (20-60mins) Video recordings	ActivPAL **(posture classification and step-count)**	100% accuracy in classifying postures. -40.31% error in walkers <0.47m/sec
Taylor et al. (2014) Octogenarians RVR (n=22) 88.1±5 years	Set tasks (4-6mins) Free movement (5-9mins) Video recordings	DynaPort MoveMonitor (accelerometer) **(posture classification)**	Med error <1% for lying and walking, sitting (med 22.3%), standing (med 24.7%) Agreement of duration >85% for all except standing (med 56.1%)

Vanroy et al. (2014) Stroke CD (n=15) 60.4±10.26 years Healthy CD (n=15) 58.07±10.37	Set tasks (3-4mins) Direct observation Video recordings	SenseWear Pro2 (SWP2A) Armband (both arms) **(step-count)** Yamax Digi-Walker SW200 pedometer (hip and knee) **(step-count)**	Even surface: Yamax (knee): correlation for healthy and stroke (r≥0.89) Treadmill: Yamax (knee): correlation for healthy (r≥0.90), stroke (speed 0.42m/sec, r=0.69) Yamax underestimated steps for other activities, reliability (0.66-0.98) SWP2A poor correlation (-0.78 to 0.6)
Webber et al. (2014) Healthy CD (n=35) Walking aid (n=13) No walking aid (n=22) 81.5±5 years	Self-paced walk (100m) Direct observation	Yamax SW-200 pedometer ActiGraph GT3X+ accelerometer SC-Step MX pedometer **(step-count)**	No difference in step-count accuracy in independent walkers: w/s 1.21±0.2m/sec (% error 0.8 to 2.6) Significant difference in step-count accuracy in w/aid users: w/s 0.8±0.2m/sec (% error 1.0 to 68.9): the SC-Step MX most accurate

Wendland et al. (2012) Older CD with cane (n=16) 75.6	Indoor and outdoor walks; various surfaces Direct observation	StepWatch Activity Monitor (SAM) (leg and cane mounted) **(step- and cane-count)**	Accuracy 93.4% on all surfaces (leg mounted) Accurate 84.7% on all surfaces (cane mounted) Stairs least accurate
White et al. (2006) Parkinson's Disease CD (n=11) 66.1±9.1 years	Set and random order tasks Video recordings	Activity Monitor (AM) (VitaPort 3) **(posture classification)**	Correlations AM ranged from r=0.63 to r=0.98 AM reports longer durations Kappa low for durations <5secs

Legend **w/aid(s)**: walking aid(s), **m**: metres, **m/sec:** metres per second, **w/s**: walking speed, **6MWT:** 6 minute walk test, **Mdiff:** Mean difference, **ICC**: Intraclass correlation coefficient, **med**: median, **IQR**: interquartile range, **% error**: percentage error, **PD**: Parkinson's Disease, **MS**: Multiple Sclerosis **COPD:** chronic obstructive airways disease, **PAD:** peripheral arterial disease, **CD:** Community-dwellers, **RVR:** Retirement village resident, **IP:** inpatient, **NHR:** Nursing home resident

3 Step-Count Accuracy of Three Motion Sensors for Older and Frail Medical In-Patients

3.1 Background to the Accuracy Study

The completed review of motion sensors showed that two accelerometers had been validated to measure time spent in the upright position, but none had been validated to measure walking activity in older medical inpatients. I was particularly interested in walking activity as this is the most common form of physical activity, and while time spent upright suggests that the wearer is walking, it does not prove that walking is taking place, whether the wearer is taking rests, or gaining a more functional speed with their recovery.

Therefore, a validation study was completed to determine whether a motion sensor would be accurate and feasible to use in this population. I chose three motion sensors: one accelerometer which appeared to be the most promising, a new trixial version of an extensively used accelerometer and a simple cost-effective pedometer which had shown good accuracy in community-dwellers.

This study has been submitted as Ms Annemarie O'Connell's MSc in Older Person Rehabilitation minor dissertation. With Dr Christina Dillon's assistance, I helped Anne Marie to design and complete the study and I supervised her analysis and completion of her dissertation. I then wrote the paper for publication in *Archives of Physical Medicine and Rehabilitation* with the assistance of Ms Anne Marie O'Connell, Dr Christina Dillon, Dr Suzanne Timmons and Prof Frances Horgan. The PDF version of the published paper is attached in Appendix C.

3.2 Summary

Objectives: To measure the step-count accuracy of an ankle-worn accelerometer, a thigh-worn accelerometer and one pedometer in older and frail inpatients.

Design & Setting**:** Cross-sectional design study conducted in a research room within a hospital**.**

Participants**:** Convenience sample of inpatients aged ≥65 years, able to walk 20 metres unassisted, with or without a walking-aid.

Intervention*:* Patients completed a 40-minute programme of predetermined tasks while wearing the three motion sensors simultaneously. Video-recording of the procedure provided the criterion measurement of step-count.

Main outcome measures: Mean percentage (%) errors were calculated for all tasks, slow *versus* fast walkers, independent *versus* walking-aid-users, and over shorter *versus* longer distances. The Intra-class Correlation was calculated and accuracy was visually displayed by Bland-Altman plots.

Results*:* Thirty-two patients (78.1 ±7.8 years) completed the study. Fifteen were female and 17 used walking-aids. Their median speed was 0.46 m/sec (interquartile range, IQR 0.36-0.66). The ankle-worn accelerometer overestimated steps (median 1% error, IQR -3 to 13). The other motion sensors underestimated steps (40% error (IQR -51 to -35) and 38% (IQR -93 to -27), respectively). The ankle-worn accelerometer proved more accurate over longer distances (3% error, IQR 0 to 9), than shorter distances (10%, IQR -23 to 9).

Conclusions: The ankle-worn accelerometer gave the most accurate step-count measurement and was most accurate over longer distances. Neither of the other motion sensors had acceptable margins of error.

Key words: walking, dimensional measurement accuracy, frail elderly, in-patients

3.3 Introduction

Research has established that older patients are physically inactive in hospitals [75, 11, 8, 16, 89] possibly leading to their functional decline [20, 7, 90]. Knowledge of patients' levels and patterns of physical activity (PA) could help healthcare professionals to prevent this decline by targeting particularly at-risk individuals, aiding individual therapy, and providing feedback and motivation to increase PA.

Patients' PA can be objectively measured through direct observation or by motion sensors[16, 49, 12]. While direct observation is suitable for research, it is labour-intensive and often impractical in the hospital setting. Motion sensors could be a more feasible option. Motion sensors report PA as (1) energy expenditure, measured in metabolic equivalents (METS)[91], (2) PA intensity, categorised into sedentary, light, moderate or vigorous[58], (3) step-count[92] or (4) time-spent-upright[93]. Neither METS nor intensity classification are suitable measurements in older or frailer patients. METS can be altered by age and acute illness by 20-25% [62] and older patients spend most of their time in sedentary PA [16, 49]. Therefore, step-count and time-spent-upright would appear most clinically meaningful in this group.

Time-spent-upright can be accurately measured in the hospital setting [13, 57] and studies have shown that older inpatients spend as little as 43 minutes per day [75] to 1.2 hours per day [14] either standing or walking. While time-spent-upright indicates how inactive the patients are in hospital, it does not tell us the nature of their physical activity as it cannot differentiate between standing (static PA) and walking (dynamic PA). Step-count indicates clearly patients' progress from static to dynamic PA and progression to mobility independence. Many older patients need to take rests during physical tasks. Time-stamped PA outlines patterns of PA – whether the patients sustain more frequent and longer bouts of PA or whether they are able to walk a certain distance in less time, with fewer steps. Researchers currently suggest that this measurement (bouts of PA)

is a valuable indicator of overall PA and health [94, 95], informing clinicians of the patient's progress to independent functional activity, necessary for community-dwelling.

Two important factors should be considered when choosing a suitable sensor for clinical use: accuracy and affordability. Many motion sensors are not sensitive to steps at speeds slower than 0.8 m/sec [57, 82, 77, 76]. Frail older inpatients walk at an average of 0.5 m/sec [57] rendering these motion sensors inaccurate for use in this cohort [57]. In fact, our recent review concluded that no motion sensor has shown accurate step-count measurement in older medical inpatients [96]. However, the Stepwatch Activity Monitor accelerometer and Piezo Step MV and the Yamax-200 (if worn at the knee) pedometers were identified as accurate in older community-dwellers who walked less than 1.0 m/sec.

While the Stepwatch Activity Monitor (SAM) has not been tested in older inpatients, its error in community-dwellers with chronic illnesses was found to be less than 10% [97, 85]. There are a number of factors which may be linked to its accuracy in slow walkers. Firstly, it is worn at the ankle, positioned well to detect trajectories of the foot. Secondly, it uses a set-up procedure to programme its sensitivity to steps which, in theory, has advantages for this population. And finally, it has a high sampling frequency of 128 Hz.

All motion sensors which measure time-stamped activity are more costly than simple pedometers (which count steps only). If a pedometer was found accurate in frail older patients, it could become a readily affordable and an easy-to-use alternative. Previously, Webber et al. [72] found the Piezo Step MV pedometer recorded step-count accurately in older community-dwellers walking at 0.8 m/sec, but found the Yamax-200 and the GT3X+ were inaccurate. Yet, when the Yamax-200 was worn at the knee (rather that at the hip), Vanroy et al [71] found it accurate in stroke community-dwellers walking at 0.5 m/sec. Nonetheless, we chose to test the Piezo Step MV over the Yamax-200 for two reasons. Firstly, Vanroy et

al [71] stated that it was well tolerated by the participants, but as inpatients spend long periods of the day sitting down, a strap holding the pedometer firmly at the knee could become uncomfortable and possibly compromise circulation of the lower limb. Secondly, Yamax-200 is a mechanical pendulum pedometer, and Piezo Step MV is a pedometer with a piezoelectric internal mechanism which thought to be more accurate [72]. We therefore decided to measure the accuracy of the Piezo Step MV.

Time-spent-upright is a useful measurement of PA in older medical inpatients, which the ActivPAL can measure accurately. However, it has failed to measure step-count accurately either in frail older patients [57] or older community-dwellers [82]. The ActivPAL 3 (AP3), a new triaxial version of the ActivPAL accelerometer has not been tested in this population, and its potential accuracy in measuring both parameters merits its inclusion in the study.

Therefore, the aim of this study was to measure the step-count accuracy of three motion sensors (SAM, ActivPAL3 and Piezo Step MV (STEP)) in older and frail inpatients and explore how their accuracy is affected by (1) walking distances, (2) walking speed, (3) use of walking aids, and (4) specific to the SAM only, its set-up procedure.

3.4 Methods

3.4.1 Participants

This prospective cross-sectional design study was conducted in a 350-bedded teaching hospital between January and June 2014 and took place in a clinical research room, similar to a single bedroom on a ward. Ethical approval was granted by the local Research Ethics Committee [EMC 3 ffff 03/12/13]. (Appendix D)

A convenience sample of 32 inpatients, aged 65 years and over, not requiring surgical intervention, who were able to walk approximately 15-20

metres independently with/without a walking aid, and able to follow simple commands in English, participated in the study. This number was deemed feasible and in line with previous studies [57, 82, 71]. Patients with or without a walking aid were purposively recruited to compare accuracy between these groups. The nursing staff was initially consulted to identify patients who fitted the criteria and only those patients were approached. If the patient appeared confused during the initial interview, the nursing staff was again consulted before proceeding with recruitment.

3.4.2 Equipment

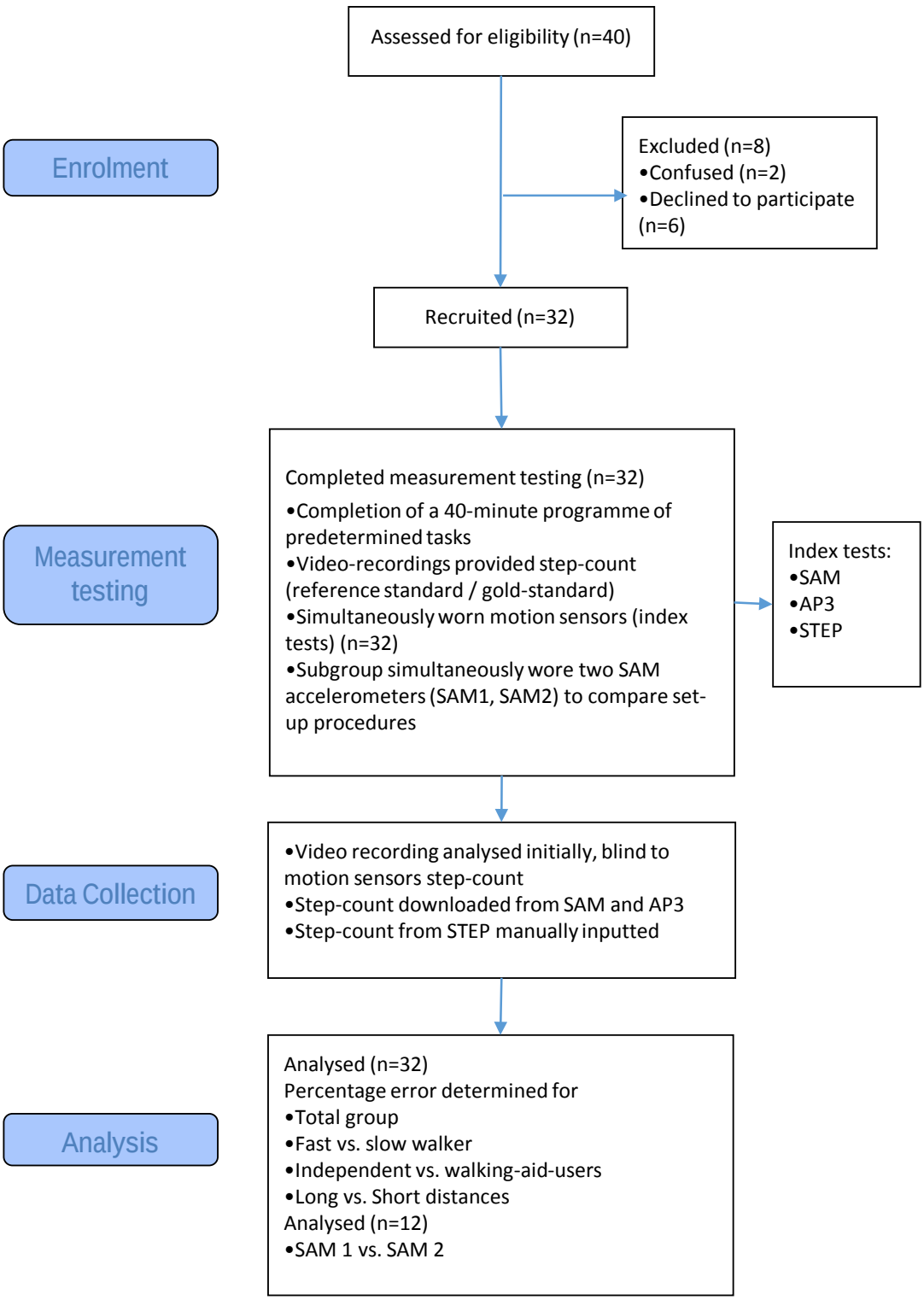
The three motion sensors tested were the SAM (Orthocare Innovations, LLC, OK, 7.5cm x 5cm x 0.2cm, 38g), the AP3, a triaxial accelerometer, (Pal Technologies Ltd, Glasgow, UK, 3.5cm x 5.3cm x 0.7cm, 15g), and the Piezo Step MV (STEP), a piezoelectric pedometer (StepsCount, Deep River, ON, 5.6cm x 3.2cm x 1cm, 20g). Video recordings using a Sony Handycam DCR-HC35 provided the gold-standard step-count measurement as it would provide the least biased measurement and is commonly used gold-standard measurement in previous studies [57, 76, 71].

3.4.3 Procedure and Baseline Measurements

The procedure (See Figure 3.1) was fully explained to all participants, and following informed and written consent (see Appendix E for the Patient Information Sheet), baseline data including patients' demographics, home environment and family/carer support was extracted from the medical notes (see Appendix F for Consent Form and the Data Collection Sheet). Comorbidity and chronic illness burden was measured using the Cumulative Illness Rating Scale-Geriatrics (CIRS-G) [98], and a higher

score reflects greater impairment in several systems. The SHARE FI [99] was used to determine the patient's frailty category (frail, pre-frail or not frail). Fear of falling was measured using the Falls Efficacy Scale-International [100] and a higher score reflects a greater concern about falling. A cut-off of above 19 points indicates a moderate to high concern about falling [101]. Physical performance was measured using the Short Physical Performance Battery (SPPB) [102]. This quick, practical and safe measurement tool assesses patients' balance, walking and chair-stand ability, and a higher score reflects better physical ability.

Figure 3.1: Flow diagram of the Validation of Motion Sensors Study



3.4.4 Equipment Preparation

The STEP is a pedometer, and therefore, did not require any synchronisation to the computer. In line with the manufacturer's instructions, it was attached at the dominant hip, directly above the knee. A belt was used to attach the STEP if the patients' clothes were loose-fitting (nightdress or pyjamas). The patient then walked 20 steps, and the step-count was checked. The pedometer attachment was adjusted until it reached the acceptable level of accuracy of 20±2 steps (in line with the manufacturer's instructions).

Both the AP3 and the SAM required computer synchronisation, and the SAM required sensitivity adjustment as part of the set-up procedure. For both, all data from the sensors was cleared prior to use and were synchronised to the computer. The AP3 was then ready for recording. It was attached to the dominant mid-thigh, in line with the manufacturer's instructions.

Sensitivity adjustment is a required step in the set-up procedure for the SAM. Its sensitivity is programmed specifically for each participant according to the manufacturers' instructions before it is attached. The level of sensitivity is based on the answer selected by the user to four questions relating to the participants' height, gait pattern and gait cycle. For each question, the user chooses the most appropriate answer from a range of answers presented. For this study, the same answers were selected for all the participants, to represent a typical older hospitalised patient, as follows:

(Question 1) "Does the client regularly participate in activities that involve short quick steps?" (Our answer) "No".

(Question 2) "Is their walking speed fast or slow? (Relative to people of similar height.)" (Our answer) "Slow".

(Question 3) “What is the client’s range of walking speeds?” (Our answer) “Rarely changes”

(Question 4) “Describe the appearance of the client’s leg motion” (Our answer) “Gentle/geriatric”.

The number of steps was saved in periods of 15 seconds (time interval/epoch). This is fixed at 15 seconds in the AP3 so it was replicated in the SAM to allow comparability. The SAM was attached to above the dominant lateral malleolus, in line with the manufacturers’ instructions. The patients then walked 20 steps and the LED light, (which only flashes for the first 40 steps recorded), was checked.

While wearing all three motion sensors simultaneously, the participants were video-recorded completing a 40-minute programme of predetermined tasks. These included bed-to-chair transfers, activities in the standing position and six walks over distances between 2.4 and 20 metres. The tasks were performed in the research room and the walks over 10 metres were completed in the corridor of the research facility. Each task began and ended in a seated position. Patients wore footwear and used their required walking aid. A 30-second rest between tasks allowed the sensors to register the break. A more detailed description of the tasks is explained in Table 3.1. At the end, the sensors were returned to their respective docking stations for data retrieval.

Table 3.1: Detailed Description of the predetermined tasks undertaken (Validation Study)

	TASK	MEASUREMENT
1	Sitting to lying down	False step-count
2	Lying to sitting	False step-count
3	Sitting at edge of bed (30 seconds)	Rest (time)
4	Transfer to chair* (30 seconds)	Transition x 1, Step-count (time)
5	Sit in chair (30 seconds)	Transition x 1, Rest (time)
6	Standing * unsupported (30 seconds)	Transition x 1, (time)
7	Sit down (30 seconds)	Transition x 1, Rest (time)
8	Stand up, turn to walk to cupboard, return to chair	Transition x 1, Step-count (time)
9	Sit down (30 seconds)	Transition x 1, Rest (time)
10	Timed walk 8ft* (2.5 m)	Transition x 1, Step-count (time)
11	Sit down (30 seconds)	Transition x 1, Rest (time)
12	Stand up, turn to sink, wash and dry hands and return	Transition x 1, Step-count (time)
13	Sit down (30 seconds)	Transition x 1, Rest (time)
14	Walk from room to corridor*(includes a turn)	Transition x 1, Step-count (time)
15	Sit down (30 seconds)	Transition x 1, Rest (time)
16	Walk-turn-walk back* (10 metres)	Transition x 1, Step-count (time)
17	Sit down (30 seconds)	Transition x 1, Rest (time)
18	Walk corridor *(20 metres)	Transition x 1, Step-count (time)
19	Sit down (FINISH)	Transition x 1, Rest

Both the raw steps counts and summary data were downloaded. The STEP step-count for each task was documented manually on the data collection sheet and manually inputted once all the recordings had been completed.

To measure how the set-up procedure affected the accuracy of the SAM, a subset of 12 patients wore two SAMs simultaneously, each with a different set-up procedure. The second SAM (SAM 2) was attached directly above the first (SAM 1). The set-up procedure for SAM 2 differed as follows: (1) the information required for programming was not standardised; instead it was specific to each patient's presentation (e.g., if the participant walked slowly or used a walking frame, we would enter "slow" for walking speed and "rarely changes" for ranges of speed) and (2) an accuracy trial was completed by counting the LED flashes while the patient took 4 sets of 12 steps and checking whether 48±2 steps count was recorded. If inaccurate, the sensor was reprogrammed by rechecking the programming information and if necessary, by adjusting "cadence" and "sensitivity" (in Advanced Settings) by two numerical values at a time until accurate.

A step was defined as a definite foot displacement with movement of body mass into a new position [103]. Two research physiotherapists analysed the recordings separately, beginning with the video recordings, and resolved any disagreements by analysing them together to reach a consensus. The video recordings were analysed first, when the researchers were blind to the motion sensors' measurements.

The twenty-metre walk was used to measure walking speed. The time taken to walk between the two-metre and the twelve-metre points was used and converted to metres per second.

3.4.5 Statistical Analysis

All continuous data was tested for normality using the Shapiro-Wilk normality test. Non-normally distributed data are reported in medians (and interquartile ranges, IQRs) and normally distributed data are reported in both means (and SD) and medians (and IQRs) in the text. Both are also reported in Table 3.3 to allow comparison with other studies. The percentage error was calculated to determine the motion sensors' accuracy, which was calculated as: (sensor count – video count)/video count multiplied by 100. A positive result indicated overcounting and a negative indicated undercounting. The Intra-class Correlation (Model 3, two-way mixed) (ICC) was calculated to determine association and accuracy was visually displayed by Bland-Altman plots, where the differences between two measurements are plotted against the averages of the two measurements, allowing visual analysis of bias or trends in the measurements. Stata (Version 13.1) was used for data analysis.

Percentage error was measured over the complete set of tasks, shorter distances (< 5 metres) versus longer distances (5 metres – 20 metres), independent walkers versus walking-aid users, for slow walkers (< 0.5 m/sec) versus fast walkers (≥ 0.5 m/sec) and between the two different set-up procedures. Over the complete set of tasks, correlation was measured and the Bland Altman plots graphically display the measurement accuracy.

3.5 Results

Forty patients were approached to participate in the study. Two patients appeared confused on initial interview, two refused because they did not want to leave the ward and four others declined to participate. Thirty-two patients consented and completed the study. No adverse events occurred during the recording procedure. The baseline data of the study participants

are described in Table 3.2. Individual analyses of the video recordings were in agreement for 28 patients. The remaining four patients' recordings were analysed together and consensus was reached.

Table 3.2: Patient Baseline Data (n=32) (validation study)

	Frequency (%)	*Mean (SD)* ***Median (25-75 IQR)***
Demographics		
Female	15 (46%)	
Age *(yrs)*		78.1 (± 7.8)
BMI *(kg/m^2)*		26.9 (± 6.1)
Medical Status		
CIRS-G *(range 0 - 56)*		6.5 (± 2.9)
Medications prescribed *(number)*		6.8 (± 3.6)
Presenting complaint:		
Respiratory	12 (38%)	
Impairments as a result of falling	9 (29%)	
Other	11 (34%)	
Frailty classification (SHARE F-I)		
Not frail	9 (28%)	
Pre-frail	7 (22%)	
Frail	16 (50%)	
Physical Ability		
No walking aid	15 (46%)	
Stick	3 (15%)	
Walking frame	7 (35%)	
Fallen in the previous six months	17 (53%)	
Falls Efficacy Scale-International		
(range 16 – 64; >19, moderate-high		
concern about falling)		***18.5 (16.3 – 37.5)***
Short Physical Performance Battery		
(range 0 – 12)		***4 (2 - 6)***
Walking speed (m/sec)		***0.46 (0.36 - 0.66)***
Independent walkers		***0.5 (0.39-0.63)***
Walking-aid-users		***0.41 (0.35-0.44)***

3.5.1 Accuracy over the total programme of tasks

The SAM generally overestimated steps (median error 1%, IQR -3 to 13) but overall, was more accurate than the AP3 and STEP, which underestimated steps (mean 44% (±0.3) and 43% (±0.2) respectively; median 40% (IQR 51 - 35) and 38% (IQR 93 - 27) respectively). Mean and median errors for all tasks are presented in Table 3.3 for comparison. Similarly, the intra-class correlation (ICC) was excellent between the video and the SAM (ICC 0.9, 95% CI, 0.9 to 1.0) but poor between the video and the AP3 (ICC 0.3, 95% CI, -0.2 to 0.6), and the STEP (ICC 0.1, 95% CI, -0.2 to 0.4).

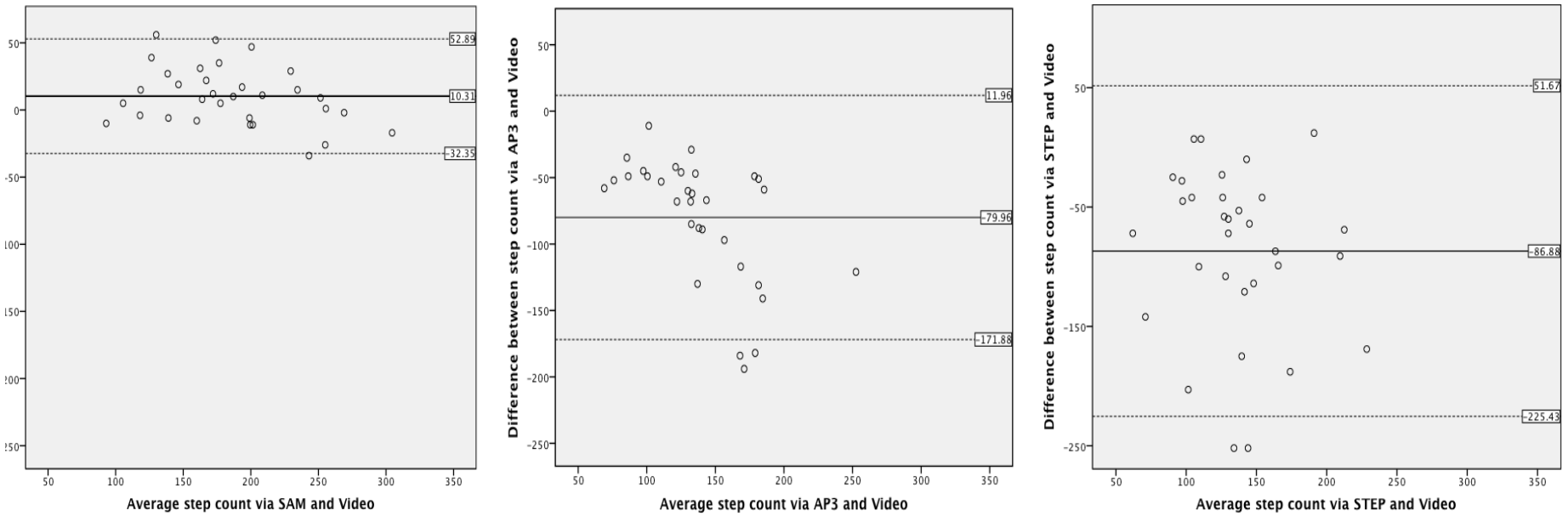
The Bland Altman plots (Figure 3.2) display that, in the overall task, the SAM overestimated steps by an average of 10.31 steps, while the AP3 and the STEP underestimated steps by 79.96 and 86.88 respectively. No trend is apparent in the SAM or the STEP data, while the difference between the video-count and the AP3-count grew larger as the step-count increased. The margins of error between the SAM and the video are narrower than the AP3 and the STEP, while they are similarly wide for both the AP3 and the STEP data. When the percentage errors of the motion sensors were compared over the shorter and longer distances, they were all found to be more accurate over the longer distances. (See Table 3.3 and Figure 3.3).

Table 3.3: Percentage Error of SAM, AP3 and STEP Motion Sensors Compared to Video.

Percentage Error

	STEP Mean (SD) *Median (IQR)*	**AP3** Mean (SD) *Median (IQR)*	**SAM** Mean (SD) *Median (IQR)*
complete tasks (n=32)	-44 (0.3) *-38 (-93 to -27)*	-43 (0.1) *-40 (-51 to -35)*	8 (0.2)* *1(-3 to 13)*
shorter distances (< 5 m) (n=32)	-68 (0.4)* *-79 (-100 to -54)*	-71 (0.8)* *-74 (-85 to -62)*	-4 (0.3)* *-10 (-23 to 9)*
longer distances (> 5 m) (n=32)	-25 (0.3)* *-15 (-45 to -4)*	-28 (0.2)* *-23 (-38 to -17)*	5 (0.8)* *3 (0 to 9)*
independent walkers (n=15)	-28 (0.2) *-29 (-42 to -24)*	-36 (0.1) *-38 (-44 to -27)*	14 (0.2)* *-7 (-2 to 22)*
walking aid users (n=17)	-59 (0.3) *-60 (-77 to -36)*	-49 (0.2) *-48 (-59 to -38)*	4 (0.1) *0 (-5 to -9)*
walking speed <0.5m/sec (n=12)	-65 (0.2) *-65 (-85 to -46)*	-54 (0.2) *-54 (-66 to -46)*	-1 (0.1) *0 (-7 to 5)*
walking speed ≥0.5m/sec (n=20)	-32 (0.3) *-33 (-43 to -20)*	-36 (0.1) *-38 (-43 to -30)*	14 (0.2)* *11 (0 to 21)*

*Non-normally distributed data

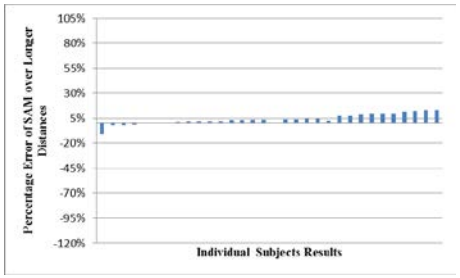


Legend: Bland Altman plots for the total step-count obtained via the motion sensors and the video. The solid line presents the mean difference between the motion sensor and the video; the dotted lines represent the 95% confidence intervals.

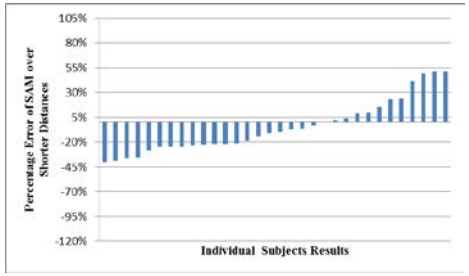
Figure 3.2: Bland Altman plots of (a) SAM (b) AP3 (c) STEP and Video Step-Count for All Patients over the Total Number of Tasks

SAM data

a

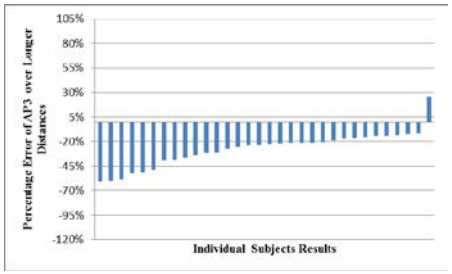


b

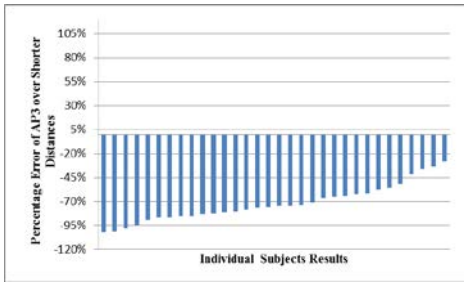


AP3 data

a

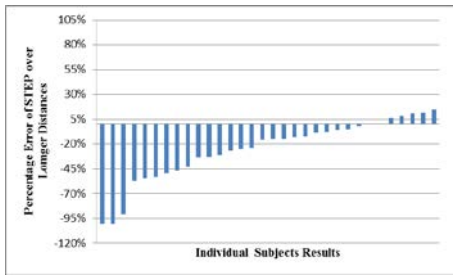


b



STEP data

a



b

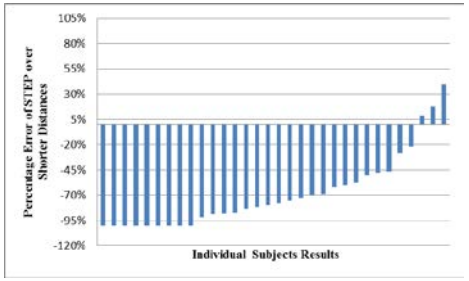


Figure 3.3: Percentage Error of SAM, AP3 and STEP Compared to Video Step-Count over (a) Longer (over 5 Metres) and (b) Shorter Distances (5 Metres or Less)

3.5.2 Accuracy for different walking speeds

The results showed that the AP3 and STEP were more accurate in patients with faster walking speeds and in independent walkers, while the SAM was more accurate in walking-aid-users and in slower walkers (see Table 3.3).

3.5.3 Influence of set-up procedure on accuracy (SAM only)

Results from the subgroup (n=12) wearing two SAM devices simultaneously (SAM 1 at the dominant ankle and SAM 2 just above SAM 1; SAM 1 programmed with standardised sensitivity and SAM 2 with individualised sensitivity) showed that while SAM 1 overestimated, SAM 2 underestimated step-count. However the set-up procedure for SAM 2 yielded marginally better accuracy (SAM 1, (median error 6%, (IQR, -1 to 16%) *versus* SAM 2, median error -6%, (IQR, -11 to -1%), p=0.003)).

3.6 Discussion

There are three main findings from this study. First, overall the SAM gives more accurate step-count measurement in older and frail inpatients than the AP3 and STEP. Secondly, the SAM is most accurate over both long and short distances. Finally, the set-up procedure for the SAM motion sensor appeared to affect step-count accuracy.

Previous literature has shown that the SAM is accurate in slower community-dwellers [97, 87] which is similar to our findings. However, the error margins reported of up to 23% over shorter distances and up to 22% with independent walkers are large and may be unacceptable in some cases. It appears that its set up procedure, which may lead to errors in measurement, should be completed carefully. Accuracy of the AP3 appears similar to that of the uniaxial ActivPAL[57]. Both have an

inclinometer and are worn at the mid-thigh, designed well to measure time-spent-upright. Previously the ActivPAL has been found to measure time-spent-upright accurately but measured step-count inaccurately in older inpatients [57]. Results of this study are similar; the AP3 appeared unable to detect the slower steps of this cohort. Finally, while the STEP was accurate in older community-dwellers [72], their study group walked faster at 0.8 m/sec than our group (median walking speed, 0.46 m/sec) and suggests that the motion sensor is not accurate for slower walking inpatients. We also attempted to attach the STEP as securely as possible, and occasionally used a belt when the patient wore nightclothes. Whether both of these factors affected its accuracy is unclear.

Older frail patients have low PA levels and need regular rests. Therefore each task began and ended in the seated position. No other accuracy study including this position transfer was found during the literature review. As patients transferred back into the chair, the walking pattern became more “shuffling” increasing potential error. There was a higher error margin over shorter distances; this may be as a result of a greater portion of the task being the transfer back into the chair. These short walks were included to mimic the typical walking activity of older inpatients, which would often include moving from the chair to their locker or transferring back to bed.

Unlike the AP3 and STEP, the SAM was found to be less accurate for faster and/or independent walkers, but as the analysis of set-up procedure suggests, this maybe because the sensor was programmed for slow and gentle/geriatric walkers and thus the sensor was over-sensitive. This may have also caused the wider interquartile ranges and error found over the shorter distances (Table 3.3 and Figure 3.3). The subgroup analysis showed that while the SAM 1 overestimated steps, the SAM 2 in contrast, underestimated steps and was marginally more accurate. Both SAM 2 and SAM 1 were worn on the same leg to ensure consistency, but SAM 2 was worn slightly above the recommended placement of above the lateral malleolus (where SAM 1 was placed). Whether its placement,

programming, or both, lessened its sensitivity, needs to be re-examined, especially over shorter distances.

For daily clinical use in hospitals (rather than for research purposes), it is important that use of the motion sensor does not increase the workload for the staff of a busy ward or that it is handled excessively during recording. It was noted during the 40 minute-observation period, that one patient who was slightly confused, interfered with the AP3 (at the thigh), but ignored the SAM (at the ankle), suggesting that patients may be less inclined to handle or interfere with the SAM at the ankle.

3.6.1 Study Limitations

There are a number of limitations to this study. We monitored 40 minutes of activity which was felt appropriate for frail older patients, but a longer period of observation would have strengthened these findings and identified false step-counts with habitual movements (i.e., fidgeting, tapping). There is no way of filtering out these habitual movements, but previous work has suggested that they do not appear to affect accuracy over a 24-hour period of monitoring [104]. However, the effect of habitual movements on the accuracy of longer periods of monitoring needs to be further evaluated. Subgroups of approximately 20-25 participants would be more appropriately sized for secondary analyses, including the set-up procedure. In hindsight, the SAM should have been programmed differently, for those who noticeably walked faster or were more restless at rest, rather than our preselected “frail/slow” programming (patient-specific programming only occurred in the subgroup analysis of the dual SAM testing). Finally, placement of the SAM 2 higher than recommended may have affected its accuracy.

3.7 Conclusions

PA in older and frail medical inpatients is low. An accurate, valid measurement of the levels and patterns of their PA would inform and guide healthcare. The results of this study show that while the SAM was the most accurate motion sensor to measure step-count in this population, the error margins of up to 23% may not be acceptable in many cases. Further work is indicated to clarify the effects of its set up procedure, its placement at the ankle, and whether habitual movements affect its overall accuracy.

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4 Conclusions from Phase 1 and Introduction to Phase 2

Phase 1 aimed to identify an accurate measurement of PA in frail older medical inpatients.

The scholarly review (Chapter 2) revealed that physical activity (PA) can be reported as energy expenditure (EE), intensity classification, time-spent-upright or step-count. As EE can be altered in the presence of an acute infection in older adults [62] and older patients spent most time in sedentary PA[49], it appears that time-spent-upright or step-count would be the most clinically relevant measurements. Time spent upright can be accurately measured in this cohort[13, 57]. However, as the main form (and in many cases, the only form) of PA accessible in hospital is walking, step-count was chosen as the most useful and clinically meaningful measurement of PA.

No commercially available motion sensor has been found to measure step-count accurately in medical inpatients. One important reason for erroneous measurement, is slow walking speed which hinders the accelerometers' ability to detect steps. However, the scholarly review completed revealed that three pedometers, the Omron HJ-720ITC, the SC Step MX and the Yamax SW-200 (worn at the knee) were found to be accurate in older adults who walk slower than 0.8 m/sec. One accelerometer, the Stepwatch Activity Monitor did not appear to be affected by slow walking speeds, and the ActivPAL3, a triaxial version of the ActivPAL, which has been commonly used in previous studies, had yet to be tested in older medical inpatients.

Therefore, the accuracy of three motion sensors in 32 older medical inpatients was tested; the ActivPAL3 (AP3), the Stepwatch Activity Monitor (SAM) and the SC Step MX (STEP) (Chapter 3). Results indicated that the

SAM was the most accurate, with better accuracy over longer distances (greater than five metres), (median 3% error) than shorter distances (less than 5 metres), (median -10% error).

Therefore, the SAM was chosen to measure PA of medical inpatients in Phase 2 of the project. The aim of Phase 2 was to explore the relationships between walking activity, patient presentation and negative health outcomes. (Figure 4.1, Phase 2). Using the SAM to measure walking, the association between walking and (1) length of stay and (2) physical performance at the end of the study (Chapter 5) was measured. Secondly, the main characteristics of patients who walk the least in hospital and the daily events that can influence walking in hospital in this cohort were identified (Chapter 6).

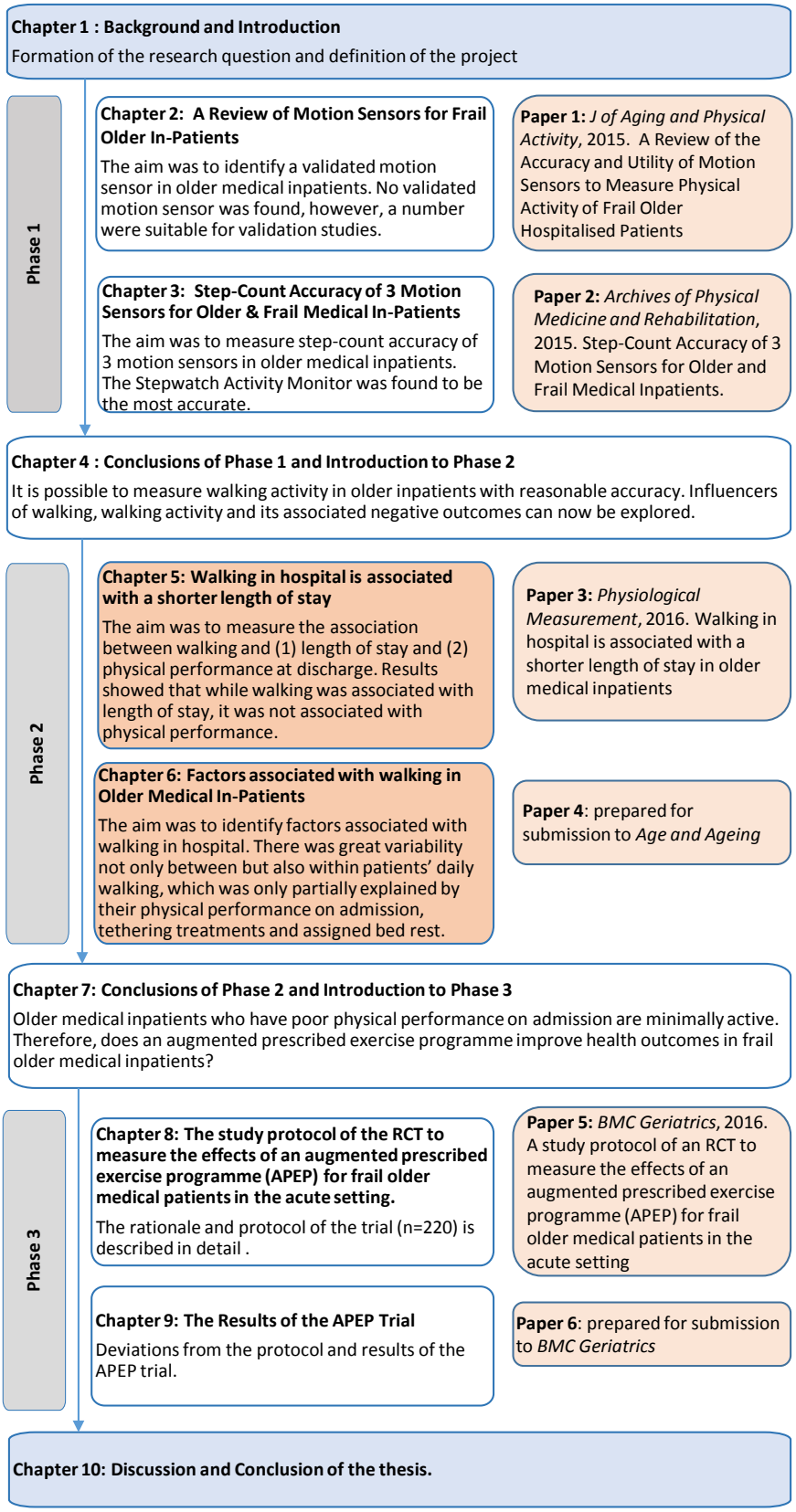


Figure 4.1: Flow diagram of the project, Phase 1 to Phase 2 (Phase 2 in orange)

5 Walking in Hospital is Associated with a Shorter Length of Stay in Older Medical Inpatients

5.1 Background to the Observation Study

The results of the accuracy study suggested that the SAM measured walking with reasonable accuracy and importantly, it was tolerated by the study cohort. Therefore, using the SAM, the aim of this observation study was to identify the patients who are most at risk of decline in hospital, and to measure whether walking was associated with this decline.

I recruited, assessed and completed the initial data analysis of results of the study, with the assistance of my supervisors, Dr Suzanne Timmons, Prof Frances Horgan, and Dr Christina Dillon, who had helped me with earlier studies. I presented the findings on the determinants of functional decline and length of stay in older medical inpatients (in poster format) at the International Conference on Ambulatory Monitoring of Physical Activity and Movement (ICAMPAM). Following the conference, all presenters were invited to submit a full paper for consideration for a Special Issue in *Physiological Measurement*. I decided, along with my supervisors, and co-author, Dr Christina Dillon, to submit a full paper. However, I realised that in its present format, patient presentation was the main focus of the data analysis; that the data from the accelerometry,(which would be the journal's topic of interest), was not. With the assistance of Professor Joe Eustace and Dr Darren Dahly at the Clinical Research Facility, I changed the focus to walking activity (i.e. the accelerometry data) as a predictor of functional decline and length of stay. We specifically limited the data used in this paper to the five weekdays, so that any intervention indicated by the outcome of the analysis may be more relevant for weekday services. The statistical analysis was completed by Dr Darren Dahly, and the paper was subsequently accepted and published in *Physiological Measurements*. The PDF version of the paper is attached in Appendix G.

5.2 Abstract

Background: Evidence suggests that inactivity during a hospital stay can lead to poor health outcomes in older medical inpatients. We aimed to estimate the associations of in-hospital physical activity with physical performance and length of stay in a sample of older patients.

Methods: Medical in-patients aged ≥65 years, premorbidly mobile, with an anticipated length of stay ≥3 days, were recruited. Measurements included physical activity, continuously recorded by a Stepwatch Activity Monitor until discharge or for a maximum of seven days; co-morbidity (CIRS-G); frailty (SHARE F-I); and baseline and outcome physical performance (Short Physical Performance Battery, SPPB). Linear regression models were used to estimate associations of physical activity (average daily step-count over 5 weekdays of observation) with SPPB score and length of stay in hospital. To meet the linearity assumption of the regression models, length of stay was log transformed in the first model, and average daily step count was log transformed in both models. Similar multivariable linear regression models were used to adjust for potential confounders.

Results: Data from 154 patients (mean 77 years ± 7.4 SD) were analysed. Based on the unadjusted linear regression estimates, for each unit increase in the natural log of average daily step count, the natural log of length of stay decreased by 0.18 (95% CI -0.27 to -0.09). After adjustment of potential confounders, the strength of the inverse association was attenuated, but the 95% CI still excluded the null hypothesis of no association ($\beta_{log(steps)}$ = -0.15, 95%CI -0.26 to -0.04). Interpreted in absolute terms, a 50% increase in average daily step count was associated with a 6% decrease in length of hospital stay in this sample. There was no apparent association between average daily step count and end of study SPPB score once SPPB at baseline was adjusted for.

Conclusions: The results indicate that PA is independently associated hospital length of stay, and merits further investigation using a randomized controlled trial.

Keywords: objective measurement, physical activity, walking, older medical inpatients, length of stay, physical performance

5.3 Introduction

Older medical patients occupy most hospital beds, and are most likely to experience prolonged hospital stays [105] and functional decline [7, 20]. While non-modifiable factors, such as age or illness severity, contribute to these outcomes, other modifiable factors may also be involved, such as physical activity (PA), which is known to be low in hospital patients [75].

The reliable, valid measurement of PA in hospital is challenging. Researchers have used nurse or self-reports [11, 19], direct observation [75] and accelerometers [19]. Direct observation can be time consuming and laborious; and while self-reports are easier to administer, busy wards schedules and high levels of delirium in this population [36, 106] may render them invalid. On the other hand, wearable step-counters can provide an objective measure of PA without burdening staff or patients. To date, only one study has used objectively measured step-count to estimate the association between PA and hospital length of hospital stay [19], finding that older medical patients (n=198) who increased their walking activity in hospital by 600 steps from the first to second day tended to stay in hospital two days less.

Two large studies have found that low PA is associated with functional decline at discharge i.e., a poorer ability to perform activities of daily living. Low PA levels, reported by the nursing staff [20] and by the patients themselves [11] were associated with functional decline at discharge. There are currently no studies relating objectively measured PA to physical performance e.g., balance, transfers and walking performance.

Therefore, the aim of this study was to measure the association between objectively measured step-count in hospital and (1) length of stay and (2) physical performance at the end of the study. We hypothesized that low levels of walking in hospital would be associated with poor physical performance and a longer length of stay.

5.4 Methods

This cross-sectional, observational study took place in a 350-bedded general teaching hospital. The study was conducted from July 2014 to January 2015. Ethical approval was granted by the Clinical Research Ethics Committee of the Cork Teaching Hospitals [ECM 3 (ss) 07/05/13] (Appendix H).

5.4.1 Patient Selection

The inclusion criteria were: medical patients aged 65 and over; who have been admitted from home and initially planned for discharge home; whose anticipated length of stay was ≥ 3 days; and who were mobile two weeks prior to admission. The exclusion criteria were: admission for more than 48 hours prior to screening; inability to follow commands in the English language; being bed or chair-bound premorbidly; admissions with an acute psychiatric condition; requiring active end-of-life or critical care; when physical activity was contraindicated (eg. hip fracture or fast atrial fibrillation); or when ankle skin condition was poor (precluding attachment of the accelerometer). Patients were approached in chronological order of admission and an average of two patients was recruited daily.

5.4.2 Procedure

Following informed and written consent (see Appendix I for the Patient Information Sheet), the baseline data was collected. Demographics, home situation and support, smoking and alcohol consumption history comorbidities and number of medications on admission were extracted from the medical records (see Appendix J for Consent Form and Data Collection Form).

The descriptive and objective measurements were taken and the Stepwatch Activity Monitor accelerometer (SAM) was attached (detailed below).

Patients were visited every weekday until discharge, or for the first five weekdays of their hospital stay when the patients' skin, where the SAM unit was attached, was checked. Patients were not visited on the weekends, but continued to wear the SAM.

On the day of discharge or after the first seven days, physical performance (SPPB), quality of life (EQ5D5L) and grip strength (kgs) was re-measured. The SAM unit was removed and the data was downloaded. Length of stay was recorded from the electronic hospital information system.

5.4.3 Outcome Measurements

The outcome measurements included walking activity during the five weekdays (weekend data was not used), physical performance, and length of stay.

5.4.3.1 Walking Activity

The Stepwatch Activity Monitor (SAM) measured the steps taken daily. It is a triaxial accelerometer that is attached directly above the wearer's dominant malleolus (unless skin fragility requires it to be worn on the opposite ankle). Previous studies have found it to be accurate in slow walkers [82, 85], and we found it accurate in older medical inpatients [107].

Sensitivity adjustment is a required step in the set-up procedure for the SAM. Its sensitivity is programmed specifically for each participant according to the manufacturers' instructions before it is attached. The level

of sensitivity is based on the answer selected by the user to four questions appearing on the screen, relating to the participants' height, gait pattern and gait cycle. For each question, the user chooses the most appropriate answer from a range of answers presented, as follows:

(Question 1) "Does the client regularly participate in activities that involve short quick steps?" (Generally, the answer was "no" for the frailer patients).

(Question 2) "Is their walking speed fast or slow? (Relative to people of similar height.)" (Generally the answer was "slow" for patients who need a walking frame or assistance).

(Question 3) "What is the client's range of walking speeds?" (For those who need a walking aid, the answer generally was "rarely changes").

(Question 4) "Describe the appearance of the client's leg motion" (Generally, the answer was "Gentle/geriatric" for the frailer patients.

Step-count was saved in periods of 15 seconds (time interval/epoch). It was attached with a disposable elastic strap, ensuring a secure attachment while giving space for ankle swelling. The unit was checked daily for skin irritation at the attachment site and for any adjustments that were required.

The total step count was summarised as the average daily step count for analysis.

5.4.3.2 Physical Performance

Objective measurement of physical performance was conducted on the ward using the Short Physical Performance Battery (SPPB)[108]. The

SPPB is a validated and widely used composite tool to measure physical performance and includes balance, walking speed and chair-stand tests. Each section is scored between 0-4. Balance is measured by the patient's ability to maintain independent balance for ten seconds with their feet together, in semi-tandem and in tandem stance. Walking speed is measured over eight feet (2.44 metres), and patients are instructed to walk at usual pace, and use their regular walking aid. And finally, the chair-stand test (time taken to stand up five times as fast as possible, with their arms folded), is measured. The total lowest possible score is 0 (unable to stand up, balance independently with feet together, or walk) and the total highest score is 12 (able to stand up five times in less than 11.1 seconds, independent tandem balance and walk four metres in less than 4.82 seconds).

5.4.3.3 Length of stay

At discharge, the patients' length of stay (bed nights) was recorded from the hospital electronic patient information system.

5.4.4 Descriptive Variables taken on admission to hospital

The descriptive variables taken on admission included co-morbidities, frailty, quality of life, cognitive ability, fear of falling and physical performance.

5.4.4.1 Co-morbidities

Comorbidities were measured using the Cumulative Illness Rating Scale-Geriatrics, (CIRS-G)[109]. This validated tool for geriatric patients, measures the severity of impairment over 14 organ systems, and

produces a possible score ranging from 0 to 56; a higher score reflecting a greater impairment in several systems.

5.4.4.2 Cognitive status

Cognitive status was tested using the Six Item Cognitive Impairment Test (6CIT)[110], which is quick to administer has similar diagnostic accuracy to the Mini-Mental State Examination[111]. For the purpose of this study, a highly sensitive cut-off of six points out of a possible 28 points was used to determine whether a patient was confused.

5.4.4.3 Frailty

Frailty was measured using the SHARE FI, a validated and simple frailty instrument based on the Survey of Health, Ageing and Retirement Survey in Europe[99]. Five SHARE variables approximating Fried's frailty definition[112] are used: fatigue, loss of appetite, grip strength, functional difficulties and physical activity. Four of the five domains are self-reported and grip strength is objectively measured. Possible scores range between -2.515 to 6.505, and SHARE-FI gender-specific calculators, freely available on the web, determine the patient's frailty category (frail, pre-frail or not frail)[99]. The SHARE FI was not repeated at discharge as the questions refer to community-dwelling activity only. However, grip strength was repeated at discharge as a surrogate measurement of frailty. Patients' grip strength was measured using the hydraulic Jamar® hand dynamometer (Sammons Preston, Roylan, Bolingbrook, IL, USA) and completed in sitting with the elbow flexed at 90 degrees and kept close to the chest wall. The strongest of two attempts was recorded.

5.4.4.4 Falls History and Falls Efficacy

Number of falls that occurred over the previous six months was recorded and fear of falling was measured using the Falls Efficacy Scale-International [100]. Its internal validity and test-retest reliability have been found high. This self-reported tool consists of 16 activity-related questions; typical community-dwelling tasks or activities, rather than activities in hospital. The questions aim to determine how concerned older adults are about falling while performing these activities on a scale of 1 (not concerned at all) to 4 (very concerned). The patients were asked to report how concerned they were when they felt well at home; in other words, before the onset of their current illness. A cut-off of above 19 points (out of a possible 64 points) indicates a moderate to high concern about falling [101]. If the patient was unable to complete the report, their next-of-kin was interviewed. Validation studies have shown that while next-of-kin have been found to overestimate patients' fear of falling, the information that they provide is consistent and valuable [113]. Once again, this was not asked at discharge as the questions relate only to community-dwelling activities.

5.4.4.5 Quality of Life

Quality of Life was measured using the EuroQol 5 Domain 5 Level Scale [114]. This is a commonly used and easy to administer scale. It covers the domains of mobility, self-care, activity, pain/discomfort and anxiety/depression, and a visual analogue scale, ranging from 0 to 100, to measure their self-reported health status. Once again, the next-of-kin was requested to complete this questionnaire on the patients' behalf if they were unable. The reliability of proxy reports has been debated and evidence exists suggesting that proxy reports are generally poorer than self-reports[115] However, some studies have found little or no difference between self and proxy reports in older adults[116], patients with traumatic brain injury and Parkinson's Disease[117]and with small numbers of

patients included in this study, the decision to include proxy reports was made.

5.4.5 Statistical Methods

Categorical variables were described by the count and proportion in each category. Continuous variables were described by their mean and standard deviation; their 25th, 50th, and 75th quantiles; and their full range.

The relationship between average daily step count and length of hospital stay was estimated with linear regression. Due to the apparent non-linear relationship between these two variables, they were both transformed by taking their natural logarithms. We estimated both a crude linear regression model ($\log(y_i) = \alpha + \beta_1 \log(x_i) + \varepsilon_i$), and a multiple linear regression model adjusted for the potential confounders described above ($\log(y_i) = \alpha + \beta_1 \log(x_i) + \sum_2^k \beta_k x_{ki} + \varepsilon_i$). The relationship between average daily step count and end of study SPPB score was similarly estimated with linear regression, though for these models only average daily step count was log transformed. We estimated a crude linear regression model ($y_i = \alpha + \beta_1 \log(x_i) + \varepsilon_i$), and a second model adjusted for baseline SBBP ($y_i = \alpha + \beta_1 \log(x_{1i}) + \beta_2 x_{2i} + \varepsilon_i$). All linear regression models used a complete case sample, and model assumptions were explored using standard methods. We report estimated regression coefficients and 95% CIs, and respective p-values are for two sided tests of the null hypothesis of no association (β = 0). All analyses were conducted using the R Project for Statistical Computing (version 3.1.2).

5.5 Results

Over the course of the recruitment period, approximately 2,154 medical patients aged 65 and over, were admitted to the hospital. We were able to screen 227 of these for recruitment to this study. Of these, 69 did not meet

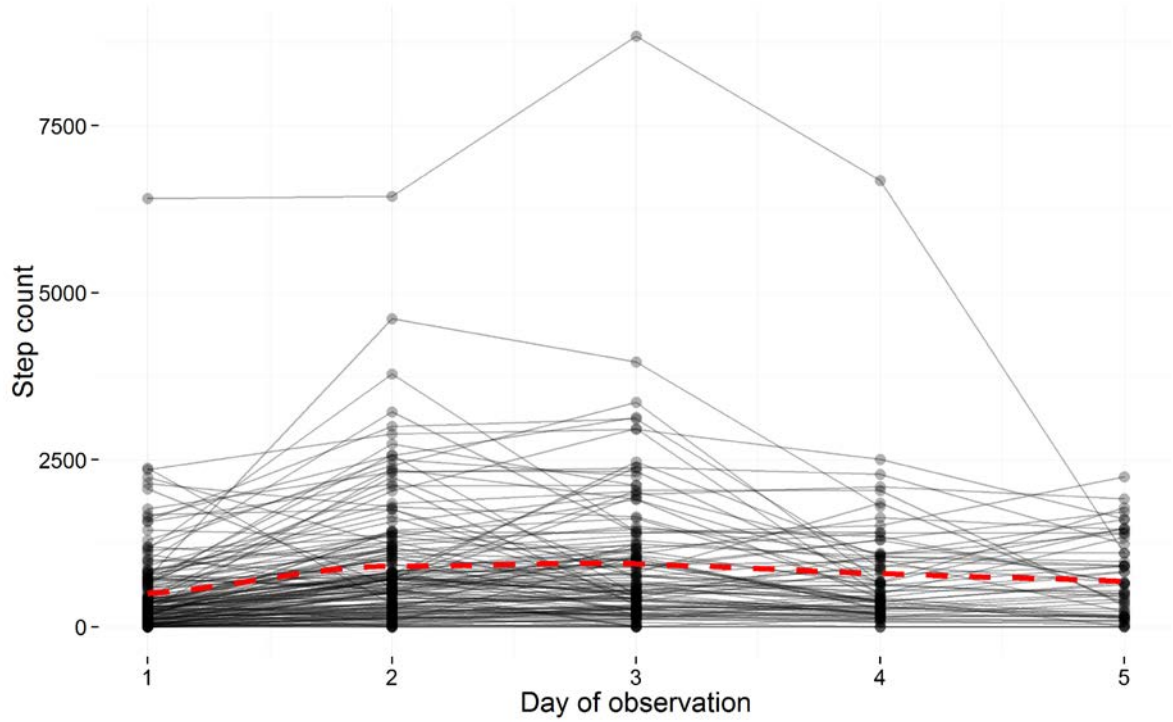
study criteria. Of the 158 eligible patients, four refused to participate in the study, leaving 154 patients who consented and enrolled (95% response rate). Patient ages ranged from 65 to 102 years of age (mean 77.5 ± 7.4 SD), and the sample was evenly split between males and females. Co-morbidity in this sample was common, with an average score of 6.9 on the CIRS-G (±2.8) and 6.5 (±3.7) medications prescribed on admission to hospital. Ninety-eight patients were categorised as frail on admission, and overall, their physical performance was poor (4 ±3.3, SPPB score) and fear of falling high (32.6 ±14.4, FES-I score). Further patient characteristics are provided in Table 5.1.

Table 5.1: Characteristics of study participants (observation study)

Variable	N	Mean ± SD or N (%)	(Min, Max)	25th, 50th, 75th quantiles
Female	154	77 (50%)		
Age (years)	154	77.5 ± 7.4	(65, 102)	71, 78, 83
Body mass index (kg/m2)	154	25.4 ± 6.3	(12.4, 46.1)	20.9, 24.5, 29.3
Height (cm)	154	169.2 ± 8	(150, 184)	163, 170, 175
Smoke	154			
Never		88 (60%)		
Former		53 (30%)		
Current		13 (10%)		
Alcohol	154			
Non drinker		73 (50%)		
Former		21 (10%)		
Current		55 (40%)		
Heavy		5 (0%)		
CIRS-G	154	6.9 ± 2.8	(0, 15)	5, 7, 8.8
Number of medications89iuo]###	152	6.5 ± 3.7	(0, 19)	4, 7, 8
Marital status	154			
Single		29 (20%)		
Partner		73 (50%)		
Widowed		52 (30%)		
SPPB at baseline	154	4 ± 3.3	(0, 12)	1, 3.5, 7
SHARE FI score	154	3.1 ± 1.7	(-0.6, 6.5)	1.9, 3, 4.5
SHARE FI category	154			
Frail		98 (64%)		
Pre frail		44 (29%)		
Not Frail		12 (7%)		
FES-I score	154	32.6 ± 14.4	(13, 64)	18, 30.5, 48
Self rated health (EQ5D)	154	53.9 ± 19.3	(0, 100)	45, 50, 70
6CIT Score	154	8 ± 7.6	(0, 28)	2, 6, 11.8
Average daily step count	148	764.4 ± 706	(16.3, 5896.6)	290.2, 603.2, 1035.5
Log (average daily step-count	148	6.2 ± 1	(2.8, 8.7)	5.7, 6.4, 6.9
Length of stay (nights)	154	8.1 ± 5.4	(1, 28)	4, 7, 10
Log (length of stay)	154	1.9 ± 0.6	(0, 3.3)	1.4, 1.9, 2.3

Abbreviations: **CIRS-G:** Cumulative Illness Rating Scale-Geriatrics; **SPPB**: Short Physical Performance Battery; **SHARE FI**: Survey of Health, Ageing and Retirement in Europe Frailty Index; **FES-I**: Falls Efficacy Scale-International; **6CIT**: 6-Item Cognitive Impairment Test

Data was incorrectly recorded for five patients; hence there were completely missing step counts for these patients. On average, the remaining 149 patients were observed for 3.75 days (median 4 days). A third of patients (n=54) had their step count measured on all five weekdays, while just two patients had their step count measured on only one day. The daily step counts for each patient, over five weekdays of observation, are displayed in Figure 5.1, as well as a curve connecting the daily medians (the median step counts for days 1 through 5 were 299, 661, 593, 458, and 586, respectively).



Caption: Each grey line reflects the set of measurements for a given patient. The red, dashed line connects the median value for average daily step count across all patients, for each weekday (n=154).

Figure 5.1: Daily step count over five consecutive days of observation

The relationship between the natural logarithms of average daily step count and length of stay in the hospital was linear (Figure 5.2). Based on the unadjusted linear regression estimates (Table 5.2), for each unit

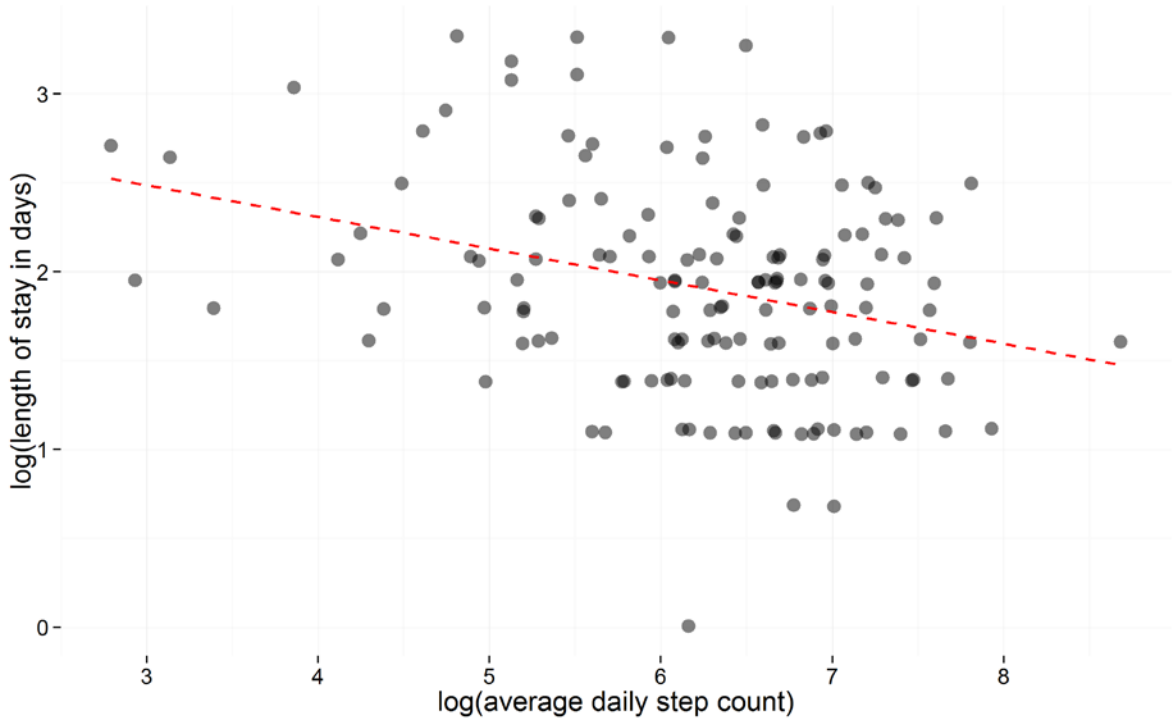
increase in the former, the latter decreased by 0.18 (95% CI -0.27 to -0.09). After adjustment of potential confounders, the strength of the inverse association was attenuated, but the 95% CI still excluded the null hypothesis of no association ($\beta_{log(steps)}$ = -0.15, 95%CI -0.26 to -0.04). If we back-transform the results from the log to the absolute scales, a 50% increase in average daily step count was associated with a 6% decrease in length of hospital stay in this sample ($\left(\frac{(1+0.5)}{1}\right)^{\beta} = 1.5^{-0.15} = 0.94 = 1 - 0.6$). The nonlinear nature of this association is further depicted in Figure 5.3. The estimated regression coefficients for the covariates included in the full adjusted model are also given in Table 5.2. These can be multiplied by 100 to give the (approximate) percent change in the geometric mean of patient length of hospital stay associated with a one unit increase in the covariate. For example, each additional chronic condition (CIRS-G) was associated with a 4% increase in length of hospital stay (β_{CIRSG} = 0.04, 95% CI 0.004 to 0.08).

Table 5.2: Unadjusted and adjusted linear regression results (n=149)

	Dependent variable: log (Length of hospital stay in days)	
	Unadjusted	Adjusted
log (Average daily step count)	-0.18*** (-0.27, -0.09)	-0.15** (-0.26, -0.04)
Female (vs. male)		0.20 (-0.08, 0.48)
Age (years)		0.0004 (-0.02, 0.02)
Body mass index (kg/m)		-0.01 (-0.02, 0.01)
Former smoker (vs. never)		0.12 (-0.11, 0.35)
Current smoker (vs. never)		-0.04 (-0.41, 0.33)
Doesn't drink alcohol anymore (vs. never)		-0.15 (-0.47, 0.16)
Still drinks alcohol (vs. never)		0.09 (-0.13, 0.32)
Heavy drinker (vs. never)		-0.31 (-0.96, 0.33)
CIRS-G		0.04** (0.004, 0.08)
Number of medications		-0.02 (-0.05, 0.01)
Married (vs. single)		0.02 (-0.26, 0.30)
Widowed (vs. single)		0.10 (-0.21, 0.41)
SPPB at baseline		-0.01 (-0.05, 0.03)
SHARE FI score		0.03 (-0.04, 0.09)
FES score		0.01 (-0.003, 0.02)
Self-rated health (EQ5D)		0.001 (-0.005, 0.01)
6CIT Score		-0.001 (-0.02, 0.01)
Constant	3.02*** (2.44, 3.60)	-1.76 (-5.16, 1.64)
Observations	148	146
R^2	0.09	0.25
Adjusted R^2	0.08	0.13
Residual Std. Error	0.57 (df = 146)	0.56 (df = 126)
F Statistic	14.63*** (df = 1; 146)	2.16*** (df = 19; 126)

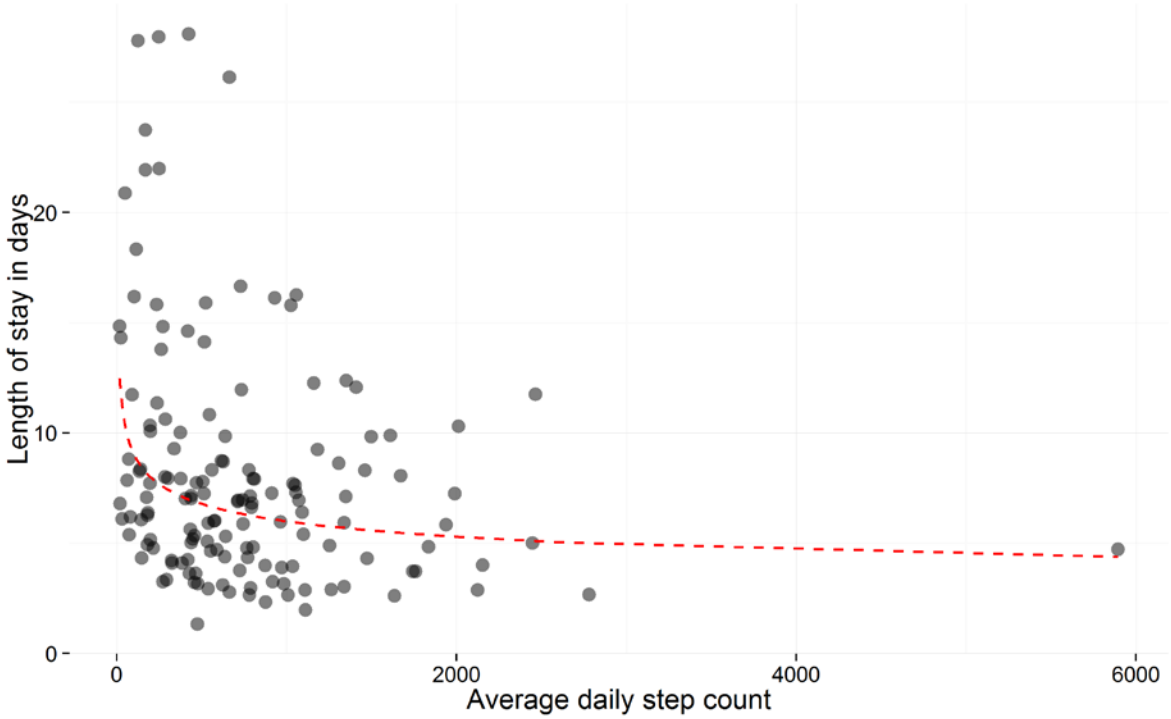
Note: *p**p***p<0.01

Abbreviations: **CIRS-G**: Cumulative Illness Rating Scale-Geriatrics; **SPPB**: Short Physical Performance Battery; **SHARE FI**: Survey of Health, Ageing and Retirement in Europe Frailty Index; **FES-I**: Falls Efficacy Scale-International; **6CIT**: 6-Item Cognitive Impairment Test



Caption: The red dashed line is the unadjusted linear regression line reported in Table 5.2.

Figure 5.2: The linear relationship between the patients' (log) length of stay (days) and (log) average daily step count



Caption: The red dashed line is the unadjusted linear regression line reported in Table 5.1, back-transformed from the log to the absolute scales of the x and y axes.

Figure 5.3: The non-linear relationship between patients' length of stay and average daily step count

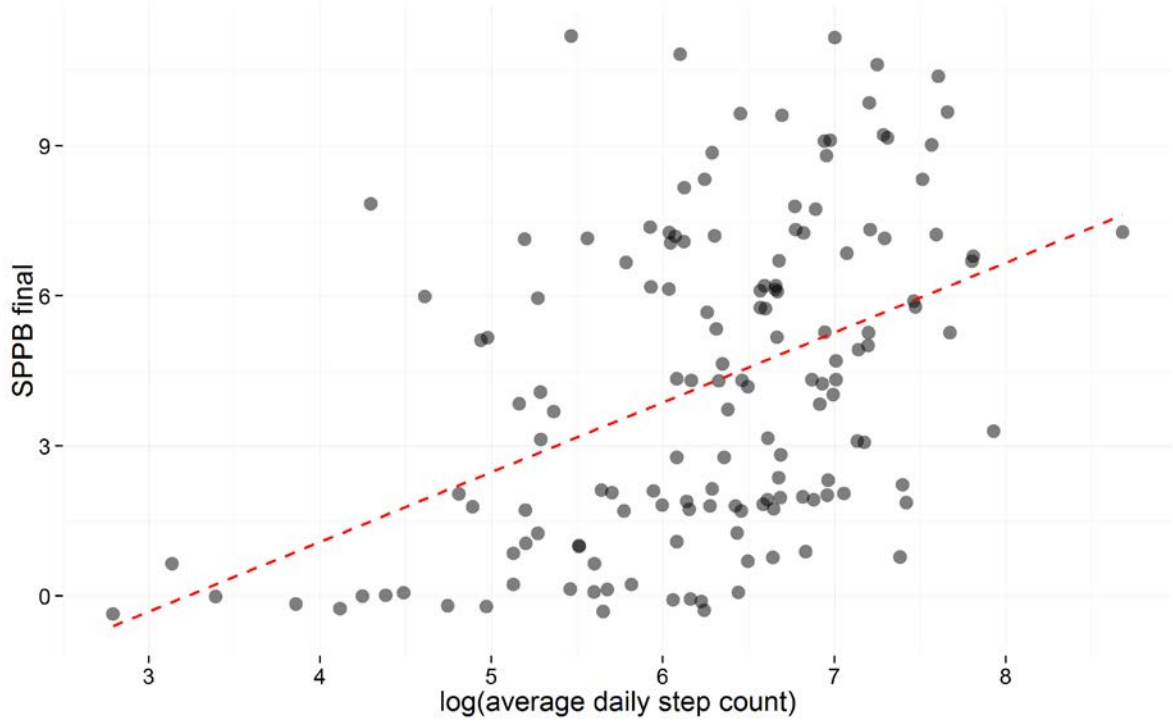
While there was a strong positive relationship between end of study patient physical performance as measured by the SPPB (Table 5.3 and Figure 5.4) and average daily step count, this relationship disappeared once physical performance at baseline was accounted for (Table 5.3). This is further illustrated by the lack of association between average daily step count and change in SPPB scores over the course of the study (Figure 5.5).

Table 5.3: Unadjusted and adjusted linear regression results (dependent variable: end of study physical performance (SPPB)

	Dependent variable: End of study SPPB	
	Unadjusted	Adjusted
Log (Average daily step count)	1.40*** (0.93, 1.86)	0.25 (-0.06, 0.57)
SPPB at baseline		0.75*** (0.66, 0.84)
Constant	-4.50*** (-7.44, -1.56)	-0.46 (-2.31, 1.39)
Observations	147	147
R^2	0.19	0.71
Adjusted R^2	0.19	0.70
Residual Std. Error	2.82 (df = 145)	1.71 (df = 144)
F Statistic	34.77*** (df = 1; 145)	172.30*** (df = 2; 144)

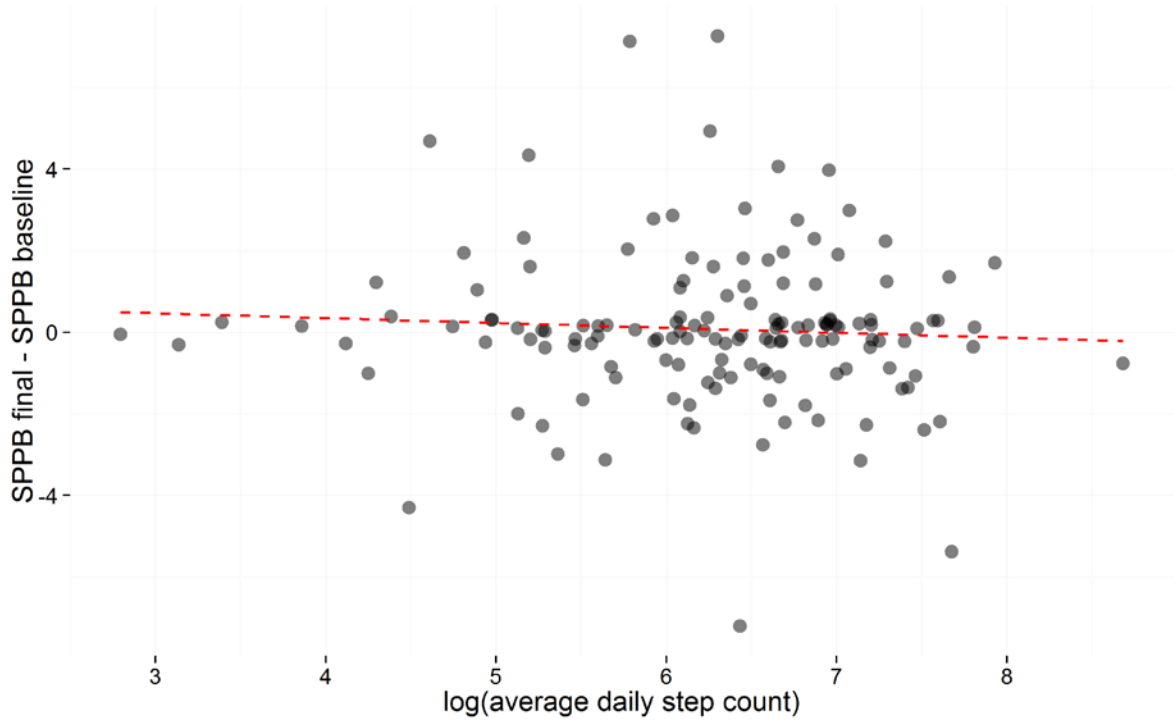
Note: *p**p***p<0.01

Abbreviations: **SPPB**: Short Physical Performance Battery



Caption: The red, dashed line is the unadjusted linear regression line reported in Table 5.3.

Figure 5.4: The linear relationship between end of study physical performance (SPPB) and the (log) average daily step count



Caption: The red dashed line is the unadjusted linear regression line.

Figure 5.5: The relationship between change in physical performance (SPPB) over the course of the study and (log) average daily step count

5.6 Discussion

There are two main findings from this study. First, average daily step count in hospital is related to length of stay even after adjustment for a number of potential confounders; and second, the positive association between average daily step count and physical performance at the end of the study (discharge or day 7 of admission) was fully explained away once physical performance at baseline was accounted for.

Physical activity in hospital has been suggested as a modifiable determinant of physical performance and length of stay, but few studies have measured their associations using objective measures e.g., step-count. To date, this appears to be the first paper which has determined the absolute association, which is of clinical value. The effect of step-count on length of stay is significant but relatively small when compared to that found by Shadmi and Zisberg [18]. They found that patients who were mobile outside of their room remained in hospital 1.5 days less. The difference in effect appears larger in their study, but this may be related to the patient selection. Shadmi and Zisberg [18] included those admitted from institutional care and those who had low mobility levels. They reported that 65% of the patients walked at least once a day outside their room, 16% walked only in their room and 19% only transferred from bed to chair. Similarly, Fisher et al. [19] included patients who were not mobile premorbidly. In contrast, only premorbidly independently mobile community-dwellers were included in this study. Nonetheless, results are comparable and all indicate the importance of mobility in hospital.

This finding may be a particularly important finding for the frailer patients, with low baseline PA. For example, doubling the walking activity in those who remain in the room or transfer from bed to chair could remain a relatively low level of walking activity in absolute terms. Alternatively, independently mobile patients might require nothing more than education, encouragement and monitoring. Therefore, relatively simple interventions may result in considerable health gains.

There are a number of limitations to this study. The aim of this study was to determine whether walking activity in hospital is associated with physical performance at the end of the study or length of stay. For this reason, physical performance was measured immediately after the period of observed walking activity, not at discharge for those patients who remained in hospital after the observation period. Therefore, we are unable to draw conclusions relating to physical performance at discharge for those with a length of stay longer than one week.

The sample size of 154 patients was relatively small, limiting the opportunity to complete logistic regression analysis and define clinically interpretable cut-off points. Only patients who were mobile premorbidly were recruited, which is a relatively narrow sample of the population. The adjusted models included all confounding variables to limit bias in their selection for inclusion. However, as a result, the number of variables is greater than the recommended 1 variable to 10 observations, thereby potentially reducing the model's power to detect associations. The average daily step count was used to represent PA in hospital; however bouts or changes in PA may have provided more sensitive information, as currently suggested by many researchers [94, 95].

5.7 Conclusion

To conclude, the results of this study show that there is a small negative association between walking activity in hospital and length of stay, independent of age, baseline physical performance, co-morbidities and frailty. Walking activity is a simple, modifiable factor. For this reason, a definitive randomised controlled trial is currently underway to determine whether increased walking activity and exercise in this population shortens length of stay and improves physical performance.

6 Factors Associated with Walking in Older Medical Inpatients

6.1 Background to the Secondary Analysis of the Observation Study

The analysis of the data from the observation study suggested that less walking was associated with a shorter length of stay. However, variability in the day-to-day walking activity could not be explained. This information would be relevant to clinical work by identifying barriers to walking that may be easily resolved.

Therefore, as part of the data collection, I recorded the presence or absence of particular factors that may influence walking activity. This paper presents the analysis of this data, using walking activity as the dependent variable. Dr Darren Dahly completed further analysis of the data for this paper, and with the assistance of Dr Suzanne Timmons and Prof Frances Horgan, this paper has been prepared for submission to *Age and Ageing*.

6.2 Abstract

Introduction: We aimed to identify patient characteristics and daily events that could influence walking among older medical inpatients.

Methods: Medical inpatients aged ≥65 years, premorbidly mobile, with an anticipated hospital stay ≥3 days, were recruited. Walking activity (Stepwatch Activity Monitor) was continuously recorded for 7 days or until discharge and potential influencers of walking on the concurrent weekdays. These included medical status, assigned bed-rest, the need for assistance or walking aid, tethering treatments such as catheters/intravenous lines, agitation/confusion, reported fatigue, pain, and fear of falling. Linear mixed effects models were used to measure the associations between log-transformed step-count and potential influencers, adjusted for each other, and key patient characteristics on admission: age, sex, height, weight, physical performance (SPPB), number of medications, and illness severity (CIRS-G).

Results: Complete data existed for 147 patients. In the fully adjusted mixed effects model, walking increased linearly (12%, 95% CI 2% - 23%) for each observed day. However, the mixed effects model with patient-level random intercept and slope factors fit the data best, suggesting there was considerable patient-level variability in step-count. Patients walked most on Wednesdays (1.26 CI 1.04, 1.53) and least on the first day of measurement (0.51 CI, 0.42, 0.62). More walking was associated with better physical performance on admission (1.15, CI, 1.08, 1.22), and with patients' improving medical status (1.33 CI 1.07-1.64). Less walking was associated with tethering treatments (0.71, CI 0.56, 0.91) and instructed bed-rest (0.31, CI 0.21, 0.45).

Conclusion: Both between- and within-patient daily walking was variable, even when adjusted for patient characteristics on admission. Tethering treatments can reduce walking and may possibly be modifiable. Physical performance on admission is a strong indicator of walking in hospital and would be a useful assessment on admission.

6.3 Introduction

We recently found that older in-patients walk an average of 600 steps per day (approximately 12 minutes walking) and that walking appears to be associated with length of stay[118]. However, relatively little is known about the day-to-day walking patterns and factors associated with walking while in hospital. Qualitative data has shown that patients feel confined to their bed space, are not encouraged to walk, receive conflicting advice from staff, and that tethering treatments (such as intravenous fluids, wall-mounted oxygen etc.) are common, preventing mobility[40]. Other non-modifiable factors include assigned bed rest. Little is known about how much each factor affects walking activity. Therefore, the aim of this study was to identify the main characteristics of patients who walk the least in hospital, describe their day-to-day walking pattern, and examine the in-hospital and treatment practices which can prevent walking in hospital.

6.4 Methods

This paper describes additional analyses of the data reported in an earlier paper [118]. This cross-sectional, observational study was conducted from July 2014 to January 2015 in a 350-bedded general teaching hospital. Ethical approval was granted by the Clinical Research Ethics Committee of the Cork Teaching Hospitals [ECM 3 (ss) 07/05/13] (Appendix H).

The patient selection has been previously described [118]. In short, medical patients aged ≥65 years, premorbidly mobile, admitted from home, with an anticipated hospital stay ≥ 3 days were recruited. They were recruited on weekdays only, and approached in chronological order of admission.

6.4.1 Procedure

Following informed consent, baseline data were recorded from the ward notes and included demographics, home situation, smoking and alcohol consumption history, comorbidities and number of medications prescribed (see Appendices I and J for the Patient Information Sheet, Consent Form and Data Collection Sheets).

Baseline measurements of co-morbidities (Cumulative Illness Rating Scale, CIRS-G[109]), cognitive status (Six Item Cognitive Impairment Test, 6CIT[110]), frailty (Survey of Health, Ageing and Retirement Survey in Europe, SHARE F-I[99]), physical performance (Short Physical Performance Battery, SPPB [108]), falls history and falls efficacy (Falls Efficacy Scale- International, FES-I[100]) and quality of life (EuroQol 5 Domain 5 Level, EQ5D5L [114]) were used to describe the patients. These have been previously detailed in Sections 5.4.3 and 5.4.4. Length of stay (bed nights) was recorded from the hospital electronic patient information system.

Walking activity was measured using the SAM. It was attached as previously described (Section 5.4.3.1). Of note, the SAM unit began recording immediately, leaving the first day of data collection truncated. All seven days data (including any weekend data) was used in the analysis.

Patients were visited every weekday until discharge or for the first five weekdays by RMcC. The nurses and patients were asked specific questions about factors that may influence walking. (See below). The skin's condition at the site of the SAM was checked. Patients were not visited on the weekends, but continued to wear the SAM.

On the day of discharge or after the first seven days, the SAM was removed and the data was downloaded using the software provided and length of stay was recorded.

6.4.2 Daily recorded potential influencers of walking

Possible influencers to walking were measured daily dichotomously (present or absent) as reported by the patient/ nursing staff. The patient/nursing staff questions are fully detailed below.

The nursing staff were asked the following questions in relation to the last 24 hours:

1. Which best described the patients' medical status: improving / stable / deteriorating?
2. Do you think that [name of patient] is more confused lately? (Single question in delirium, SQiD)
3. Has the patient been confused or agitated, or "wandering" on ward, or need continuous monitoring?
4. Have their consciousness levels deteriorated?

The patients were asked the following questions:

1. Do you think that you have been a little more confused lately?
2. How many walks did you take yesterday?
3. Did you see the physiotherapist or the occupational therapist yesterday?
4. What do you need to walk around today? Do you need a walking aid or someone to walk with you?
5. Have the nurses asked to you call them for help if you want to walk?
6. Have you been instructed to stay in bed?
7. Are you frightened of falling or do you have any pain?
8. Did you sleep well last night?
9. Are you feeling tired today?

The presence of equipment tethering the patient to the bed, such as intravenous (I/V) lines, wall-supplied oxygen etc., was also noted.

Responses from those who were known to have some confusion were checked with the nursing staff and documentation in the medical notes.

6.4.3 Statistical Methods

Categorical variables were described by count and proportion. Normally distributed continuous variables were described by their mean (± SD), and non-normally distributed data, by their median [IQR], and their range.

The relationships between log-transformed step-count and daily recorded influencers of walking were estimated with linear mixed-effects regression models. We estimated four models in total. Each included a random effect for patient to account for the clustered/longitudinal nature of the data. The first, an empty model with no covariates showed the crude within and between-patient variability in step-count. Preliminary analyses of the data showed differences in walking on the first day and Wednesdays; therefore, in the second model, we adjusted for these days. In the third model we added the patient baseline presentation measurements taken on admission (described above), and in the final model, the daily recorded potential influencers (described above). All models used a complete case sample, and model assumptions were explored using standard methods.

Fixed effects estimates from the mixed models are presented as ratios of geometric means, with 95% confidence intervals. Any p-values are for two sided tests ($\beta = 0$). All analyses were conducted using the R Project for Statistical Computing (version 3.4.0).

6.5 Results

We screened 227 of the 2,154 medical patients aged ≥65 admitted to hospital during the recruitment period. Of these, 69 did not meet study criteria, four refused, and 154 (77.5 ± 7.4 SD years, 50% female)

consented (67.8% of those screened). Seven patients had missing data, leaving 147 patients in our analytical sample.

6.5.1 Characteristics on Admission

On admission, co-morbidity (CIRS-G 6.9, ±2.8) and prescribed medicine were common (6.6, ±3.7). Ninety-eight patients (64%) were categorised as frail; physical performance was poor (mean SPPB 4.0, ±3.4) and fear of falling high (mean FES-I 32.6, ±14.4). Seventy-three (47%) patients were independently mobile, 43 (29%) needed a walking aid, 24 (16%) needed assistance and seven (5%) were unable to walk on admission (although premorbidly mobile). Patients' median length of stay was 7 (IQR 4-10) days. (Table 6.1).

Table 6.1: Patient characteristics on admission (n=147) (observation study)

Variable	Mean ± SD or n (%)	(Min, Max)	25th, 50th, 75th quantiles	Effect
Female (vs male)	73 (49.7%)			1.13 (0.75 to 1.69)
Age (years)	77.5 ± 7.4	(65, 102)	71, 78, 83	0.97 (0.94 to 1)
Height (cm)	169 ± 8	(150, 184)	163, 170, 175	0.99 (0.96 to 1.01)
Weight (kg)	72.9 ± 18.2	(40.3, 131.4)	58, 70, 84.2	1 (0.99 to 1.01)
Number of medications	6.6 ± 3.7	(0, 19)	4, 7, 8.5	1.03 (0.97 to 1.09)
CIRS-G	7 ± 2.8	(0, 15)	5, 7, 9	1.05 (0.98 to 1.13)
SPPB	4 ± 3.4	(0, 12)	1, 4, 7	1.18 (1.12 to 1.25)

* Effect size was estimated using linear mixed effects models with log (step-count) as the dependent variable.

6.5.2 Daily recorded potential influencers

A total of 529 observations of daily potential barriers to walking were made and are described in Table 6.2. Over the total number of events, 347 (84.5%) patients were stable or improving, and 157 (30%) had therapy the previous day. While only 14 (2.6%) reported a fall, 145 (27%) reported fear of falling. Less than 156 (30%) reported pain, 287 (54%) complained of tiredness, 220 (42%) needed an aid and 153 (29%) needed assistance to walk.

Table 6.2 Daily recorded potential barriers to walking

Variable	n (%)	Effect*
Medical status		
stable	261 (49.3%)	-
critical	6 (1.1%)	**2.39 (1.01 to 5.67)**
deteriorating	35 (6.6%)	0.72 (0.48 to 1.09)
improving	186 (35.2%)	**1.95 (1.58 to 2.42)**
At baseline	41 (7.8%)	**1.65 (1.14 to 2.38)**
Any therapy on the day prior		
No	372 (70.3%)	-
Yes	157 (29.7%)	0.83 (0.65 to 1.07)
Assigned bedrest		
No	487 (92.1%)	
Yes	42 (7.9%)	**0.25 (0.17 to 0.37)**
Tethered		
No	402 (76%)	
Yes	127 (24%)	**0.58 (0.44 to 0.76)**
Fear of falling		
No	384 (72.6%)	-
Yes	145 (27.4%)	**0.48 (0.36 to 0.65)**
Fell the previous day		
No	515 (97.4%)	-
Yes	14 (2.6%)	0.66 (0.35 to 1.23)
Pain		
No	373 (70.5%)	-
Yes	156 (29.5%)	**0.71 (0.54 to 0.94)**
Tired		
No	242 (45.7%)	-
Yes	287 (54.3%)	**0.73 (0.58 to 0.91)**
Needs assistance to walk		
No	376 (71.1%)	-
Yes	153 (28.9%)	0.86 (0.66 to 1.12)
Needs an aid to walk		
No	309 (58.4%)	-
Yes	220 (41.6%)	1.07 (0.81 to 1.41)
Confusion(SQiD)		
No	435 (82.2%)	-
Yes	94 (17.8%)	**0.55 (0.39 to 0.8)**
Agitated		
No	520 (98.3%)	-
Yes	9 (1.7%)	0.98 (0.43 to 2.23)

6.5.3 Walking Patterns

On average, potential influencers were recorded for 4.1 out of 5 possible weekdays, and just 22 patients were observed for less than 3 weekdays. There were a total of 529 patient-days of observation. The patient-level step-count trajectories are displayed in Figure 6.1. The crude within-patient estimated variance was 1.23, which was 53% of the total variance in log (step-count). This proportion of variance was consistent across the four models (estimates not shown). With this level of variance within patients over time, it was impossible to summarize and compare patterns between patients over time.

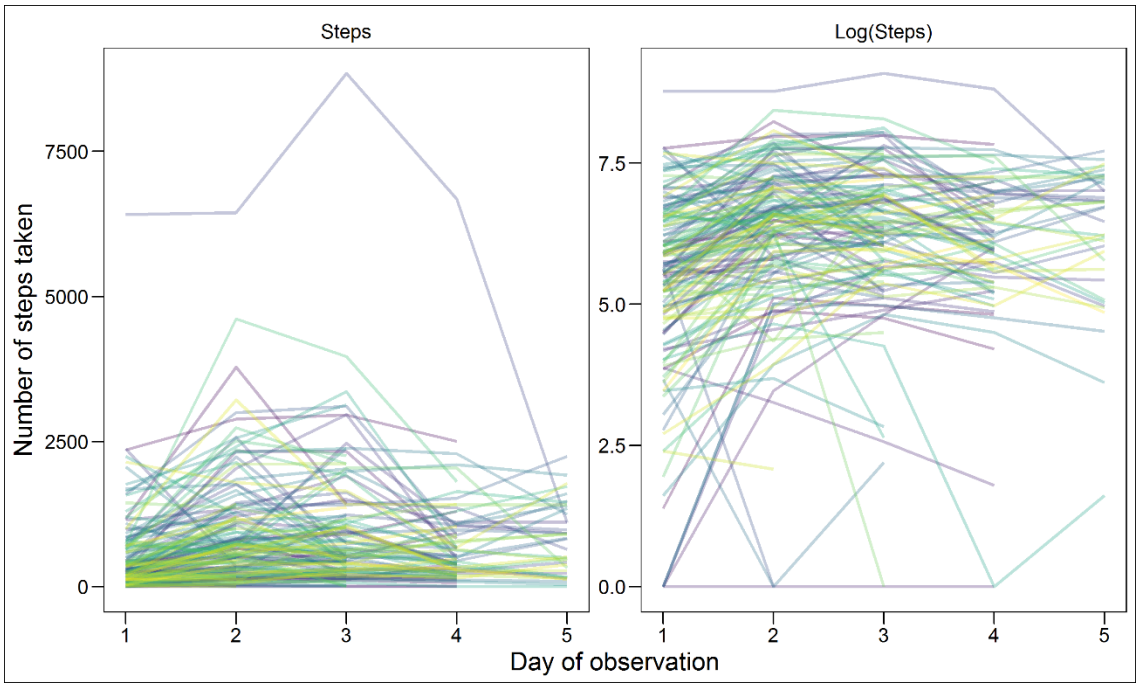


Figure 6.1: Step-count trajectories for patients over recorded days (n=147)

Step-counts on the first day were 56% lower than other days (0.44 95%CI 0.37 to 0.52, Table 6.3), which was expected as many wore the accelerometers for only half the day. A preliminary analysis found that step-counts were 25% higher on Wednesdays than other days of the week (1.25 95%CI 1.02 to 1.52, Table 6.3).

6.5.4 Measurements on admission associated with step-count

A one-unit increase in SPPB measured on admission was associated with a 15% increase in step-count (1.15 CI, 1.08-1.22, Table 6.3). No other measurement on admission was strongly associated with step-count.

6.5.5 Daily recorded potential influencers to walking

Unadjusted measurement of association between walking and daily recorded influencers suggest that deteriorating medical status, assigned bed-rest, tethering treatments, fear of falling, pain, tiredness and confusion are significantly associated with less walking. However, when adjusted, only improving medical status (1.33 CI, 0.95-1.10), assigned bed rest (0.31 CI, 0.21-0.45), and tethering treatments (0.71 CI, 0.56-0.91) were strongly associated with step-count. Needing assistance and fear of falling also showed a trend towards association with reduced step-count (by 15%). Assigned bed-rest and tethering treatments appeared to be the predominant drivers, and occurred frequently (151 observations). When these observation days were removed from the model, we found broadly similar results (Table 6.4).

Table 6.3: Measurements associated with log (step-count) (n=147)

	Dependent variable: Log(step-count)			
Variable	Empty	+ Day effect	+ Assessment on Admission	+ Daily reported barriers
	(1)	(2)	(3)	(4)
Wednesday		**1.25 (1.02, 1.52)**	**1.24 (1.02, 1.51)**	**1.26 (1.04, 1.53)**
First day		**0.44 (0.37, 0.52)**	**0.44 (0.37, 0.52)**	**0.51 (0.42, 0.62)**
Age (years)			1.00 (0.98, 1.03)	1.00 (0.98, 1.02)
Female (vs. male)			1.01 (0.63, 1.61)	0.95 (0.62, 1.46)
Height (cm)			0.98 (0.95, 1.01)	0.98 (0.96, 1.01)
Weight (kg)			1.00 (0.99, 1.02)	1.00 (1.00, 1.01)
Total medications			1.02 (0.96, 1.07)	1.02 (0.97, 1.07)
CIRS-G			1.03 (0.95, 1.10)	1.02 (0.95, 1.08)
SPPB at baseline			**1.19 (1.12, 1.27)**	**1.15 (1.08, 1.22)**
Medically critical				1.79 (0.81, 3.94)
Medically deteriorating				0.74 (0.50, 1.08)
Medically improving				**1.33 (1.07, 1.64)**
Medically at baseline				0.81 (0.56, 1.17)
Any therapy the day prior				0.85 (0.68, 1.07)
Assigned bedrest				**0.31 (0.21, 0.45)**
Fear of falling				0.88 (0.65, 1.18)
Falls				1.13 (0.65, 1.97)
Pain				0.85 (0.66, 1.10)
Tethered				**0.71 (0.56, 0.91)**
Tired				0.92 (0.75, 1.12)
Needs assistance				0.84 (0.63, 1.11)
Needs an aid				1.08 (0.82, 1.44)
SQiD				1.05 (0.76, 1.46)
Agitated				1.58 (0.76, 3.32)
Constant	387.73 (315.77, 476.00)	474.67 (383.07, 588.35)	174.80 (96.18, 317.36)	279.80 (154.36, 504.32)
Observations	529	529	529	529
Log Likelihood	-877.57	-837.34	-817.8	-780.83
Akaike Inf. Crit.	1,761.13	1,684.68	1,659.59	1,615.66
Bayesian Inf. Crit.	1,773.95	1,706.03	1,710.85	1,730.97

Note: p>0.05 in bold. Abbreviations and possible score ranges: **SPPB:** Short Physical Performance Battery [a higher score reflects a better physical performance, range 0-12]; **CIRS-G**: Cumulative Illness Rating Scale [a higher score reflects greater illness burden; range 0-56]. **SQiD:** Single Question in Delirium [yes/no answer].

Table 6.4 : Measurements associated with log (step-count) with tethering treatments and assigned bed rest removed

	Dependent variable: Log(step-count)			
	Empty	+ Day effect	+ Assessment on Admission	+ Daily reported barriers
	(1)	(2)	(3)	(4)
Wednesday		1.20 (0.98, 1.48)	1.21 (0.99, 1.48)	1.19 (0.97, 1.46)
First day		**0.53 (0.44, 0.64)**	**0.52 (0.43, 0.63)**	**0.58 (0.47, 0.72)**
Age (years)			0.99 (0.96, 1.01)	0.99 (0.96, 1.01)
Female (vs. male)			0.84 (0.57, 1.25)	0.86 (0.58, 1.27)
Height (cm)			0.97 (0.95, 1.00)	0.98 (0.95, 1.00)
Weight (kg)			1.01 (1.00, 1.02)	1.01 (1.00, 1.02)
Total medications			0.99 (0.94, 1.04)	1.00 (0.96, 1.05)
CIRS-G			1.04 (0.98, 1.11)	1.03 (0.97, 1.09)
SPPB at baseline			**1.14 (1.08, 1.20)**	**1.12 (1.06, 1.18)**
Medically poor				0.94 (0.39, 2.24)
Medically critical				0.51 (0.32, 0.81)
Medically improving				1.24 (0.98, 1.56)
Medically at baseline				0.81 (0.58, 1.12)
Any therapy the day prior				0.86 (0.68, 1.08)
Fear of falling				0.86 (0.63, 1.18)
Falls				0.64 (0.33, 1.25)
Pain				0.86 (0.66, 1.11)
Tired				0.94 (0.77, 1.15)
Needs assistance				0.84 (0.62, 1.12)
Needs a walking aid				1.12 (0.83, 1.52)
SQID				1.10 (0.79, 1.51)
Agitated				1.44 (0.61, 3.36)
Constant	511.61 (426.34, 613.14)	580.35 (480.17, 700.95)	296.46 (176.22, 497.27)	347.47 (195.91, 615.27)
Observations	378	378	378	378
Log Likelihood	-560.93	-539.45	-519.25	-504.45
Akaike Inf. Crit.	1,127.86	1,088.91	1,062.50	1,058.89
Bayesian Inf. Crit.	1,139.67	1,108.58	1,109.72	1,157.27

Note: p>0.05 in bold. Abbreviations and possible score ranges: **SPPB:** Short Physical Performance Battery [a higher score reflects a better physical performance, range 0-12]; **CIRS-G**: Cumulative Illness Rating Scale [a higher score reflects greater illness burden; range 0-56]. **SQiD:** Single Question in Delirium [yes/no answer].

6.6 Discussion

There are four main findings from this study. Firstly, great variability in walking activity exists between patients, but also within patients. Secondly, patients are 25% more active on Wednesdays. Thirdly, physical performance on admission appears to be the strongest predictor for walking activity in hospital. And finally, patients who are on assigned bed-rest, or tethered to the bed were less active, whilst patients who were medically improving were more active.

Probably the most important and surprising finding of this study is the considerable variability in within-patient walking activity. The study attempted to explore why a patient would walk more (or less) in hospital by examining their presentation, medical stability, and potential barriers to walking each day. While definite barriers were identified, much of the variability remains unexplained. This suggests that the patient's response to the hospital may play a greater role than expected. Anxiety, liaison with staff or other patients or response to information from health professionals may have a strong effect. Perhaps, ethnographic analysis of the daily influencers, when patients are interviewed and observed within the hospital setting, may better explain the variability.

The suggestion that patients are 25% most active on Wednesdays would be in keeping with this theory. We postulate that, at the start of the week, many patients may remain at the bedside to speak with the medical team after the weekend. Similarly, Friday is the last day to meet their regular team before the weekend, thus possibly limiting walking. While this finding is not remarkable in itself, patients walk more on Wednesdays, regardless of the day of admission, suggesting that the hospital environment may have a greater influence than originally thought.

Physical performance on admission was the strongest predictor of walking in hospital and walking in hospital has been found associated with length of stay[118]. This may be a useful indicator of those who need help to stay active.

While assigned bed rest is not modifiable, tethering treatments may possibly be overcome. Large portable oxygen canisters can often require two staff-members for safety, but smaller canisters may allow many to walk independently and oxygen requirements may be reviewed more frequently. Similarly, intravenous fluids can be attached overnight, freeing patients during the day.

This study was exploratory in nature and has many limitations. As previously stated, ethnographic data may yield more information. Many variables were added to the models to detect associations, and a total of 529 observations (noted at Table 6.3) allowed for the inclusion of all covariates. However, the clustering of the data impacted the effective sample size. Therefore, it is important to note that a lack of association should be interpreted cautiously as lack of evidence rather than “no association”. The daily potential barriers are measured dichotomously, limiting their level of effect in the models. Physiotherapy and Occupational Therapy was recorded from the day previous, and the walking variability makes it difficult to detect associations. Nonetheless, limited evidence exists of daily potential barriers to walking. Tethering treatments could be addressed, and patients’ physical performance on admission may predict walking activity in hospital. And most importantly, walking variability was not fully explained by patient presentation and daily recording of potential influencers.

7 Conclusions of Phase 2 and Introduction to Phase 3

The aim of the second phase of the study was to identify those patients (on admission) who are most at risk of a prolonged hospital stay and poor physical performance at discharge. These results would inform patient selection for the RCT.

We measured the association between walking and (1) length of stay and (2) physical performance in 154 medical inpatients (Chapter 5). Univariable analysis showed that walking activity was associated with physical performance at discharge, however, when adjusted for physical performance on admission, the association was lost. This suggested that the patients who have poor physical performance on admission were unable to walk, rather than walking in hospital influencing physical performance at discharge.

However, length of stay was associated with walking even when adjusted for patient presentation on admission. The model indicated that every 50% increase in walking is associated with a 6% decrease in length of stay. This is an important finding when considering those patients who walk minimally in hospital. Half the patients in the study walked less than 600 steps per day. A trebling of this walking (from 600 to 1,800 steps per day; in other words, from 12 to 36 minutes walking) could be associated with a one-day shorter hospital stay. This is a clinically feasible goal and strengthens the suggestion that patients who are prevented from walking need to be helped. The causal link now needs to be determined; does additional exercise and walking improve health outcomes (Phase 3)?

The second paper from Phase 2 (Chapter 6) explored the association between walking and potential influencers of walking in hospital. Considerable between-patient and within-patient variability in walking was

detected. Patients' physical performance on admission was a strong predictor of walking activity in hospital, while tethering treatments and assigned bed rest are associated with less walking. Methods of overcoming these barriers may possibly be addressed, such as switching tethering treatment time to night and providing portable oxygen tanks.

In Phase 3, those patients with poor physical performance on admission were specifically targeted for an RCT of additional exercises in hospital. (Figure 7.1, Phase 3). Patients who were admitted following a fall were also included as it seemed appropriate. Tethering treatments was detected as a modifiable risk factor from the secondary analysis. However, this was not used to refine the inclusion criteria for two reasons. Firstly, the secondary analysis was completed after the RCT had begun and the protocol published. And secondly, it is difficult to identify the patients who will receive tethering treatments, or for how long, on admission. The intervention included twice daily exercises, assistance walking and promotion of independent walking.

The primary outcome measure was length of stay. This was chosen as it is a key healthcare utilisation, with minimal risk of missing data (complete data was available from the hospital patient electronic system and unaffected by the high attrition rate predicted in this cohort). Furthermore, a shorter hospital stay is a desired outcome for staff, patients and their families. Secondary measures included physical performance, quality of life and re-admission rates for the subsequent three months after discharge (Chapter 8). Physical performance was chosen as it seemed likely that the exercises would impact the patients' walking and mobility rather than their functional ability (i.e., their ability to complete daily activities of living). Additional exercises had shown some small improvements in function in previous trials[119], whereas the effects of the additional exercises on physical performance remain unclear. Previously the Timed Up and Go test was used in this patient group, and the authors reported that 27% of patients were unable to attain a score at baseline [119]. For this reason, we piloted the Short Physical Performance Battery

in the observation study and found that all patients fitting the inclusion criteria, were able to attain a score at baseline. Readmission rates were measured to determine whether the intervention reduces the risk of early re-hospitalisation. Quality of life, has been recently advocated as an indication to evaluate publicly funded services and clinical trials as it is the individual's perception of their life[115], and this can be used in further economic evaluation analysis. We completed the follow-up assessment at three months post discharge. This may seem to be a short follow-up but with a longer gap, it would be difficult to extract the effect of other confounders, such as other co-morbidities or social issues. The APEP trial was completed and the results are presented and discussed (Chapter 9).

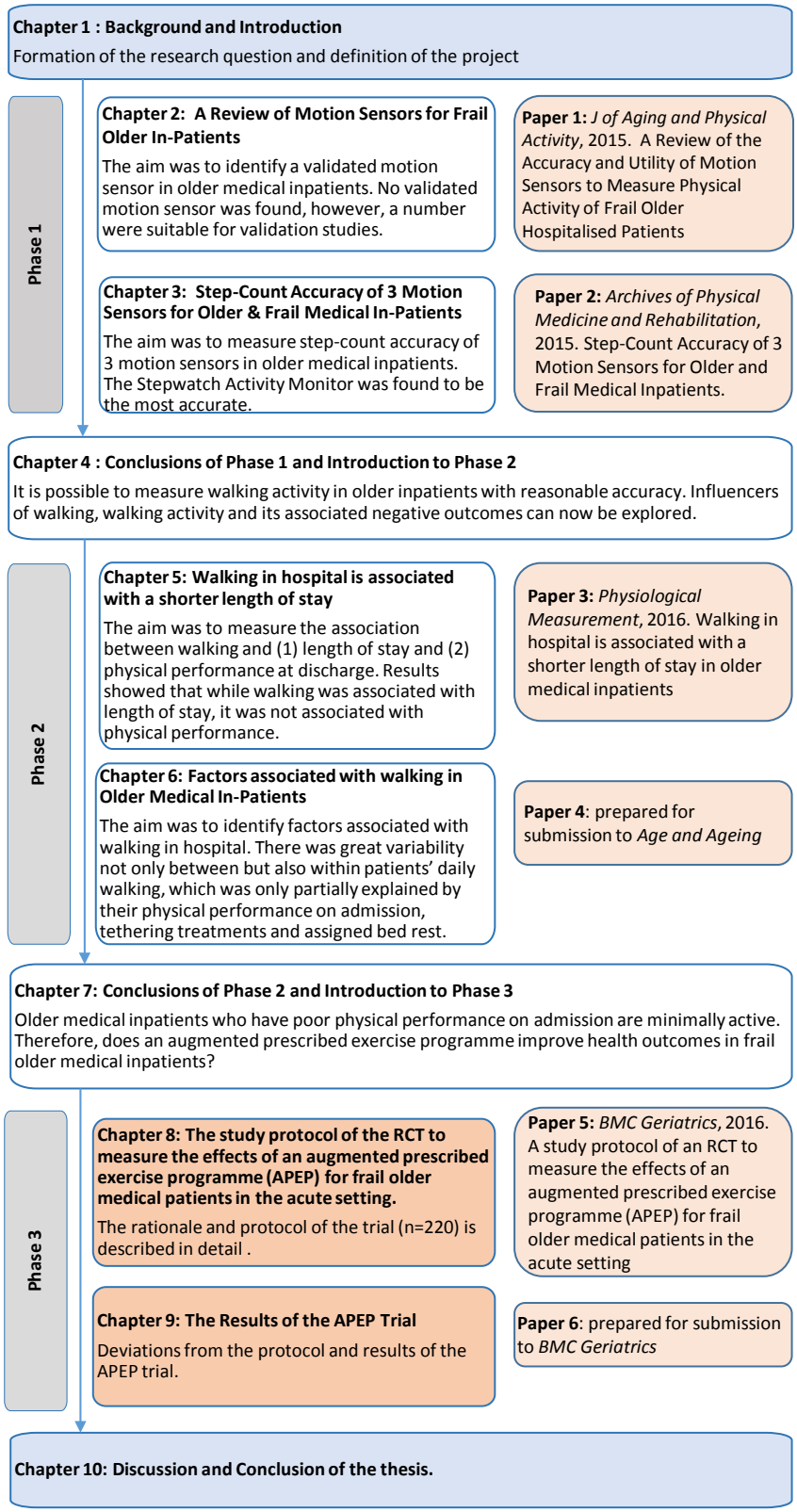


Figure 7.1: Flow diagram of the project: Phase 2 to Phase 3 (Phase 3 in orange)

8 A Study Protocol of a Randomised Controlled Trial to Measure the Effects of an Augmented Prescribed Exercise Programme (APEP) for Frail Older Medical Patients in the Acute Setting

8.1 Background to the protocol paper of the RCT

CONSORT recommends that a proposed clinical trial should be registered and its protocol published prior to its completion. We followed these recommendations by registering the trial and published the protocol.

Authors included Prof Perry, Chair of the Department of Epidemiology and Public Health, UCC, and Dr O'Connor, Consultant in Geriatric Medicine, who along with my supervisors, Dr Timmons and Prof. Horgan, gave me expert advice and ensured that robust research methods and sound clinical questioning were employed. Dr Anthony Fitzgerald, Senior Statistician, guided me with the statistical analysis; Ms O'Connell, Senior Physiotherapist, blindly assessed the participants and Ms Sarah O'Meara, Research Assistant, completed the data entry and assisted in the blinded allocation.

This paper was submitted in the early stages of the RCT. Therefore, it has been written in present and future tense. It was published in *BMC Geriatrics* in 2016. The PDF version of the published paper is attached in Appendix K.

8.2 Abstract

Background: Older adults experience functional decline in hospital leading to increased healthcare burden and morbidity. The benefits of augmented exercise in hospital remain uncertain. The aim of this trial is to measure the short and longer-term effects of augmented exercise for older medical in-patients on their physical performance, quality of life and health care utilisation.

Design & Methods: Two hundred and twenty older medical patients will be blindly randomly allocated to the intervention or sham groups. Both groups will receive usual care (including routine physiotherapy care) augmented by two daily exercise sessions. The sham group will receive stretching and relaxation exercises while the intervention group will receive tailored strengthening and balance exercises. Differences between groups will be measured at baseline, discharge, and three months. The primary outcome measure will be length of stay. The secondary outcome measures will be readmission rates, walking activity (accelerometry), physical performance (Short Physical Performance Battery), falls history in hospital and quality of life (EQ-5D-5L).

Discussion: This simple intervention has the potential to transform the outcomes of the older patient in the acute setting.

Trial registration: ClinicalTrials.gov Identifier: NCT02463864, registered 26.05.2015

Key words: frail, medical, inpatients, exercise, physiotherapy, length of stay

8.3 Background

8.3.1 Older medical patients can experience a prolonged acute hospital stay and functional decline.

In Ireland in 2011, 11.6% of the population was aged 65 years and over [120], and this is set to rise to 22% by 2041 [121]. Extended periods of poor health are predicted with this longevity [121]. Older patients occupy most acute hospital beds and most frequently experience a prolonged length of stay (of greater than 30 days) [105], functional decline, high re-admission rates, falls, and institutionalisation [7]. Frailty is described as a geriatric syndrome with reduced capacity of the individual to resist stress and includes characteristics of slow mobility, low physical activity (PA) and energy levels [4]. Inactivity has been identified as a major determinant in the onset of frailty, and exercise has been found to prevent or slow down this decline [5]. Therefore, maintenance of older adults' functional independence while in hospital is of utmost importance.

8.3.2 Physical activity levels and exercise intervention for medical patients in hospital

We recently found that older medical patients walk an average of 764 (± 706) steps per day in hospital and that length of stay was inversely associated with daily step-count, even when adjusted for age, gender and physical performance on admission [89]. Similarly, Fisher et al [19] found that older adults, who increase their walking activity by 600 steps on the second day of observation, were discharged home two days earlier. These findings suggest that walking in hospital may directly influence length of stay and supports the theory that patients should exercise and remain active in the acute setting. Exercise programmes in hospital have been delivered independently or as a component of a multidisciplinary

intervention and have been shown to improve physical performance, quality of life, reduce falls incidence and reduce healthcare utilisation [31, 26, 24, 122, 34]

8.3.3 The evidence of effectiveness of augmented exercise in hospital

To date, small benefits from augmented exercise on function and healthcare utilisation have been found. A systematic review found limited benefits from exercise as part of a multidisciplinary service on function, length of stay and discharge destination for acutely hospitalised older medical inpatients [119]. Three trials investigated the benefits of additional exercise alone [29, 31, 30]; none of which showed a significant improvement on length of stay in the acute setting. The authors suggested that the findings might have been weakened by using inappropriate outcome measures (Timed Up and Go test), recruitment of patients who had good baseline physical performance levels, and poor adherence to the exercise intervention.

8.3.4 Rationale for the trial and protocol

To date, additional exercise has not been found to shorten frail older patients' hospital stay but the issues reported by previous authors may have weakened the results. To address these issues, the proposed protocol differs from previous studies in key parameters. A qualified physiotherapist will deliver and support the exercise sessions. Only patients who are less able to maintain physical activity will be recruited; those who need a walking aid and/or physical assistance on admission. Those who are unable to walk with assistance will be excluded from the trial. The Short Physical Performance Battery (SPPB) and walking speed will be used to measure physical performance, as these were previously

found to be sensitive and appropriate for the study group [42]. The control arm will include sham exercises, to control for the considerable increase in patient-physiotherapist contact time. Finally, independent physical activity (usually walking) will be promoted outside the exercise sessions, in the intervention group.

Therefore, the aim of this study is to measure the effects of an augmented prescribed exercise programme for frail older medical inpatients on their physical performance, quality of life and healthcare utilisation.

8.4 Methods

8.4.1 Design and Study Size

The study is a single blind randomised controlled trial set in an acute 350-bedded teaching hospital. Power calculations based on the results of a pilot study indicated that a sample size of 200 (100 patients in each arm) would be required. The pilot study showed a median of two days reduction in length of stay. This was used as the primary outcome measure for this study, as full data would be available for all patients electronically, even if their assessments were missed at discharge. Similar to the results if the pilot study, a two-day change in length of stay was determined as the change to be detected, and set at 80% power. To allow for an expected attrition rate of 5% [123], two hundred and twenty medical patients aged 65 years and over are randomly allocated to either the intervention or sham arm in a ratio of 1:1. (See Figure 8.1). The study has been approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals. (ECM 3 (jjjj) 15/11/16) (Appendix L).

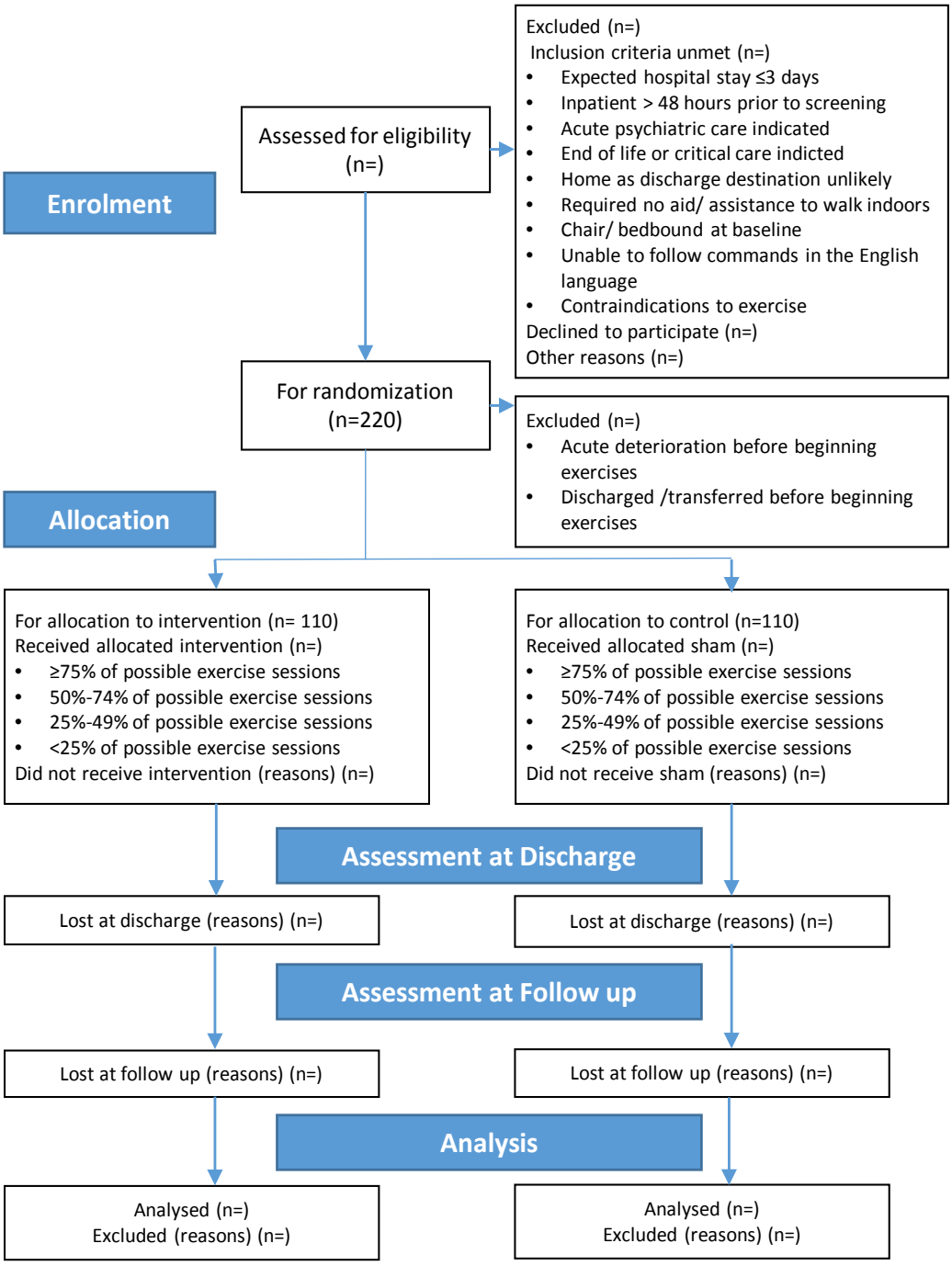


Figure 8.1: CONSORT Flow diagram of the proposed APEP Trial

8.4.2 Selection of Participants and Allocation

All suitable patients are screened and if eligible, are informed of the study and written consent is sought (Appendix M for Patient Information Sheet). The inclusion criteria are: medical patients aged 65 and over, who have been admitted from home and initially planned for discharge home, whose anticipated length of stay is greater than 3 days, and who require a mobility aid or assistance to walk. The exclusion criteria are: patients who have been an in-patient for more than 48 hours prior to screening, who are unable to follow commands in the English language, unable to exercise with the assistance of one person only, bed or chair-bound at baseline, admitted with an acute psychiatric condition, require active end-of-life or critical care or when exercise is contraindicated.

To ensure adequate treatment time is given to each patient, recruitment is paused when there are five patients active in the trial. Based on the hospital's usual length of stay, this usually results in one patient recruited each weekday. If more than one patient is eligible for the study on one day, they are approached in chronological order of admission.

The patients are randomly allocated to either the intervention (APEP) or control group. A computer-generated random allocation sequence is used. Block randomisation is applied (in groups of approximately 50 patients). *Post hoc* power analysis will be calculated when the first seventy-five patients have completed the trial.

8.4.3 Roles of the Researchers

Randomisation and data entry is completed by the Research Assistant (RA, SO'M). Screening, recruitment, baseline measurements and all exercise sessions are completed by the Principal Investigator (PI, RMcC).(Appendix N for assessment sheets and consent form) The discharge and follow-up assessments are completed by the blinded

Research Physiotherapist (RPT, EO'C), who has no involvement in either the allocation or intervention components of the trial. (See Appendices O and P for the discharge and follow-up data collection sheets)

8.4.4 Measurements

Patients are assessed within 48 hours of admission, at discharge and at three months following discharge. The assessment tools are summarized in Table 8.1. Baseline data includes demographics, co-morbidity, medication use and home situation.

The primary outcome measure is length of stay, a key healthcare utilisation metric. The secondary outcome measures includes patient-related measures: changes in physical performance (SPPB), and quality of life at 3 months following discharge, differences in walking activity between groups in hospital (based on accelerometry data) and re-admission rates over three months. The baseline assessment is designed to capture frailty, co-morbidity and disability. Measurements that are appropriate and quick to administer have been chosen to limit patient fatigue. These tools have been used previously in the observation study and were found to be feasible in this study cohort.

Table 8.1: Summary of Measurements proposed for use in the APEP Trial

DOMAIN	ON ADMISSION	DISCHARGE AND 3 MONTHS
Medical Morbidity	Cumulative Illness Rating Scale (CIRS-G[98]); Total number of medications	
Frailty	SHARE- FI [99]	Grip Strength (kgs)
Physical Performance	Short Physical Performance Battery (SPPB) (includes walking speed)[108]	SPPB (includes walking speed)[108]
Falls History	Number of Falls and injuries sustained	Number of falls and injuries sustained
Falls Efficacy	Falls Efficacy Scale-International (FES-I) [100]	
Self-Reported Functional Ability	Nottingham Extended Activities of Daily Living Scale (N-EADL) [124]	Nottingham Extended Activities of Daily Living Scale (N-EADL) [124] (at 3 month follow-up only)
Functional Ability	Functional Ambulatory Classification (FAC) [126]	Functional Ambulatory Classification (FAC) [126]
Cognition	6CIT [125]	6CIT [125] (at discharge only)
Quality of Life	EQ-5D-5L [114]	EQ-5D-5L [114]
Walking Activity	Accelerometers (Stepwatch Activity Monitor, SAM) during hospitalisation only	

8.4.5 Descriptive Measures

On admission, the patients' demographics and medical history are noted. Similar to the observation study (Phase 2), their home situation, medication use, co-morbidity (Cumulative Illness Rating Scale-Geriatrics, CIRS-G[109]), cognition (Six Item Cognitive Impairment Test, 6CIT) [125], frailty, which included grip strength (Survey of Health, Ageing and Retirement in Europe, SHARE-FI) [99], falls history over the previous six months and falls efficacy (Falls Efficacy Scale International, FES-I) [100]

are measured on initial assessment. Cognition will assessed on admission and discharge only; it will not be assessed at follow-up, as this screening tool is being used to detect delirium associated with the acute illness. Full details of these descriptive measures are described in Sections 5.4.4.1 – 5.4.4.5.

8.4.6 Outcome Measures

Once again, similar measurements to the observation study are used, along with some additional measurements. The effects of the intervention on healthcare utilisation, physical performance (SPPB)[102] and quality of life (EQ5D5L)[114] are measured. These measures have been fully described previously (Section 5.4.3 and 5.4.4). In addition, the effects on functional independence (Nottingham Extended Activities of Living, [124] described below), falls rate, and functional ambulation (Functional Ambulatory Classification, FAC[126]) are also measured.

8.4.6.1 Healthcare Utilisation

The primary outcome measure is length of stay (bed nights) (LOS). The number of readmissions over the subsequent three months is also recorded; both from the hospital information system.

8.4.6.2 Physical Performance and Daily Activity

Functional Independence is measured using The Nottingham Extended Activities of Daily Living Scale (N-EADL,) [124] premorbidly, on admission, and at three month follow-up. The N-EADL , used to measure self-efficacy [124] is a self-reported tool measuring the patients' ability to complete 16 community-based activities. On admission, patients are asked to report their functional ability both pre-morbidly (before the onset of the illness)

and on admission (the day before they were admitted) and again, at the three month follow-up assessment. Patients can score 0 (unable to complete the activity with/without help) or 1 (able to complete the score with/without help). This has been used extensively in older adult populations, including patients with stroke and fallers [127, 128].

The Short Physical Performance Battery (SPPB, Section 5.4.3.2) [108] is used to measure physical performance on admission, at discharge and at follow-up.

A patient's functional ambulation is measured using the Functional Ambulatory Classification (FAC). Patients' walking is observed on admission, at discharge and at follow-up. On admission, the patients are asked to self-report their premorbid ambulatory level. Self-report is also used at the follow-up when the patient cannot attend in person. Patients are asked if they need assistance or walking aid to walk around their home or climb steps. They score four if they needed assistance on level surfaces, five if they are independent on level surfaces; and six if they are independent on stairs. While this has not been validated as a self-reported tool, it did provide some information about their ambulatory level when observation is impossible.

Walking is continually measured using the Stepwatch Activity Monitor (SAM, Section 5.4.3.1). All patients with good skin condition at the ankle are asked to wear the SAM. They are attached on the first day of recruitment and worn continuously while in hospital or for the first seven days. All staff are informed of their application. The accelerometry data will be analysed to measure

1. Differences in walking between groups.
2. Differences in walking activity compared to the recently completed observation study (which assisted in identifying those who were at risk / not at risk of functional decline).

8.4.6.3 Falls and Quality of Life

The number of falls over the previous six months is self-reported on admission. The number that occur in hospital is recorded from the medical and nursing notes at discharge, and the number that occur after discharge home is self-reported at follow-up.

Quality of Life is measured using the EuroQol 5 Domain 5 Level Scale**[114]** on admission, discharge and at follow-up (Section 5.4.4).

Changes in living arrangements (change in accommodation, support or home adaptations) are recorded at discharge and follow-up.

8.4.7 Procedure

8.4.7.1 Intervention and Routine Care Schedule

Both groups receive usual interdisciplinary care. The medical team refer patients to physiotherapy if required. Usual care is delivered an average of three times weekly, by the ward physiotherapist and is routine in nature. Most of the care is conducted on the ward, and consists of assessment, discharge planning, walking-aid provision, exercise prescription and rehabilitation. The physiotherapists designs and familiarises the patient with a suitable exercise programme, however, resources limit supporting the patient to an average of three times weekly. Limited physiotherapy-assistant service is also available to assist patient who require support the most. Similarly, while walking aids would be provided, patients would not be assisted daily.

Both the control and the intervention groups also receive two augmented, twenty minute to half-hour exercise sessions (tailored to the patient's endurance), five days per week, delivered on a one-to-one basis by the PI.

8.4.7.2 Consent, Assessment and Exercise Procedure

Upon screening, the medical team are contacted to confirm that there are no medical contra-indications to exercise for the patient. Eligible patients are informed of the study verbally and given a copy of the patient information leaflet, which clearly explains that they will be randomly allocated to the intervention or control group, thereby receiving the APEP or stretching and relaxation exercises.8.4. They give written informed consent to the study, including access to their medical notes, assessment at baseline, outcome and follow-up, and the twice daily exercise sessions (see Appendices M and N for the Patient Information Sheet, Consent Form and Data Collection Forms at Admission, Discharge and Follow up). If the patient is considered to be cognitively impaired by the medical or nursing staff, the patients' next of kin was contacted to assent their inclusion. Patients with severe confusion, who are unable to follow commands, or are agitated, are not recruited to the study.

If recruited, patients are assessed (Time 1, Table 8.1), and through concealed allocation, randomly allocated to the control group or the intervention (Augmented Prescribed Exercise Programme, APEP) group at that time. The accelerometer (SAM) is fitted to all who give consent to wearing the SAM and with good skin condition at the ankle

There are two main components to the APEP intervention. Firstly, an exercise programme aiming to improve lower limb strength and balance, sit-to-stand function, balance and walking is prescribed. All patients will receive these exercises at the bedside. The exercises will include lower limb strengthening exercises (foot and ankle exercises in sitting and heel raises in standing, knee extension exercises in sitting, hip abduction and extension exercises in standing, semi-squats, marching on spot), transfer practice (lying to sitting, sitting to standing with and without arms, bed to chair practice) and balance training (static eyes open, eyes closed, and dynamic reaching for items, carrying items). Their fatigue levels and safety

will guide the progression of exercises. It is anticipated that this might fluctuate daily in the presence of the acute infection. Following the bedside exercise session, patients are walked as much as they can tolerate. This may be only on the ward, whereas others may be physically able to walk further around the hospital. The sessions last between 20-35 minutes, depending on the patients exercise tolerance. Secondly, the patients are provided with a suitable walking-aid as soon as the assessment is complete. They are encouraged to walk around the hospital or ward as much as possible. Patients are shown suitable off-ward locations such as the shop, canteen and seating areas. Their family and carers are also encouraged to walk with them. The hospital volunteers, who are all trained in manual handling, are asked to walk those patients who need supervision and guidance only to walk.

The sham exercise sessions for the control group are not prescribed but consist of standardised stretching and relaxation exercises.

All exercise sessions begin within 24 hours of group allocation and continue until the day before discharge. Verbal consent for each session is sought.

To ensure false step-count does not occur, the accelerometer (SAM) is turned upside-down (it is unable to record steps in this position) when the patient is exercising at the bedside, i.e., not walking, and returned to the upright position before walking or at the end of the session.

Patient compliance, exercise prescription and session duration is recorded. Within one day of planned discharge, all patients are re-assessed and the accelerometer (SAM) is removed from the patient by the RPT (Time 2; see Table 8.1). Patients who are deemed for long-term care (as they are unable to manage at home) or for end-of-life care are re-assessed on the date that the decision is made and those results are used.

The patients are reassessed at three months post discharge, by the RPT (Time 3, see Table 8.1). New onset of illness, physical performance, walking speed, quality of life and self-reported functional ability is measured. Hospital, and Accident & Emergency utilisation since discharge is recorded.

8.4.8 Safety, Reporting of Adverse Events and Serious Adverse Events

The main adverse events anticipated in this study are skin rashes from the accelerometer, and falls, cardiac ischaemia or pulmonary embolism during exercise. All adverse events are recorded using an adverse event recording worksheet, and causality to the study intervention is determined, in consultation with the treating physician, by a study physician (KO'C). The Sponsor's Clinical Research Supporting Officer is notified electronically, within 24 hours, of any serious adverse event that occurs during the trial. From a previous local longitudinal study, the Cork Dementia Study, the in-hospital mortality of this cohort is expected to be approximately two per cent [123]. This predicts approximately 5 deaths of trial subjects. However, the type of exercise involved is similar to usual care, patients with a contraindication to exercise will be excluded at source, and patients who are unwell on a particular day will not exercise.

8.4.9 Statistical Analysis

The results will be analysed and presented as recommended by the CONSORT guidelines [31]. The primary outcome measure will be length of stay. This will be described using Kaplan-Meier "survival" curves and the results between groups will be compared using a log-rank test. Univariate and multivariate linear regression analysis will be used to determine differences in walking activity in hospital and physical performance, quality

of life at discharge and three months post-discharge, and re-admission rates at three months.

This analysis will help to define whether a simple physiotherapy-led exercise intervention will shorten length of stay, increase walking in hospital, limit functional decline and readmission rates and improve quality of life in frail older hospitalised patients.

8.5 Discussion

This study has been designed to measure the effects of the APEP for frail older hospitalised patients. The study design is based upon results of an earlier pilot study and issues reported from previously published studies. Therefore, this protocol differs from previous studies in three key areas: patient selection, intervention and outcome measurements.

Previous studies included patients who were fully independently mobile, however, de Morton et al [129] found that the intervention was most effective for those requiring an aid or assistance to walk. For this reason, we will exclude those who are independently mobile. For pragmatic reasons, we will also exclude those unable to walk at baseline, i.e., bed or chair bound.

There is strong evidence of low physical activity in hospital [75, 16] and Broderick et al [40] found that many of the barriers could be addressed easily. For these reasons, we will not only deliver supervised exercise sessions, but in addition, will encourage mobility while in hospital and provide walking aids initially, if required. The exercises are designed to improve physical performance, transfer function, walking, balance and strength in order to maintain functional mobility as much as possible.

Our pilot study [34] showed that there was a considerable difference in physiotherapy contact time with the intervention, possibly introducing a Hawthorne effect. This has been addressed by using a sham intervention

for the control group. To the authors' knowledge, this is the first time that a sham intervention has been included in this type of study.

The intervention will be delivered by a senior physiotherapist. The interventions of previous studies have been delivered by a physiotherapy assistant or student, under the guidance of a qualified physiotherapist [30, 34, 31]. However, patients' physical performance fluctuates in the acute setting. If a qualified physiotherapist delivers the programme, they can adjust the exercises, address possible barriers to exercise and walking and give timely advice on a daily basis.

Up to 27% of the patients were unable to complete the Timed Up and Go Test in previous studies [30, 31]. Therefore, the Short Physical Performance Battery will be used, which was found to be feasible and sensitive to change in a previous pilot study [34]. Length of stay will be used as the primary outcome measure as this is available electronically and absolutely complete data. A high attrition rate is predicted for the three-month follow-up attendance as our study group consist of frailer older adults.

A small number of studies have shown that interventions to increase older medical inpatients' physical activity can be modestly beneficial. Previous authors discuss issues such as patient selection, intervention type and outcome measures. This protocol has been designed to include the frailer patient, to include a tailored and comprehensive intervention, and to measure the effects with the most valid outcome measure.

9 Results of the Augmented Prescribed Exercise Programme (APEP) Trial

9.1 Background to the results of the APEP trial

This chapter is presented as a complete paper for submission to the journal *BMC Geriatrics.* As the trial progressed, there were a number of reasonable and unavoidable deviations from the previously published protocol. Therefore, I felt that the complete report should be written in its entirety.

In order to adhere to the CONSORT recommendations, Ms O'Connell, Senior Physiotherapist completed the assessments at discharge and at follow-up and Ms O'Meara, Research Assistant, assisted with the concealed allocation, together with administration and data entry. Dr O'Connor, Consultant in Geriatric Medicine, assisted with the safety monitoring. I completed the screening, recruitment, and treatments, and with the assistance of my supervisors, completed the data analysis and the manuscript.

9.2 Abstract

Aim: To measure the effects of an augmented prescribed exercise programme on physical performance, quality of life and healthcare utilisation for frail older medical patients in the acute setting.

Methods: Within two days of admission, older medical inpatients with an anticipated length of stay ≥3 days, needing assistance/aid to walk, were blindly randomly allocated to the intervention or control group. Until discharge, both groups received twice daily, Monday-to-Friday half-hour assisted exercises, assisted by a staff physiotherapist. The intervention group completed tailored strengthening and balance exercises; the control group, stretching and relaxation exercises. Length of stay and readmission rates were recorded and physical performance (Short Physical Performance Battery), and quality of life (EuroQOL-5D-5L) were measured at discharge and at three months. Time-to-event analysis was used to measure differences in length of stay and unadjusted and adjusted linear regression models were used to measure differences in physical performance and quality of life.

Results: Data from 190 patients (aged 80 ±7.5 years) were analysed. Groups were comparable at baseline. Crude analysis showed that the intervention reduced length of stay slightly but did not reach statistical significance (HR 1.09 (CI, 0.77-1.56) p=0.6). When patients transferred to rehabilitation were excluded and data adjusted for confounders, the effect was greater, but remained insignificant (n=125, HR, 1.3 (CI, 0.9-1.87) p=0.16). Adjusted and unadjusted physical performance was significantly and meaningfully better in the intervention group at discharge (β=0.88 CI, 0.20-1.57) p=0.01), but lost at follow-up (β=0.45 (CI, -0.43 – 1.33) p=0.3). A small but significant improvement in quality of life was detected at follow-up in the intervention group. (β=0.28 (CI, 0.9 – 0.47) p=0.004).

Conclusion: The significant improvements in physical performance and quality of life suggest that this intervention is of value to frail medical inpatients. Its effect on length of stay remains unclear.

9.3 Introduction

It is well established that older medical inpatients are minimally active in hospital. Evidence shows that patients walking an average of 600 steps daily [118] [16] which equates to twelve minutes of walking[17], that 35% of older patients do not leave their hospital room[18], or less than 19% of patients walk hospital corridors[75]. In Phase 2, our observation study suggested that this inactivity was associated with a longer hospital stay, and those with poor physical performance on admission were the least active in hospital[118]. These frailer patients are most at risk of functional decline following a hospital admission[130].

Interdisciplinary team care has been found to improve patients' health outcomes and length of stay [23-27] . While effective, it requires a considerable investment and change in clinical practice. However, a simple exercise programme could be easier to implement. Studies have shown limited effectiveness of exercise alone interventions on length of stay [30, 29] with conflicting evidence of its effectiveness on physical and functional performance [30, 31]. It has been suggested that the exercises are most effective for the frailer patients[31]; the frailer patients are least active, and that this lack of activity is associated with a prolonged hospital stay[118]. However, to date, exercise interventions specifically targeted for this cohort has yet to be tested.

Therefore, the primary aim of this trial was to measure the effectiveness of an augmented prescribed exercise programme (APEP) on length of stay of frail older medical patients in the acute setting. The secondary aims were to measure its effectiveness on their physical performance and quality of life at discharge and at three months post discharge, and readmission rates over the subsequent three months following discharge from hospital.

9.4 Methods

A detailed description of the APEP trial protocol has been presented previously[131]. The trial received ethical approval from the local clinical research ethics committee (EMC 3 (jjjj) 15/11/16) (Appendix L). The conduct and report of this trial follows the CONSORT guidelines (checklist provided, Figure 9.1: CONSORT checklist).

Figure 9.1: CONSORT checklist

Item	Criteria	Description
1a	Title	Identification as a randomized trial in the title
1b	Abstract	Structured summary of trial design, methods, results and conclusions
2	Introduction	Scientific background and explanation of rationale, specific objectives
3	Trial design	Description of trial design including allocation ratio
4	Participants	Eligibility criteria for participants
5	Interventions	Interventions for each group with sufficient details to allow replication
6	Outcomes	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
7	Sample size	How sample size was determined
8	Randomisation	Method used to generate the random allocation sequence, type of randomisation; details of any restriction
9, 10	Allocation Concealment and Implementation	Mechanism used to implement the random allocation sequence; who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
11	Blinding	If done, who was blinded after assignment to interventions and how
12	Statistics	Statistical methods used for primary and secondary outcomes
13	Participant flow	For each group, the numbers of participants randomly assigned, analysed; losses and exclusions
14	Recruitment	Dates defining the periods of recruitment and follow-up
15	Baseline data	A table showing baseline demographic and clinical characteristics
16	Numbers analysed	For each group, number of participants included in each analysis
17	Outcomes	For all outcomes, results for each group, estimated effect size and precision
19	Harms	All important harms or unintended effects in each group
20	Limitations	Trial limitations, addressing sources of potential bias, imprecision
21	Generalisability	Generalisability (external validity, applicability) of the trial findings
22	Interpretation	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

9.4.1 Design

The study was a prospective, sham-intervention controlled, randomised trial, with blinded randomisation and outcome measurement. It was completed between March 2015 and January 2017.

9.4.2 Participants and Inclusion/Exclusion Criteria

Medical patients aged 65 years and older, with an anticipated length of stay of three nights or more, who needed either an aid or assistance to walk on admission, were included in the trial. Patients were excluded if they were medically too unwell; a contra-indications to exercise was present (e.g., hip fracture, with uncontrolled heart rate); the assistance of more than one person to walk safely was required; the baseline Short Physical Performance Battery score was 0/1;, they were admitted for surgical, critical, end of life, or acute psychiatric care; they were unable to follow commands in the English language (eg., unable to understand English or too confused or agitated to follow commands) or they had participated in the trial within the previous twelve months.

9.4.3 Recruitment process

Using the electronic hospital management system, the principal investigator (PI, RMcC) identified all patients aged 65 and over, admitted to the hospital or the emergency department within the previous forty eight hours. Patients were not recruited on Fridays as no exercises sessions were delivered over the weekend. Their medical notes were checked for exclusion criteria and their nursing and medical team contacted to confirm their suitability. They were then approached in chronological order of admission, informed about the study, and invited to participate. All participants consented to inclusion. Where the patients' cognition appeared or was reported to be poor, their next of kin of was also contacted (by phone, or if visiting, face-to-face), to assent to their inclusion. Patients were recruited as capacity allowed, which was limited to five patients participating in the study simultaneously. Recruitment to the trial was completely independent from routine physiotherapy referrals and services. (see Appendix M and N for the Patient Information Sheet and Consent Form)

9.4.4 Interventions

There were two groups in this trial: usual care with an augmented prescribed exercise programme (APEP group), and usual care with an additional sham exercise programme (control group).

Routine physiotherapy was not affected by the APEP trial. It was provided to all patients, including ward and gym-based physiotherapy. When the responsible medical team identified the patient's need for routine physiotherapy, they would make the referral to physiotherapy. Physiotherapy would be delivered based on the physiotherapist's assessment and competing caseload, however, they aimed to see patients at least three times weekly.

Both groups completed additional exercises. They received instructions and assistance to complete the exercises twice-daily, Monday-Friday. The sessions lasted up to thirty minutes, depending upon the patient's exercise tolerance. Prior to each session, the PI (RMcC) checked for new contraindications to exercise and the patient's verbal consent.

9.4.4.1 Augmented Prescribed Exercise Programme

The intervention group were assisted to complete strengthening, balance and gait exercises. Based on the patient's self-reported mobility issues and objective assessment, the PI (RMcC, a senior physiotherapist who has specialised in geriatric care) prescribed a tailored exercise programme. The exercises were assisted by the PI only. The initial treatment was kept simple and straightforward to maintain patient compliance and the intensity was increased as tolerated in the subsequent sessions.

Exercises were designed to improve the patient's transfer ability, balance and walking endurance. They were completed at the bedside. They were mainly lower limb strengthening exercises completed in sitting, sit to stand exercises, transfer training (bed to chair, chair to chair), hip and core stability training and walking. Infection control regulations prevented the use of weights, therefore, body weight was used as a resistance. Exercises were progressed by increasing the number of repetitions and the challenge of the exercises. Aids and appliances, including walking aids and portable oxygen, were provided as needed, in consultation with the ward staff and attending physiotherapist. Family members were encouraged to walk with the patients during visits. Advice and education about walking, general physical fitness and performance was given to the patients and their carers as required.

9.4.4.2 Sham Exercise Programme

The control group completed sham exercises which mainly consisted of stretching and relaxation exercises. They were completed either in the lying or sitting position only. While the patients were encouraged to talk about their condition and exercise, none were given education, encouragement or were assisted to exercise or walk more. The exercises were not progressed but rather repeated at each session.

The PI kept a register of the exercises completed as well as the total number of sessions that the patients could have possibly completed, number that were actually completed, and the reason for missed sessions such as absence from ward, refusal, medical status, or care in isolation.

9.4.5 Descriptive Measures

On admission, the patients' demographics and medical history were noted. Similar to the observation study (Phase 2), their home situation,

medication use, co-morbidity (Cumulative Illness Rating Scale-Geriatrics, CIRS-G[109]), cognition (Six Item Cognitive Impairment Test, 6CIT) [125] frailty, which included grip strength (Survey of Health, Ageing and Retirement in Europe, SHARE-FI) [99], falls history over the previous six months, and falls efficacy (Falls Efficacy Scale International, FES-I) [100], were measured on initial assessment. Full details of these descriptive measures are described in Sections 5.4.3 and 5.4.4.

9.4.6 Outcome Measures

The assessment schedule is described in Table 9.1.

Similar measurement to the observation study were used, along with some additional measurements. The effects of the intervention on healthcare utilisation (length of stay and readmission rates), physical performance (SPPB, Section 5.4.3.2)[102] and quality of life (EQ5D5L, Section 5.4.4.5)[114] were measured. In addition, the effects on functional independence (Nottingham Extended Activities of Living, N-EADL[124]), functional ambulation (Functional Ambulatory Classification, FAC[126]), (both described fully in Section 8.4.6.2), and falls rate, were also measured.

9.4.6.1 Healthcare Utilisation

The primary outcome measure was length of stay (bed nights) (LOS). The number of readmissions over the subsequent three months was also recorded; both from the hospital information system.

9.4.6.2 Physical Performance and Daily Activity

Functional Independence was measured using N-EADL[124], premorbidly, on admission, and at three month follow-up.

The SPPB[108] was used to measure physical performance on admission, at discharge and at follow-up.

The FAC was used to measure their functional ambulation. Patients' walking was observed on admission, at discharge and at follow-up. On admission, the patients were asked to self-report their premorbid ambulatory level. Self-report was also used at the follow-up when the patient couldn't attend in person. While the FAC has not been validated as a self-reported tool, it did provide some information about their ambulatory level when observation was impossible.

A patient's walking was continually measured using the Stepwatch Activity Monitor (SAM, Section 5.4.3.1).

9.4.6.3 Falls and Quality of Life

Number of falls over the previous six months was self-reported on admission. The number that occurred in hospital were recorded from the medical and nursing notes at discharge, and the number that occurred after discharge home was self-reported at follow-up.

Quality of Life was measured using the EuroQol 5 Domain 5 Level Scale**[114]** on admission, discharge and at follow-up (Section 5.4.4). The next-of-kin was requested to complete this questionnaire on the patient's behalf if they were unable. The reliability of proxy reports has been debated and evidence exists suggesting that proxy reports are generally poorer than self-reports[115] However, some studies have found little or no difference between self and proxy reports in older adults[116], patients with traumatic brain injury and Parkinson's Disease[117]and with small

numbers of patients included in this study, the decision to include proxy reports was made.

Changes in living arrangements (change in accommodation, support or home adaptations) were recorded at discharge and follow-up.

Table 9.1: Descriptive and Outcome Measurements Assessment Schedule.



Premorbid *self-reported on admission*	Admission *≤ 48 h of admission*	Discharge *≤ 24 h of discharge*	Follow-up *face-to-face/ telephone*
-	SHARE-FI (*incl. Grip Strength*)	Grip Strength	Grip Strength
-	6CIT	6CIT	-
-	CIRS-G	-	-
-	FES-I	-	-
NEADL	NEADL	-	NEADL
FAC	FAC	FAC	FAC
-	SPPB	SPPB	SPPB
-	EQ5D5L	EQ5D5L	EQ5D5L
No of Falls		No. of Falls	No. of Falls
-	-	LOS	Readmissions

Abbreviations: **SHARE FI**: Survey of Health, Ageing and Retirement in Europe Frailty Index; **6CIT**: 6-Item Cognitive Impairment Test; **CIRS-G:** Cumulative Illness Rating Scale-Geriatrics; **FES-I**: Falls Efficacy Scale-International; **N-EADL:** Nottingham Extended Activities of Daily Living; FAC: Functional Ambulatory Classification; **SPPB**: Short Physical Performance Battery; **EQ5D5L:** EuroQol 5 Domain 5 Level Scale; **LOS:** length of Stay.
Descriptive Measurements in Purple. Outcome Measurements in Black.

9.4.7 Data Collection

The initial assessment was completed within forty-eight hours of admission. The discharge assessment was completed within twenty-four hours of discharge, or, on Friday if discharge was planned over the weekend. The follow-up assessment was completed between two and three months of discharge home. This was usually completed when the patient returned for their medical check-up with the consultant, or otherwise, a physiotherapy outpatient appointment was arranged for them. The discharge and follow-up assessments were completed by a blinded research physiotherapist (EOC).

9.4.8 Randomisation and Concealment of Allocation

Once the initial assessment was complete by the PI (RMcC), the patients were blindly randomly allocated to either the intervention or the control group. The PI contacted the Research Assistant (SOM) who assigned the patient using a computer-generated randomisation sequence. Patients were randomised in blocks of between 50 and 55 numbers. Only the RA had access to this sequence and recorded the allocation.

9.4.9 Blinding

When providing the patient the information regarding the trial, the PI informed the patients that they would be allocated to *either* the APEP or control group. This was also documented on the Participant Information Sheet. Again, upon allocation, they were neither explicitly informed nor encouraged to ask about their allocation. The blinded outcome assessor remained unaware of which group the patient had been allocated. While she worked in the hospital, the exercises sessions were completed in her absence.

9.4.10 Withdrawals

Those patients who were recruited and allocated, but did not begin the exercise sessions before withdrawal, transfer or discharge, were replaced using the same process as usual. Those patients who began the exercise sessions before withdrawal from the study, were not replaced.

9.4.11 Contamination

To prevent contamination, it was planned that patients who were in the same room, but allocated to different exercise groups, would complete their exercise sessions in different locations separately. However, this event never occurred during the trial. Therefore, all patients were treated by their bedside.

9.4.12 Adverse Events

An adverse event was defined as any unfavourable or unintended event during the intervention phase of the trial. This included a fall, cardiac ischaemia or pulmonary embolism during exercise, or an exacerbation of a condition as a result of the intervention (e.g., exacerbation of painful joints). Death or admission to intensive or critical care were considered as Serious Adverse Events.

In the occurrence of adverse events, the Sponsor's Clinical Research Supporting Officer and the Hospital Risk Manager was informed. The consultant responsible for the clinical care of the patients was also contacted. All the necessary hospital procedures and documentation was completed.

9.4.13 Deviations from the published protocol

There were four significant deviations from the protocol. Firstly, walking activity data using an accelerometer was collected on a significantly lower number of patients than planned. Secondly, the trial was terminated early, when 190 patients of the planned 220 patients had been recruited to the study. Thirdly, we only recruited patients who scored two or more on the SPPB on admission. And finally, we introduced a phone call follow-up

assessment for patients who were unable to attend for the face-to-face follow-up assessment. These deviations are now described in detail.

9.4.13.1 Walking Activity Data Collection

While every attempt was made to collect walking activity data in hospital, this data proved difficult to collect. Reasons preventing its application included poor skin condition at the ankle (n=41), refusal or data collection for less than one full day (n=15) and time and manpower limitations (n=85), allowing data collection on a total of only 49 patients (26 in the exercise group and 23 in the control group). Prioritisation was given to effective recruitment, intervention and assessments.

9.4.13.2 Early termination of the trial

The trial began in March 2015. Originally, it was planned to recruit 220 acute medical inpatients to the study. Power calculations (Section 8.4.1) suggested that 200 participants were required, with an additional 20 to allow for dropouts. However, the trial was terminated in January 2017 when 190 patients were recruited to the trial.

The aim of the trial was to measure the effectiveness of augmented exercise on length of stay in acute care, and the patients' physical ability and quality of life at discharge. In September 2016, an off-site transitional care unit opened. Many trial participants were transferred to this unit, prior to discharge home. This resulted in their length of stay in *acute* care being truncated, and their physical performance scores (assessed at discharge from acute care) poorly reflecting their readiness for discharge home. The trial could not be continued in the transitional care unit for two reasons; the patients were no longer in acute care, and logistically, it was impossible to recruit and provide twice daily exercises to patients over two sites.

Therefore, following consultation with local expert statistical support, it was decided to terminate the trial in January 2017, with 190 patients recruited.

9.4.13.3 Exclusion of Patients with SPPB score of ≤1 on admission

Shortly after beginning the trial, the SPPB measurements from the observation study were examined in closer detail. It was noted that most patients scored less than 5/12, (mean score = 4). Many of the patients in the observation study were independently mobile, and therefore, we predicted that the mean SPPB trial score would be lower. The aim of the trial was to measure the effects on functional decline, but if the SPPB scores were too low, it would be impossible to detect functional decline. Therefore, from that point onwards, we recruited patients who scored two or more in the SPPB only. The decision to retain all the previously collected data was made to ensure that we reached the target of 220 within the trial's timeframe.

9.4.13.4 Introduction of a Phone Call Follow-up Assessment

In the early stages of the trial, it was noticed that a number of patients were being lost at follow up. There were a number of reasons why they were unable to attend. Firstly, the patient group is generally frail, so many patients were directed to attend their local GP, not the hospital, for their medical follow-up. Secondly, while we provided taxi services to attend, those who lived far from the hospital declined to attend their follow-up visit. And finally, there was a large number of patients who simply refused to attend. Therefore, if it was clearly impossible for a patient to attend the hospital for the follow-up, or if the patient refused, we decided to collect as much information as possible by phone. We asked them for verbal permission to complete a phone-call interview. The phone interview prevented the measurement of their physical performance or grip strength, however, other self-reported data was collected, including a self-reported

functional ambulation. If the patient was unable to complete the interview, their next of kin was approached to provide the information.

9.4.14 Statistical Methods

All the descriptive information is presented in Table 9.1. Throughout the results, means (±SD) are presented for normally distributed data and medians [IQR] are used for non-normally distributed data. Normality of their distribution was determined using histograms.

Intention-to-treat analysis was employed on the length of stay, death and readmission rates as full data was available irrespective of drop-outs. Time-to-event analysis was used to measure the effect of the APEP on length of stay (time to discharge) i.e. discharge being the event. The effects of the APEP on walking activity in hospital, and physical performance and quality of life, both at discharge and at follow-up was measured using linear regression. Logistic regression was used to measure its effects at follow-up on falls, readmissions and deaths. The models measured the effects of the intervention on the absolute scores, rather than the changes in scores.

Covariates for the adjusted models were chosen based on the results from the preceding observation study, clinical judgement, and the significance of the variables in simple univariate analysis, and each model included their corresponding baseline score. Backwards regression was used to build the linear and logistic models and stepwise forward regression was used to build the survival model. Similar covariates appeared to have the most statistical effect on each model and were the most clinically meaningful, and therefore, the same covariates were used for most adjusted linear and logistic models. However, the effects of APEP on time to discharge and step-count appeared to fit best when adjusted for age and frailty only. All models were tested for multicollinearity. Goodness of fit was assessed using the adjusted R^2 score for linear model testing, the

Hosmer Lemeshow test for logistic model testing, and proportional hazards assumption for survival model testing. (Appendix 9.2).

9.5 Results

9.5.1 Participant Description

During the 23 month recruitment period, approximately 5,569 medical patients, aged 65 and over were admitted to the hospital. We were able to screen 1,614 patients, of which 1,398 did not meet the inclusion criteria and 17 declined to participate. One hundred and ninety-nine patients were randomised, and a further nine were excluded post randomisation as they failed to begin the exercise sessions. One patient dropped out from the study, leaving results from 189 patients who had completed the exercise programme for data analysis (11.7% of those screened). As per the CONSORT guidelines[132], details, including adherence, are provided in the flow diagram, (Figure 9.1). .

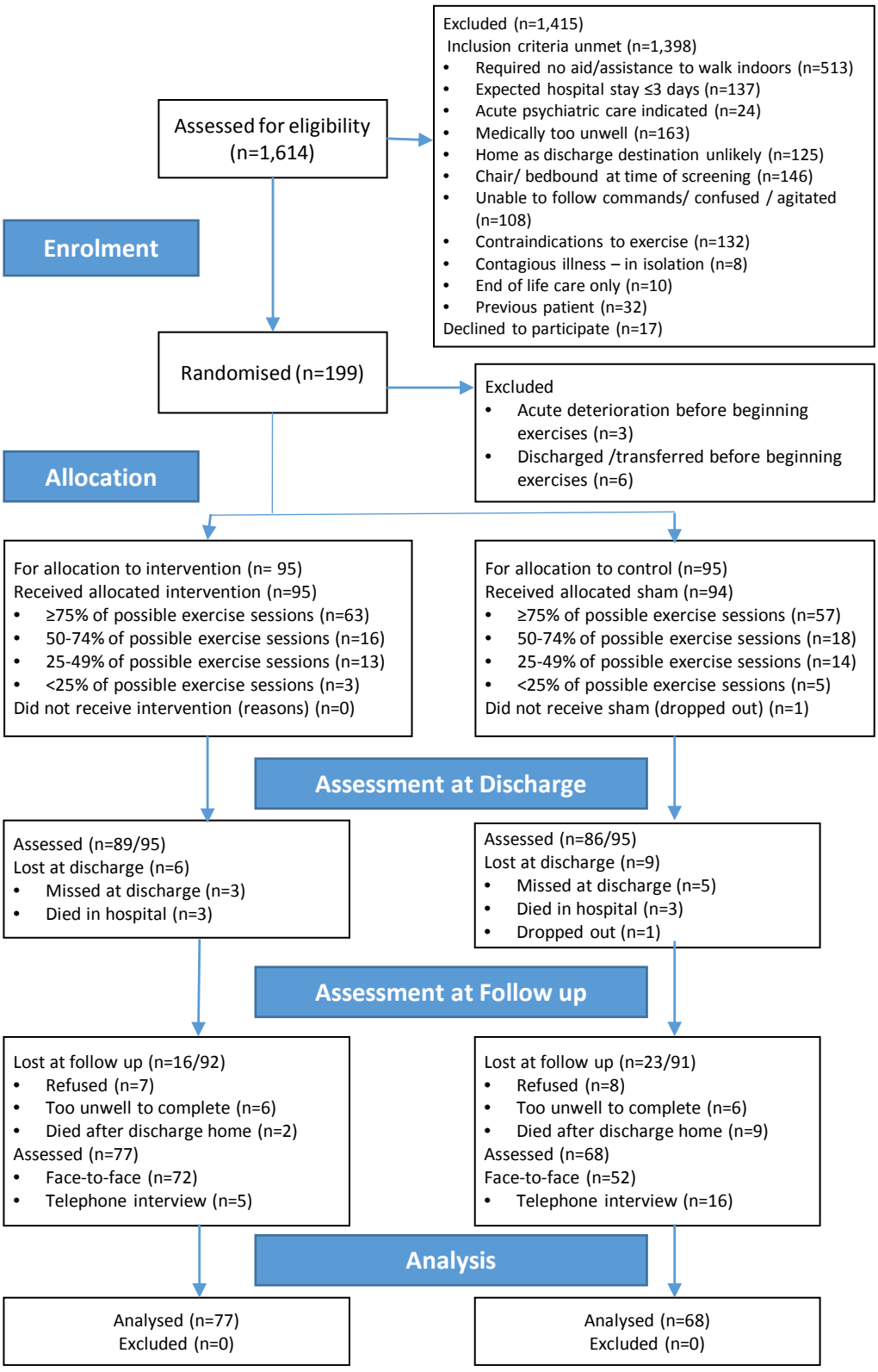


Figure 9.2: CONSORT Flow diagram of the completed APEP

Patients' average age was 80 (±7.47) years, and there was a higher proportion of women in the trial (61%). Co-morbidity in this sample was common, with an average score of 10.15 (±3.93) on the CIRS-G and 7.4 (±3.86) medications prescribed on admission. One hundred and forty four patients (76%) were categorised as frail, and overall, their physical performance was poor (SPPB 3.46 ±2.06) and fear of falling high (FES-I, 46.71 ±15.92). On admission, 39 (20%) patients walked independently with an aid, 45 (24%) needed assistance but no walking aid, and the remaining 105 (55%) patients needed both an aid and assistance on admission. Most patients presented with respiratory complaints (52, 26%), and falls (45, 24%). Other common complaints included renal complaints (n=25, 13%), strokes or transient ischaemic attacks (n=12, 6%), general malaise (n=11, 6%), cardiac (n=10, 5%), and gastric complaints (n=8, 4%). There were no significant differences between the groups on admission except, in the control group, there was a considerably larger number of women (61 (64%) versus 39 (41%) in the intervention group). Further patient characteristics are provided in Table 9.2.

Table 9.2 : Baseline Characteristics of the APEP Participants (n=190)

Variable	Control Group (n=95)	Intervention Group (n=95)
	N (%)	**N (%)**
Female	39 (41%)	61 (64%)
Smoke		
Never	57 (60%)	55 (58%)
Former	26 (27%)	26 (27%)
Current	12 (13%)	14 (15%)
Marital Status		
single	21 (22%)	17(18%)
partner	33 (35%)	30 (32%)
widowed	41 (43%)	48 (51%)
Alcohol		
Never/Former	74 (77%)	73 (76%)
Current	21(22%)	22 (23%)
SHARE F-I category		
Not Frail	3 (3%)	7 (7%)
Pre-frail	18 (20%)	14 (15%)
Frail	74 (77%)	74 (78%)
No of falls		
none	50 (53%)	49 (52%)
1-2	31 (32%)	34 (36%)
> 2	14(14%)	12 (13%)
IND		
Independent Walking	10 (11%)	14 (15%)
Not Independently Walking	84 (89%)	81 (85%)
	Mean (SD)	**Mean (SD)**
Age	81.7 (7.3)	79.7 (7.5)
BMI (kg/m^2)	26.8 (6.8)	26.3 (6.5)
No. of medications	6.9 (3.87)	7.2 (3.9)
CIRS-G	10 (3.9)	10.3 (4)
VAS SR Health	52.9 (18.9)	56.5 (18.7)
FacA	3.49(0.77)	3.59 (0.9)
	Median (IQR)	**Median (IQR)**
6CIT Score	6 (2-16)	8 (2-18)
FES-I	3.7 (2.8 - 4.6)	3.8 (2.7 - 4.6)
Walking Speed (sec)	11.3 (7.4-17.2)	10 (7.6-14.9)
SPPB score	3 (2-4)	3 (2-5)
PreN-EADL	6(0-11)	7 (0-13)
N-EADL	2 (0-4)	1 (0-4)

Abbreviations and possible score ranges: **CIRS-G:** Cumulative Illness Rating Scale-Geriatrics [higher score reflects greater impairment in several systems, range 0-56]; **6CIT**: 6-Item Cognitive Impairment Test [a higher score reflects a higher cognitive impairment, range 0-28]; **SHARE FI**: Survey of Health, Ageing and Retirement in Europe Frailty Index [a higher score reflects a higher level of frailty, range -2.55 to 6.505]; **FES-I**: Falls Efficacy Scale-International [a higher score reflects a greater concern about falling, range 0-64]; **SPPB**: Short Physical Performance Battery [a higher score reflects a better physical performance, range 0-12]; **IND**: ability to walk independently on level surfaces. **PreN-EADL:** Premorbid Nottingham Extended Activities of Daily Living [a higher score reflects a better level of independence, range 0-22]; **N-EADL:** Nottingham Extended Activities of Daily Living on Admission [a higher score reflects a better level of independence, range 0-22]; **VAS** SR Health (EQ5D5L): Visual Analogue Scale EuroQol 5-Domain 5-Level, [range 1-100]; **FacA:** Functional Ambulatory Classification on Admission [a higher score reflects a better level of ambulation, range 0-6] .

Table 9.3 : Unadjusted and Adjusted regression and Time-to-Event analyses results between groups

Variable	*N*	Co-ef	Unadjusted	*p*	*N*	Adjusted	*p*
LOS *(time to discharge)*	128	**HR**	1.09 (0.77 - 1.56)	0.6	125	1.3 (0.9 -1.87)	0.16
Steps	48	**β**	262.1 (-80 - 604)	0.1	48	316(-25 - 656)	0.07
SPPB Score *Discharge*	178	**β**	0.88 (0.20 - 1.57)	0.01*	174	0.78 (0.28 - 1.29)	0.003*
SPPB Score *Follow-up*	123	**β**	0.45 (-0.43 -1.33)	0.3	122	0.67 (-0.74 - 0.87)	0.87
VAS SR Health *Discharge*	178	**β**	3.96 (-1.65 - 9.6)	0.1	172	5.10 (-0.78 - 10.98)	0.9
VAS SR Health *Follow-up*	145	**β**	0.276 (0.9 - 0.47)	0.004*	143	0.26 (0.07 - 0.45)	0.008*
READMISSION *Follow-up*	176	**OR**	1.95 (0.94 - 3.39)	0.06	172	2.25 (1.09 - 4.66))	0.03*
FALLS *Follow-up*	189	**OR**	0.6 (0.26 - 1.36)	0.2	184	0.57 (0.24 - 1.38)	0.2
DEATH *Follow-up*	190	**OR**	0.42 (0.14 - 1.26)	0.12	184	0.38 (0.11 - 1.33)	0.13
IND *Follow-up*	167	**OR**	3.64 (1.3 - 10.2)	0.01*	165	2.47 (0.82 - 7.44)	0.1

LOS and Steps multivariate models adjusted for age and frailty only.
All other multivariate models adjusted for age, gender, frailty, fear of falling, physical performance on admission and the baseline score.
Abbreviations and possible score ranges: **LOS**: length of stay (nights); **Steps**: average daily step-count; **SPPB Score**: Short Physical Performance Battery [a higher score reflects a better physical performance, range 0-12]; **IND:** ability to walk independently on level surfaces; **VAS SR Health** (EQ5D5L): Visual Analogue Scale EuroQol 5-Domain 5-Level, [range 1-100]; **READMISSION:** medical readmissions.

9.5.2 Differences in length of stay between groups

The total number of bed nights for the control group was 970 (median, 8 (IQR 6-13)) nights, which was more than the intervention group, with a total of 880 nights (median 8 (IQR 5-11)) nights. Cox regression analysis showed that difference between groups was not significant (HR 1.11 (CI 0.83-1.5) p=0.48). An equal number of patients were transferred to sub-acute rehabilitation in each group, which, in effect, artificially truncated their length of stay. There was little change to the results when we removed these in the unadjusted model (n=128), (HR 1.09 (CI 0.77-1.56), p=0.6; Table 9.3). However, when adjusted for age and frailty, while it remained insignificant, the effect was greater and differences became

clearer (n=125), (HR 1.3 (CI 0.90-1.87) p=0.16; Table 9.3). Kaplan Meier curves display the differences between the models (Figure 9.2).

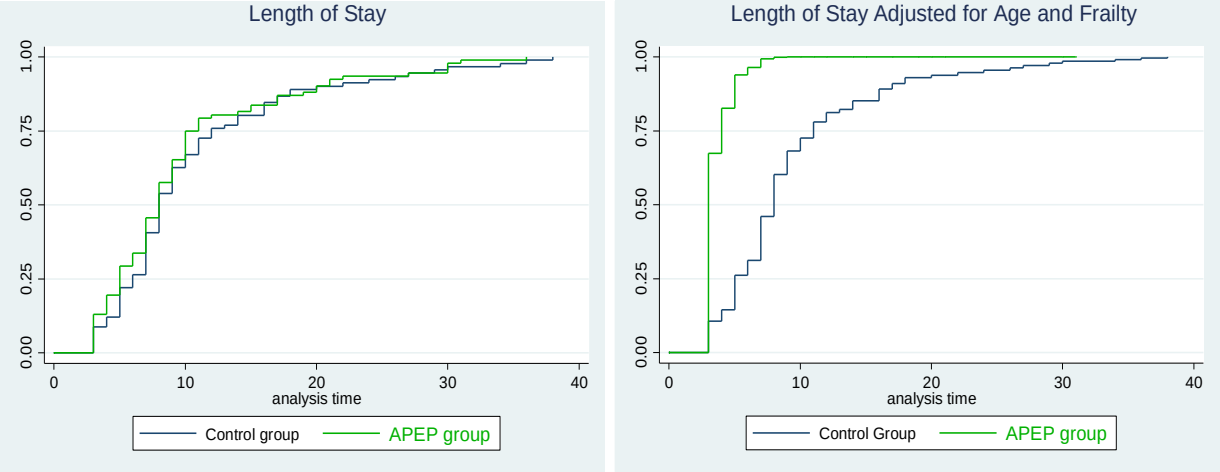


Figure 9.3: Length of Stay between Groups (APEP Trial) (n=128)

9.5.3 Differences in step-count in hospital

Step-count data was collected on only 49 patients and their range of activity is high. The APEP group were found to be more active (steps= 889 (IQR 575-1088) compared to the control group (steps= 597 (IQR 346-846)), (p=0.1). Once again, the difference between the groups became more apparent when adjusted for age and frailty (additional steps 316 (CI -25-656), p=0.07).

9.5.4 Differences in physical performance and functional independence at discharge and at follow-up

Patients' physical performance scores were better in the intervention group at discharge (4.6 ±2.5) than in the control group (3.0 ±2.1), (β 0.88

(CI 0.20 – 1.57), p=0.01), and this difference remained significant when adjusted (β 0.78 (CI 0.28-1.29) p=0.003). (Table 9.3).

At follow-up, physical performance was measured in 123 patients (who attended for their assessment), and the difference between groups was not significant at this time point (β 0.45, (CI -0.43 to 1.33) p=0.3), adjusted difference (β 0.67 (CI -0.74-0.87) p=0.87). The patients' self-reported functional ambulation had been collected in 167 patients. These were categorised into independent or not independent walkers (needing assistance or not needing assistance to walk). Using this as a surrogate marker for physical performance, a greater number were independent in the intervention than the control group (58 versus 44 respectively, OR 3.64 (CI 1.3 – 10.2), p=0.01, (Table 9.3)). However, the significance was lost when adjusted (OR 2.47 (CI 0.82 – 7.44) p=0.01).

9.5.5 Differences in quality of life at discharge and at follow-up

Differences in quality of life were not detected at discharge. Unadjusted regression at discharge suggested that there was no difference between the control (62.4 ±21.31) and the intervention groups (67.7 ±18.38), (β 3.96 (CI -1.65 – 9.6) p=0.1), adjusted scores (β 5.10 (-0.78-10.98), p=0.9). (Table 9.3).

At follow-up, a small difference was observed between the control (58.5 ±21.6) and the intervention groups (65.2 ±21.2), (β 0.28 (CI 0.9 – 0.47), p=0.004) adjusted scores (β 0.26 (CI 0.07 – 0.45), p=0.008).

9.5.6 Differences in death, medical readmissions and adverse events rates

Six patients died during their hospital stay; three in each group. At follow-up, a total of twelve patients had died in the control group, and five in the

intervention group (OR 0.38 (CI 0.12 – 1.12) p=0.08), adjusted difference (OR 0.33 (CI 0.34-0.21) p=0.08).

In total, six patients did not get home in the three months following discharge. Five patients remained in sub-acute care from the control group, and one patient from the intervention group. At follow-up, three patients had been admitted to long-term care in the intervention group, with no patients admitted in the intervention group.

In total, 30 falls occurred during the study period; 18 in the control group and 12 in the intervention group (OR 0.6 (CI, 0.26-1.36) p=0.2) with little change when adjusted (OR 0.57 (CI 0.24-1.38) p=0.2).

As the number of negative events was small, *post hoc* analysis was completed with a combined adverse outcome of falls, or prolonged hospital stay, or long-term care admission, or death. Crude logistic regression suggested that the intervention reduced the odds of one of these adverse outcomes occurring (OR 0.46 (CI 0.24 – 0.92) p=0.03), adjusted scores (OR 0.42 (0.2 – 0.92) p=0.03).

To examine readmission rates, those patients who remained in hospital were excluded. In the remaining 176 patients, 46 medical readmissions occurred in the follow-up period. Sixteen medical readmissions occurred in the control group and thirty in the intervention group (OR 1.95 (CI 0.93 – 3.93) p=0.06) with the difference becoming significant when adjusted (OR 2.25 (CI 1.09 – 4.66) p=0.03).

9.6 Discussion

There were three main results from this study. Firstly, the APEP programme appeared to reduce length of stay by 30% in patients who were discharged home, however, this did not reach statistical significance, even when adjusted for age and frailty. Secondly, patients' physical performance was significantly better at discharge in the intervention group,

however this improvement was lost at follow-up. Finally, while significantly more readmissions occurred in the intervention group, more prolonged hospital stays, deaths and falls and admissions to long-term care occurred in the control group.

The effect of the APEP on length of stay is similar to the findings of previous studies. Neither Siebens et al. [29] nor de Morton et al. [30] detected a shorter length of stay with an additional exercise programme in hospital. Jones et al. [31] showed that additional exercises shortened hospital stay, but only when they included patients in sub-acute care. Unadjusted analysis of the results showed that the effect was not significant. When adjusted for patient frailty and age, (and excluding patients transferred to another hospital), the effect appeared greater. This may suggest that the APEP has a greater effect for the frailer group. This finding correlates well with an individual patient meta-analysis completed by de Morton et al. [129] who found that the exercises benefitted mostly patients who needed assistance to walk on admission. Jones et al. [31], also found that the intervention was most effective for those with poorer physical performance on admission.

The power calculations for this study were based on a previously completed pilot study [34] (n=40, median length of stay of 10 [IQR 8-12] days for the intervention group, and 12 [IQR 9-15] for the control group), and suggested that 220 patients were required to detect a difference in length of stay. In this study, the median length of stay was considerably shorter, at 8 [IQR 6-12] days. There are two plausible reasons for this difference. Since 2011 (when the pilot study was completed), nationally, there has been a considerable increase in pressure for access to acute beds, resulting in the average length of stay becoming shorter. And secondly, the pilot study was completed in the geriatric ward only, whereas participants were also recruited from the general medical wards for this trial. The length of stay is not indicative of readiness for discharge home in those patients transferred to another hospital for continuing care or rehabilitation. When transferred patients were omitted from the analysis,

the intervention effect was greater on length of stay, but the power was weakened (n=125), which may explain its failure to reach statistical significance.

A significant difference in physical performance was detected at discharge in the APEP arm and this is similar to the findings of Jones et al. [31]. de Morton et al. [30] were unable to detect improvements with exercise but explained that 27% of patients were unable to score on the Timed Up and Go, affecting the validity of this finding. Siebens et al. [29] did not assess patients at discharge. The changes that we detected suggest that they were also clinically meaningful. The change in SPPB scores of 0.78 (adjusted scores) was detected in this group. This change lies well within the estimates for clinically meaningful change of between 0.3 and 0.8, and within the estimates for substantial clinical change of between 0.4 and 1.5[133].

The statistically significant difference in quality of life detected at follow-up was minimal; a difference of less than one unit (range 0-100 units) was detected. The difference was greater at discharge (crude, 3.96 units, and adjusted 5.10 units) but these failed to reach significance. While there is no clearly defined minimal clinical important change in the older population, a difference of seven units has been defined as the cut-off point for patients with chronic pulmonary disease[127]; considerable greater than the difference detected in this cohort.

The number of prolonged hospital stays (one versus four), total deaths, (five versus eleven) and falls (12 versus 18), and long-term care admissions (zero versus three) were considerably higher, and when analysed together (*post hoc*) occurred significantly more often in the control group. Of note, the number of falls and deaths that occurred in hospital were similar between groups at discharge. One adverse outcome was detected in the intervention group; a considerably greater number of readmissions occurred (30 versus 16 in the control group). Reasons for

this are unclear but as a greater number of frailer patients were discharged home, they may have a natural tendency for readmissions.

While the results of this trial need to be interpreted with caution, they can be used to inform future research in this area. Firstly, many frailer patients are not discharged directly home, and the health service is developing "step-down" pathways which include sub-acute, transitional and integrated care services. The APEP programme sits well within these services and may well suit patients who are recovering from their acute illness. Secondly, the aim of the service is to reduce functional decline and measurements which reflect this (rather than length of stay) would highlight the impact of the service. Finally, many older inpatients are robust, but remain inactive in hospital. While physiotherapists lead patients exercise and activity, everyone is responsible for exercise promotion. Future research should measure the effectiveness of a broader, more inclusive intervention including changes to the hospital environmental and interdisciplinary management of walking activity in hospital.

9.6.1 Study Limitations

There are a number of limitations in this study. We aimed to recruit frailer inpatients, and so we recruited those who needed assistance or an aid to walk. However, study resources did not allow us to recruit patients who needed the assistance of two people to walk safely, leaving the selection of patients narrow.

In order to maintain adequate dosage of the APEP intervention, we recruited patients within two days of hospital admission. However, many patients remained too unwell to participate within that timeframe, but after the 48 hour window, gradually did improve. Once improved, these patients were clinically very suitable for the APEP intervention. In hindsight, these patients may have responded well to the intervention and questions whether the dosage or the patients' ability to participate is more important when choosing the eligibility criteria.

The above factors may have led to only 12% of older medical patients screened being recruited to the trial. Future studies should include patients who are in hospital for over 48 hours, and who require assistance of more than one person, possibly increasing the proportion of patients who might benefit from the intervention.

While patients aged 65 and over were eligible, the average age of the recruited patients was much higher at 80 years. Much time was spent on the screening process and in hindsight, perhaps increasing the inclusion age to 75 years and over may have improved the screening efficiency.

While we intended to recruit 220 patients, we were forced to terminate the trial earlier with 190 patients recruited due to the significant changes that the new translational care unit brought to the hospital discharge process. This could have led to our results being underpowered, and therefore, the exact effect of the intervention remain unclear.

Many frailer patients were transferred to sub-acute care for further rehabilitation. We were particularly interested in this frailer group but this change would affect the outcome measurements collected on this group. It was noted that once the clinical decision to offer sub-acute rehabilitation was made, it was difficult to withdraw this offer, even if the patient improved. Therefore, it would appear that the intervention did not affect the transfer rate, even if it had improved function.

Sufficient objective walking activity data was not collected on the patients to add information to the study. This information would have demonstrated the effect intervention had on walking activity in hospital and should be given consideration in further studies. Nonetheless, even with low numbers, the difference is apparent with an increase of 300 steps daily in the intervention group.

The improvement in physical performance had been lost at the three month follow-up. It was apparent that the patients were less motivated to exercise or walk alone in hospital – the daily visits and support helped

them to remain active. Their activity after discharge is unclear. The patients were not supported after discharge, nor were their activity levels monitored. Future studies should incorporate some support and or measurement of activity post discharge home.

And finally, more information regarding patients' fear of falling and frailty at follow-up may have provided us with a better indication of changes in their self-efficacy.

9.7 Conclusion

The results of this APEP study suggest that the intervention improves patients' physical performance and quality of life. Length of stay was considerably reduced; however this failed to reach statistical significance. Reasons such as a short median length of stay and insufficient numbers linked to a new service in the hospital may explain the lack of significance. Economic evaluation of the intervention and qualitative analysis of the patients' perception of the intervention are now underway to help us further determine the value and effectiveness of the intervention.

10 Conclusions of the Thesis

10.1 Motivation and background

While working clinically in the acute geriatric setting, I noticed that older patients were physically inactive in hospital. Initially, I reviewed studies which measured the effects of additional exercises for older medical inpatients, and realised that the patient selection of these studies did not reflect the typical frailer patient [29], and that the outcome measure used (Timed Up and Go) [30, 31], required a patient's ability to stand up independently, which many of the frailer patients are unable to do. Therefore, with the assistance of Dr Suzanne Timmons, Dr Kieran O'Connor and Ms Eilis Fitzgerald (student physiotherapist, RCSI), I completed a pilot study (n=40) to measure the effects of an additional exercise programme on the geriatric ward in the Mercy University Hospital for a period of two months. This was funded by the HRB Student Scholarship programme. The results showed that patients in the intervention group had better physical performance and quality of life at discharge, with a median reduction in length of stay of 2 days. This was later published in *Physiotherapy Research and Practice* (the PDF version of the paper is attached in Appendix G). These results indicated that the intervention should be further evaluated in a large randomised controlled trial. I was subsequently awarded a HRB Health Professional Fellowship Award (HPF 2013 451).

The original aim of the thesis was to measure the effects of an additional exercise programme for frail medical inpatients in the Mercy University Hospital. However, in order to determine which patients would benefit from additional exercise, we needed to firstly identify the patients who were least active in hospital. This was the aim of the observation study (Phase 2). Objective measurement of activity, using motion sensors, seemed to be

the most feasible and reliable. Delirium is common in inpatients aged 80 years and over [36], limiting self-report reliability, and the nursing staff were busy, limiting their availability to report. Therefore, I completed a literature review to identify a suitable accelerometer. I was most interested in walking activity as this is the most common and accessible form of physical activity in the acute hospital. Furthermore, other measurements of physical activity, such as energy expenditure, appear to be affected by as much as 25% in the presence of an acute infection in older adults [62] and are more difficult to interpret clinically. However, the literature review showed that there had been no accelerometer validated to measure step-count in frail inpatients. For this reason, the accuracy study was completed to determine the most suitable motion sensor for both the observation study and the trial (Phase 1).

Therefore, the thesis took the form of three phases; Phase 1 to identify a suitable motion sensor, Phase 2 to identify the patients who are least active in hospital, and Phase 3 to measure the effects of an additional exercise programme in this identified cohort.

10.2 Phase 1

Phase 1 consisted of two studies: a review study to identify a suitable motion sensor for used in frail older medical inpatients, and an accuracy study.

10.2.1 A Review of the Accuracy and Utility of Motion Sensors to Measure Physical Activity in Frail Older Hospitalised Patients

The review study was focused on validation studies of sensors (accelerometers and pedometers) that measured either step-count or time

spent upright. Time-spent-upright has been used in the literature as a measurement of time-spent-walking, making the assumption that if the wearer is standing, they are walking. However, time-spent-upright does not inform us of bouts of walking – whether the wearer is progressing towards a more functional walking performance with their recovery from an acute illness. I felt that a motion sensor which measure walking (ie., step-count) would be more clinically meaningful. A total of 693 papers were identified, 669 were excluded, and 24 were reviewed for utility and accuracy in older medical patients.

The review showed that step-count accuracy appears to depend greatly on walking speed. Eleven motion sensors appeared to lose their accuracy at walking speeds less than 0.1m/sec. Many older medical patients walk slower than 0.5m/sec [57], the speed at which arm, waist and thigh mounted accelerometers appear to lose their accuracy. Three pedometers, the Omron HJ-720ITC, the SC Step MX and the Yamax SW-200 (worn at the knee) were found to be accurate in older adults who walk slower than 0.8 m/sec. Pedometers measure step-count only. In other words, the steps are not time-stamped and there is no indication of the pattern of walking activity. However, their relative in-expense merited their validation testing in the older medical inpatients. The Stepwatch Activity Monitor (SAM) was the only accelerometer which had shown good accuracy at walking speeds of 0.5 m/sec.

Two accelerometers which measure time-spent-upright had shown good accuracy in older hospitalised patients; the ActivPAL and AugmenTec. The ActivPAL (a thigh-worn uniaxial accelerometer), has been used extensively in the literature and is capable of measuring step-count. However, at slower walking speeds, it has been shown to lose its step-count accuracy [57]. The step-count accuracy of a newer triaxial version, the ActivPAL3 had yet to be tested in older inpatients.

To conclude, the results of the review study showed that no accelerometer had shown good accuracy in older medical inpatients, however, it

highlighted a number of motion sensors that were worth testing. Therefore, an accuracy study was conducted on the SAM, the ActivPAL3 and the SC Step MX.

10.2.2 Step-Count Accuracy of three Motion Sensors for Older and Frail Medical Inpatients

The accuracy study was completed between January and June 2014 by Ms Annemarie O'Connell as her taught MSc dissertation project. It is described here as it explains part of the scientific rationale of this thesis. For the purpose of the study, 32 older medial inpatients were recruited. The step-count of the motion sensors, which were worn concurrently, were compared to video recordings of a patient's movements. The patients completed a set of predetermined tasks, typical of a routine day in hospital, and included standing up and sitting down, turning, and walking over shorter (5 metres) and longer (>5 - 20 metres) distances.

The accelerometers were set up as per manufacturer's instruction. The sensitivity of ActivPAL 3 and the SC StepMX could not be adjusted. However, the SAM required further details of the wearers walking pattern in order to further refine its sensitivity. These details were inputted by responding to four questions as part of its set-up procedure. For the first 20 patients, those responses were standardised to represent the frail older patient. For the remaining 12 patients, the responses reflected each patient. The video footage was analysed separately by two independent researchers (RMcC and AO'C).

Results showed poor step-count accuracy in the ActivPAL 3 and the SC StepMX, with an error margin of over 40%. However, the SAM showed acceptable error margins of less than 10%. Therefore, it appeared that the SAM had reasonable accuracy in older medical inpatients, and was chosen to measure step-count in the observation study (Phase 2).

The studies of Phase 1 were completed to inform the final APEP clinical trial. The scholarly review showed that time spent upright was the preferred objective measurement of activity and that no valid method of measuring patients' walking activity had been identified. The validation study showed that the SAM was the most accurate measurement of walking in older medical inpatients and with a 10% error margin, was felt sufficiently accurate for use in this cohort. Both of these studies have now been published.

10.3 Phase 2

The second phase of the thesis was to identify which patients are least active in hospital, and to measure the level of association between physical activity and negative healthcare outcomes, namely, poor physical performance and prolonged length of stay. By identifying the patients who are least active on admission, the inclusion criteria of the intervention trial could be refined to include those patients.

10.3.1 Walking in hospital is associated with a shorter length of stay

The observation study was completed from September 2015 to March 2016. One hundred and fifty-four medical patients, aged ≥65 years, and who were mobile premorbidly, were recruited to the study. Baseline assessments included all potential confounders to poorer healthcare outcomes, including age, gender, comorbidity, physical performance, quality of life, cognition, falls and falls efficacy. Their physical activity (i.e., walking) was measured continuously for the first seven days of their hospital stay, or until discharge. Their physical performance and quality of life was re-assessed after the period of observation.

The results of the study showed that patients walk an average of 600 steps daily, which equated to approximately 12 minutes of daily walking. Their median length of stay was seven nights. Regression analysis indicted that a 50% increase in daily walking was associated with a 6% shorter length of stay, even when adjusted for age, frailty, co-morbidities and physical performance on admission. Previous studies had shown that patients who remain in their bedroom mostly tend to stay in hospital longer [18] and that walking activity which was increased by 600 steps from the first to second day, was associated with a shorter hospital stay of 2 days [19]. However, in these previous studies, the patient characteristics on admission were not taken into consideration, nor was walking activity measured objectively over a prolonged period of time. As the step-count measured in our study was low, a doubling or even trebling of walking is possible through advice and education, and helping those patients who are unable to remain active independently. Most importantly, the results suggest that walking is a modifiable factor associated with length of stay and supports the need for the planned intervention trial. This paper has now been published.

10.3.2 Influencers of Walking in Older Medical Inpatients'

The observation study suggested that walking was associated with a longer hospital stay. However, it did not show the possible influencers to walking. Therefore, secondary analysis of the data was completed to help determine the barriers and facilitators to walking. Possible daily influencers had been collected. These included factors such as medical status, confusion, physiotherapy /occupational therapy, procedures completed, fear of falling, tethering treatments, need for walking aid or assistance or ordered bed-rest. The results indicated that there was great variability in walking activity, not only between patients, but also within patients over time. Patients walked most on Wednesdays. The influencers that

significantly reduced walking was ordered bed-rest, and tethering treatments, while improving medical status and better physical performance on admission were associated with more walking.

These results suggest that, while the more obvious influencers on walking activity (ordered bed rest, tethering treatments etc.) were detected as influential, the degree of variability over time suggests that other, less obvious factors remain unclear. Fear of falling, the need for physiotherapy or occupational therapy did not appear to influence walking activity. However, the fact that patients walk most on Wednesdays suggest that the environment may have some influence on patients walking. An ethnographic study, where observation and interviewing of patients occurs the hospital environment, may reveal these other undetected influencers. This second paper is being prepared for submission.

The results of the second phase supported previous evidence that patients are very inactive in hospital, taking an average of 600 steps per day. It also showed that there was an association between walking and length of stay, which further justified the intervention trial. Secondary analysis suggested that there was great variability in walking activity. While certain influencers were identified such as physical performance on admission, tethering treatments and instructed bed-rest, much of the variability remains unexplained. The environment may have a stronger influence than previously thought and should be examined in future studies. Therefore, the observation study supports the belief that patients remain inactive in hospital. Nonetheless, no causal link has been determined, and justifies the completion of the intervention trial.

10.4 Phase 3

The second phase of the thesis had demonstrated that patients are inactive in hospital, and this inactivity is associated with a longer hospital stay. Physical performance on admission to hospital appeared to

determine walking and physical performance at discharge. The observation study did not explain the causal link. It was now important to measure the effectiveness of an intervention to increase activity in hospital. Therefore, the aim of the third phase of the thesis was to measure the effects of an augmented prescribed exercise programme (APEP) for frail medical inpatients in the acute hospital setting.

10.4.1 A randomised controlled trial to measure the effects of an augmented prescribed exercise programme (APEP) for frail older medical patients in the acute setting

Patients who had been mobile premorbidly, but had poor physical performance on admission, were recruited to the study. As the original aim of the study was to measure the effects on functional decline, we only recruited those patients whose baseline score was ≥2/12 on the Short Physical Performance Battery (SPPB). Patients were randomly allocated to either the intervention or sham (control) groups. The intervention group received twice-daily prescribed and assisted exercise programmes and support and advice regarding walking activity in hospital. The control group received stretching and relaxation exercises only. The exercise programmes were delivered at the bedside.

The exercise sessions were originally planned to last for up to 20 minutes, but I found that many patients, especially in the early days of the hospital admission, were unable to exercise for more than 10 minutes. Patients with poor cognition were included in the trial, as long as they and their family gave consent, and they were able to follow simple commands. Sometimes, these patients found the bedside exercises difficult to understand. However, I found that these patients, and those on tethering oxygen therapy, appreciated the walking practice more than the bedside exercise sessions. I believe that walking was very meaningful for them, it gave them a break from the ward, a chance to talk about concerns either

in the hospital, or at home. Many patients remarked that they “enjoyed that” on return from a walk. I feel that the bedside exercises were more effective to help the frailer patients who had difficulty getting up from the chair and transferring etc. Their balance and strength was challenged more when completing the bedside exercises.

Patients consent levels were considerably higher than originally anticipated. A far higher proportion of patients refused to complete the validation study (8/32) than the intervention trial (17/190), suggesting that they could understand the potential gains from the intervention. Many were reluctant on daily approach, but would agree to “try a few exercises” or simply “go for a short walk”. It was clear that without the daily contact and support, many would have found it very difficult to exercise. While some patients simply could not move with tethering treatments (wall mounted oxygen therapy especially), the frailer, or those with poor cognition, felt too unwell or too weak to motivate themselves to exercise independently. Perhaps this is why the intervention appeared to be more effective on length of stay when adjusted for age and frailty.

The introduction of the transitional care unit in September 2016, prevented me from recruiting the required 220 patients. This was unfortunate as the results on length of stay remain inconclusive. Patients who were suitable for the transitional care unit were also the patients who were suitable for the intervention study. As soon as patients were admitted to acute care, they were assessed for transitional care. This made the recruitment process to the intervention trial more complicated, and some patients who began the trial, were transferred in less than 48 hours. With these changes, it was decided to terminate the trial in January 2017, with 190 patients recruited to the trial.

The results of the APEP trial showed that physical performance and quality of life was significantly improved, the reduction in length of stay did not reach statistical significance. Possible reasons could include power calculations based on a longer length of stay, and 35% (n=66) of patients

transferred to sub-acute care. When transferred patients were excluded, and adjusted for age and frailty, the differences became clearer but remained insignificant. Nonetheless, the effect was considerable at 30% reduction.

The negative effect of increased readmissions needs to be carefully examined. Positive effects on falls, admissions to long-term care, prolonged hospital admissions and death rates were not in keeping with the negative effect on readmission rates. As a greater proportion of frail patients were successfully discharged home in the treatment arm, they were possibly more likely to experience more readmissions. A second plausible reason may be that the patients were simply sent home too soon. Every attempt was made to keep the clinicians blinded to the treatment allocation of the patients. However, it may be possible that as the patients were more mobile, clinicians perceived them as more ready for discharge home. This needs to be explored in future studies.

The objective measurement of walking activity was poor in this trial and is possibly the weakest point. Even so, the limited data collection shows a difference of 300 steps per day between groups, which is an increase of 50% in daily walking. The findings also suggest that the number of participants needed to detect a change in walking activity is lower than anticipated (possibly as they are homogenously an inactive group).

10.5 Clinical Implications

Clinically, these results are promising. They support the concept that activity in hospital is an important determinant of health outcomes. Approximately half of the patients in the observational study were independently mobile, yet remain inactive. Rather than assisted exercises, this cohort need permission and encouragement to walk or exercise regularly in hospital. Changes in hospital environment and culture can help bring about this change with patients, family members, volunteers,

healthcare professionals and hospital management involvement. A trial exploring the feasibility of a larger multidisciplinary team intervention is currently being planned.

The APEP intervention was simple and clinically feasible. The proportion of patients transferred to sub-acute care, was large, and the national healthcare trend towards sub-acute, transitional care and supported home discharge for this patient group is growing. Future studies should explore the application of the APEP in the sub-acute setting, when the acute illness has been treated. With careful trial design, whether the APEP can prevent sub-acute care is worth examining.

10.6 Limitations of the Study

There are three main limitations to this study – it was a single centre trial, limiting its external validity. The measurement of walking activity was completed on only 49 patients, and number of patients who were discharged home limited the analysis to 124 patients, which is considerably lower than the power calculation of 220. And finally, adherence or continuity of exercise at home was not measured and may have explained the loss of benefits at follow-up.

10.7 Implications for Future Research

In conclusion, this study could inform a new RCT. It gives a considerable amount of information that could direct future research. This study supports the concept that the exercise programme benefits the frailer patients. Results also support the concept that walking is important and that it should be a part of the APEP programme. Sub-acute care needs to be explored in conjunction with the APEP concept – whether it should be delivered in the sub-acute setting or whether it may actually prevent its requirement for some patients should be examined. The negative consequence of increased readmissions needs to be examined closely. As the patients find it so hard to self-motivate, the benefits of continued

support through home-visits or phone-calls after discharge should be explored. Further examination as a multicentre trial and through qualitative and economic analysis would clarify its effectiveness. And finally, whether this is effective only for a small number of patients; whether an interdisciplinary team targeting many aspects of care for older adults be a more clinical and cost effective model of care, needs to be examined.

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Appendix A: Measurement Tools used throughout the thesis

CUMULATIVE ILLNESS RATING SCALE (CIRS-G) (SALVI ET AL, 2008)

Include presenting complaints and past medical history.

Body system	Score				
1. Cardiac (heart only)	0	1	2	3	4
2. Hypertension (rating is based on severity; organ damage is rated separately)	0	1	2	3	4
3. Vascular (blood, blood vessels and cells, bone marrow, spleen, lymphatics)	0	1	2	3	4
4. Respiratory (lungs, bronchi, trachea below the larynx)	0	1	2	3	4
5. EENT (eye, ear, nose, throat, larynx)	0	1	2	3	4
6. Upper GI (esophagus, stomach, and duodenum; pancreas; do not include diabetes)	0	1	2	3	4
7. Lower GI (intestines, hernias)	0	1	2	3	4
8. Hepatic (liver and biliary tree)	0	1	2	3	4
9. Renal (kidneys only)	0	1	2	3	4
10. Other GU (ureters, bladder, urethra, prostate, genitals)	0	1	2	3	4
11. Muscolo-skeletal-integumentary (muscle, bone, skin)	0	1	2	3	4
12. Neurological (brain, spinal cord, nerves, do not include dementia)	0	1	2	3	4
13. Endocrine-Metabolic (includes diabetes, thyroid; breast; systemic infections; toxicity)	0	1	2	3	4
14. Psychiatric/Behavioral (includes dementia, depression, anxiety, agitation/delirium, psychosis)	0	1	2	3	4

Score: _____

FALLS EFFICACY SCALE-INTERNATIONAL (YARDLEY ET AL, 2005)

		Not at all concerned 1	Somewhat concerned 2	Fairly concerned 3	Very concerned 4
1	Cleaning the house (e.g. sweep, vacuum, dust)				
2	Getting dressed or undressed				
3	Preparing simple meals				
4	Taking a bath or shower				
5	Going to the shop				
6	Getting in or out of a chair				
7	Going up or down stairs				
8	Walking around in the neighborhood				
9	Reaching for something above your head or on the ground				
10	Going to answer the telephone before it stops ringing				
11	Walking on a slippery surface (e.g. wet or icy)				
12	Visiting a friend or relative				
13	Walking in a place with crowds				
14	Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)				
15	Walking up or down a slope				
16	Going out to a social event (e.g. religious service, family gathering, or club meeting)				
	Sub Total				
				TOTAL	**/64**

EUROQOL 5 DOMAIN 5 LEVEL (VAN HOUT ET AL, 2012)

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑

I have slight pain or discomfort ❑

I have moderate pain or discomfort ❑

I have severe pain or discomfort ❑

I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑

I am slightly anxious or depressed ❑

I am moderately anxious or depressed ❑

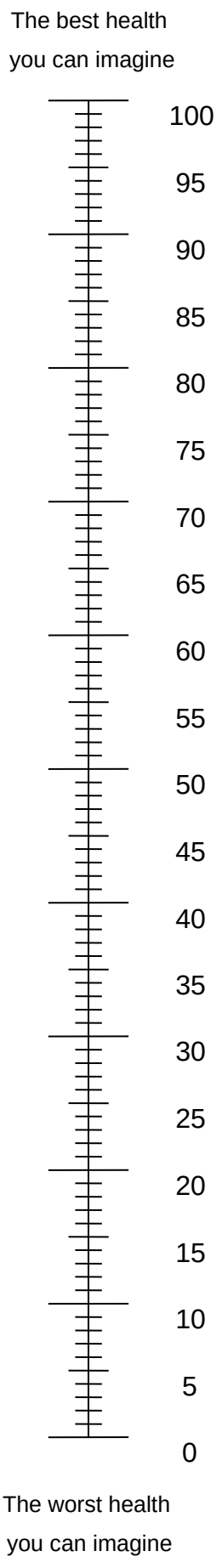
I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

We would like to know how good or bad your health is TODAY.

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



NOTTINGHAM EXTENDED ACTVITIES OF LIVING SCALE (LINCOLN ET AL, 2009)

Nottingham Extended ADL Scale

The following questions are about everyday activities. Please answer by ticking ONE box for each question. Please record what you have ACTUALLY done in the last few weeks.

DID YOU…….	Not at all	with help	on your own	on your own with difficulty
1. Walk around outside?	☐	☐	☐	☐
2. Climb stairs?	☐	☐	☐	☐
3. Get in and out of a car?	☐	☐	☐	☐
4. Walk over uneven ground?	☐	☐	☐	☐
5. Cross roads?	☐	☐	☐	☐
6. Travel on public transport?	☐	☐	☐	☐
7. Manage to feed yourself?	☐	☐	☐	☐
8. Manage to make yourself a hot drink?	☐	☐	☐	☐
9. Take hot drinks from one room to another?	☐	☐	☐	☐
10. Do the washing up?	☐	☐	☐	☐
11. Make yourself a hot snack?	☐	☐	☐	☐

	No	With help	On your own with difficulty	On your own
12.Manage your own money when out?	☐	☐	☐	☐
13. Wash small items of clothing?	☐	☐	☐	☐
14.Do your own housework?	☐	☐	☐	☐
15.Do your own shopping?	☐	☐	☐	☐
16. Do a full clothes wash?	☐	☐	☐	☐
17.Read newspapers or books?	☐	☐	☐	☐
18.Use the telephone?	☐	☐	☐	☐
19. Write letters?	☐	☐	☐	☐
20.Go out socially?	☐	☐	☐	☐
21. Manage your own garden?	☐	☐	☐	☐
22. Drive a car?	☐	☐	☐	☐

SURVEY OF HEALTH, AGEING AND RETIREMENT SURVEY IN EUROPE FRAILTY INSTRUMENT (SHARE FI) (ROMERO-ORTUNO ET AL, 2010)

1. Exhaustion

"In the last month, have you had too little energy to do the things that you wanted to do?"

Yes (1) **No (0)**

2. Appetite

"What has your appetite been like?"

If answer is unspecific, "So, have you been eating more or less than usual?"

Poorer appetite (1) Normal appetite (0)

3. Weakness

(2 attempts - both hands. Use the strongest score & document side)

Right: Score (kgs): (1) (2)

Left Score (kgs): (1) (2)

4. Walking Difficulties

"Because of a health problem, so you have difficulty [expected to last more than 3 months] walking 100 metres" or "…climbing one flight of stairs without resting"

1 /2 answers "yes" (1)

2 x "no" (0)

5. Low physical activity

"How often do you engage in activities that require a low or moderate level of energy, such as gardening, cleaning the car, or doing a walk?

More than once a week (1) **Once a week (2)**

Once to three times a month (3) **Hardly ever / never (4)**

SIX ITEM COGNITIVE SCREEN TEST (6-CIT) (KATZMAN ET AL, 1983)

1. What year is it?	Correct - 0 points Incorrect - 4 points
2. What month is it?	Correct - 0 points Incorrect - 3 points
3. Give the patient an address phrase to remember with 5 components, eg John, Smith, 42, High St, Bedford	
4. About what time is it (within 1 hour)	Correct - 0 points Incorrect - 3 points
5. Count backwards from 20-1	Correct - 0 points 1 error - 2 points More than one error - 4 points
6. Say the months of the year in reverse	Correct - 0 points 1 error - 2 points More than one error - 4 points
7. Repeat address phrase	Correct - 0 points 1 error - 2 points 2 errors - 4 points 3 errors - 6 points 4 errors - 8 points All wrong - 10 points
6CIT score = [ ] /28	

SHORT PHYSICAL PERFORMANCE BATTERY (SPPB) (GURALNIK ET AL, 1994)

Date : _____

Balance Score

Unable to hold side by side stance for > 9 seconds	0 points
Side by side stance for 10 sec, but unable to hold semitandem for 10 sec	1 point
Semitandem for 10 sec, unable to hold full tandem for > 2 sec	2 points
Full tandem for 3-9 sec	3 points
Full tandem for 10 sec	4 points

Walk Score (4 Meter or 13.12 feet)

Unable to walk	*Walking aid:*	0 points
If time is more than 8.70 seconds		1 point
If time is 6.21 to 8.70 seconds		2 points
If time is 4.82 to 6.20 seconds		3 points
If time is less than 4.82 seconds	Time 2: _____	4 points

Chair Stand Score

If the participant was unable to complete the 5 chair stands		0 points
If chair stand time is 16.7 seconds or more		1 point
If chair stand time is 13.7 to 16.6 seconds		2 points
If chair stand time is 11.2 to 13.6 seconds		3 points
If chair stand time is 11.1 seconds or less	Time: _____	4 points

Total Score _____

Converted Gait Velocity (13.12/time in seconds)*0.68 = mph) _____

FUNCTIONAL AMBULATORY CLASSIFICATION (FAC) (HOLDEN ET AL, 1986)

Functional Ambulation Classification

Category	Definition
0 Nonfunctional Ambulation	Patient cannot ambulate, ambulates in parallel bars only, or requires supervision or physical assistance from more than one person to ambulate safely outside of parallel bars.
1 Ambulator-Dependent for Physical Assistance—Level II	Patient requires manual contacts of no more than one person during ambulation on level surfaces to prevent falling. Manual contacts are continuous and necessary to support body weight as well as maintain balance and/or assist coordination.
2 Ambulatory-Dependent for Physical Assistance—Level I	Patient requires manual contact of no more than one person during ambulation on level surfaces to prevent falling. Manual contact consists of continuous or intermittent light touch to assist balance or coordination.
3 Ambulator-Dependent for Supervision	Patient can physically ambulate on level surfaces without manual contact of another person but for safety requires standby guarding of no more than one person because of poor judgment, questionable cardiac status, or the need for verbal cuing to complete the task.
4 Ambulator-Independent Level Surfaces Only	Patient can ambulate independently on level surfaces but requires supervision or physical assistance to negotiate any of the following: stairs, inclines, or nonlevel surfaces.
5 Ambulator-Independent	Patient can ambulate independently on nonlevel and level surfaces, stairs, and inclines.

Appendix B: Published Paper: A Review of the Accuracy and Utility of Motion Sensors to Measure Physical Activity of Frail Older Hospitalised Patients (PDF)

Appendix C: Published Paper: Step-Count Accuracy of Three Motion Sensors for Older and Frail Medical Inpatients (PDF)

Appendix D: Ethical Approval for the Validation Study (incorporated into the observation study) (PDF)

Appendix E: Patient Information Sheet for the Validation Study

Appendix F: Consent Form and Data Collection Form for the Validation Study

Appendix G: Published Paper: Walking in Hospital is associated with a shorter length of stay in older medical inpatients (PDF)

Appendix H: Ethical Approval for the Observation Study (PDF)

Appendix I: Patient Information Sheet for the Observation Study

Appendix J: Consent Form and Data Collection Form for the Observation Study

Appendix K: Published Paper: A study protocol of an RCT to measure the effects of an augmented prescribed exercise programme (APEP) for frail older medical patients in the acute setting (PDF)

Appendix L: Ethical Approval for the RCT (PDF)

Appendix M: Patient Information Sheet for the RCT

Appendix N: Consent Form and Data Collection Forms for the RCT

(Admission, Discharge and Follow Up)

Appendix O: Published Paper: The functional decline of hospitalised older patients: are we doing enough? (PDF)