Validity of the Actigraph GT3X Accelerometer in Identification of Body Position and Step Count in Adult Hospitalised Patients Recovering from Critical Illness

Jayne Lesley Anderson

Submitted in accordance with the requirements for the degree of Doctor of Philosophy

The University of Leeds
York St John University
School of Health Sciences

September, 2017

Intellectual property statement

The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others.

Acknowledgements

I wish to express gratitude to my supervisory team, Professor Howard Hall, Dr Samantha Yoward and Dr Angela Green for their support and guidance. I would also like to thank Professor Patrick Doherty for his never-ending belief in my ability to achieve the step from Graduate Diploma in Physiotherapy to PhD submission.

Sincere thanks are given to Nicola Gilchrist (Head of Physiotherapy) and Amanda Hancock (Inpatient Physiotherapy Manager, Castle Hill Hospital), both of Hull and East Yorkshire Hospitals NHS Trust (HEYHT). Their constant encouragement and funding for the first year of study was greatly appreciated. Special thanks also to Health Education England who funded the remaining years of study.

Heartfelt thanks are extended to clinical physiotherapy colleagues who assisted in the feasibility study and identified potential participants for the study which enrolled a hospital inpatient population. Special thanks to Dr Victoria Allgar and Mr Alan Rigby from the Hull York Medical School (HYMS) for advice concerning statistical analysis. A debt of gratitude is given to Christine Jones, senior technician, School of Health Sciences, York St John University (YSJU), for her supportive humour during the stressful times. This journey was undertaken with other fellow PhD students who were always a constant source of friendship and understanding.

Finally, love and gratitude is extended to my husband Gavin and my children Alex and Ewan who never doubted my capabilities. Love and thanks to my mother Mollie for her everlasting moral support. During the course of the PhD my father Leslie passed away suddenly and unexpectedly. This PhD is dedicated to him and all those who will experience critical illness at some point in their lives.

Abstract

Validity of the Actigraph GT3X accelerometer in identification of body position and step count in adult hospitalised patients recovering from critical illness

Purpose: Physical recovery from critical illness is complicated by neuromuscular weakness. Evidence suggests mobility commencing within the intensive care unit results in improved function upon discharge. Despite this, persistent inactivity is reported throughout hospital admission. Greater attention should be given to monitoring activity in this setting. Observation and self-report methods may encounter difficulties. Activity monitors (accelerometers) may offer a solution. This PhD thesis aimed to systematically review evidence investigating the validity of accelerometry to quantify purposeful activity within hospitalised adults experiencing acute or critical illness. It also aimed to investigate the validity of the Actigraph GT3X accelerometer in identification of body position (lying, sitting and standing) and step count in patients recovering from critical illness.

Methods: A systematic review explored how accelerometer validity had previously been investigated within acute and critically ill hospitalised populations. Another study investigated the feasibility of the GT3X to identify body position and quantify typical activities undertaken by patients' recovering from critical illness. Thirty healthy participants (mean age 58.8, SD 6.8) simulated this patient group, performing a movement protocol. Twenty ward based patients' (mean age 62.3, SD 11.5), who had required prolonged ventilation in the ICU (≥ 48 hours) also completed a movement protocol containing typical daily activities. The validity of the GT3X to identify body position and step count was investigated using observation as the criterion measure.

Results: A median (interquartile range) of Kappa = 0.94 (0.90, 0.98) for identification of body position was determined interpreting data from two GT3X accelerometers positioned in combination at the ankle and thigh. A mean difference (95% limits of agreement) of -0.84 steps (2.2 to -3.88) compared to observation was found for the ankle placement in step count quantification.

Conclusions: The GT3X accelerometer is valid in identification of body position when positioned in combination on the thigh and ankle of the non-dominant leg in patients recovering from critical illness. An ankle placement is valid in quantification of step count.

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List of Abbreviations

APE	Absolute percentage error
BMI	Body Mass Index
CI	Chief Investigator
CSP	Chartered Society of Physiotherapy
95% CI	95% Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
CPAx	Chelsea Critical Care Physical Assessment Tool
CPM	Counts per minute
CVD	Cardiovascular disease
ECMO	Extra Corporeal Membranous Oxygenation
EE	Energy expenditure
HEYHT	Hull and East Yorkshire Hospitals NHS Trust
HRA	Health Research Authority
HYMS	Hull York Medical School
ICC	Intraclass correlation coefficient
ICNARC	Intensive Care National Audit and Research Centre
ICU	Intensive care unit
ICUAW	Intensive care unit acquired weakness
IQR	Interquartile range
κ	Kappa
LFE	Low Frequency Extension
95% LOA	95% Limits of agreement
MDT	Multi-disciplinary team
m/s	Metres per second
NHS	National Health Service

NICE	National Institute of (health) and clinical excellence
OT	Occupational Therapy
PICO	Population, Intervention, Comparator, Outcome
PICOS	Population, Intervention, Comparator, Outcome, Study Design
PIM	Proportional Integrated Mode
PTSD	Post traumatic stress disorder
r	Correlation coefficient
RCT	Randomised controlled trial
SD	Standard deviation
SE	Standard error
SIRS	Systemic inflammatory response syndrome
TATM	Time Above Threshold Mode
TEE	Total energy expenditure
VAS	Visual analogue scale
WS	Walking stick
WZWF	Wheeled zimmer walking frame
YSJU	York St John University
ZCM	Zero Crossing Mode

Chapter 1

Introduction

1.1 Title of the PhD thesis

Validity of the Actigraph GT3X Accelerometer in Identification of Body Position and Step Count in Adult Hospitalised Patients Recovering from Critical Illness

1.2 Hospitalisation and immobility

Sedentary behaviours (prolonged adoption of sitting or lying postures) within acutely admitted older patients (greater than 65 years of age) is well documented in studies (Pedersen et al. 2013; Brown et al. 2009; Birchall and Waters 1996). However, recent evidence suggests that low mobility levels amongst hospitalised adults are not exclusive to this patient group (Mudge et al. 2016). Studies report high levels of sedentary behaviour (lying or sitting) in patients recovering from critical illness throughout the entire duration of hospital admission (Connolly et al. 2017; Borges et al. 2015; Schujmann et al. 2015b). Access to specialist, post discharge rehabilitation programmes for this patient group is rare in the UK, with only 6.8% (95% CI 3.1-10.5) of organisations offering this service (Connolly et al. 2014). This often means that following hospital discharge progression of function is dependent on patient motivation and the support administered by informal caregivers, most often who are family members (van Beusekom et al. 2016).

Prolonged sedentary behaviour during hospital admission, lack of access to specialist post discharge services and the extra burdens placed on carers is far from ideal. Evidence for this is provided by reports of persistent functional limitation experienced by those who have endured critical illness, negatively impacting on quality of life for years after discharge (Hashem et al. 2016; Herridge et al. 2011; van der Schaaf et al. 2009). Increased attention should be given to monitoring activity levels of this population during recovery. Adoption of this practice could provide a number of benefits, which will now be discussed in the following paragraph.

Evidence of the persistent adoption of sedentary behaviours within hospitalised patients recovering from critical illness locally could be supported by previous studies reporting low activity levels within this population (Connolly et al. 2017; Borges et al. 2015; Schujmann et al. 2015b). Further evidence highlighting the positive effects of early activity promotion within this population on recovery of function (McWilliams et al. 2015; Morris et al. 2011; Schweickert et al. 2009; Bailey et al. 2007) will assist in the construction of robust business cases to emphasise the need for increased specialist post discharge rehabilitation facilities for this patient group. Activity monitoring could also afford the clinician invaluable information. If patients are identified as regularly undertaking periods of activity under their own volition, this behaviour may be more likely to continue after discharge. Conversely, prolonged adoption of sedentary postures may suggest poor motivation levels. Further burden on informal caregivers may result, who have been reported to suffer from anxiety, depression and post-traumatic stress disorder (PTSD) as a result of caring for those who have experienced critical illness (van Beusekom et al. 2016). Identification of those who although physically able, do not undertake regular activity will assist in the discharge planning process, ensuring appropriate allocation of physiotherapy and occupational therapy (OT) resources to improve exercise tolerance and motivation.

Prior to discussion of the possible methods of monitoring activity, the physiological mechanisms which precipitate functional impairment within this patient group are now considered.

1.3 Physiological, functional and economic consequences of critical illness

Physical recovery following critical illness is often complicated by profound respiratory impairment and generalised muscle weakness, commonly referred to as Intensive Care Unit Acquired Weakness (ICUAW) (Hermans and Van den Berghe 2015). Research seeking to understand the aetiology of ICUAW has revealed a complex molecular process involving alterations in the normal balance between protein synthesis and catabolism resulting in a shift towards

an overall catabolic state (Bloch et al. 2012). Other studies have identified a reduction in muscle force generation (Friedrich 2008; Khan et al. 2008), with development of polyneuropathy, myopathy or a combination of both (Batt et al. 2013; Confer et al. 2012; Koch et al. 2011). Disruption in general muscle structure is evident, with decreased myosin: actin ratios (Derde et al. 2012), accompanied by abnormal muscle electrophysiology (Friedrich 2008; Khan et al. 2008). These studies provide insight into the widespread, physiological effects of critical illness at cellular and molecular levels. They also highlight the negative consequences of these processes, both on muscle composition and the neural structures supplying them.

A more overt consequence of these diffuse physiological and neuromuscular aberrations is the increased time period required to wean from ventilator support, precipitating significant mobility and functional impairment (Latronico et al. 2012; Latronico and Bolton 2011). The incidence of ICUAW appears dependent on the patient population (Hermans and Van den Berghe 2015). It is particularly prevalent in those diagnosed with severe sepsis and systemic inflammatory response syndrome (SIRS) (De Jonghe et al. 2002; Tennilä et al. 2000). Sepsis is a clinical syndrome resulting from the inflammatory response of the body to an invading microbial pathogen (Namas et al. 2012). The latest international definition of sepsis is ‘life threatening organ dysfunction caused by a dysregulated host response to infection’ (Singer et al. 2016). A multisystem inflammatory response to an invading pathogen from biochemical, cellular and organ to organ networks occurs in response to infection, which while attempting to prevent further harm to the body, causes further damage through the proinflammatory effects of ‘damage associated molecular pattern molecules’ (Namas et al. 2012).

Development of severe sepsis is part of the evolving process of increasing severity of the host’s inflammatory response to infection (Kaukonen et al. (2015). This response increases in severity from infection, to sepsis, to severe sepsis and septic shock (Kaukonen et al. 2015). Two criteria necessary for a diagnosis of severe sepsis are the presence of organ dysfunction (which may

be single or multiple body organs) and two or more SIRS criteria (Kim et al. 2017; Singer et al. 2016). The SIRS criteria relate to the ‘clinical expression’ of a hosts (the human body) response to inflammation (Bone et al. 1992). SIRS is evident in a variety of infections and its presence is not solely limited to sepsis or severe sepsis. It includes the presence of a body temperature greater than 38°C or less than 36°C, a heart rate greater than 90 beats per minute, a high respiratory rate, manifested by a rate greater than 20 breaths per minute or hyperventilation and an alteration in white cell count greater or lesser than normal values and the presence of more than 10% immature neutrophils (Bone et al. 1992).

Beginning to understand the physiological processes underpinning ICUAW was deemed a research priority by the National Institute of Health and Clinical Excellence (NICE) in their clinical guideline CG83, ‘Rehabilitation After Critical Illness in Adults’ (NICE, 2009). This is easily justified considering the latest government figures on the prevalence of sepsis within the UK, with an accompanying financial burden placed on a National Health Service recently referred to by the British Red Cross as in ‘Humanitarian Crisis’ (BBC News 2017). Sepsis is reported to now claim more lives than lung cancer (NHS England 2015). Each year there are approximately 123,000 cases of sepsis reported in England alone (UK Parliament 2015), with 35% mortality (Daniels 2011). Figures report the estimated cost of sepsis to the NHS to be £2.5 billion a year (The UK Sepsis Trust 2017).

1.4 Early mobilisation following critical illness.

Mobility interventions and functional activities commencing in the ICU involving sitting over the edge of the bed, practising sitting to standing, bed to chair transfers and walking variable distances (determined by an individual’s physical capability at the stage of their recovery) may play a part in reducing muscle weakness (McWilliams et al. 2015; Morris et al. 2011; Schweickert et al. 2009). These interventions are reported to be safe, well tolerated and effective (Adler and Malone 2012). These activities should continue following transfer from the ICU to the ward as part of the rehabilitation continuum. Research evidence

suggests that early mobility interventions reduce days spent on a ventilator and improve functional status by the time of discharge (Schweickert et al. 2009). A quality improvement project undertaken in the United Kingdom of early rehabilitation resulted in improved levels of mobility upon discharge from ICU, reduced ventilator days and a reduction in both ICU and hospital length of stay (McWilliams et al. 2015). Furthermore, evidence suggests that commencement of early mobilisation involving ambulation (walking) reduces readmission and mortality within the first year following discharge from the acute setting (Morris et al. 2011; Schweickert et al. 2009; Needham 2008).

Regardless of this compelling evidence, doubts exist over the universal adoption of an early mobilisation culture, commencing in the ICU (Connolly et al. 2017; Berney et al. 2015; Nydahl et al. 2014; Berney et al. 2013). This is despite findings that early mobilisation appears both safe and effective when undertaken within this environment (McWilliams et al. 2015; Morris et al. 2011; Schweickert et al. 2009; Bailey et al. 2007). In the first 48 hours following transfer from the ICU to the hospital ward, studies report a decline in the distances mobilised compared to those undertaken within the ICU (Hopkins et al. 2012). A study which investigated ward based activity of patients recovering from critical illness reported that during the two consecutive days prior to hospital discharge patients who were able to mobilise spent up to 90% of the day in sedentary (lying or sitting) postures (Borges et al. 2015). These studies suggest activity levels of patients recovering from critical illness in hospital remain low, regardless of location (ICU or the ward).

It is evident that a number of authors have reported prolonged adoption of sedentary behaviours by those recovering from critical illness throughout hospital admission (Connolly et al. 2017; Berney et al. 2015; Borges et al. 2015; Nydahl et al. 2014; Berney et al. 2013; Hopkins et al. 2012). Hopkins et al. (2012) suggested that a factor for the prolonged adoption of sedentary behaviours on the ward was the decreased intensity of staff to patient ratio compared to the ICU. Nursing staff are responsible for the care of a greater number of patients on a hospital ward, all with varying levels of health care

needs. This decreased capacity may result in less time being available to mobilise patients on a regular basis, especially those who continue to require assistance or supervision whilst mobilising to progress physical function. Mobility may only be undertaken once or twice a day during rehabilitation sessions with therapists, which other authors have reported only account for less than 1% of the day in older hospitalised populations (Patterson et al. 2005). This lack of regularity of activity will delay recovery of independence in mobilising, prolonging hospital stay.

Whilst an expanding evidence base supports early mobilisation, the delivery of structured rehabilitation programmes during hospital admission is often limited due to the intensity of resources required. This evidence base provides justification for the consideration that should be given to monitoring the regularity of activity undertaken by this patient group to assist in targeting rehabilitation therapy resources to those who require them the most. This is especially true in the final days of hospital stay. Clinicians must empower patients with the necessary confidence, motivation and physical ability to facilitate continued functional recovery upon discharge. This is particularly important in patients who developed severe neuromuscular weakness as a result of ICUAW, adversely impacting on recovery of physical function (Hermans and Van den Berghe 2015); especially in areas where access to specialist post discharge rehabilitation options are limited. If regularity of activity is to be monitored or quantified, the methods available to the clinician in order to do so require consideration.

1.5 Methods of monitoring activity undertaken during hospital admission

A number of methods exist for monitoring and quantifying physical activity. These include direct observation (Connolly et al. 2017; Cattanach et al. 2014; Brown et al. 2008; Patterson et al. 2005) and patient self-report (Warren et al. 2010; Bisgaard et al. 1999. These options are now considered and discussed within the general context of the hospital setting, but also consider specific factors associated with those recovering from critical illness.

1.5.1 Direct observation

Direct observation permits an ability to identify the specific type and duration of activity undertaken, including the time it occurred (real time) (Patterson et al. 2005). Consequently, the regularity of periods of activity (or inactivity) can be quantified. However, direct observation is time consuming and resource intensive. As a result, it is considered infeasible as part of a continuous daily routine for individual patients within the clinical setting (Cheung et al. 2011). Patients may also dislike being continuously observed for lengthy periods. Evidence of this was reported in an observational study where some participants withdrew consent precisely due to this reason (Brown et al. 2008). Privacy and dignity also requires consideration. A sit to stand transfer may be required to put on or remove underwear for example. Patients' able to undertake these activities independently may consider the presence of an observer monitoring activities such as these an invasion of their privacy.

Direct observation relies on health care staff directly witnessing activity. As recovery progresses, patients' may regain the ability to independently undertake activities such as walking. These patients may be discharged from physiotherapy or occupational therapy teams before discharge from hospital, if they are independently mobilising and successfully undertaking all aspects of self-care, for example washing and dressing. Where necessary, patients will have also completed a stairs assessment, to ensure safety and the ability to ascend and descend stairs, should this be necessary upon discharge home. A kitchen assessment may have been completed by the occupational therapist in order to ascertain the ability to function at home. At this point in a patient's recovery, if they are not closely observed by health care staff working on the ward, all activity undertaken may not be accurately quantified due to not being witnessed. Equally as importantly, prolonged inactivity may go unnoticed. It is imperative to ensure that patients' discharged by therapy professionals continue to regularly undertake activity independently to prevent functional decline which could prolong length of hospital stay. For those still receiving physiotherapy or occupational therapy; only a brief snapshot of activities undertaken during treatment sessions is provided. Furthermore, studies undertaken in older populations have demonstrated that these sessions only

account for 0.5% to 0.6% of the day (Patterson et al. 2005). It is evident that direct observation within the day to day hospital setting faces significant challenges, including the staffing resources required and patient acceptance of the method.

1.5.2 Self-report measures

Self-report is dependent on a patient providing feedback concerning their own level of physical activity through the day, which may include regular activities of daily living such as postural changes undertaken to wash and dress. Studies suggest patients may fail to accurately self-report levels of activity (Cheung et al. 2011; Prince et al. 2008; Sager et al. 1992). Self-report tools in adult populations show generally low to moderate correlations with more directly measured activity and may fail to recognise low intensity activities undertaken within frail populations (Prince et al. 2008). Persistent cognitive impairment, common within patients who have experienced critical illness may also adversely affect the ability to recall information (Pandharipande et al. 2013). This may negatively impact on the ability to self-report activity levels. Therefore, it is evident that this method may encounter significant operational difficulties if used as a method of quantifying daily activity within this patient group. Due to the risk of persistent cognitive impairment, patients may not recall any activity undertaken, or simply forget to record it in a diary for example, leading to inaccurate information being collected concerning daily patterns of activity. Alternative methods of activity monitoring require exploration in order to understand if a technique exists which does not encounter the same limitations as direct observation or self-report.

1.6 Alternative methods of monitoring activity within the hospital setting

There remains a need to explore other methods which may capture the pattern and duration of activity undertaken by patients recovering from critical illness. Consideration of the pitfalls of more conventional methods of activity monitoring assist in understanding what is likely to be required to effectively capture the

quantity and type of activity performed throughout the day. Methods which are objective rather than subjective may control for the inaccuracies demonstrated from self-report measures (Cheung et al. 2011; Prince et al. 2008; Sager et al.; 1992). However, they must be unobtrusive, respect privacy and dignity and yield clinically meaningful data. This could be for the clinician, the researcher or the patient. It may include information related to time spent in activity, the number of individual episodes of mobility, or quantification of the total amount of time patients spend in sedentary postures (lying or sitting). This data could be used to inform individual goal setting and motivation. Methods must also be acceptable to the patient. If this is not realised, compliance will not be achieved, resulting in an inability to quantify activity levels or patient withdrawal from research studies (Kramer et al. 2013; Brown et al. 2008).

Exploring alternative methods of capturing information on physical activity, including the type, regularity and intensity could provide invaluable feedback. The clinician would be able to monitor either an increase or decline in activity levels, assisting in the evaluation of how individual patients are progressing. This would be especially useful as patients' continue to improve, regaining sufficient function to undertake activity independently under their own volition. The ability to capture information in real time would yield an opportunity to identify if patients are more active during certain parts of the day, for example the morning, afternoon or evening. Conversely, it could assist in identification of prolonged periods of sedentary behaviour occurring at regular times, potentially delaying further recovery of function and prolonging overall length of hospital stay (McWilliams et al. 2015; Schweickert et al. 2009). Knowledge of general patterns of activity (or inactivity) over the day could also assist the planning and timely targeting of rehabilitation resources (Browning et al. 2007).

Consideration of these aspects resulted in the formulation of a clinically based question:

Is there an objective method which could quantify the type, frequency and pattern of purposeful activity undertaken by patients recovering from critical illness in the hospital setting?

The answer may be found in the use of movement sensor technology, providing they can demonstrate validity within the hospital setting and patient population. This PhD thesis embraces this task. It explores how the validity of a certain type of movement sensor called an accelerometer, has previously been investigated within hospital based populations likely to undertake low intensity activities at slow speed. It also investigates the validity of a particular commercially available accelerometer in identification and quantification of purposeful activity within a population recovering from critical illness. Ultimately, it seeks to further understanding of whether this technology may have a role to play in activity monitoring specifically within populations recovering from critical illness.

1.7 Why choose an accelerometer?

An accelerometer has the potential to quantify the type, duration, frequency and intensity of activity undertaken during the day. Analysis of the data captured by these devices may permit understanding of rest and activity patterns. Accelerometers detect activity by sensing changes in acceleration, which in turn are recorded as a numerical count. Variation in the speed of acceleration will produce variations in the magnitude of the numerical count, permitting the ability to quantify activity intensity. As the numerical count increases, eventually reaching a certain value, activity intensity classification increases (Freedson et al. 1998). Activity counts are accumulated over a time period (epoch) which can be stored within an accelerometer's memory. An epoch can last less than a second, a number of minutes or longer; accumulating data for all activity undertaken within the chosen epoch setting (Actigraph Engineering/ Marketing, 2009).

Data can be continuously captured by an accelerometer over a number of days and downloaded onto a computer at an appropriate time. As all data is captured in real time the actual duration of activity (or inactivity) including the time it occurred can be ascertained. Some accelerometer models contain an inclinometer within their design specifically for identification of body position (lying, sitting or standing), whilst some also possess the ability to quantify step

count. There are a number of commercial models available which do not always possess the same combination of measurement modes. Knowledge of the measurement modes inherent within certain designs will assist in making the appropriate selection, depending on the aspect of activity desired to be quantified.

Few studies have undertaken investigation of the validity of accelerometry measurement to quantify purposeful activity in hospitalised patients recovering from critical illness (Edbrooke et al. 2012; Winkelman et al. 2005). Purposeful activity is operationalised as maintaining body position, moving (activity), which may involve postural transfers and walking. This terminology concurs with definitions provided by the World Health Organisation International Classification of Functioning, Disability and Health (ICF) (World Health Organisation 2001). Other studies have investigated the validity of accelerometry to quantify non-purposeful movement in assessment of agitation and sedation levels within the ICU (Grap et al. 2011; Grap et al. 2005). This PhD thesis focuses on the use of accelerometers to quantify purposeful movement only.

1.8 Validity and accelerometry

It is important to investigate the validity of accelerometer models directly within the patient groups that they are intended to be employed. Typical activities characteristic of that population can then be captured to understand if the data yielded is valid, reliable and ultimately clinically meaningful. This is an important consideration as research suggests that the accuracy of accelerometry measurement depends on the tasks being analysed (Cuesta-Vargas et al. 2010). Patients recovering from critical illness may require considerable physical support when sitting in a chair to ensure maintenance of a comfortable and safe position. This may cause unconventional adoption of these sorts of postures. It is vital therefore that any validity investigation embraces this aspect. The researcher must consider if there is a specific stage of recovery from critical illness where they wish to use accelerometry and ensure every effort to capture the most likely postures adopted at this stage is made.

For a particular accelerometer model to be considered valid there must be compelling evidence suggesting that it is measuring what it is intending to measure (Stolarova et al. 2014). Formulation of methodological protocols investigating accelerometer validity must consider the aspect (or aspects) of purposeful movement desired to be quantified. This could be the intensity of activity undertaken in general or specific identification of postural changes, such as moving from sitting to standing. The ability for accelerometers to identify and quantify periods of ambulation may also be required, possibly through quantification of activity intensity or step count. Measurement modes inherent within individual accelerometer models require consideration in order to understand whether a particular model has the potential to yield the particular data desired by the clinician or researcher.

Data output from accelerometers must also be consistent when movements are repeated in a similar manner, thus providing evidence of reliability (Berchtold 2016; Stolarova et al. 2014). Reliability is the ability of a test or measurement tool to produce similar results when it is repeated (Berchtold 2016). Assessment of reliability should form part of validity assessment (Sullivan 2011). It relies on study participants being willing and physically able to repeat a particular aspect of purposeful activity in an identical manner. Two sets of accelerometer data are then captured which are compared for consistency. This methodology is often described as a ‘test-retest’ design investigation (Berchtold 2016; Stolarova et al. 2014; Sullivan 2011). Assessment of accelerometer reliability in this way within populations recovering from critical illness encounters difficulty. Evidence for this was found in a study by Edbrooke et al. (2012), who investigated the validity of a commercial accelerometer to quantify step count. A refusal of a participant to repeat a walk of known distance led to their withdrawal from reliability analysis.

1.9 Capturing typical daily activity of patients in hospital using accelerometers

Determination of lying, sitting or standing positions using accelerometers has facilitated the ability to identify postural transitions, for example moving from

sitting to standing in hospitalised adult populations. These include acute stroke, older populations and those experiencing end stage cancers (Taraldsen et al. 2012; Skipworth et al. 2011; Harris et al. 2006). The ability to identify body position has enabled quantification of time spent in sedentary (lying/ sitting) or standing positions (Pedersen et al. 2013; Brown et al. 2009; Brown et al. 2008, Browning et al. 2007). These studies have revealed that minimal time during the day is spent in activities involving standing and walking in both older and post upper abdominal surgery populations (Pedersen et al. 2013; Brown et al. 2009; Browning et al. 2007).

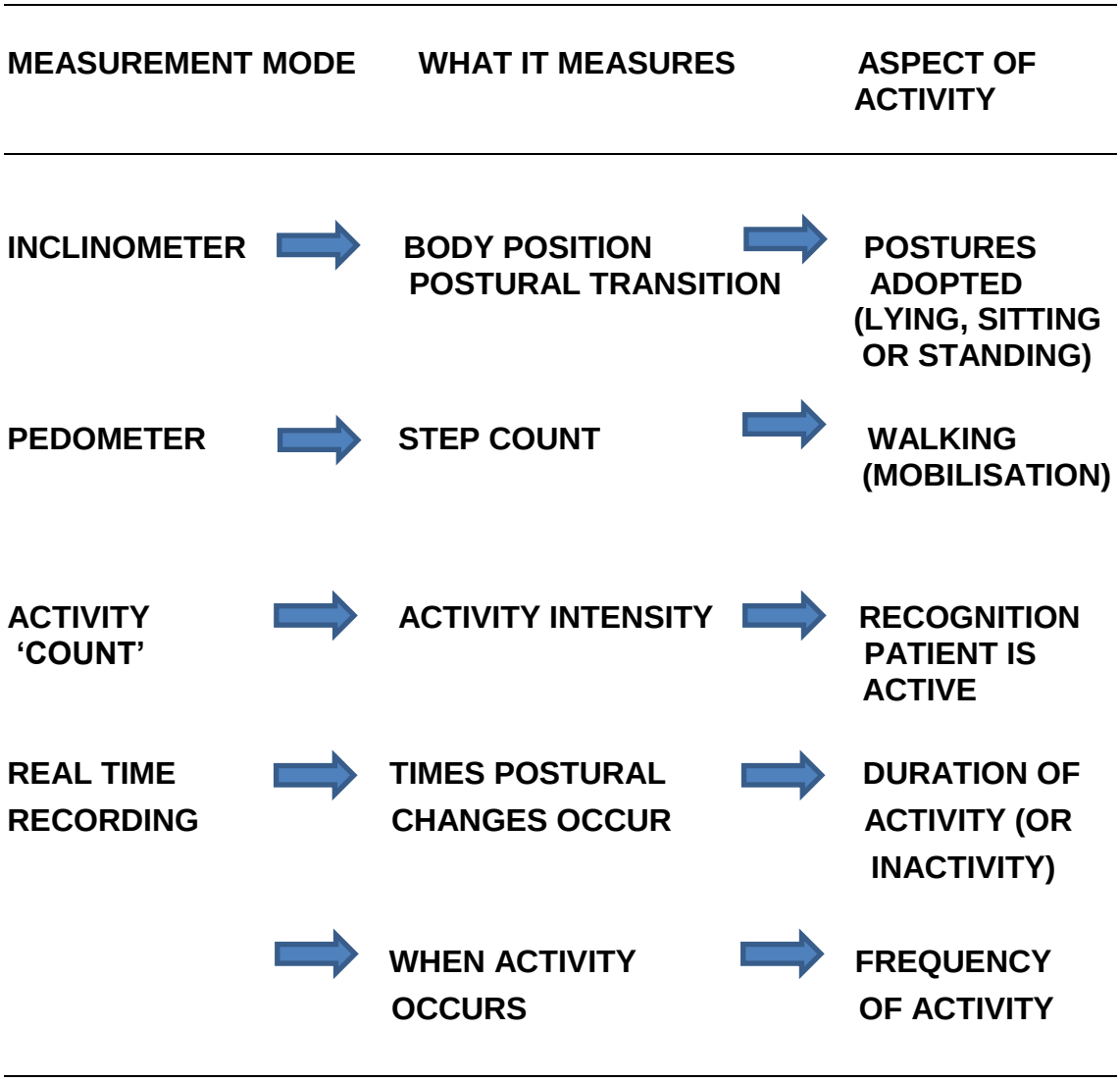
Browning et al. (2007) were unable to distinguish between standing and walking as the accelerometers used were designed to be able to identify body position only, for example lying, sitting or standing (upright). Therefore, during walking activities the accelerometers would have only registered that an individual was in a standing position, not that they were actually mobilising. The ability to differentiate standing from walking is an important consideration, enabling understanding of how regularly patients are engaging in periods of ambulation. The importance of including walking in early mobilisation regimes for those recovering from critical illness is well documented (McWilliams et al. 2015; Morris et al. 2011; Schweickert et al. 2009). The ability of an accelerometer to distinguish between standing and walking would permit recognition of when episodes of mobilisation have been undertaken. This distinction may be possible in models possessing both the ability to identify body position and quantify step count.

It is important to determine whether particular accelerometer models which possess the ability to detect step count can accurately quantify steps taken when small distances are covered (e.g. 10 metres) at slow walking speeds. This is particularly characteristic of acutely hospitalised populations, especially those over 70 years of age, where usual walking speeds of 0.46m/s have been reported (Peel et al. 2013). These distances may be the limit of a patient's physical capability at a specific moment in time. Although small, distances such as these may represent a huge milestone of functional achievement for those

who have experienced critical illness. Difficulties have been encountered using accelerometers to quantify step count in other populations likely to walk at slow speeds, including end stage cancer sufferers, those who experience acute stroke and acutely admitted older hospital inpatients (Taraldsen et al. 2011; Skipworth et al. 2011).

Consideration of the possible measurement modes an accelerometer must possess in order to permit recognition of all activities and postures typically adopted by patients recovering from critical illness is essential. This enables exploration of models which may contain all of these modes within their design. Assimilation of this information enables the construction of a heuristic model, suggesting a combination of measurement modes likely to capture all purposeful activity undertaken by this patient group. This model is presented in Figure 1.1 on page 15. It is postulated that if this combination of measurement modes were contained within an accelerometer model, the ability to capture the type, frequency, intensity and pattern of ‘real time’ activity patients typically undertake would be achieved. This would permit understanding of just how active (or inactive) patients are during the day as they recover, including the specific type of activities performed and the amount of time spent in specific postures (lying, sitting or standing).

Figure 1.1 Heuristic model



Accelerometers measure body position and activity as a result of changes in acceleration due to gravity or actual body movement (Mathie et al. 2004). Detection of changes in acceleration due to gravity facilitates identification of body position, whereas detection of changes in acceleration due to body movement permits activity intensity recognition (Mathie et al. 2004). If an accelerometer possessed the ability to identify both body position and step count, differentiation between standing and walking would be possible. Walking activities would generate a step count, with corresponding time periods indicating an individual was in a standing position. Furthermore, the ability to detect body position would facilitate an understanding of whether walking activities were actually being undertaken (i.e. mobilising or marching on the

spot) or whether a patient was sitting in a chair exercising (e.g. undertaking marching activities in a chair). Fewer or intermittent recording of step counts whilst registered in a sitting position might suggest patients were fidgeting, or undertaking small positional alterations whilst sitting in a chair.

Justification for the statements within the previous paragraph can be found in Table 1.1 below, using the typical activities described in studies investigating mobility interventions in patients recovering from critical illness (McWilliams et al. 2015; Adler and Malone 2012; Schweickert et al. 2009).

Table 1.1 Recognition of activity type using inclinometer and step count measurement modes only.

Typical examples of activity undertaken by patients recovering from critical illness	**Measurement modes postulated which will identify the activity**
Adoption of lying, sitting or standing postures	Inclinometer (with step count if differentiating standing from walking)
Postural transfers (e.g. lying to sitting or sitting to standing)	Inclinometer
Transferring from a bed to a chair	Inclinometer and step count
Marching whilst sitting in a chair	Inclinometer and step count
Marching whilst standing on the spot	Inclinometer and step count
Mobilising (walking)	Inclinometer and step count

Table 1.1 described the typical activities undertaken by patients recovering from critical illness, postulating that all of these activities could be identified using inclinometer and step count measurement modes alone. A number of commercial accelerometers possess both inclinometer and step count

functions. One of these models is called the Actigraph GT3X accelerometer (Actigraph LLC, Pensacola, Florida, USA).

Studies have been identified where this particular model has been used to quantify activity in patients' resident within the ICU, without prior investigation of its validity directly within this population (Schujmann et al. 2015a; Schujmann et al. 2015b). The specific patient population (for example medical or surgical ICU patients) was not reported. Algorithms classifying activity intensity as sedentary, light, moderate or vigorous were used. These activity intensity 'cut-off' numerical values have undergone investigation of validity within healthy subjects, not the critically ill (Freedson et al. 1998). A further study was identified on the ClinicalTrials.gov website (ClinicalTrials.gov identifier: NCT02263716). It aimed to determine the feasibility of the use of a similar Actigraph model (GT3X+) within both 'medical and surgical' patients recovering from critical illness resident within the ICU. They also planned to investigate the validity of the activity intensity count measurement modes within this model. Interest concerning the use of the Actigraph GT3X within the critically ill provides justification for the choice of this particular model to undergo investigation of its validity. Access to sufficient numbers of these devices was made possible through a temporary loan from a supply held by YSJU.

1.10 The Actigraph GT3X accelerometer

The Actigraph GT3X accelerometer possesses both an inclinometer and step count measurement mode. It was postulated in Table 1.1 on page 16 that the combination of these two modes may capture the typical daily activity and adoption of postures of patients recovering in hospital following critical illness. Activity including postural transfers or walking short distances may initially require assistance within this population, until such a time that sufficient functional ability is regained to enable activity to be undertaken independently, under one's own volition. The Actigraph GT3X accelerometer is a compact and lightweight device, with dimensions of 3.8 x 3.7 x 1.8 centimetres and a weight of approximately 28 grams (see Figure 1.2 on page 18). Changes in

acceleration are measured in three axes (triaxial); specifically vertical, horizontal and lateral axes (Barwais et al. 2013).

Figure 1.2 The Actigraph GT3X accelerometer

Manufacturers recommend that the device is secured around the waist by a belt, resting above the hip for detection of posture (lying, sitting or standing). However, a study reported disappointing results for the waist placement in determination of posture, advising caution in interpretation due to the regularity of postural misclassifications, with lying and standing postures only correctly identified 15% and 20% of the time respectively (Hänggi et al. 2013). Another study undertaken within a population of community dwelling older adults with and without walking aids found encouraging results for a similar Actigraph model (the GT3X+) in quantification of step count using an ankle placement (resting above the lateral malleolus) (Korpan et al. 2015). This same placement site was used by Schujmann et al. (2015b), using the GT3X in a population recovering from critical illness resident within the ICU. It is important when undertaking investigation of the validity of any accelerometer within this population that an optimum body placement site is found which will yield meaningful and valid information yet is comfortable, unobtrusive and acceptable by those wearing the devices. Optimal body placement site (or sites) may change depending on what aspect of purposeful activity is desired to be quantified.

1.11 Potential uses of accelerometry

Accelerometry could complement the use of validated physical function outcome measures developed for patients recovering from critical illness, such as the Chelsea Critical Care Physical Assessment Tool (CPAx) (Corner et al. 2013). Whilst the CPAx scores the maximum level of physical function being achieved at a given time, an accelerometer could capture how often this is being practiced, for example getting out of bed, transferring into a chair from the bed or walking. Evidence of decreasing activity levels in those who have previously been mobilising regularly may indicate a clinical deterioration. This could alert the clinician to undertake investigations to ascertain whether there is an underlying clinical cause for the decline in activity levels.

As patients' independence improves, accelerometers have the potential to provide useful feedback determining the patterns of activity being undertaken, either under one's own volition or with encouragement from health care staff. This could deliver useful information for the clinician, highlight increases (or a decline) in mobility levels, assisting with effective decision making regarding when discharge from the acute hospital setting is deemed most appropriate. An objective improvement in activity levels could serve as useful feedback for the patient recovering from critical illness. Achievable goals could be agreed between therapist and patient regarding a certain number of steps to aim for throughout the day. In conclusion, accelerometry has the potential to provide clinical information that translates an evaluation of patients' progress from single terms such as 'mobile' and 'active' to something with far greater relevance, quantification and meaning, both within the clinical environment and for research purposes.

1.12 Construction of the thesis and formulation of research questions

Studies focusing on early rehabilitation following critical illness highlight a progressive approach to early mobilisation. These activities invariably include sitting over the side of the bed, practicing sitting to standing and transferring a

few steps from the bed to sit in a chair. Ambulation over increasing, achievable distances also commences (McWilliams et al. 2015; Hopkins et al. 2012; Schweickert et al. 2009). In the early stages of recovery, patients often require varying degrees of physical assistance from hospital staff, moving and handling equipment or mobility aids to complete a particular functional task, for example getting out of bed or walking short distances.

This PhD thesis seeks to investigate whether the Actigraph GT3X accelerometer demonstrates validity within hospitalised adults recovering from critical illness in identification of typical purposeful activity undertaken during the day. Chapter 2 presents the results of an initial research project which aimed to identify and systematically review previous studies investigating the validity of accelerometers to identify body position and quantify purposeful activity within hospitalised adults recovering from acute or critical illness. Completion of a systematic review enabled construction of an evidence base concerning the validity of a number of different accelerometer models, both commercial and custom made which have already undergone investigation of their ability to identify and quantify purposeful activity. These investigations included accelerometers which were positioned in isolation or combination.

Assimilation of knowledge from the systematic review assisted in the development of methodological protocols for two studies where the investigation of the validity of the Actigraph GT3X accelerometer in identification of typical activities undertaken by those recovering from critical illness was commenced. The first study, presented in Chapter 3, investigated the feasibility of using this particular model within hospitalised adults. It aimed to increase understanding of whether the Actigraph GT3X possessed the potential to identify and quantify body position, postural transition and step count (walking) during activities typically undertaken on a hospital ward and whether there was a superior placement site. Evaluation of comfort and acceptability of the devices by those who were wearing them was also investigated as a further aim. The feasibility study recruited healthy participants, who simulated patients weakened by critical illness. Healthy

participants were invited due to the number of movements required to be repeated within a movement protocol and the potential adverse effects this may have had on fatigue levels of those early in their recovery from critical illness. Fatigue may have precipitated refusal to perform repeat movements, leading to loss of data.

The final study, presented in Chapter 4 enrolled hospitalised patients recovering from critical illness resident within a ward environment. The methodological protocol for this study was developed following assimilation of the findings from both the systematic review and the feasibility study. It aimed to investigate the validity and reliability of the Actigraph GT3X accelerometer in identification and quantification of both body position and step count in this patient group. Participants completed a semi-structured movement protocol containing typical activities expected to be undertaken through the day by this patient group. Evaluation of comfort and acceptability of the devices from the patient's perspective was also an aim of the research.

Chapter 5, titled 'Synthesis', collectively assimilated the findings from each of the individual studies undertaken as part of the PhD thesis. It also aimed to demonstrate that although each project was distinct, they were interrelated and informed each other. Strengths and limitations of the research undertaken as part of the PhD thesis were also discussed. Presentation in this way permitted construction of a platform leading to the concluding chapter. The final chapter (Chapter 6) aimed to present a summary of the conclusions, followed by recommendations for future research. It synthesised a set of recommendations for the application of the Actigraph GT3X accelerometer to identify body position and step count within those recovering from critical illness**.** These recommendations are planned to be disseminated nationally via critical care networks and the Association of Chartered Physiotherapists in Critical Care. Dissemination of the findings in this way demonstrates the commitment to translating research into practice and sharing knowledge with those involved in the delivery of care to people recovering from critical illness.

The thesis sought to explore and answer the following questions:

1. How has investigation of the validity of accelerometry measurement previously been undertaken in acute or critically ill hospitalised adults and what have these studies concluded?

2. To what extent can the Actigraph GT3X accelerometer quantify the functional activity (postural changes between lying, sitting and standing) typically undertaken by hospitalised adults recovering from critical illness?

3. To what extent can this accelerometer model quantify step count in hospitalised adults recovering from critical illness when compared with observed step count?

4. What are the optimum body placement sites in which to position the Actigraph GT3X in order to identify lying, sitting, standing postures and step count in hospitalised adults recovering from critical illness?

5. Is the Actigraph GT3X accelerometer valid and reliable in detection of body position and step count within hospitalised adults recovering from critical illness?

The first question is addressed in Chapter 2, commencing on page 23, which presents a systematic review. It explores how the validity and reliability of accelerometry to quantify purposeful activity within acute and critically ill hospitalised adults has previously been investigated.

Chapter 2

Systematic Review

2.1 Introduction

The introductory chapter presented evidence reporting high levels of sedentary behaviours in hospitalised adults, regardless of age (Mudge et al. 2016). Specific examples were highlighted in patients' who were recovering from critical illness (for example severe sepsis or septic shock), where an observational study reported up to 90% of the day was spent inactive in lying or sitting positions during the final days of hospital stay (Borges et al. 2015). This prolonged inactivity may become habitual if patients are poorly motivated and do not receive any encouragement or incentive to undertake activity following discharge. This may provide some explanation for why persistent functional limitation continues to be experienced years after hospital discharge (Herridge et al. 2011; van der Schaaf et al. 2009). Immobility during hospital stay contributes to irreversible functional decline in older populations, often necessitating nursing home placement at discharge (Graf 2006; Covinsky et al. 2003).

Prolonged adoption of sedentary behaviours is associated with development of chronic illness, including cardiovascular disease (CVD) (Warren et al. 2010). It has been estimated that 17.7 million people died from CVD in 2015 (31% of all global deaths), of which 7.4 million of these were attributable to coronary heart disease, whilst 6.7 million were due to stroke (World Health Organisation 2017). Warren et al. (2010) examined the relationship between time spent in sedentary postures (specifically driving a car and watching television) and the incidence of CVD in later life. In 1982, they recruited a sample of 7,774 males (age range 20-89) who did not have any diagnosis of CVD. Participants completed a survey reporting the time spent driving a car and watching TV during a typical week. Data on mortality of those who participated in 1982 was collected 21 years later, where 377 deaths directly attributable to CVD were identified. Following age adjustment, men who had reported greater than 10

hours a week of driving or greater than 23 hours of combined sedentary activity (sitting watching TV and sitting generally) had ‘82% and 64% greater risk of dying from CVD than those who reported less than 4 hours a week spent riding in a car and less than 11 hours in combined sedentary activity’. Conversely, being ‘older’ (over the age of 60), normotensive, normal BMI and being ‘physically active’ was associated with a reduced risk of death from CVD. This compelling evidence demonstrates the potentially life threatening effects of adoption of prolonged sedentary postures and the negative impact it exerts on healthcare utilisation. Four out of the 20 participants recovering from critical illness enrolled in the validity study reported in Chapter 4 of this PhD thesis, commencing on page 150, had CVD. This emphasises the impact of CVD on healthcare utilisation, which in these particular cases led to an increased length of overall hospital stay due to complications which necessitated prolonged stays on the ICU.

Chronic disease characteristically progresses slowly over lengthy periods, usually years (Hoffman et al. 1996). A recent systematic review by González et al. (2017) emphasised the relationship between physical inactivity, sedentary behaviours and development of ‘non-communicable’ chronic diseases including CVD, obesity and type 2 diabetes. The World Health Organisation recommends that adults between the ages of 18 to 64 should accumulate 150 minutes of moderate intensity aerobic physical activity per week or 75 minutes of vigorous aerobic activity, or perform a combination of both activity intensities (World Health Organisation 2010). Physical inactivity is independently associated with development of obesity and type 2 diabetes, regardless of age, sex, ethnicity or BMI (Admiraal et al. 2011). González et al. (2017) stressed the ‘increased institutional scientific recognition’ of the study of sedentary behaviours in addition to physical activity, highlighting that both were distinct from each other and should be considered as individual concepts. Sedentary behaviours and physical inactivity have both been independently associated with higher levels of healthcare utilisation, frailty and poor self-reported health (Blodgett et al. 2015).

A Canadian study reported that incidences of obesity were significantly higher in both men and women who watched television for over 21 hours a week compared to those who watched less than five hours a week (25% to 14 % respective in men and 24% to 11% in women). This was independent of the intensity and amount of physical activity undertaken throughout the week (Shields and Tremblay 2008). This study also highlighted that sedentary behaviours are an independent risk factor for development of chronic disease, in this case obesity. The evidence and figures presented in the paragraphs above are worrying, they highlight the negative impact of adoption of sedentary behaviours independently, providing justification for exploring methods of reducing the prolonged adoption of sedentary postures both within hospitals and beyond to discourage the habitual adoption of these behaviours.

The evidence presented above supports exploring methods of quantifying the daily activity undertaken by adult hospitalised patients to prevent prolonged adoption of sedentary behaviours, maintain their functional ability and prevent further deterioration. Conventional methods, including direct observation and self-report are both subject to operational or methodological weaknesses (Cheung et al. 2011; Prince et al. 2008; Sager et al. 1992). These were discussed on page 6 in section 1.5 of Chapter 1. Wearable motion sensing technology, such as accelerometers, could offer an objective and unobtrusive alternative to monitoring the purposeful activity undertaken within the hospital environment. However, in order to be considered as a viable alternative, the information they yield must be valid, reliable and clinically meaningful. It could provide the clinician (or patient) with useful information related to time spent in activity; recognition of an improvement in the number of times spent mobilising or the increase (or decrease) in daily step count to motivate or encourage. It seems appropriate at this point to revisit the first of the research questions constructed in Chapter 1:

How has investigation of the validity of accelerometry measurement previously been undertaken in acute or critically ill hospitalised adults and what have these studies concluded?

Accelerometer models have been used to directly quantify purposeful activity undertaken by hospitalised critically ill adults with severe sepsis without prior investigation of their validity within this population (Borges et al. 2015; Schujmann et al. 2015a; Schujmann et al. 2015b). If accelerometers are to be used to quantify purposeful activity within adult hospitalised populations who undertake movement at slow speeds, a necessity arises to evaluate the extent of validity and reliability investigation that has been undertaken so far. Measurement modes contained within models produced by different manufacturers vary, together with body placement sites. As a result, it cannot be assumed that the validity and reliability evidenced by one model can be generalised to all.

Research investigating the validity and reliability of accelerometers to quantify purposeful movement has been conducted within the hospital setting in a variety of patient populations. No study has assimilated and systematically evaluated the findings of those undertaken so far within both hospitalised acutely admitted and critically ill patients. Patients may be admitted to hospital acutely for a variety of reasons, including experiencing a stroke, rapid deterioration in general health, following an accident (such as a fall) or an exacerbation of a chronic disease such as chronic obstructive pulmonary disease (COPD). Critically ill patients may require a period of ventilation and supportive therapy to maintain blood pressure and the bodies systems in cases of organ failure in severe sepsis.

In order to address this, the following study aims to identify and systematically review evidence investigating the identification of body position and quantification of purposeful activity using accelerometers in hospitalised adults recovering from acute or critical illness. Both of these populations are likely to undertake activities which are of low intensity and performed at slow speeds. This systematic review focuses on studies where the validity or reliability (or both) of specific accelerometer models has undergone investigation, particularly within these populations. An operational definition of purposeful activity was previously described within section 1.7 of Chapter 1 (page 11).

2.2 Methods

Good practice dictates that the synthesis and reporting of systematic reviews evaluating health care interventions is performed in accordance with the Preferred Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Liberati et al. 2009). It is also recommended that methodological protocols for systematic reviews conducted within the field of health care are registered on the International Prospective Register of Systematic Reviews (PROSPERO). A methodological protocol detailing the research questions and the methodological processes to be undertaken in order to answer them was successfully registered on this database (PROSPERO CRD 42013006707).

2.2.1 Formulation of the systematic review questions

A systematic review seeks to answer questions which have been formulated about a specific topic through identification; appraisal and synthesis of the available evidence relating to it (Uman 2011). During data synthesis, gaps in the knowledge base may become evident. Identification of these gaps stimulates the synthesis of new questions and ideas. The researcher must consider whether these questions have the potential to be answered and the study methodology which might achieve this (Robinson and Goodman 2011). If gaps in the evidence base become evident, the questions formulated in response will generate innovative and novel research. This ideology was adopted when undertaking this thesis, providing justification that the initial project should be a systematic review.

To date, no study has assimilated evidence and systematically evaluated findings of research investigating the validity and reliability of accelerometers to quantify purposeful movement within populations recovering from acute or critical illness. Therefore, in order to address this, the following research questions were formulated:

1. Can movement sensors (accelerometers) quantify purposeful movement in adult hospitalised patients recovering from acute or critical illness?

2. To what extent has their validity and reliability been evaluated directly within these populations?

2.2.2 Eligibility criteria

Eligibility criteria for inclusion of studies within the systematic review were constructed, using the Participants, Intervention, Comparator, Outcome and Study Design (PICOS) framework (Liberati et al. 2009). These criteria are presented in Table 2.1 on page 29.

Table 2.1 Eligibility criteria

Criterion (PICOS)	Inclusion	Exclusion
Participants	• Adult hospital inpatients recovering from acute, sub-acute or critical illness • Ward based patients with dementia, delirium or cancer	• Populations residing in nursing homes • Paediatric populations • Animal studies
Intervention	• Investigation of an accelerometer based model alone to identify body position, postural transition or quantify purposeful activity (e.g. general activity through the day or step count) • Accelerometers with inclinometers inherent within their design identifying body position	Studies evaluating accelerometry use in: • Assessment of energy expenditure • Delirium or sedation level within the intensive care unit • Sleep, finger tapping, falls, tremor, balance or specific aspects of gait analysis • Accelerometers investigated in combination with other technology (e.g. gyroscopes)
Comparator	• Accelerometers being compared against a criterion measure (e.g. observation) • Device undergoing repeated measures (e.g. test retest)	• The interventional accelerometer under investigation is NOT undergoing a test retest design or being compared against a criterion measure
Outcome	• Strength of relationships (correlations) or agreement between intervention and comparator	• Studies using accelerometers in direct quantification of activity, not employing any psychometric evaluation of accelerometry within the stated inpatient populations
Study Design	• Study specifically evaluating the validity and/or reliability of accelerometry measurement within the contexts described above	• Those using accelerometers in direct quantification of activity, not in assessment of their psychometric characteristics

2.2.3 Information sources and search strategy

Electronic database searches were undertaken using an online library system ('Discover' accessed via YSJU) during the month of October 2014. Searches were repeated in July 2016 and June 2017 to ascertain whether any further studies had been published. Database searches were conducted within CINAHL, MEDLINE, EMBASE, AMED, Cochrane Library, PEDro, PsycINFO and SPORTDiscus from inception to June 2017. These databases were selected due to their connection to the medical and nursing professions, professions allied to medicine and sports rehabilitation. It was considered useful to include databases with a connection to sports rehabilitation due to the possibility of health care research being undertaken within this field, particularly involving the use of accelerometers. Figure 2.1 on page 42 presents a flow diagram detailing the full article selection process.

Keywords used within search strategies remained constant throughout, regardless of database. Indexing terms were mapped using MeSH, thesaurus or subject options, depending on the referencing system of each individual database. As indexing terms differed between databases, separate searches were undertaken within each database. It was felt that this would maximise the opportunity of identifying relevant articles within particular databases, especially when not duplicated in others. Indexing terms were ascertained through the use of scoping searches, the benefits of which are considered in section 2.2.3.1 on the following page.

Literature searching within each database produced a high number of duplicates (1211). Duplicates were removed by entering the results of the literature searches from each individual database search into the reference management programme EndNote (Version X7.7.1). A single file was created which contained the massed results of searches undertaken within each database. The reference management system was able to highlight duplicated articles which were then removed, permitting a single record only of each source of evidence to remain. Duplicates could have been identified by undertaking a literature search within multiple databases simultaneously. This

was not deemed appropriate for this project as it did not permit entry of the bespoke indexing terms specific to each database. Indexing terms were important in order to increase the possibility of ensuring the sources of evidence identified bore direct relevance to the chosen area of enquiry. Using a combination of both keywords and indexing terms during literature searches maximised the likelihood of this occurring.

2.2.3.1 Scoping searches

Scoping exercises enable the researcher to explore the extent, breadth and range of research performed in a particular area of interest (Levac et al. 2010; Arksey and O'Malley 2005). Arksey and O'Malley (2005) emphasised the importance of a clearly defined research question from which search strategies are constructed around. Initial literature searches used keywords alone to increase knowledge of how articles pertinent to the systematic review questions might be indexed in the various databases selected. This process assisted in refining the search terms used for the final literature searches performed, which eventually included a combination of both key words and indexing terms.

When articles were identified which appeared relevant, the full reference, including its indexing terms and complete abstract was retrieved from the database in which it was discovered. The importance of this was evidenced within the database EMBASE. Articles incorporating the use of activity monitors were indexed under the term ‘Actimetry’. This term was exclusive to this database; with the name suggesting a combination of the terms ‘Actigraphy’ and ‘Accelerometry’. Both of these particular indexing terms were often present within the other databases searched. This finding emphasised the importance of undertaking this preliminary scoping exercise to increase awareness of the bespoke indexing systems inherent within individual databases. It also demonstrates the rigour of the literature searching process used in this systematic review.

The PICOS framework (Liberati et al. 2009) was used to assist construction of search strategies within each database. Each of its constituent parts (e.g. Participants) was initially searched as a separate concept within each database. Each concept consisted of search lines using either MeSH, thesaurus or subject headings (depending on the database), followed by a search for free text words located either within a title or abstract. All separate search lines constructed within each concept were combined to conclude the search, using 'OR' Boolean phrasing terminology. This returned a number of articles for each separate PICOS concept. The final results for each concept searched were then combined using 'AND' Boolean phrasing terminology. This ultimately returned a final collection of articles containing aspects pertinent to all the individual concepts within the PICOS framework. This methodological approach is demonstrated in Table 2.2 on page 33, using the database search undertaken within MEDLINE during October 2014 as an example. Its construction was based on the recommendations of the Cochrane Collaboration (Lefebvre et al. 2011).

Article type was not limited, enhancing the opportunity of identifying a wide variety of data sources, including any relevant grey literature such as Conference Proceedings (Whiting et al. 2016). Reference lists of selected articles and literature review or systematic review papers considered relevant to the research questions were hand searched to identify any further potential sources of evidence. The professional online network of the Chartered Society of Physiotherapy (CSP), called the interactive CSP was also searched to explore if there had been any relevant posts made to this resource concerning the use of activity monitors within the selected hospitalised populations. Publication date of articles was also not limited, permitting an opportunity to understand when research interest in the validity and reliability of accelerometry measurement to quantify purposeful movement had commenced within the chosen hospitalised patient populations. No language restrictions were set, with English translations of abstracts obtained for any non-English articles identified during the literature searching process.

Table 2.2 MEDLINE electronic database search strategy (October 2014)

Search Order	Search terms incorporating Boolean terminology	Article yield
S16	S7 AND S10 AND S15	629
S15	S11 OR S12 OR S13 OR S14	4,918,957
S14	AB hospital* OR AB inpatient* OR AB clinic* OR AB acute* OR AB critical* OR AB intensive OR AB unit* OR AB ICU* OR AB ITU* OR AB HDU* OR AB ward*	4,140,806
S13	TI hospital* OR TI inpatient* OR TI clinic* OR TI acute* OR TI critical* OR TI intensive OR TI unit* OR TI ICU* OR TI ITU* OR TI HDU* OR TI ward*	1,503,819
S12	(MH "Intensive Care+")	19,763
S11	(MM "Inpatients") OR (MH "Hospital Units+")	84,486
S10	S8 OR S9	618,187
S9	TI valid* OR AB valid*	418,426
S8	(MH "Reproducibility of Results+") OR (MH "Validation Studies")	274,884
S7	S1 OR S4 OR S5 OR S6	10,549
S6	TI actigraph* OR AB actigraph*	2,977
S5	TI acceleromet* OR AB acceleromet*	7,277
S4	S2 AND S3	565
S3	(MH "Walking+") OR (MM "Mobility Limitation")	20,579
S2	(MH "Acceleration+")	8,291
S1	(MH "Accelerometry+")	2,162

Table 2.3 on page 34 details when the literature searches were initially undertaken and repeated. Databases were searched from inception to June 2017.

Table 2.3 Literature searches undertaken

Database	Date searches undertaken
SPORTDiscus	5th October 2014 4th July 2016 10th June 2017
AMED	7th October 2014 4th July 2016 10th June 2017
PsycINFO	7th October 2014 5th July 2016 12th June 2017
MEDLINE	7th October 2014 4th July 2016 10th June 2017
CINAHL	8th October 2014 4th July 2016 12th June 2017
Embase	15th October 2014 5th July 2016 12th June 2017
PEDro	23rd October 2014 5th July 2016 12th June 2017
Cochrane Database	23rd October 2014 5th July 2016 10th June 2017

2.2.4 Study selection

Following completion of the literature searching phase, two individuals independently reviewed the articles yielded to assess their eligibility. The first individual was Jayne Anderson, (PhD candidate) and author of this thesis. The second individual was Dr Angela Green, Lead Clinical Research Therapist at HEYHT and a co-supervisor of the PhD. A two-stage screening process was used. The first stage selected articles based on their title and abstract alone, using the eligibility criteria previously described in Table 2.1 on page 29. Articles selected following the first stage progressed to a second stage review of their full text to ascertain if their full content truly satisfied the eligibility criteria for inclusion. If there was uncertainty expressed by both authors regarding a particular study's eligibility following a review of its title and abstract, the article progressed through to a full text review. Any disagreements between the reviewers regarding study eligibility were resolved by discussion and consensus, without the need for a third reviewer. Efforts were made to contact study authors where further information was required to determine the eligibility of some articles.

2.2.5 Controlling for bias

Two reviewers worked independently during the first stage review of title and abstract, second stage full text review, assessment of methodological quality and data extraction phase. The use of two reviewers avoided potential bias that may have arisen if one individual with a clinical interest in the use of accelerometers to quantify activity within hospitalised populations had reviewed the articles alone. Although eventually not required, if agreement concerning a particular article had not been achieved, a third reviewer had been enlisted to assist in reaching a decision whether to include or exclude a particular article.

The decision not to limit studies to solely English language also assisted in controlling for bias. English translations of abstracts of non-English sources of evidence permitted opportunity to identify if any of these articles may have potentially been relevant but not able to be fully appraised due to being unable to translate their full text. It was possible that important, pertinent sources of

evidence which may have impacted on the overall conclusions reached following data synthesis may have resulted. Translation of the full text of these articles was not possible as this research received no funding. Therefore, there was no ability to employ interpreters to undertake this task.

2.2.6 Methodological quality assessment of studies

Methodological quality of the studies satisfying the eligibility criteria for inclusion was determined using the Critical Appraisal Skills Programme (CASP) Cohort Study Checklist (CASP 2013). The version used was dated 31st May 2013. This checklist is found in Appendix A1, commencing on page 249. Selection of an appropriate critical appraisal tool can be difficult as there is no single tool that can be used to critically appraise every type of study (Centre for Reviews and Dissemination 2009). All 12 questions within the checklist were considered by both reviewers to be pertinent to all studies selected for inclusion. This tool also permitted consideration of whether the individual study results could be locally applied. As a result, utilisation of this aspect of the checklist assisted in the formulation of ideas for further research projects which lie within the thesis. The checklist focussed on three distinct areas:

1. The validity of the study results
2. Study results in general
3. Whether the study results could be applied to local populations.

Nine of the 12 questions required a ‘yes’, ‘no’ or ‘can’t tell’ answer. If information related to a certain question was clearly reported it was marked as ‘yes’ and given a score of 1. Where this was not the case, both ‘no’ or ‘can’t tell’ answers scored 0. Two of the nine questions were divided into two components (‘a’ and ‘b’), also requiring a response as described above. This permitted a maximum score of 11 which could be achieved. Higher scores for studies indicated those which demonstrated greater methodological quality based on the questions able to be numerically scored. Three questions within the CASP checklist could not be scored numerically (questions 7, 8 and 12 which can be viewed in Appendix A1, commencing on page 249). These related to consideration of the study results, their precision and the implications of the

study for practice. These aspects were considered using the information documented by both reviewers within the relevant sections of the CASP checklists and as part of the data extraction process.

Both reviewers undertook methodological quality assessment and scoring of all included studies independently. In the case of disagreements between both reviewers, consensus was achieved through discussion to produce an agreed final numerical score. No numerical cut off point was set to categorise the methodological quality of a particular study and no study was excluded on the basis of the quality score achieved. This produced a rank order to the studies included within the systematic review, based on assessment of the specific aspects of methodological quality which were designed to receive a score. This assisted in providing an indication of the internal validity of the various findings of the systematic review, appraising the extent to which systematic errors or bias were avoided within the individual studies selected for inclusion (Ahmad et al. 2010). Recommendations or conclusions which were formulated following completion of the systematic review were based on the studies that were selected for inclusion. Hence, appraising the quality of the studies was an important task to complete.

2.2.7 Data extraction and synthesis

A data collection form accompanied by a standard operating procedure ensured consistency between reviewers during the data extraction phase of the systematic review. The data collection form can be viewed in Appendix A2 on page 255. Data extraction from eligible studies again utilised the Participants, Intervention, Comparator, Outcome, Study Design (PICOS) format (Liberati et al. 2009). Data concerning study results and implications for practice was assimilated using the data extraction forms and information entered by both reviewers within the relevant sections of the CASP checklists. This was an important exercise as it was this information which greatly assisted in the formulation of ideas for new research projects which were subsequently undertaken. All independently extracted information was shared, discussed and agreed by both reviewers for each study selected for inclusion.

Data concerning participants was extracted in order to identify which acute or critically ill hospitalised populations had undergone investigation of the validity or reliability of accelerometry to quantify purposeful movement. This task would assist in identifying any gaps within the current evidence base where accelerometry validity required further investigation within populations of this type. Assimilation of this information would direct recommendations for future research investigating accelerometry validity within the selected populations. It was envisaged that new research questions would arise as a result which would assist in providing direction for the thesis, augmenting the evidence base on the validity of accelerometry measurement within hospitalised adult populations. The processes described above, demonstrate how this systematic review concurred with the statements by Robinson and Goodman (2011) concerning what systematic reviews should set out to achieve.

Sample sizes recruited to each study were extracted and considered. During construction of the systematic review it was not only important to evaluate the validity of accelerometry measurement but to also consider the generalisability of the findings from the studies included. Extraction of sample size permitted opportunity to consider whether the populations under investigation were representative of the larger patient population. This exercise assisted in determination of the external validity of the systematic review findings, which is an important consideration for studies of this type (Kukull and Ganguli 2012).

Age was extracted to investigate the diversity of age ranges of hospitalised adult populations where the validity of accelerometry measurement had undergone investigation. This provided some indication of whether research into accelerometry validity was being undertaken in hospitalised populations other than older people. Extraction of this data responded to the concerns of Mudge et al. (2016) regarding the high levels of inactivity in hospitalised adults of all ages. Efforts could be made to ascertain the diversity of hospitalised populations that had already undergone investigation of the validity of accelerometry measurement to quantify purposeful activity, regardless of age. Synthesis of this information would assist in determining whether activity

monitoring through the use of accelerometry within the hospital setting may be a viable alternative to direct observation or self-report.

The reasons why participants were lost to follow up within the individual studies also received consideration. Increased understanding of the reasons why patients might withdraw from studies of this type would occur as a result of synthesis of this information. Information of this type was important, especially to inform construction of future methodological protocols investigating accelerometry validity within the chosen populations, where gaps in the evidence base had been recognised. If methods could be devised in future studies to control for some of the reasons identified, the risk of further loss to follow up with loss of valuable data for analysis might be decreased. This would maximise the possibility of all data collected being able to undergo analysis.

2.2.8 Data Analysis

Percentage agreement between both reviewers for methodological quality assessment of included studies was calculated based on items within the CASP checklist able to be scored as a 1 or 0. In order to correct for chance agreement and take all three possible responses into consideration a kappa (κ) co-efficient was calculated using IBM SPSS (Version 20.0). This analysis was possible due to the categorical nature of the responses (Rigby 2000). These processes permitted determination of inter-observer agreement in the initial assessment of methodological quality, prior to the discussion and consensus phase, where a final score was agreed by both reviewers.

Preliminary synthesis compiled patient population, sample sizes and study objectives using information recorded within the CASP checklists and data extraction forms. This exercise assisted in identifying the adult hospital inpatient populations which had undergone investigation of accelerometry validity or reliability in quantification of purposeful movement. Accelerometer models and epoch lengths were also tabulated where possible to assess homogeneity of time periods used to capture, accumulate and store data.

Heterogeneity of studies, including accelerometer model, placement site (or sites), patient population, activities investigated, epoch setting and methods of data analysis precluded the ability to undertake a meta-analysis. Therefore, a systematic exploration and subsequent assessment of the evidence was developed through narrative synthesis (Ryan 2013). Internal and external validity of the findings were considered. , taking into account methodological quality scores and sample sizes of the individual studies respectively. Data synthesised from the methodological quality assessment assisted in consideration of the internal validity of the findings which were assimilated within the systematic review. Data extraction of the sample sizes recruited to the various studies assisted in consideration of the generalisability of the study findings and their external validity. The overall strengths and weaknesses of the systematic review also received consideration.

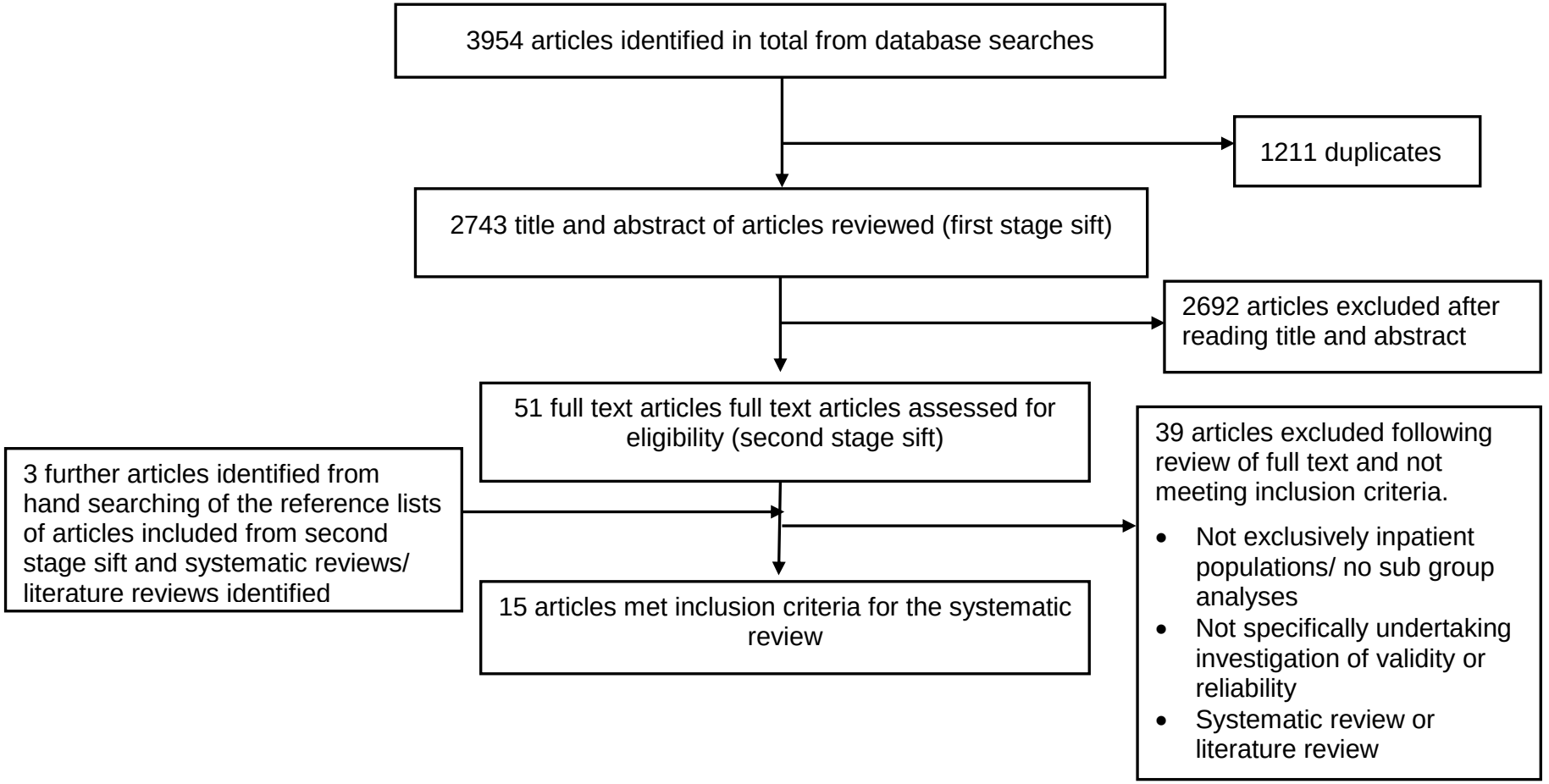
2.3 Results

2.3.1 Study selection

The initial searches yielded 3954 citations, of which 1211 duplicates were removed, where articles had been identified in more than one database. The title and abstract of 2743 articles were reviewed to determine their eligibility, using the criteria previously presented in Table 2.1 on page 29. Following this first stage of the review process, 2692 articles were deemed not eligible by both reviewers. All non-English sources of evidence identified (n = 51) were not relevant for inclusion following a review of their English abstracts. Consensus between reviewers was achieved for all articles where there were initial disagreements regarding their inclusion or exclusion. Where both authors had remained unclear about the eligibility of a particular article, the full text was obtained and it entered into the second stage of the review process. Fifty-one articles progressed onto the second stage, where their full text was reviewed by both authors to determine eligibility. Figure 2.1 on page 42 details the evidence selection process in a flow chart.

A rigorous systematic review demands that attempts are made to contact study authors in cases where determination of article eligibility is more difficult (Whiting et al. 2016). It was necessary to contact three authors to obtain further information about study participants and accelerometer model (Pedersen et al. 2013), to enquire if a further paper had resulted from a conference proceeding (Harris et al. 2006) and to determine article eligibility in relation to the population investigated (Skipworth et al. 2011). Two articles were eventually included (Pedersen et al. 2013; Harris et al. 2006). The third was excluded as participants (all experiencing end stage cancer) were not all hospitalised, with no evidence of subgroup analysis for the inpatient population only (Skipworth et al. 2011). Presence of a diagnosis of cancer was not an exclusion criterion for the systematic review. The article by Skipworth et al. (2011) was excluded as a result of not being able to distinguish which participants were inpatients and which were outpatients. Exclusion of this article due to some participants being outpatients assisted in maintaining the focus of the systemic review on patients with acute or critical illness who were resident in hospital. No paper had been published following the conference proceeding written by Harris et al. (2006).

Figure 2.1 Flow diagram detailing the article selection process



Following determination of eligibility, 15 articles were selected for inclusion. These ranged in publication year from 1999 (Bisgaard et al. 1999) to 2016 (Webber and St John 2016). Fourteen papers were research articles and one a conference proceeding, which contained the necessary information to satisfy inclusion (Harris et al. 2006). All studies were prospective and observational in their methodological design.

2.3.2 Study Characteristics

2.3.2.1 Methodological quality assessment

Reviewers achieved 87% agreement for the 11 methodological quality assessment items contained within the CASP Cohort Study Checklist able to be scored as 1 or 0. Overall inter-observer agreement was $\kappa = 0.60$ ($p < 0.001$), indicating moderate agreement between the two reviewers (Landis and Koch 1977). Whilst both 'no' and 'can't tell' answers both scored 0, where one reviewer would answer a question with 'no', the other would often record 'can't tell' (or vice-versa). This provides an explanation for the overall moderate score determined by Kappa analyses, where all the responses were considered individually. Any disagreements regarding aspects of methodological quality, particularly where one reviewer scored a 1 for yes and the other scored a 0 for either a 'no' or 'can't tell' answer were resolved by discussion without the need for a third reviewer. This was encountered on 22 out of a possible 165 occasions. Table 2.4, located on page 44 details the results of methodological assessment for all included articles based on the 11 questions able to be scored. The question numbers within this table are identical to those within the CASP checklist, which can be found in Appendix A1, commencing on page 249. Quality scores ranged from three (Godfrey et al. 2010; Choquette et al. 2008) to ten (Webber and St John 2016; Raymond et al. 2015) out of a maximum of 11.

Table 2.4 Results of methodological quality assessment agreed by both reviewers

Study	1	2	3	4	5a	5b	6a	6b	9	10	11	Quality Score
Webber and St John (2016)	1	1	1	1	1	1	1	1	1	0	1	10
Raymond et al. (2015)	1	1	0	1	1	1	1	1	1	1	1	10
Brown et al. (2008)	1	1	1	1	0	0	1	1	1	1	1	9
Pedersen et al. (2013)	1	1	1	1	0	0	1	1	1	0	1	8
Culhane et al. (2004)	1	1	1	1	0	0	1	1	0	1	1	8
Taraldsen et al. (2011)	1	1	1	0	0	0	1	1	0	1	1	7
Winkelman et al. (2005)	1	1	1	1	0	0	0	0	1	1	1	7
Harris et al. (2006)	1	0	1	1	0	0	1	1	0	1	0	6
Edbrooke et al. (2012)	0	1	1	1	0	0	1	1	0	0	0	5
Kramer et al. (2013)	1	0	1	1	0	0	0	0	1	0	1	5
Bisgaard et al. (1999)	0	1	0	0	0	0	1	1	0	1	1	5
Rowlands et al. (2014)	0	1	0	0	0	0	1	1	0	0	1	4
Nagels et al. (2007)	0	1	0	0	0	0	1	1	1	0	0	4
Godfrey et al. (2010)	0	1	1	1	0	0	0	0	0	0	0	3
Choquette et al. (2008)	0	0	1	0	0	0	1	1	0	0	0	3

The most common methodological shortcomings were identification of all confounding factors and the subsequent consideration given to these in the research design or data analysis. Examples included placement of an accelerometer under investigation at a different body placement site to the accelerometer being used as the criterion measure (Rowlands et al. (2014). This led to difficulty interpreting whether the actual placement site (wrist) or the accelerometer itself (GENEactiv) accounted for the predominantly fair epoch by epoch agreement (Landis and Koch 1977) with its thigh mounted activPAL criterion measure for quantification of time spent in lying, sitting and standing positions. A further example concerned the choice of criterion measure (self-report) used to rate perceived exertion in a group of patients following upper abdominal surgery (Bisgaard et al. (1999). Possible differences in the subjective interpretation of pain levels between subjects or numbers of attachments (catheters, intravenous drips or presence of wound drains) may have impacted on perceptions of the intensity of a certain physical activities which were compared to accelerometer quantified activity intensities.

The best considered areas were recruitment of a cohort in an acceptable way, measurement of the exposure to minimise bias and follow up of subjects being both complete and long enough. Following assessment of methodological quality, data extraction from the 15 articles was undertaken independently by both authors. Study characteristics were tabulated using the Population, Intervention, Comparator and Outcome (PICO) format (Liberati et al. 2009). Table 2.5, beginning on page 46 and ending on page 53 details all the data extracted and agreed by both authors. All studies were prospective and observational in their design.

Table 2.5 PICOS study characteristics

Author	Population Age	*n*	Objective	Interventional accelerometer model, placement site(s) and epoch setting	Comparator	Outcome(s)
Webber and St John 2016	Post-acute and sub-acute inpatient geriatric rehabilitation Age (Mean ± SD) 83.2 ± 7.1 years	38	To compare the step count accuracy of a commercial accelerometer placed in isolation at two trial sites (using two data filtering options – default and LFE) with another commercial model during a hospital hallway walk	GT3X+ (Actigraph, Pensacola, FL) worn above the right hip (around the waist) and around the left ankle above the lateral malleolus Step Watch 3.0 activity monitor (SW1002, Orthocare Innovations, Oklahoma City). Worn on the right ankle above the lateral malleolus. One second epoch for GT3X+ and three second epoch for Step Watch 3.0	Observation of steps recorded using a hand tally counter. Single observer, no information on the training received	APE Median (IQR) and ICC values (95% CI) for hospital hallway walk: StepWatch3 2.3 (5.1) 0.96 (0.92, 0.98) GT3X+ Ankle/LFE 2.5 (13.0) 0.94 (0.87, 0.97) < 1 step difference (‘narrow’ 95% CI) for ankle / LFE setting GT3X+ Hip/ LFE 18.9 (23.1) 0.83 (0.33, 0.94) GT3X+ Ankle/default 47.2 (37.4) 0.68 (-0.21, 0.90) GT3X+ Hip/ default 96.6 (20.9) -0.05 (-0.19, 0.15)
		21	To compare total steps captured over a full day	GT3X placed at the hip only (not the ankle) and Step Watch 3.0 placed as above.	Total daily step count from both accelerometer models compared	StepWatch3 Median 2740 steps (IQR 2626.0) GT3X+ Hip/ LFE Median 3112.0 steps (IQR 919.05) GT3X+ Hip/ default Median 357 step (IQR 434.5)

Author	Population Age	*n*	Objective	Interventional accelerometer model, placement site(s) and epoch setting	Comparator	Outcome(s)
Raymond et al. (2015)	Older inpatients Age (mean ± SD) 79.8 (± 7.26)	12	To investigate the validity of an accelerometer to monitor body position and measure physical activity.	Position Activity Logger – PAL 2 (Gorman Promed Pty. Ltd). Placed on the outer side of the leg. Two tilt switches, placed on the outer thigh and lower leg below the knee. Three second epoch	Video recordings, analysed by a single assessor	No difference in time spent in each position between PAL2 and video recordings (*p*-values ranged from 0.06 to 0.65.) Tendency for PAL2 to overestimate time in lying and activity and underestimate time in other positions Walking speed and PAL2 strongly correlated (r = 0.91 $p < 0.01$) 100% agreement for transitions between sitting and lying Sit to stand transitions (and reverse): under (or overestimation) by the PAL2 by a maximum of 10.5% respectively
Rowlands et al. 2014	Acute exacerbation of COPD Age: (mean ± SD) 75.9 ± 9.7	10	To determine if an accelerometer could determine posture (sitting/lying or standing) using wrist position alone.	GENEactiv (Activinsights, Cambridgeshire UK). Wrist placement 15 seconds epoch	activPAL (PAL technologies, Glasgow, Scotland) worn on the thigh	Significantly fewer minutes sitting and more minutes standing classified by GENEactiv compared to activPAL ($p<0.05$). Sitting time correlation 0.78 ($p <0.05$) Intraindividual epoch agreement (κ) (mean ± SD) 0.38 ± 0.11

Author	Population Age	*n*	Objective	Interventional accelerometer model, placement site(s) and epoch setting	Comparator	Outcome(s)
Pedersen et al. 2013	Older adults Age: median (IQR) 84.7 (78.6:87.2)	6	To cross validate an algorithm combining data from two accelerometer placement sites in identification of body position during various activities.	'Wireless monitors' (Augmentative Incorporated Pittsburgh, PA). Two placement sites: 15cm above the patella and 15cm above the ankle of the ipsilateral leg. One second epoch	Observation of body position/ walking activity, Single observer, training not reported within the paper	Percentage agreement (mean (range): Lying activities 98.3% (90.81 - 100%) Sitting 97% (95.28 - 98.61%) Standing/walking 93% (89.62 - 96.49%)
Kramer et al. 2013	Acute stroke Age: median (IQR) 80 (76.5:83.5)	26	To determine agreement between observation (behavioural mapping) and accelerometry in identification of body position.	Position Activity Logger – PAL 2 (Gorman Promed Pty. Ltd). Placed on the lateral side of the unaffected leg. Two accelerometer tilt switches, placed above and below the knee. One second epoch	Observation (behavioural mapping). Single observer, training not reported in the paper	Intra Class Correlations (95% CI) reported recognition of lying, sitting and upright positions: Lying 0.74 (0.46-0.89) Sitting 0.68 (0.36-0.86) Upright 0.72 (0.43-0.88)

Author	Population Age	*n*	Objective	Interventional accelerometer model, placement site and epoch setting	Comparator	Outcome(s)
Edbrooke et al. 2012	Resident on an ICU Age (mean ± SD) 62.1 ± 14.1	20	To investigate the validity and reliability of an accelerometer to quantify step count during repeated walks of known distances.	Activity Monitoring Pod – AMP 331 (Dynastream Innovations Inc., Cochrane, AB, Canada) Left ankle placement No epoch length reported.	Observation. Single observer, training not reported Known distance walks timed and repeated twice using a stopwatch	Correlations of 0.99 (95% CI 0.99-1.00) for step count reliability SE measure step count 0.11 steps Mean difference between observed and accelerometer determined step count 0.92 95% limits of agreement: -3.27 to 5.11 steps
Taraldsen et al. 2011	Older patients Acute stroke and older patients Age: (mean ± SD) Acute stroke group 75.2 ± 6.2 Older patient group 84 ± 5.8	 14 14	To determine the accuracy of an accelerometer to identify body position, postural transition or step count when placed in isolation or in combination.	activPAL Thigh placement in isolation Thigh and sternum when placed in combination One second epoch	2D Sony mini digital camera	Single placement showed no misclassifications of time in sedentary (lying/ sitting) or upright positions. 100% agreement for two sensor placement for number of lying to sitting and sit to stand transfers. Also permitted differentiation between lying and sitting postures. High APE for step count (53.40%) when placed on the affected leg in stroke patients and a community based cohort three months post hip fracture compared to unaffected leg (26.91%) for speeds ≤ 0.47m/s

Author	Population Age	*n*	Objective	Interventional accelerometer model, placement site and epoch setting	Comparator	Outcome(s)
Godfrey et al. 2010	Inpatients with and without delirium Age: (mean ± SD) 68.4 ± 11.9	40	To establish the validity of an accelerometer in determination of time (minutes) spent in certain body postures (lying/ sitting, standing and walking).	Non-commercial accelerometer Placed on the lateral aspect of the mid-thigh, with a data logger positioned anteriorly on the thigh of the same leg. Raw data setting	activPAL accelerometer lying directly underneath the non-commercial device.	Percentage agreement between non-commercial accelerometer and activPAL. Sitting/lying - 99% Standing - 99% Walking - 97%
Brown et al. 2008	Older adults (veterans) Age:(mean ± SD) 73.9 ± 6.5	50	To validate readings from a combination of two accelerometers to measure time spent in lying, sitting or standing/ walking.	Wireless accelerometer (AugmenTech Inc., Pittsburgh, Pennsylvania). Two accelerometers placed on the thigh and ipsilateral ankle. 20 second epoch	Direct observation (one observer each session) Initial interrater reliability analyses, coding behaviours using video excellent. Changes of body position accurate to within 8 seconds of each other	Correlations for time spent in: Lying $r = 0.98$ ($p < 0.001$) Sitting $r = 0.97$ ($p < 0.001$) Standing/ walking $r = 0.91$ ($p < 0.001$) Individual agreement (per participant): $\kappa = 0.28 - 0.98$ Median agreement: $\kappa = 0.92$ (IQR not reported)

Author	Population Age	*n*	Objective	Interventional accelerometer model, placement site and epoch setting	Comparator	Outcome(s)
Choquette et al. 2008	Older adults undergoing post-acute rehabilitation Age:(mean ± SD) 77.4 ± 5.2	5	To compare estimates of active time during therapy sessions captured by accelerometers to directly observed activity. A combination of three placement sites (M3) and a single placement site (M1) underwent evaluation.	Non-commercial accelerometer model. (M3) Placement sites were the dominant hand, contralateral ankle and right hip (M1) Hip alone 10 second epoch	Direct observation by the same observer for each participant, using a programme on a tablet computer. Amount of training the observer received in order to use the technology not explicitly reported.	Correlations by measure of active time during entire rehabilitation sessions: (M3) 0.93 ($p \leq 0.001$) (M1) 0.79 ($p \leq 0.001$) ICC per subject: (M3) 0.65 to 0.98 ($p \leq 0.01$) (M1) 0.63 to 0.89 ($p \leq 0.01$) ICC depended on the activity undertaken. Worst for antalgic gait therapy: (M3) 0.32 (CI -0.39 to 0.79) (M1) 0.29 (CI -0.42 to 0.78) Range of ICC for all other categories within rehabilitation sessions per subject: (M3) 0.68 to 0.95 (M1) 0.55 to 0.93 Both M3 and M1 placements had a tendency to underestimate active time during therapy sessions. M3 better than M1.

Author	Population Age	*n*	Objective	Interventional accelerometer model, placement site and epoch setting	Comparator	Outcome(s)
Nagels et al. 2007	Older adults with dementia Age:(mean ± SD) 78 ± 8	110	To correlate accelerometer readings from three different measurement modes with nurses' observations of activity in dementia	Basic Motion Logger (Ambulatory Monitoring Inc. Ardsley, New York, USA) Worn on the non-dominant wrist 30 minutes epoch (1800 seconds)	Direct observation by 'experienced' nursing staff. Single observer. Numbers used and type of training not explicit	Correlations between activity scores and the different measurement modes (Zero Crossing Mode - ZCM, Proportional Integrated Mode - PIM, Time Above Threshold Mode - TATM) were comparable. Spearman rank correlational analysis: ZCM $r = 0.48$ ($p < 0.001$) PIM $r = 0.50$ ($p < 0.001$) TATM $r = 0.50$ ($p < 0.001$)
Harris et al. 2006	Acute stroke Age: Not reported	6	To establish the accuracy of an accelerometer to quantify the number of sit to stand transitions during a 30 minute rehabilitation session.	activPAL accelerometer Placed on the thigh Two seconds	Direct observation. Single observer, training received not described (conference proceeding)	Mean difference in count was 2.3 sit to stand transfers (SD 5.1), 95% CI -7.7 to 12.2
Winkelman et al. 2005	Resident on an ICU Age:(mean ± SD) 59.8 ± 16.45	20	To compare accelerometry and observation in measurement of frequency and duration of activity	Motionlogger (Ambulatory Monitoring Inc. Ardsley, New York, USA). Wrist One minute epoch	Direct observation of activity logged by 2 observers (90% agreement at participant 10)	Average agreement (frequency) 76% (range 40 – 100%) Average agreement (duration) 66% (range 40-80%)

Author	Population Age	*n*	Objective	Interventional accelerometer model, placement site and epoch setting	Comparator	Outcome(s)
Culhane et al. 2004	Older patients Age:(mean ± SD) 72 ± 13	5	To establish the accuracy of a combination of two accelerometers to monitor postures/ mobility for extended periods. Investigated two methods of interpreting the data.	Analogue devices ADXL202 (Analog Devices. BV Ltd, Limerick, Ireland). Thigh and sternum placement sites. Small data logging device and cabling also part of system. One second epoch	Direct observation by a single observer. Type of training received not explicit. Observer manually logged activity in a tabulated paper record whilst 'shadowing' patient.	Mid - point threshold (mean % agreement): Sitting 73% Standing 97% Lying 77% Best estimate threshold (mean % agreement): Sitting 92% Standing 98% Lying 95% Detection of dynamic activity (walking) overall mean detection accuracy of 97%
Bisgaard et al. 1999	Major abdominal surgery (first few days post-operatively) Age:(median and range reported) 30 (18-67)	12	To investigate the validity of accelerometry to capture periods of activity and quantify their intensity	Mini-Motion Logger Actigraph (Ambulatory Monitoring Inc. Ardsley, New York, USA). Wrist placement. One minute epoch	Patient self-report	Mean agreement of perceived intensity of activity was 80% (SD 12%). Spearman correlations 0.4 to 0.8 for the 12 participants ($p < 0.05$). Patients noted a median of 40 visual analogue score registrations, rating perceived intensity on each occasion (range 18 - 55).

2.3.2.2 Participants

The 15 studies investigated a variety of hospitalised populations. One study recruited patients admitted with an acute exacerbation of Chronic Obstructive Pulmonary Disease (COPD) (Rowlands et al. 2014). Two studies were undertaken directly within the ICU (Edbrooke et al. 2012; Winkelman et al. 2005). Eight studies investigated cohorts of older hospital patients (Webber and St John 2016; Raymond et al. 2015; Pedersen et al. 2013; Taraldsen et al. 2011; Brown et al. 2008, Choquette et al. 2008; Nagels et al. 2007; Culhane et al. 2004). Data only directly related to cross validation of an algorithm to identify lying, sitting, standing and/ or walking was extracted from the article by Pedersen et al. (2013). The primary aim was to quantify 24 hour mobility using the same accelerometers within an acutely admitted older population. The cross validation component was a secondary aim, which satisfied all eligibility criteria for inclusion.

The study by Taraldsen et al. (2011) included two distinct sub groups of older hospitalised populations. One group were inpatients within a department of geriatrics, whilst a second group were resident on an acute stroke unit. Two other studies investigated patients admitted acutely following stroke (Kramer et al. 2013; Harris et al. 2006). One study investigated patients who had recently undergone major abdominal surgery (Bisgaard et al. 1999). Only data relating to the investigation of the validity of the accelerometer device to quantify physical activity intensity was extracted. Additional data relating to investigation of sleep in this study was considered beyond the scope of the research question and not extracted. Finally, one study investigated a palliative care cohort (Godfrey et al. 2010). Although not specifically an acutely admitted cohort, the two reviewers agreed that this article bore relevance to the research question, directly in terms of the intervention, the types of activities they were likely to undertake, the use of a comparator, the aims of the particular study and location of the research.

Data synthesis on population type revealed that a variety of acute and sub-acute hospitalised populations have participated in research investigating

accelerometry validity in quantification of purposeful activity. Only two studies enrolled populations recovering from critical illness (Edbrooke et al. 2012; Winkelman et al. 2005). Both of these were undertaken directly within the ICU. No studies had investigated the validity of accelerometry measurement within a ward based population recovering from critical illness. However, studies have used accelerometry to quantify activity within the ward environment in populations who are recovering from critical illness (Borges et al. 2015). No investigation of validity of the particular accelerometer used in this study was undertaken specifically within a population recovering from critical illness. Therefore a gap in the evidence base was identified. Although validity studies have been undertaken within the ICU (Edbrooke et al. 2012; Winkelman et al. 2005), none have been performed beyond this setting, as patients recover on the ward and increase their activity further.

Eight studies (53%) used sample sizes of between five and 15 participants, either in total or enrolled separately within sub groups. Sample sizes ranged from five (Choquette et al. 2008; Culhane et al. 2004) to 110 (Nagels et al. 2007). The mean age (or median where presented) of participants was greater than 65 years in 11 studies. This finding was not surprising, considering the cohorts who had undergone investigation, with the majority comprising ‘older’ or acute stroke populations (NHS choices: Stroke 2014). It was not possible to determine the age of participants in the study which was presented as a conference proceeding, although participants were undergoing therapy within a rehabilitation setting following acute stroke, suggesting an older population again was enrolled (Harris et al. 2006).

Only three studies enrolled participants with mean ages of less than 65 years, including those recovering from critical illness and following major upper abdominal surgery (Edbrooke et al. 2012; Winkelman et al. 2005; Bisgaard et al. 1999). Although these studies increased the diversity of hospitalised populations who have undergone investigation of the validity of accelerometry measurement to quantify purposeful movement, most studies (*n* = 11) involved investigation of accelerometer validity within older people (greater than 65

years of age). This suggests a misconception that older populations are the only group who are inactive whilst in hospital for which methods of monitoring activity require investigation of their validity. Mudge et al. (2016) highlighted that older people (above the age of 65) are not the only adult populations who are inactive during a hospital admission.

Following extraction of sample sizes and age, reasons lost to follow up were considered. Several studies encountered participant withdrawal due to technical problems experienced with the accelerometers or criterion measures used (Raymond et al. 2015; Kramer et al. 2013; Brown et al. 2008). Lack of data from both the accelerometers and direct observational analysis precipitated the withdrawal of two participants from the study by Brown et al. (2008). Logistical difficulties, including unscheduled patient transfers to another department or discharge home before data collection could begin were also encountered (Kramer et al. 2013; Winkelman et al. 2005).

Some participants withdrew consent due to dislike of study conditions, in particular being constantly observed for a period of hours within the confines of a single room (Brown et al. 2008). One participant refused to undertake a repeated walk of a known distance in order to assess accelerometer reliability (Edbrooke et al. 2012). Participants in another study were withdrawn due to experiencing general distress from wearing the accelerometers, perceived either by the participants or their relatives during the data collection period (Godfrey et al. 2010). Necessity for medical procedures or general deterioration in condition precipitated withdrawal of some participants (Kramer et al. 2013; Godfrey et al. 2010; Brown et al. 2008). Finally, a few participants were excluded from some methods of statistical analysis due to the adoption of constant postures (lying) throughout the entire investigation period, in particular Kappa (κ) analysis measuring agreement between the accelerometer and its comparator (Brown et al. 2008).

Synthesis of this evidence suggested some reasons for withdrawal (e.g. accelerometer malfunction) would be more difficult to anticipate or control for. Acutely admitted older populations and the critically ill are two patient groups who may experience deterioration in their condition. This deterioration may be unexpected, hence an unknown entity prior to enrolment in a study. Other findings (e.g. dislike of being constantly observed) are aspects that require consideration in the design of future methodological protocols. Attention to the length of observation period, the environment in which they are observed or exploration of other criterion measures may control for potential participant withdrawal. Any alternative criterion measure, however, should demonstrate evidence of validity itself. Effective communication between patients, family and health care professionals would assist in decreasing the risk of loss to follow up. Knowledge of when clinical procedures have been arranged may decrease the risk of premature removal of the accelerometer with accompanying loss of data.

2.3.2.3 Intervention

Both commercial and custom made accelerometer models have undergone investigation within the selected hospitalised populations. The makes and models investigated were presented in Table 2.5, commencing on page 46. The lightest single accelerometer weighed five grams (Pedersen et al. 2013). The heaviest unit reported weighed 192g, comprising two accelerometers, a data logger and associated cabling (Culhane et al. 2004). The majority of studies (*n* = 9) reported their primary or secondary objective was to investigate the validity of accelerometry measurement to capture body position (lying, sitting or standing) or postural transition. Four of these studies also investigated whether the accelerometers investigated could distinguish between dynamic (e.g. walking) and static activity (standing) (Raymond et al. 2015; Taraldsen et al. 2011; Godfrey et al. 2010; Culhane et al. 2004). Walking was either included as a specific component of a movement protocol (Raymond et al. 2015; Taraldsen et al. 2011) or as part of volitional, spontaneous activity undertaken at will by the participants (Godfrey et al. 2010; Culhane et al. 2004).

Four studies incorporated movement protocols within their study design (Raymond et al. 2015; Pedersen et al. 2013; Edbrooke et al. 2012; Taraldsen et al. 2011). It was unclear in the conference proceeding by Harris et al. (2006) whether identification of the sit to stand postural transition specifically under investigation was part of a movement protocol or whether it was performed as part of the usual rehabilitation process within acute stroke patients. The remaining studies investigated accelerometeter validity through the use of spontaneous volitional movement undertaken by participants.

Three studies investigated direct quantification of step count, all using different commercially available models (Webber and St John 2016; Edbrooke et al. 2012; Taraldsen et al. 2011). One of these studies also investigated accelerometer reliability (Edbrooke et al. 2012). This was the only study which actually stated an intention to investigate both validity and reliability of accelerometry measurement. Investigation of reliability was achieved by participants undertaking known distance walks twice, using a test-retest design. The measured distances walked were five, 10, 25 and 50 metres, each of which was repeated. The data was analysed for the strength of the correlation (ICC (95% CI) between the step counts recorded by the accelerometers from both identical distance walks.

Quantification of general activity using accelerometers was investigated in four studies (Choquette et al. 2008; Nagels et al. 2007; Winkelman et al. 2005; Bisgaard et al. 1999). One study focussed on investigation of the validity of activity intensity outputs (registered as numerical ‘counts’) from three different measurement modes inherent within a commercial model compared to observation (Nagels et al. 2007). The intensity of a particular activity (e.g. getting out of bed to sit in a chair) was investigated in another study, to understand if particular functional movements could be identified by activity intensity count alone (Winkelman et al. 2005). The final two studies investigated the validity of accelerometry to quantify time in activity during rehabilitation sessions (Choquette et al. 2008) and to quantify activity intensity when compared with self-reported intensity (Bisgaard et al. 1999).

Considerable heterogeneity between the study objectives was clearly evident, even when similar models produced by the same manufacturer were used.

The most frequently set epoch length, where accelerometer data was accumulated and stored within the devices, was one second (Webber et al. 2016; Kramer et al. 2013; Pedersen et al. 2013; Taraldsen et al. 2011; Culhane et al. 2004). Smaller epoch lengths capture data at higher resolution and increase the richness of the data able to be analysed (Actigraph Engineering/ Marketing 2009). Epoch lengths, where reported, ranged from raw data collection (less than one second) (Godfrey et al. 2010) to 30 minutes (Nagels et al. 2007). Other epoch lengths used were two seconds (Harris et al. 2006), three seconds (Webber and St John 2016; Raymond et al. 2015), ten seconds (Choquette et al. 2008), 15 seconds (Rowlands et al. 2014), 20 seconds (Brown et al. 2008) and one minute (60 seconds) (Winkelman et al. 2005; Bisgaard et al. 1999). Data extracted for epoch length demonstrated wide variablity in the data resolutions captured and thus the richness of the data obtained for analysis.

The accelerometers investigated were positioned either in isolation or in combination. The lower limb was most frequently utilised; in particular the thigh and ankle, either in combination or as single isolated sites (i.e. thigh or ankle). This appeared to be dependent on which context of purposeful activity was being investigated (body position (lying, sitting or standing), step count or generalised activity). All studies which specifically investigated quantification of step count used data collected from a single accelerometer, mounted either on the ankle or the thigh (Webber and St John 2016; Edbrooke et al. 2012; Taraldsen et al. 2011). Eleven studies positioned accelerometers on various aspects of the lower limb (see Table 2.5, commencing on page 46), highlighting the popularity of choice of the lower limb for placement.

Four studies positioned the accelerometers under investigation on the wrist, whilst two studies chose the mid-sternum. The mid-sternum position was never used in isolation and always in combination with a further accelerometer placed

on the thigh (Taraldsen et al. 2011; Culhane et al. 2004). This combination was used to identify body position (lying, sitting and standing) in both studies. Taraldsen et al. (2011) also investigated the ability of this placement combination to identify postural transitions (lying to sitting and sitting to standing). Both of these studies investigated different accelerometer models yet reported similar findings, suggesting that placement site may play a pivotal role in determination of accelerometry validity depending on the aspect of purposeful activity being quantified.

Five studies investigated the validity of accelerometers when placed in combination for recognition of body postures (Raymond et al. 2015; Kramer et al. 2013; Pedersen et al. 2013; Taraldsen et al. 2011; Culhane et al. 2004). Accelerometer data was captured by two identical accelerometers placed at different body sites. Finally, one study investigated a combination of three body sites; specifically the wrist, hip and ankle (Choquette et al. 2008) to capture time spent during rehabilitation sessions. Accelerometry data was compared against a variety of criterion measures in all studies included which are now considered.

2.3.2.4 Comparator

All studies examined the relationship or agreement between the data captured by the intervention (accelerometer under investigation of validity or reliability) and that of its comparator. The comparator was believed to be a gold standard of measurement; a criterion measure yielding data which the accelerometers could be directly compared against. The strength of the relationship (correlation) or agreement between the intervention and comparator was the way in which validity or reliability was ascertained, hence an important aspect to consider during data synthesis.

Direct observation was the most commonly employed comparator, used in ten of the 15 studies (see Table 2.5 commencing on page 46 for further information on the individual studies). This suggests that most authors regarded this

particular method of measurement as the gold standard to function as a criterion measure when evaluating accelerometer validity within the hospitalised adults investigated. One study employed two observers who simultaneously logged the activity undertaken (type, frequency and duration in seconds) in a population recovering from critical illness (Winkelman et al. 2005). An interrater reliability analysis undertaken prior to commencement of data collection and at the mid-point (subject 10) revealed 90% agreement in the documentation recorded by both observers. All other studies employed a single observer to undertake data collection. In the study by Brown et al. (2008), prior to commencement of data collection, an interrater reliability analysis was also undertaken to compare activity logging by all those who were undertaking the role of the single observer. Interrater reliability was described as 'excellent', with those who were to be coding activity being accurate to within eight seconds of each another when capturing a change in body position or activity (lying, sitting, standing or walking). No further evidence of interrater reliability analyses for logging activity by direct observation was found in any other studies. Little information regarding the type of training delivered to observers was supplied in any of the studies included.

One study which enrolled patients with dementia employed nurses who specialised in the care of this patient group to observe and log activity. Level of activity was scored on a four-point scale: 1 = asleep, 2 = awake but inactive, 3 = active, 4 = maximally active (Nagels et al. 2010). It was deemed that the nurses' experience of observing behavioural disturbances in dementia was sufficient training to be able to accurately log data on activity by this patient group. No undertaking of interrater reliability analysis was evident in this study, which took the form of a short research report. No evidence of the use of standardised activity logs was found in any study, with all studies designing specific activity observation checklists which were unique to their investigation. Some activity logs were electronic rather than paper based, with data collection taking place on a tablet computer (Choquette et al. (2008).

Whilst also undergoing investigation of its own validity in some of the studies (Taraldsen et al. 2011; Harris et al. 2006), the thigh mounted activPAL commercial accelerometer (PAL technologies, Glasgow, Scotland) was used as the criterion measure in two studies (Rowlands et al. 2014; Godfrey et al. 2010). Rowlands et al. (2014) reported that the activPAL was selected as a result of it demonstrating 'acceptable validity and reliability' as a measure of posture and step count. Two studies were cited to support this statement (Lyden et al. 2012; Grant et al. 2010). One of these studies did not investigate the validity of the activPAL, using it instead to directly quantify free living activity within older populations in both hospital and community settings (Grant et al. 2010). The other, whilst investigating the validity of the activPAL to identify breaks in sedentary behaviours, enrolled a healthy population who were not age matched to the COPD patients enrolled in the study by Rolands et al. 2014 (Lyden et al. 2012). This questions the appropriateness of the evidence cited to support the use of this model as a criterion measure by Rowlands et al. (2014).

Two studies selected video recording as the comparator (Raymond et al. 2015; Taraldsen et al. 2011). A single study compared accelerometer data against self-reported activity and participant perceived intensity (Bisgaard et al. 1999). The interventional accelerometers were compared against their respective criterion measure, examining the relationships and agreement between the two sets of data captured.

2.3.2.5 Outcome

The final stage of the data extraction process was synthesis of the results following data analysis within the individual studies. It was important to understand the strength of the relationships and agreement between intervention and comparator in order to evaluate validity and reliability of the interventional accelerometers investigated within each of the contexts of purposeful activity described previously. Knowledge of this information would determine how closely the interventional accelerometer data was mirroring the data captured by the gold standard it was being compared against. Evidence of

strong relationships and agreement would suggest the interventional accelerometers were accurately quantifying the purposeful activities under investigation and, therefore, demonstrating evidence of their validity in this setting.

Data from the interventional accelerometers were compared against their chosen criterion measure using a variety of both statistical and descriptive methods. Parametric and non-parametric correlational statistics assessed the strength of relationships between the interventional accelerometer and its comparator in nine studies for time spent in certain body positions, time spent 'active', step count or walking speed. (Webber and St John 2016; Raymond et al. 2015; Rowlands et al. 2014; Kramer et al. 2013, Edbrooke et al. 2012; Brown et al. 2008; Choquette et al. 2008; Nagels et al. 2007; Bisgaard et al. 1999). Three of these studies examined the relationships between accelerometer quantified time spent in certain body positions (lying, sitting or standing) and a criterion measure (Rowlands et al. 2014; Kramer et al. 2013; Brown et al. 2008). Two studies examined relationships between accelerometer derived step count and observed step count (Webber and St John 2016; Edbrooke et al. 2012). One study examined the relationship between accelerometer determined walking speed and timed walking speed (Raymond et al. 2015). A single study examined the relationship between accelerometer determined time spent in activity and observed time (Choquette et al. 2008). Finally, two studies examined relationships between activity intensity quantified by accelerometry and nurses observations of activity levels (Nagels et al. 2007) and patient self-report (Bisgaard et al. 1999).

Agreement between accelerometer and criterion measure data was calculated statistically in five studies, either using Kappa (κ) or Bland Altman analyses (Webber and St John 2016; Rowlands et al. 2014; Edbrooke et al. 2012; Taraldsen et al. 2011, Brown et al. 2008). The choice of analysis was dependent on whether the data was categorical (for identification of body position) or numerical (step count). Percentage agreement between the data

captured by the intervention and comparator was the chosen method of analysis in seven studies (Raymond et al. 2015; Pedersen et al. 2013; Taraldsen et al. 2011; Godfrey et al. 2010; Winkelman et al. 2005; Culhane et al. 2004; Bisgaard et al. 1999). Table 2.5, commencing on page 46 details the results of data analysis for all studies included within the systematic review. Only data related to determination of body position, quantification of step count or general activity are detailed. A general overview of the results now follows.

Correlational analysis was undertaken in nine studies. Correlations of r = 0.68 to 0.98 and levels of agreement of κ = 0.28 to 0.98 have been reported for recognition of body position, dependent on the accelerometer model (Rowlands et al. 2014; Kramer et al. 2013; Brown et al. 2008). Isolated thigh mounted accelerometers, such as the activPAL and a non-commercial model did not differentiate between lying and sitting positions (Rowlands et al. 2014; Taraldsen et al. 2011; Godfrey et al. 2010). However, the activPAL encountered no misclassifications of time spent in sedentary (lying or sitting) and upright (standing) positions when compared to video recordings in acutely admitted older and stroke hospitalised populations (Taraldsen et al. 2011). Inability to differentiate between lying and sitting would not permit identification of all postural transitions in isolated thigh mounted models of this type. A wrist worn model (GENEActiv) reported only fair to moderate epoch by epoch agreement against its uniaxial activPAL criterion measure for time spent in lying (or sitting) and standing (Rowlands et al. 2014).

Accelerometers placed in combination permitted identification of the distinct postures of lying and sitting. Two studies used similar AugmenTech models positioned in combination on the thigh and ankle of the same leg (Pedersen et al. 2013; Brown et al. 2008). Pedersen et al. (2013) reported excellent results for recognition of lying and sitting with a mean (range) percentage agreement for recognition of lying and sitting of 98.3% (90.81% - 100%) and 96.9% (95.28% - 98.61%) respectively. Brown et al. (2008), also reported excellent correlations when compared with direct observation for time spent in lying or sitting positions ($r \geq 0.97$ ($p < 0.001$)). These studies scored 8 (Pedersen et al.

2013) and 9 (Brown et al. 2008) for assessment of methodological quality. Thigh and sternum placement combinations of the activPAL also enabled differentiation between lying and sitting, permitting 100% recogniton of lying to sitting and sitting to standing postural transfers (Taraldsen et al. 2011). The PAL2, positioned above and below the knee also identified lying to sitting postural transitions, but over or underestimated sit to stand and stand to sit transfers by ≤ 10.5% (Raymond et al. 2015).

Correlations of r = 0.4 to 0.8 have been determined for activity detection using accelerometers (Nagels et al. 2007; Bisgaard et al. 1999). Three studies investigated wrist worn models produced by the same manufacturer, called 'Motion Loggers' (Nagels et al. 2007; Winkelman et al. 2005; Bisgaard et al. 1999). One study determined only moderate correlations compared with observed activity intensity for three different measurement modes inherent within a Motion Logger model (Nagels et al. 2007). No measurement mode appeared superior to another for capturing activity intensity using this model within a population of older hospitalised adults with dementia, evident in Table 2.5 on page 52. Two of the three same measurement modes were used in another study comparing activity intensity recorded by accelerometry to self-reported intensity in patients following major abdominal surgery (Bisgaard et al. 1999). Self-reported activity intensity level was recorded using a 100mm visual analogue scale (VAS). The scale, developed by Bisgaard et al. (1999) ranged from 'sleep or no activity' to 'highest possible activity'. Participants were instructed to register a different VAS activity level whenever they felt a change in self-perceived activity intensity, whether this was increased or decreased. They were also requested to note the duration of each different change in activity intensity they perceived and recorded. Activity intensity VAS recording was performed over a 24 hour registration period, starting at 7am and concluding at 7pm. A mean (SD) agreement of 80% (12%) was reported, with individual participant correlations between self reported intensity and that registered by the accelerometers ranging from $r = 0.4$ to 0.8 ($p < 0.001$).

Identical measurement modes to those investigated in the study by Nagels et al. (2007) were used to quantify activity intensity in a population resident within the ICU (Winkelman et al. 2005). Frequency and duration of activity were investigated. Mean (range) percentage agreement between observation and accelerometer data was 76% (40 – 100%) for frequency and 66% (40 – 80%) for duration of activity. Finally, one study investigated a custom made accelerometer to identify time in activity in older patients udergoing rehabilitation (Choquette et al. 2008). A combination of placement sites (hip,wrist and ankle) produced the best correlations for time spent active (ICC 0.93 ($p \leq 0.001$). Poor results were returned for recognition of time spent active during gait re education activities regardless of whether accelerometers were placed in isolation (hip only) or in combination. This particular finding suggests that the ability of accelerometers to identify when activity is being undertaken may be dependent on the actual activity being undertaken.

Several ankle mounted commercial accelerometers, including the AMP 331, Actigraph GT3X+ and Step Watch 3.0 have demonstrated validity in quantification of step count in hospitalised populations who are likely to walk at slow speeds (Webber and St John 2016; Edbrooke et al. 2012). Webber and St John (2016) reported an ICC (95% CI) of 0.94 (0.87- 0.97) and 0.96 (0.92-0.98) for Actigraph GT3X+ and Step Watch 3.0 models respectively. Step count quantified by the accelerometers was compared against directly observed step count which was captured using a hand tally counter. Intermethod reliability and agreement between accelerometer data and observed step count were both investigated as part of the data analysis. The study by Webber and St John (2016) scored well for assessment of methodological quality, with 10 out of a possible 11.

Edbrooke et al. (2012) reported a mean difference in step count between observation and accelerometer determined step count of 0.92 steps for the AMP 331, with 95% limits of agreement (LOA) of -3.27 to 5.11 steps. The authors concluded that this small overestimation of steps was not clinically significant. Participants walked over variable measured distances of 5, 10, 25

and 50m walks, from which step counts quantified by AMP 331 were compared against observed step count. The AMP 331 was also determined to be reliable, with an ICC (95% CI) of 0.99 (0.99 - 1.0). Repeating each known distance walk enabled determination of reliability through the use of a test-retest design of methodology. The study by Edbrooke et al. (2012) scored 5 out of 11 for assessment of methodological quality; therefore the results were interpreted with caution. Nevertheless, the excellent results reported for the AMP 331, both for quantification of step count and reliability of this particular model support continued investigation of the validity of this particular model in populations likely to walk at slow speed.

To summarise, the main findings following data synthesis were as follows

- Both commercial and custom made accelerometers have undergone investigation of their validity in identification of purposeful activity in hospitalised adults recovering from acute or critical illness
- Most studies (11 of the 15 studies included) have investigated hospitalised adults over the age of 65 years
- Accelerometer validity has been investigated in patients following an acute admission due to a stroke, acute general medical admissions, following an acute exacerbation of Chronic Obstructive Pulmonary Disease (COPD) and post upper abdominal surgery
- Only two studies have investigated the validity of accelerometers to quantify purposeful movement within patients recovering from critical illness (Edbrooke et al. 2012, Winkelman et al. 2005). Both of these studies were undertaken within the ICU.
- No studies were identified where the validity of accelerometry had been investigated as patients are discharged from the ICU to the ward following improvement in their condition
- The validity of accelerometers has been investigated in identification of body position or postural transition, activity recognition (both intensity and time spent ‘active’) and in quantification of step count within hospitalised adults recovering from critical illness

- Single thigh mounted accelerometers encounter difficulty distinguishing between lying and sitting postures
- Combinations of placement sites enable to ability to detect lying, sitting and standing body positions and transitions between them
- Ankle mounted accelerometers have demonstrated validity and reliability in quantification of step count in hospitalised patients admitted following acute or critical illness
- Only one study explicitly stated an intention to investigate the reliability of accelerometer within these settings

Aspects of the results presented following data extraction are now considered in the discussion section. Following a brief introduction to this section, subheadings indicate whether accelerometers were being used to identify body position, quantify step count or recognise general activity. Presentation in this manner assists the reader to understand what aspect of purposeful activity each accelerometer was undergoing investigation of its validity or reliability for. The specific interventional accelerometer models used are also discussed.

2.4 Discussion

Evidence presented within this systematic review has determined that hospitalised older patients (over the age of 65) recovering from acute illness have undergone most investigation. Acutely admitted older populations are often frail, with increased risk of functional decline during their hospital stay, with correspondingly poor health outcomes (Dent et al. 2014). Functional decline is cited as one of the most negative consequences of hospital admission, especially in older people (Covinsky et al. 2011). This evidence highlights the importance of maintenance of regular activity and emphasises the need to discover valid and unobtrusive methods of monitoring how often activity is being undertaken within the hospital setting. Any method must try to overcome the operational weaknesses encountered by other methods such as direct observation and self-report (Cheung et al. 2011; Prince et al. 2008; Sager et al. 1992).

Mudge et al. (2016) found no differences between older (≥ 65 years) and younger hospitalised adults (≤ 65 years) in activity levels. Only 9% of time during the day was spent in standing or walking activities. This suggests a more universal approach to activity monitoring within the hospital inpatient setting is required. Evidence has been assimilated within this systematic review concerning the investigation of the validity and reliability of an alternative method of monitoring activity using accelerometers. This research appears timely and is considered one of its strengths. It responds to recommendations made by the National Institute of Health and Care Excellence (NICE) in a draft NHS quality standard consultation paper titled 'Physical Activity: encouraging activity in all people in contact with the NHS (staff, patients and carers) (NICE 2014). Emphasis is placed on encouragement of regular physical activity for all those who access NHS Institutions. If valid methods of activity quantification can be determined, identification of those who adopt prolonged periods of sedentary behaviour despite being physically able will assist in effective targeting of resources to assist or encourage regular physical activity.

Fifteen studies investigated the validity of accelerometers in quantification of purposeful activity in hospitalised adults recovering from acute and critical illness. However, only one of these studies specifically aimed to incorporate investigation of accelerometer reliability within its methodological design (Edbrooke et al. 2012). The results of these studies, presented in Table 2.5, commencing on page 46 and section 2.3.2.5 on page 62 are now further considered. They are categorised according to whether the interventional accelerometers were being investigated to identify body position, quantify step count or recognise activity in general. Attention is also given wherever possible to contextualise the findings to the clinical environment.

2.4.1 Identification of body position or postural transition

Differentiation between lying and sitting positions was not possible in a single thigh mounted commercial uniaxial activPAL accelerometer (Taraldsen et al. 2011). The ability to achieve the sitting position is an important functional milestone of recovery in patients experiencing acute stroke and critical illness

(Corner et al. 2014; Corner et al. 2013; Kramer et al. 2013; Mahoney and Barthel 1965). Once this is achieved, regular practice and adoption of this position facilitates the progression onto other milestones in the hierarchy of physical function (McWilliams et al. 2015; Schweickert et al. 2009; Mahoney and Barthel 1965). The ability to distinguish between sitting and lying positions therefore is an important clinical consideration, especially within the hospitalised patient populations included within this systematic review.

Placement of a second activPAL accelerometer on the sternum, in combination with a thigh placement permitted differentiation between lying and sitting postures (Taraldsen et al. 2011). As a result, the ability to successfully identify all transitions between lying, sitting and standing was achieved (Taraldsen et al. 2011). The results reported by Taraldsen et al. (2011) suggest this placement combination for the uniaxial activPAL demonstrates validity within hospitalised populations in identification of all postural transitions and time spent in lying, sitting or standing. Another study, which enrolled both inpatient and outpatient end stage cancer sufferers concurred with this finding (Skipworth et al. 2011). If only a single thigh mounted activPAL is used, the ability to detect whether someone is lying in the bed or is sitting in a chair is lost. However, if only identification of sedentary postures (lying or sitting) or time spent upright is desired, the findings of Taraldsen et al. (2011) support the clinical use of this particular model positioned on the thigh in isolation.

A thigh and sternum combination also demonstrated validity in recognition of lying, sitting and standing in a different accelerometer model (Analogue devices ADXL202 accelerometer) (Culhane et al. 2004). Placement of a second accelerometer on the sternum may not be universally appropriate for certain hospitalised populations, for example following cardiac surgery where pacing wires or cardiac monitoring may be used. Other populations such as the critically ill may also have cardiac monitoring in progress. Further research is recommended using the activPAL or Analogue devices ADXL202, exploring alternative placement sites to use in combination with a thigh placement which may also distinguish between lying and sitting positions. An ankle and thigh

placement is recommended to be investigated based on the excellent results for identification of lying, sitting and standing positions reported by both Pedersen et al. (2013) and Brown et al. (2008) for this combination using AugmenTech accelerometers. Pedersen et al. (2013) reported that identification of these positions was achieved successfully over 90% of the time when compared against observation. Brown et al. (2008) reported correlations for time spent in these same positions of greater than $r = 0.91$ when comparing this combination of accelerometer placement sites against observation of body position of ward based medical patients. AugmenTech models went on to be used in another study investigating adoption of body postures and activity in hospitalised patients with heart failure using the same thigh and ankle combination (Howie-Esquivel and Zaharias 2013). The authors referenced the study by Brown et al. (2008) as evidence of its validity and reliability. This placement combination, if demonstrating validity in other models may enable application on a more diverse range of hospitalised acute and critically ill populations.

The uniaxial activPAL was used as the criterion measure in two studies (Rowlands et al. 2014; Godfrey et al. 2010). Validity of the commercial wrist mounted GENEActiv was investigated in one study (Rowlands et al. 2014) and a custom made model in the other, worn directly under the activPAL (Godfrey et al. 2010). As mentioned previously, an isolated thigh worn activPAL cannot distinguish between lying and sitting (Bassett et al. 2014; Taraldsen et al. 2011). Consequently, it could not be ascertained whether either of the accelerometers under investigation could distinguish between these two postures themselves. Only fair to moderate agreement was found between the GENEActiv and activPAL for time spent in lying or sitting and standing. It could not be ascertained whether the GENEActiv itself was less accurate than the activPAL or whether its wrist placement was a confounding factor. A study has reported the thigh as the optimum placement site for detection of sedentary and standing static postures (Fortune et al. 2014). Another study suggested placement around the knee optimised detection of postural transitions due to the active involvement of this body part during activities of this type (Atallah et al. 2011).

Some studies were unable to distinguish between standing and walking using accelerometers (Pedersen et al. 2013; Kramer et al. 2013; Brown et al. 2008). Two studies distinguished standing from walking by setting thresholds for the standard deviations returned from accelerometry data, with wider values indicating more dynamic activities such as walking were taking place (Godfrey et al. 2010; Culhane et al. 2004). Both studies reported identical mean percentage agreements of 97% for recognition of dynamic activity (walking) when compared against their respective criterion measures (activPAL accelerometer and observation respectively). Whilst the Analogue device ADXL202 was used in one study, using the thigh and sternum combination (Culhane et al. 2004), a custom made, isolated thigh mounted model was investigated in the other (Godfrey et al. 2010). Evidence of the importance of identifying activities specifically involving walking is found in a study where older acutely admitted medical patients who increased their step count by ≥ 600 steps from the first to the second full day were discharged from hospital 1.7 days earlier than those who did not (Shadmi and Zisberg 2011).

Distinction between standing and walking is useful, indicating if patients are actually undertaking physical activity at regular intervals during the day. However, the accelerometer data required in order to make this distinction must be readily accessible for the busy clinician. If data analysis is required in order to calculate standard deviations from accelerometer derived activity counts to ascertain if a threshold has been reached to suggest dynamic activity is being undertaken, it is unlikely busy clinicians would have time during the day to undertake the task for all patients under their care. If data could be readily viewed upon accelerometer data download that immediately indicated that an individual had been walking, for example step count, this is likely to be a more viable and acceptable option. Therefore, the method advocated by both Godfrey at al. (2010) and Culhane et al. (2004) to distinguish standing from walking is unlikely to be acceptable or feasible within the everyday clinical setting due to the demands already on therapist time and limited resources.

Accelerometers possessing both a step count and inclinometer to measure body position such as the activPAL, GT3X and GT3X+ could possess the ability to distinguish between standing and walking within the hospital setting if found to be valid. Standing still would not be expected to generate a regular step count, whereas walking would do so. The ability to recognise body position would also permit identification of whether individuals were standing or adopting a sedentary posture. If a sedentary posture was identified at the same time step counts were registered, it may suggest patients' were making small positional changes whilst sitting in a chair or fidgeting. Recognition of a standing posture and a more regular step count for a period of time would suggest a walking activity was being undertaken. The reader is reminded of Table 1.1 on page 16 within section 1.9 of the introductory chapter where this method of discriminating between static postures and walking was first proposed.

2.4.2 Activity recognition

Data extraction revealed considerable variability in how accelerometers have been investigated in quantification of general activity in hospitalised populations (Choquette et al. 2008; Nagels et al. 2007; Winkelman et al. 2005; Bisgaard et al. 1999). This heterogeneity was described previously within section 2.3.2.3 on page 57. Three studies used wrist worn Motion Logger accelerometers (Nagels et al. 2007; Winkelman et al. 2005; Bisgaard et al. 1999). A variety of measurement modes inherent within these devices which capture activity intensity via numerical 'counts' were investigated. Essentially, activity is categorised as sedentary, light, moderate or vigorous according to the counts per minute (CPM) quantified by the accelerometers (Freedson et al. 1998).

Nagels et al. (2007) and Bisgaard et al. (1999) used direct observation and self-report respectively as criterion measures. The range of correlations reported by Bisgaard et al. (1999) for perceived exertion compared to accelerometer derived activity intensity were more diverse than the correlations reported by Nagels et al. (2007). An explanation for this may have been the different populations enrolled within each study and the actual choice of

criterion measure (direct observation by experienced nurses in the study by Nagels et al. (2007) and patient self-report in the study by Bisgaard et al. (1999). Nagels et al. (2007) investigated a population with dementia whilst Bisgaard et al. (1999) enrolled a population who had undergone major abdominal surgery. Greater diversity in correlations reported by Bisgaard et al. (1999) may have been due to the variability of participants self-perception of how intensive an activity was. Factors such as pain or the presence of intravenous infusions, drains and catheters may have been confounding factors, affecting how intensive a particular activity was perceived to be. Even standing from a chair may have been perceived as a difficult task had the presence of any of these factors been evident within the population investigated.

One study undertaken within the ICU investigated if specific activities (e.g. sitting over the side of the bed) could be identified from accelerometer intensity count alone (Winkelman et al. 2005). However, lack of opportunity for participants to undertake what were deemed higher intensity activities (e.g. getting out of bed or walking) meant determination of activity by intensity count alone was not possible. Activities such as moving from lying to sitting over the edge of the bed or sitting to standing are likely to be undertaken in different ways, depending on the level of physical assistance required at the time. This could produce considerable variation in the accelerometer activity intensity counts which are captured, especially in populations where a number of methods are employed to assist postural transitions and movement generally. Hence, quantification of activity in this way may not be consistent in these types of populations. Further investigation is required to support or refute this hypothesis, encompassing typical activities undertaken by acute or critically ill populations.

Combinations of placement sites (wrist, hip and ankle) appeared superior to an isolated site (hip) for recognition of time spent active during a therapy session (Choquette et al. 2008). Evidence for this is found within Table 2.5 on page 51, where correlations of 0.93 for accelerometers placed in combination and 0.79

for a hip placement alone (both $p \leq 0.001$) were reported when compared against direct observation. However, 95% LOA were wide for percentage differences in active time detected by accelerometry compared to observation. The worst results for accelerometers placed in isolation or combination in recognition of activity was during antalgic gait therapy. The ICC (95% CI) reported for this activity in particular suggested it could not easily be identified as time spent in activity (see Table 2.5, on page 51). This suggested that the ability to detect when an individual is active may depend on the activity being undertaken. This finding also supports the hypothesis in the previous paragraph regarding the potential inadequacies of identifying specific activity type using accelerometer activity intensity counts alone, especially in populations who undertake movements at slow speed and low intensity generally. Certain activities, for example transferring from a bed to a chair may yield a wide range of activity intensities depending on how they are completed, including whether they are undertaken with assistance or independently. Conversely, an activity intensity count may not be quantified at all during some postural transfers, possibly due to inappropriate choice of accelerometer placement site and the particular activity being performed (Fortune et al. 2014, Atallah et al. 2011). This aspect requires further consideration and exploration in future studies.

Data synthesis revealed that combinations of placement sites have been used both for recognition of general activity and in identification of body position and postural transitions. Here, it is appropriate to consider privacy, dignity, comfort and acceptability for hospitalised patients, especially if multiple placement sites are being used (Fortune et al. 2014; Atallah et al. 2011). This is also an important consideration if they are to be worn for prolonged periods throughout the whole day (Allen et al. 2006), especially if they may pose additional risks such as tissue viability concerns.

2.4.3 Measurement of step count

Three studies investigated the validity of quantification of step count using accelerometry within acute or critically ill hospitalised populations. All studies

used commercial models; the Actigraph GT3X+, Step Watch 3.0 (Webber and St John 2016), AMP 331 (Edbrooke et al. 2012) and the activPAL (Taraldsen et al. 2011). Only one study stated an intention to evaluate both validity and reliability (Edbrooke et al. 2012). A systematic review and meta-analysis determined usual walking speed to be 0.46m/s in acute care settings for hospitalised adults ≥ 70 years of age (Peel et al. 2013). Using this as a standard reflecting typical gait speed of acutely admitted older populations, both studies which enrolled older populations (≥ 70 years of age) achieved this (Webber and St John 2016; Taraldsen et al. 2011). The external validity of the findings of these particular studies was enhanced as a result.

The study which investigated the AMP 331 accelerometer enrolled a population recovering from critical illness, with a mean age of 62.1 years (SD 14.1 years) (Edbrooke et al. 2012). Mean gait speed of participants was not reported in this study. It cannot be assumed that the 0.46m/s walking speed reported for older acutely admitted patients by Peel at al. (2013) is reflective of other hospitalised populations. This includes those recovering from critical illness, although slow walking speeds are likely to be encountered during early stages of recovery. Information on preferred gait speeds for certain populations and valid methods to determine this provides useful guidance for construction of future methodological protocols investigating the validity and reliability of accelerometers (Graham et al. 2008). This is especially true for laboratory based investigations when certain walking speeds must be achieved in order to simulate specific populations, enhancing the external validity of their findings.

A single thigh mounted activPAL was not found to be valid at speeds of ≤ 0.47m/s. (Taraldsen et al. 2011). Less error in step count was present when it was worn on the unaffected leg in populations experiencing acute stroke. Webber and St John (2016) determined that both an ankle mounted Actigraph GT3X+ (with its Low Frequency Extension (LFE) data filter initialised) and Step Watch 3.0 accelerometer also positioned on the ankle were both valid within older hospitalised populations. The LFE increases the sensitivity of the GT3X+ to capture low intensity movement (Cain et al. 2013); evidenced in the study

results both for isolated ankle and hip placements of the GT3X+ (Table 2.5). The ankle placement was superior to the hip when the LFE was activated, evidenced by a higher ICC value and considerably smaller 95% CI. The study by Edbrooke et al. (2012) also determined the ankle mounted AMP 331 accelerometer was valid in step count quantification in a population recovering from critical illness. Synthesis of the findings of Webber and St John (2016), Edbrooke et al. (2012) and Taraldsen et al. (2011) suggested that an ankle placement appears to be the optimum placement site for quantification of step count in hospitalised populations who walk at slow speeds.

2.4.4 Reliability of accelerometry measurement

Although all studies investigated validity, only one study specifically stated an intention to investigate accelerometer reliability, using the AMP331 ankle mounted model to quantify step count in survivors of critical illness (Edbrooke et al. 2012). Methods of investigating accelerometer reliability should be incorporated into future methodological protocols as part of the investigation of the validity of accelerometry measurement. This could be within a simulated environment; ensuring typical activities are included within movement protocols that are likely to be undertaken by the target patient population.

2.5 Potential future uses for accelerometry in the hospital setting

Objective methods of activity monitoring could be used to identify hospitalised patients who although functionally able, may have poor activity levels. This will assist in the appropriate allocation of rehabilitation resources, targeting those who need more encouragement and support to mobilise and undertake regular periods of activity. Clinicians may wish to share aspects of the data collected during the day with patients under their care to encourage and motivate. Achievable goals could be agreed between therapist and patient to reach certain step counts during the course of a day, assisting in promoting physical activity. This would respond positively to recommendations by NICE regarding encouragement and enablement of physical activity within all NHS institutions

(NICE 2014). Accelerometer based technology is being developed which can be programmed onto smartphones, providing direct feedback on activity levels in older people (Vankipuram et al. 2012). Researchers may wish to use accelerometers in outcome measurement for interventional or observational studies. Accelerometer models that have undergone validity or reliability investigation within the parameters and patient populations they wish to investigate will strengthen the methodological quality of future studies.

Assimilating evidence of the extent of validity and reliability investigation undertaken using both commercial and custom made accelerometers within the chosen populations will assist in making informed choices regarding selection of the most appropriate model. This will be dependent on the aspect of purposeful activity required to be quantified, which could be identification of body position, step count or general activity. Presentation of evidence in this systematic review will assist the reader to understand which models have demonstrated validity within each context. This format is considered another of its strengths and highlights the strong clinical focus of this PhD thesis. Accelerometer choice depends on the postures or activities to be quantified and the measurement modes inherent within different accelerometer models.

Commercial accelerometers are likely to be more easily accessible than custom made designs for the clinician wishing to quantify patient activity. They can be easily purchased on line with instructions for their use. Accelerometer placement sites also require consideration depending on the patient population as some placement sites may not be considered appropriate. A variety of placement sites have been used in studies within this systematic review, both in isolation and combination, depending on the type of purposeful activity under investigation. It is envisaged this will also prove useful for the reader and is, therefore, considered a further strength of the systematic review.

Previous systematic reviews have explored accelerometry use within the ICU, older people and following stroke (McCullagh et al. 2016; Verceles and Hager 2015; Taraldsen et al. 2012; Cheung et al. 2011; Gebruers et al. 2010). The

ability of the Actigraph GT3X+ to determine step count in older populations was questioned by McCullagh et al. (2016). The authors reviewed the accuracy of different types of motion sensors, including accelerometers in older, frail hospitalised patients. Data on the GT3X+ was synthesized from studies which enrolled community based populations which positioned this model at the hip (Webber et al. 2014; Barreira et al. 2013; Storti et al. 2008). A more recent study moved the placement of the GT3X+ to the lateral side of the ankle, enrolling a hospitalised older population who undertook a hallway walk (Webber and St John 2016). This device was determined to be valid in determination of step count within this population in this study, highlighting the importance of consideration of placement site when investigating the validity of accelerometry, depending on the aspect of purposeful activity desired to be quantified.

The systematic review presented in this chapter is the first to focus on the validity and reliability of accelerometry to identify body position and quantify purposeful activity within a variety of adult hospitalised populations likely to experience marked functional loss. It will assist the reader in understanding the measurement modes inherent within certain commercial models and the validity and reliability demonstrated so far within the chosen populations. It will also enable informed decisions to be made regarding accelerometer choice and placement, dependent on the aspect of activity required to be quantified.

2.6 Limitations of the systematic review

Several limitations of this systematic review exist. Small sample sizes in some studies limit generalisability or the external validity of the findings to larger, similar populations (Pedersen et al. 2013; Choquette et al. 2008; Harris et al. 2006; Culhane et al. 2004). A number of studies scored poorly on methodological quality assessment, which may have negatively impacted on the internal validity of some of the systematic review findings. One study which scored three recruited the smallest sample size of five patients (Choquette et al. 2008). Participants had a wide variety of admission diagnoses, including stroke, lower limb fracture, amputation and ‘immobilisation syndrome’, leading

to a heterogeneous sample with a diverse selection of movement impairment. Furthermore, this heterogeneity led to some categories of activities not able to be performed due to participants not being able to physically complete them, for example stair climbing. One of the sets of participant data in the study by Choquette et al. (2008) was eventually unable to be analysed due to a software malfunction, further decreasing the sample size.

Another study which scored four did not take into consideration that the different placement sites for the interventional GENEactiv accelerometer and its activPAL comparator (wrist and thigh respectively) may have accounted for the significant differences in sitting time calculated between the two models (Rowlands et al. 2014). Other studies included within the systematic review provided evidence that accelerometers placed at different body placement sites (ankle and the hip, worn around the waist) yield different results when measuring the same aspect of activity (Webber and St John 2016). None of the 15 studies identified following the literature searching process were excluded due to scoring low values for methodological quality. The total numbers of articles identified as eligible was relatively small. Data synthesis was undertaken using the findings from all 15 studies in order to understand the extent of investigation that has been undertaken to investigate accelerometry validity within the selected hospitalised populations.

Only three studies investigated similar models by the same manufacturer (Nagels et al. 2007; Winkelman et al. 2005; Bisgaard et al. 1999). Heterogeneity between all 15 studies in terms of activities undertaken, epoch lengths, measurement modes, accelerometer models investigated and data analysis methods resulted in a limited number of studies measuring the same aspect of purposeful movement. This meant that difficulty was encountered comparing studies against each other to determine if there were similarities or differences between them.

Only papers which explicitly stated within their title or abstract an intention to investigate the validity or reliability of accelerometry measurement within acute

or critically ill hospitalised populations progressed to the second stage of review. Adopting this methodology may have caused some aspects of validity investigation which only lay within the main text of some papers to be missed. This may have led to loss of data which would have borne relevance to the systematic review aims. Also, only studies enrolling hospitalised populations were eligible for inclusion. Other systematic reviews which have investigated the validity of accelerometry within older people included both hospitalised patients and community dwelling populations (McCullagh et al. 2016). The widening of inclusion criteria to include both community and hospitalised populations for the systematic review presented within this chapter may have provided further relevant data which could have been synthesised.

Studies undertaken within patients experiencing critical illness have thus far only been undertaken within the ICU (Edbrooke et al. 2012; Winkelman et al. 2005). The systematic review did not identify any studies where the validity of accelerometry measurement was undertaken within patients recovering from critical illness who were resident on a hospital ward following discharge from the ICU. This presents perfect opportunity however for further research in this area and identification of this gap in the research evidence base is thus considered a further strength of this systematic review. The reliability of accelerometry measurement within acute and critically ill populations has received little attention and is considered a limitation of this review. Insufficient data on this aspect meant that the reliability of accelerometry measurement could not be fully determined for all the aspects of purposeful activity described.

2.7 Conclusion

A number of accelerometer models have undergone investigation of validity or reliability within a variety of hospitalised acute and critical care populations. The majority of research has been undertaken within acutely admitted older people (≥ 65 years of age) with limited evidence of other populations having been investigated. Methodological quality of studies that have investigated accelerometry validity within the selected populations was variable, with a number of studies that were determined to be of poor quality, with some

scoring ≤ 4 out of 11 (Godfrey et al. (2010); Choquette et al. (2008) and Nagels et al. (2007). However, a number of studies scored well (≥ 8 out of 11), including those investigating step count, body position or postural transition (Webber and St John (2016); Raymond et al. (2015); Brown et al. (2008); Pedersen et al. (2013) and Culhane et al. (2004). Evidence of these findings is found in Table 2.4 on page 44.

A variety of accelerometer models, both commercial and custom made in design have demonstrated validity in determination of identification of body position or postural transition (Pedersen et al. (2013); Taraldsen et al. (2011); Godfrey et al. (2010); Brown et al. (2008), Culhane et al. (2004). Individual results depend on the model undergoing investigation, emphasising the importance of undertaking investigation of validity on a model by model basis. Excellent correlations or almost perfect agreement compared to their respective criterion measures has been demonstrated for some models either using inclinometer measurement modes or by the setting of accelerometer derived activity intensity threshold. These include the uniaxial activPAL (Taraldsen et al. (2011), AugmenTech models (Pedersen et al. (2013); Brown et al. (2008) and the Analogue Devices ADXL202 (Culhane et al. (2004). Other custom made models have also demonstrated similar results (Godfrey et al. (2010).

Combinations of body placement sites, especially the thigh and ankle or thigh and sternum permit identification of lying, sitting and standing postures (Pedersen et al. (2013); Taraldsen et al. (2011); Skipworth et al. (2011); Brown et al. (2008), Culhane et al (2004). A sternum and thigh combination permits differentiation between lying and sitting when using the uniaxial activPAL, which a single isolated thigh placement of the same model cannot achieve (Skipworth et al. (2011); Taraldsen et al. (2011). Combinations of placement sites have also demonstrated superiority to a single placement site in determination of general rest and activity patterns (Choquette et al. (2008). Consideration must be given to patient comfort should multiple accelerometers be used to identify body position or activity in general. They must be acceptable

to the populations to maximise compliance with wearing them (Fortune et al. 2014; Atallah et al. 2011).

The single placement site of the ankle for the AMP 331, Actigraph GT3X+ and Step Watch 3.0 commercial models demonstrated validity for determination of step count in hospitalised populations likely to walk at slow speeds (Webber and St John (2016); Edbrooke et al. (2012). The AMP 331 was also deemed to be reliable. A single thigh placement of the activPAL accelerometer produced a high percentage error with walking speeds of less than 0.47m/s (Taraldsen et al. (2011). Placement on a non-affected limb appeared to improve the accuracy of step count quantification in this model and is a useful consideration generally in populations who have suffered acute stroke or hip fracture (Taraldsen et al. (2011).

The validity of accelerometer derived activity intensity count to determine particular activities undertaken by the selected populations requires further exploration. Presently there is insufficient evidence to support the use of these measurement modes alone to determine particular types of functional movement undertaken (Winkelman et al. (2005). Also, evidence suggests not all typical activities undertaken by populations who are weakened as a result of illness may be able to be quantified by activity intensity count alone (Choquette et al. (2008).

Future research should focus on investigation of the validity of accelerometry measurement beyond the ICU in critical care populations. Placement site is an important area to consider in future methodological protocols. The same accelerometer model may deliver different results in quantification of a particular aspect of purposeful activity when positioned at different body sites (Webber and St John 2016). Consideration should also be given to determination of appropriate sample sizes when investigating the validity of accelerometry in order to ensure a representative sample of a particular population is undergoing investigation. This will enhance the generalisability and external validity of the findings generated.

Construction of future methodological protocols investigating the validity of accelerometry measurement in hospitalised populations should give consideration to the choice of an appropriate criterion measure. Consideration of possible confounding factors which may be specific to a certain population may assist in the choice of which criterion measure to use. Any criterion measure must be acceptable to those who kindly consent to participation in studies of this type. Furthermore, the criterion measure must also have demonstrated validity within the aspect of purposeful activity being investigated within the context of the study. Relevant citations related to demonstration of the evidence of validity must be included within publications.

Research in naturalistic settings is encouraged, permitting evaluation of whether accelerometers can identify all typical postures adopted by acutely unwell or critically ill populations during their recovery. If undertaken within a more laboratory type setting, the activities undertaken must be accurately simulated, including typical walking speeds. Privacy, dignity and acceptability of the devices undergoing investigation are also of paramount importance. Future studies should aim to incorporate methods of analysis to evaluate the reliability of accelerometry measurement within these settings.

Chapter 3

Feasibility study

3.1 Introduction

The preceding chapter synthesised data from studies investigating the validity or reliability of a number of accelerometer models used to quantify purposeful activity within acute or critically ill hospitalised adult populations. Populations included acutely admitted older people (including those who had experienced a stroke), those recovering from critical illness, major abdominal surgery and acute exacerbations of chronic respiratory disease (COPD). These populations are likely to experience variable degrees of functional impairment (Torres-Sanchez et al. 2017; McWilliams et al. 2015; Graf, 2006). The activities undertaken are likely to be of low intensity, with slow walking speeds, where a typical example for acutely admitted populations over the age of 70 was determined to be 0.46m/s (Peel et al. 2013).

Investigation of accelerometer validity should be on a model by model basis. Accelerometer models produced by different manufacturers do not quantify purposeful activity in an identical manner when compared with each other. Placement site, may have also accounted for the differences in quantification of time spent in sedentary positions (lying or sitting) and standing between the wrist mounted GENEActiv and thigh mounted activPAL in patients admitted following an acute exacerbation of COPD (Rowlands et al. 2014). The thigh has been reported as the optimal placement site for identification of static and dynamic movement, with misclassification errors of 10% using a custom built tri-axial model in healthy subjects (Fortune et al. 2014). This laboratory based experiment compared accelerometers positioned on the ankle, thigh and waist. A wrist placement was not investigated hence it could not be determined how it may have performed when compared against the lower limb placement sites described.

The activPAL has been deemed valid in determination of time spent in sedentary postures and standing within hospitalised older populations (Taraldsen et al. 2011) and more recently in rheumatology outpatients (Larkin et al. 2016). These sources of evidence lend support for the activPAL to be used as a criterion measure in quantification of this specific aspect of purposeful activity in these populations. However, both studies found the activPAL was not valid in determination of step count within these patient groups. Larkin et al. (2016) also deemed it not valid in estimation of postural transition count. Future studies investigating accelerometer validity within clinical populations must be aware of the aspects of purposeful activity that the activPAL has demonstrated evidence of its validity if wishing to use it as a criterion measure. Knowledge of aspects of purposeful activity where it has not demonstrated validity is equally as important. Using a criterion measure that has not been found to be valid within a certain aspect of measurement questions the credibility of any findings.

The systematic review did not identify any studies where the validity of accelerometry measurement was undertaken within patients recovering from critical illness who were resident on a hospital ward following discharge from the ICU. As a consequence, a gap in the evidence base was identified. This knowledge assisted in the construction of further methodological protocols and the patient focus for subsequent studies which follow in this thesis. Despite no evidence of investigation of their validity in the ward environment in those recovering from critical illness, accelerometers have been used to directly quantify activity in this setting (Borges et al. 2015). A different model was also used to quantify activity within patients' resident within the ICU without evidence of undergoing investigation of its validity in this setting (Schujmann et al. 2015a; Schujmann et al. 2015b). The model used was the Actigraph GT3X. Therefore, a need arises to commence investigation of the validity of the GT3X within this population, which became the primary aim of this PhD. Access to this model was made possible via a loan from a University supply. Both evidence of commencement of its use within the critical care setting and its ease of availability provided justification for the choice of accelerometer model to commence investigation of its validity.

The systematic review presented in Chapter 2 (commencing on page 23) assisted in the formulation of a methodological protocol for a feasibility study, seeking to explore how the GT3X interpreted different postures and activity. This initial empirical study commenced the process of investigation of the validity of the Actigraph GT3X during typical activities likely to be undertaken by patients recovering from critical illness. Knowledge gained concerning the methodology of how previous validity studies had been conducted including the choice of criterion measure, reasons for participant withdrawal and methods of data analysis served as a major resource in the development and completion of the study which is presented in this chapter.

Actigraph accelerometers have been widely used for research investigating physical activity (Bassett and John 2010). Continued interest in Actigraph models, in particular the GT3X is demonstrated directly within those recovering from critical illness (Schujmann et al. 2015a; Schujmann et al. 2015b). A further study was identified on a clinical trials databases where a similar model, the GT3X+ was to undergo feasibility and validity investigation within the ICU (ClinicalTrials.gov identifier: NCT02263716). Both of these models possess an inclinometer, which identifies body position (lying, sitting or standing), permitting the potential to identify adoption of specific postures and postural transitions between them. Other measurement modes include activity intensity count, measured using up to three axes termed ‘x’, ‘y’ and ‘z’, which measure vertical, mediolateral and anteroposterior accelerations respectively. Both Actigraph models can also quantify step count. This particular combination of measurement modes has the potential to quantify all typical activities undertaken by populations recovering from critical illness. The heuristic model presented in Figure 1.1 on page 15 in the introductory chapter highlighted how this may be achieved.

3.2 Background and rationale

Two studies have investigated the validity of data captured by different accelerometer models within hospitalised populations recovering from critical illness (Edbrooke et al. 2012; Winkelman et al. 2005). Winkelman et al. (2005)

went on to use the same Motion Logger model in a further study, capturing data on purposeful activity within medical and surgical populations resident in the ICU and a medical step down facility (Winkelman et al. 2007). A later study by the same author enrolled patients admitted to ICU following an acute exacerbation of Chronic Obstructive Pulmonary Disease (COPD) (Winkelman 2010). A different accelerometer model was used in this study (MiniMitter Actical). Both of these later studies did not continue investigation of the validity of either the Motion Logger (Winkelman et al. 2007) or the MiniMitter Actical (Winkelman 2010). Both studies examined relationships between activity and serum levels of inflammatory biomarkers.

Multiaxial accelerometers have been used to objectively quantify the physical activity undertaken by critical illness survivors in the final two full days on a hospital ward prior to discharge (Borges et al. 2015). Patients were found to spend a mean (SD) of 90% (± 34%) of their day in lying or sitting positions. The Dynaport Minimod accelerometer (McRoberts, Netherlands) used in this study, mounted posteriorly on the lumbar spine had not been validated within a population recovering from critical illness. Investigation of its validity had been undertaken in other populations including those with COPD, Parkinson's disease and community based older populations (Dijkstra et al. 2010a; Dijkstra et al. 2010b; Langer et al. 2009). Other studies investigating activity levels within ICU and ward settings have used observational techniques and reviews of medical, nursing and mobility data (Connolly et al. 2017; Berney et al., 2015; Hopkins et al., 2012). These studies concurred with the findings of Borges et al. (2015) related to detection of low activity levels within this population during hospitalisation. The range of studies covered the rehabilitation continuum from ICU through to the ward. This suggested the data captured by the accelerometer model used by Borges et al. (2015) was concurring with the findings from other studies which had used other methods to quantify activity levels.

This evidence of persistent inactivity whilst recovering in hospital from critical illness is worrying, especially when other evidence reports continued functional

limitation and negative health related quality of life in ICU survivors up to five years following hospital discharge (Herridge et al. 2011; van der Schaaf et al. 2009; Cheung et al. 2006). Moreover, it supports the need for the investigation of more objective methods of monitoring the regularity of purposeful activity undertaken, given the possible weaknesses of other methods within this population discussed in section 1.5.1 and 1.5.2 on pages 7 and 8 of the introductory chapter. Closer monitoring of activity whilst in hospital will assist in identifying prolonged periods of sedentary behaviour adopted by individuals. This will assist clinicians in optimising allocation of resources to those who require the necessary encouragement and assistance to increase the frequency of volitional activity.

The AMP 331 accelerometer, determined to be valid in quantification of step count in a hospitalised population recovering from critical illness, went on to be used to quantify physical activity in a critical care population following discharge from hospital (Denehy et al. 2012). This prospective observational study used the accelerometers to measure free-living physical activity levels and to correlate accelerometry measurements with scores calculated on the standardised Physical Activity Scale for the Elderly (PASE) questionnaire (Washburn and Ficker 1999). This tool was originally developed to evaluate lifestyle physical activity in older people over a seven day period, demonstrating moderate correlations (British Medical Journal 2017) of r = .43 ($p < 0.01$) with accelerometer quantified activity within a healthy elderly population (Dinger et al. 2004). This tool had not undergone investigation of its validity directly within a population of survivors of critical illness. Denehy et al. (2012) reported a fair correlation (British Medical Journal 2017) between the questionnaire and the average number of steps recorded per day (r = 0.33, p = 0.05) and average distance walked per day (r = 0.31, p = 0.05).

The fair correlation (British Medical Journal 2017) between step count and the questionnaire in the study by Denehy et al. (2012) may have been as a result of poor estimation of self-reported activity levels (Cheung et al. 2011; Sager et al. 1992). Persistent cognitive impairment, often present within this population may

also have affected the ability to recall and document the quantity of physical activity undertaken (Pandharipande et al. 2013). The findings continued to reveal persistent inactivity (90% of the day), with only 3% of time spent walking at two months following discharge from the hospital setting. This was not dissimilar to the findings of Borges et al. (2015) of persistent inactivity reported in the final few days of hospital stay. Therefore, these findings suggest that there is minimal progression of activity at two months compared to levels reported in the final days of hospital stay for those recovering from critical illness.

Studies which have investigated the validity of accelerometers to quantify purposeful activity within populations recovering from critical illness have so far taken place within the ICU (Edbrooke et al. 2012; Winkelman et al. 2005). Whether an accelerometer possesses the ability to capture the type, pattern and quantity of all activity typically undertaken throughout the entire inpatient rehabilitation continuum in this population remains unexplored. It is important that any investigation of validity of a particular model incorporates all typical activities encountered, as evidence suggests that the accuracy of accelerometry measurement appears to be dependent on the tasks being analysed and where the sensors are applied (Cuesta-Vargas et al. 2010).

Models possessing the ability to detect both body position and step count would enable differentiation between standing and walking. The Actigraph GT3X accelerometer possesses the ability to detect body position (via its inclinometer) and to quantify step count, enabling the potential to differentiate between standing and walking, should it demonstrate validity within this setting. An ankle mounted Actigraph GT3X+ accelerometer was valid in quantification of step count in hospitalised older populations, with an ICC (95% CI) of 0.938 (0.870, 0.969) (Webber and St John, 2016). This provides justification for further investigation of Actigraph models within other populations likely to walk at slow speeds to see if similar results are evidenced. Another study questioned the validity of the step count measurement mode in those with mobility impairment, when investigating the Actigraph GT3X (O'Neil et al.

2014). O'Neil at al. (2014) investigated a small sample of a paediatric population with cerebral palsy, using the GT3X (*n* = 8). The GT3X was worn around the waist above the hip (the manufacturers recommended position), not around the ankle. Hence, body placement site and differences between the populations enrolled may have accounted for differences in the findings between the two studies.

The inclinometer (body position) function of the Actigraph GT3X has demonstrated misclassification of body position when worn above the hip, correctly identifying only 33.9% of body positions adopted during a movement protocol (Berendsen et al. 2014). It was important therefore to assess the validity of the GT3X using a movement protocol that included typical activities likely to be undertaken by patients in hospital recovering from critical illness to understand how this device performed during these movement conditions. The manufacturers recommended position (above the hip) and a placement site already employed in a previous study to identify body position within a population recovering from critical illness (the lateral aspect of the ankle), were investigated (Schujmann et al. 2015a; Schujmann et al. 2015b).

The measurement modes of step count, activity intensity and body position (inclinometer) can all be programmed simultaneously onto the Actigraph GT3X to capture data. Development of the heuristic model (Figure 1.1, found on page 15 of the introductory chapter) permitted a deeper understanding of which combination of measurement modes could potentially identify all activities typically undertaken by patients recovering in hospital from critical illness. This would include postural transitions from lying to sitting over the side of the bed, sitting to standing from a bed or chair and their reverse movements. Walking short distances in the early stages of recovery would also be undertaken (Hodgson et al. 2015; McWilliams et al. 2015; Berney et al. 2013). These activities may initially require considerable physical assistance over short distance (e.g. 10 metres), progressing to independent movement as functional ability improved. Synthesis of evidence from the systematic review and data

gathering from subsequent literature searches resulted in the formulation of a methodological protocol for a feasibility study which is now reported.

3.3 Purpose of the feasibility study

The purpose of the feasibility study was to investigate whether the Actigraph GT3X accelerometer possessed the potential to identify and quantify body position, postural transition and step count (walking) during activities typically undertaken by patients continuing their recovery from critical illness in a ward setting. The introductory chapter emphasised that assessment of reliability should form part of validity assessment (Sullivan 2011). The data yielded from accelerometers should be consistent when movements are repeated in a similar manner, providing evidence of reliability (Berchtold 2016; Stolarova et al. 2014). Therefore, assessment of reliability would rely on patients being willing and physically able to repeat a particular aspect of purposeful activity in an identical manner as possible in order to obtain two sets of data which can be compared for consistency. This is often described as a 'test-retest' study design (Berchtold 2016; Stolarova et al. 2014; Sullivan 2011).

The introductory chapter (Chapter 1) and systematic review in Chapter 2 highlighted that undertaking assessment of accelerometer reliability within a population recovering from critical illness is not without difficulty. An example of this was demonstrated in the study by Edbrooke et al. (2012), who investigated the validity of a commercial accelerometer to quantify step count. A refusal of a participant to repeat a walk of known distance led to loss of data which required them to be withdrawn from an accelerometer reliability analyses. Synthesis of this information following data extraction during the systematic review permitted the opportunity to consider how this potential threat to loss of data could be avoided.

To maximise the possibility of participants being willing to repeatedly undertake specific tasks the decision was made to invite healthy adults. Instruction was given immediately prior to data collection concerning how to simulate someone

weakened as a result of critical illness that may or may not require assistance in order to perform a particular purposeful movement. This included transferring over the side of the bed, rising from sitting or walking a short distance. The level of active participation requested from subjects for the assisted movements was 50%, with the remaining 50% assistance provided by two physiotherapists. Independent postural transfers were requested to be undertaken at a slower pace than they may usually do so, but no restriction was placed regarding how they performed them. Participants were also instructed on the use of walking aids, including a wheeled zimmer walking frame (WZWF) or a walking stick (WS). Further detail regarding instruction, training and the movements undertaken is found in section 3.8.1 on page 108. The methodological approach of simulation was successfully employed in another study investigating the validity of accelerometry for detection of typical behavioural states in patients resident in the ICU (calm, restless and agitated) (Grap et al. 2011). Healthy adults with a mean age of 34.7 (SD 14.1) received training in how to simulate all three of these behavioural states on a single training session prior to data collection. Grap et al. (2011) reported that 'each behavioural state was described to the participant and demonstrated by a study member'. A calm state was classed as a state when 'one was resting comfortably or sleeping well (less than 10 movements a minute). A restless state was described as 'some, but not excessive movement, such as that experienced during a restless nights sleep (approximately 10 to 20 movements a minute). An agitated state was described as 'a condition of almost continuous or extreme intermittent movement (greater than 20 movements per minute)'. Each state was simulated for ten minutes directly following the period of instruction and demonstration.

Healthy participants were recruited for the feasibility study in order to develop an understanding of whether there was a superior isolated accelerometer placement site which could identify body position, postural transition and walking using the combination of measurement modes inherent within the Actigraph GT3X. Data synthesised from the systematic review and the feasibility study was to be used to develop the methodology for a further study, where the Actigraph GT3X would be trialled within a population of ward based

patients recovering from critical illness. As a result the feasibility study functioned as a precursor to inform another study which is presented in the next chapter of this thesis.

The systematic review determined that ankle mounted accelerometers demonstrated validity in quantification of step count in hospitalised populations (Webber and St John 2016; Edbrooke et al. 2012) One of these studies investigated the Actigraph GT3X+ (Webber and St John 2016). The GT3X model itself was mounted on the ankle in both studies by Schujmann et al. (2015a and 2015b), which were undertaken within the ICU. No evidence of determination of its validity in identification of body position or activity intensity when worn in isolation on the ankle within this population was identified. It was important, therefore, to commence the process of investigation of its validity using this placement site. The second placement choice was around the waist, resting above the hip. This placement site is recommended by the manufacturers in order to quantify activity intensity, record step count or identify body position via the inclinometer measurement mode inherent within its design (Actigraph Engineering/ Marketing 2009).

3.4 Study Objectives

1. To determine the criterion validity of the Actigraph GT3X accelerometer in recognition of body position (lying, sitting or standing) during the postural transitions of lying to sitting, sitting to standing and vice versa under two different movement conditions (independent and physically assisted movement).
2. To discover if there was a superior body placement site that a single accelerometer may be positioned. The two sites were the hip (the manufacturers recommended placement site) and the lateral aspect of the ankle. Both devices were positioned on the left.
3. To assess the mean difference and 95% LOA between a step count recorded by the GT3X at the hip or ankle in isolation and observational

step count recorded by video camera when walking two ten-metre distances, first with a WZWF, then a walking stick WS.

4. To evaluate the test - retest reliability of the step count measurement mode of the Actigraph GT3X when worn at the left ankle or left hip, when two ten metre walks are undertaken within two minutes of each other, firstly with a WZWF and then a WS.

5. To explore the reproducibility of activity intensity (vector magnitude) during the postural transitions of lying to sitting, sitting to standing and the reverse of these transitions.

6. To assess the comfort of the accelerometer at the two placement sites from a user perspective.

The left side was chosen to place both accelerometers as it enabled the possibility of continuously visualising the flashing light present on these models to demonstrate they were actively collecting data, particularly during parts of the movement protocol that were performed on the hospital bed due to the position of the video camera (see Figure 3.3 on page 108).

3.5 Hypotheses

1. The waist accelerometer placement site (manufacturers recommended position) would be liable to misinterpretation of body position (lying, sitting or standing) during typical activities undertaken by patients recovering from critical illness due to the adoption of possible unconventional postures.

2. The ankle placement site would be superior to the waist in quantification of step count when participants undertook ten metre walks with either a wheeled zimmer walking frame (WZWF) or walking stick (WS) at slow walking speeds using observation as a criterion measure.

3. Very strong correlations of 0.8-1.0 (as defined by the British Medical Journal 2017) would be calculated for test-retest reliability for the step count mode for both the ankle and hip mounted accelerometers, regardless of walking aid used.

4. Both placement sites would be well tolerated by participants, based on a response of ‘very comfortable’ or ‘somewhat comfortable’ from a self-report scale of accelerometer comfort completed by participants following their removal.

3.6 Materials and Methods

3.6.1 Study design and setting

The study was observational, prospective and exploratory in design and was undertaken on a hospital ward based at Castle Hill Hospital, East Yorkshire. This site formed part of Hull and East Yorkshire Hospitals NHS Trust (HEYHT). Permission was granted from HEYHT to use the ward for the purposes of data collection as it was not currently accepting patients. Participants were required to attend for a single session in order to undertake data collection. The first participant attended on the 26th November 2014. Data collection was completed on January 27th 2015.

3.6.2 Participants

Healthy adult participants were recruited following advertisement using flyers containing brief study details and contact information of the Chief Investigator (CI) to obtain further information. Flyers were disseminated across both main Hospital Trust sites (Castle Hill Hospital and Hull Royal Infirmary) to departments and wards for placement on staff room noticeboards, inviting hospital employees to participate (see Appendix B1, page 262). A poster was accepted for display at the HEYHT Innovation Day to assist in raising the profile of the study and to seek recruitment of participants (see Appendix B2, page 263). This event was attended by hospital employees and members of the public. Information sheets and separate consent forms were available to take away from this event by those demonstrating interest in participating (Appendix B3 and B4, pages 264 and 266). The CI was not present at the stand, receiving support from a clinical colleague informed of the study’s objectives and able to answer any questions. This process limited contact of the CI with potential participants to decrease the risk of possible coercion into participation.

The CI responded to any questions arising from initial enquiries and detailed the expected level of physical capability necessary for participation. Those who made contact following reading the flyers on staff room noticeboards were provided with an information sheet and a separate consent form upon request. Participants comprised hospital employees and members of the public who were willing to undertake travel to the hospital at their own expense as the study received no funding. This was made explicit as part of the informed consent process and detailed within the patient information sheet. Demographic information was collected including gender, age, height and weight in order to calculate Body Mass Index (BMI). The demographic data collection form used can be found in Appendix B5 on page 268.

Participants wore comfortable clothing, with their shoes (but not socks) removed for all aspects of the protocol. They were supervised throughout the entirety of the data collection period to ensure safety was maintained at all times. There were no incidences of slips, trips or falls during any of the movement protocols undertaken by the participants.

3.6.3 Sample size

A recruitment target of 30 participants was set, based on assumptions of the central limit theorem (CLT), proposing that a dataset of thirty is required to establish a normal distribution of a population under investigation, where sample size calculations are not available (Trapp and Dawson 2004).

3.6.4 Inclusion and exclusion criteria

Table 3.1, found on page 98 details the inclusion criteria for participation in the study and their rationale. Consideration was given to each of the inclusion criteria in relation to the eventual aim of undertaking research using the accelerometers within a population of patients recovering from critical illness. Participants were excluded if consent could not be obtained to undertake video recording of movement protocols. Individuals who suffered from significant neurological or coordination impairment which made independent movement

difficult were also excluded. A final exclusion criterion was the inability to speak English. This study received no funding and it would not have been possible to finance interpreter services for those unable to converse in English.

Table 3.1 Inclusion criteria

Inclusion Criteria	Rationale
Over 18 years of age, ideally above the age of 55.	Plan for a future study to focus on an adult inpatient population. Recruitment above age 55 would assist in age matching a healthy adult sample to patients admitted locally onto the ICUs within HEYHT throughout 2012
Able to independently perform and repeat the movements of lying to sitting/ sitting to lying, sitting to standing / standing to sitting and walk a total of 40 metres (four x ten - metre distances).	All movements required for completion of the movement protocol, simulating those undertaken by patients recovering from critical illness. Repeated movements were necessary to investigate the reliability of physical activity intensity measurement.
Willing to undergo instruction on how to simulate a patient 'weakened' by critical illness; accepting physical assistance from two physiotherapists' for parts of the movement protocol undertaken on a hospital bed.	Simulation of what would occur within a patient population recovering from critical illness during a typical day.
Willing to permit application of two Actigraph GT3X accelerometer devices, resting just above the left hip and around the left ankle, positioned slightly above the lateral malleolus.	The accelerometers were the devices under investigation.
Willing to consent to the use of video recording, capturing the movement sequences undertaken for observational analysis.	Video recordings (observation) were the criterion measure with which the accelerometers were being compared against

A request was made to the Intensive Care National Audit and Research Centre (ICNARC) to calculate the mean (SD) age of patients admitted onto the intensive care units at HEYHT during 2012. This was determined to be 64.6 years (SD 15.9). These data derive from the Case Mix Programme Database, which is the national, comparative audit of patient outcomes from adult critical

care coordinated by ICNARC. Mean age was similar to that reported by Edbrooke et al. (2012), whose participants (resident in an ICU) had a mean age of 62.1 years (SD 14.1). The feasibility study aimed to age match a healthy population with those admitted onto local ICUs. Age matching participants would assist in controlling for any possible differences in movement patterns during independent postural transfers which have been reported in populations in different decades of age (Mount et al. 2006; Ford-Smith and VanSant 1993).

3.6.5 Ethical approval

Ethical approval was obtained from the YSJU Research Ethics committee (REF: UC/25/2/14/JA) and the NHS Research Ethics Committee (REF: 14/NI/1023). Copies of these communications are located in Appendix B6 and B7 respectively (pages 269 and 270). A minor amendment related to a change of location for the study, although still based within HEYHT was considered, approved and acknowledged by the NHS Research Ethics Committee (Appendix B8 on page 274). The study was deemed appropriate for proportionate review by the NHS Research Ethics Committee. Participants were non-hospitalised, healthy and there were no risks anticipated from undertaking the movement protocol. Participants were free to withdraw from the study at any point, without the requirement for an explanation of their reasons for doing so. Any future health care participants may have required in the future from HEYHT would not have been compromised as a result of a decision to withdraw from the study. All accelerometer data and video recordings were downloaded directly onto a password protected laptop computer, which only the CI knew the password for. Any paper data, including the PARQ and consent forms were stored in a filing cabinet that was kept locked when not in use, inside an office that was always locked when vacant.

3.6.6 Informed consent

Informed consent was collected via a separate consent form (Appendix B4, page 266), requested to be returned within a week upon receipt of the written study information should individuals satisfy all inclusion and no exclusion criteria and wished to participate. A stamped addressed envelope was supplied

in order to increase the likelihood of its safe return. No individuals who had contacted the CI in the first instance for further information received a follow up call if a consent form was not returned within the recommended time period. A further week was permitted following receipt of the consent form to permit participants time to reconsider their decision to participate. If no further contact had been received to change their decision, an appointment was made to attend the hospital for purposes of data collection. Upon arrival the CI signed the consent form which had been received and the participant received a duplicate copy to retain for their own records.

3.7 Measurement

3.7.1 The Actigraph GT3X accelerometer

The Actigraph GT3X accelerometer weighs approximately 27g and has dimensions of 3.8 x 3.7 x 1.8 centimetres (see Figure 3.1 below). This model was chosen due to its combination of measurement modes which are able to be initialised simultaneously. These included an inclinometer to identify body position and further modes to quantify activity intensity and step count. These devices were loaned from a supply held by YSJU, negating the need to seek funding in order to purchase them.

Figure 3.1 The Actigraph GT3X accelerometer

Activity can be quantified over a number of days if desired, depending on the combination of measurement modes which are activated during programming (initialisation). Time stamped activity data is captured and stored over pre-set periods (epochs) ranging from less than a second to a number of minutes. Accelerometer data was downloaded onto a computer where Actilife software was installed (version 4.2.0; Actigraph LLC, Fort Walton Beach, Florida, USA).

The Actigraph GT3X possesses a Low Frequency Extension data filter (LFE) which can be activated to increase its sensitivity to capturing low intensity activity (Cain et al. 2013). Consideration of the target patient group and the low intensity of activity highlighted within this population (Borges et al. 2015; Berney et al. 2015; Hopkins et al. 2012) precipitated the decision to activate the LFE during the initialisation process. Justification for employing the LFE data filter was found in a study within the systematic review, reporting it yielded the best results when quantifying step count in older people who walked at slow speed, with an ICC (95% CI) of 0.938 (0.870, 0.969) when an Actigraph GT3X+ accelerometer was positioned on the ankle (Webber and St John 2016).

3.7.2 Measurement of Body Mass Index (BMI)

Participants' height was measured using a stadiometer (SECA model 213, Seca Ltd, Birmingham, United Kingdom). This consists of a vertical ruler, detailing both metric and imperial measures over which is placed a sliding horizontal rod, adjusted to rest on the top of the head. A window in the horizontal rod permits the height to be read from the vertical bar in relation to a small marker present on the bar. Participants removed their shoes for BMI measurement, whilst socks remained. BMI was calculated by dividing the weight in kilograms (kg) by the participant's height in metres (m) and dividing the answer by the height in metres again (NHS Choices 2015a). Weight (kg) was measured by bathroom scales which the participants stepped onto with shoes but not socks removed. Manual calculations were verified using a web based programme (NHS Choices 2015b).

3.7.3 Video recording

The Logitec HD Pro Webcam, model c920 (Logitech Europe S.A, EPFL-Quartier de l'Innovation, Daniel Borel Innovation Center, 10105 Lausanne, Switzerland) was the criterion measure employed within the study. This model was able to record in high definition (HD) yet was of a small dimension, which was considered less intimidating for participants, with little impact on the setting (Parry et al. 2016). This model connected directly to a password protected laptop computer, negating the need for the transfer of any data from a card within the camera, assisting in data protection, in accordance with the Data Protection Act 1998 (Legislation.gov.uk 2018).

The use of video recording as the criterion measure permitted unlimited opportunity to revisit the movement protocols of each of the 30 participants. This enabled close observation of movement on a second by second basis, for time synchronised comparison with the accelerometers. The systematic review identified two other studies where video cameras had been used as a criterion measure, comparing data captured from an accelerometer against what was observed when participants with impaired function undertook movement (Raymond et al. 2015; Taraldsen et al. 2011). As the movement protocol for this feasibility study was undertaken on a closed ward with no other individuals present other than the participant, the CI and an assistant there were no ethical concerns regarding the inadvertent filming of others not directly involved in the research.

3.7.4 Time synchronisation

The laptop computer used for the video recordings was also used to initialise the accelerometers with the measurement modes of inclinometer (for identification of lying, sitting and standing postures), activity intensity count and step count. Data was programmed to be captured and stored in one second epochs for eventual download onto the same laptop computer. Essentially this provided a reading for each measurement mode used for every second that the accelerometers were worn until their eventual removal from the participant. The accelerometers possessed the ability to record data in real time. Time settings

on the computer were identical for both the accelerometers and the video camera, providing assurance that both were time synchronised. It became apparent during pilot testing that the ability to visualise the time stamp on the video recordings could only be achieved when its motion sensor option was being used. If no movement was detected whilst in this mode, the camera ceased to record and was only reactivated when movement recommenced.

Aspects of the movement protocol undertaken within the hospital bed required participants to remain still. To prevent the camera from potentially turning off the standard recording mode was used. However, this mode did not possess the ability to time stamp recordings. A solution was found by the purchase of a Precision radio controlled alarm clock (Model AP004: Peers Hardy Group, Precision House, Starley Way, Birmingham International Park, Bickenhill Lane, Solihull). This was manually synchronised to the set time on the computer and on-going synchronisation throughout the video recording period was ascertained through comparison with the time set on the laptop computer. The clock was placed within the view of the video camera so it was clearly evident within the video screen to permit comparison with the time setting on the accelerometers during data analysis.

Aspects of the movement protocol which required participants to walk were always less than ten minutes duration. A method was established of transporting the laptop computer on a wheelchair, resting the video camera on one of its arms. When used this way the motion sensor mode of the camera could be employed effectively, enabling visualisation of its time stamp function. The camera was not rendered inactive throughout any ten metre walk when used in this manner in the motion sensor mode. The number of steps taken between the first footfall over the ten metre line and the last footfall before the line marking the end of the ten metre distance were counted by two people; one was the CI and the other an assistant (also a qualified physiotherapist).

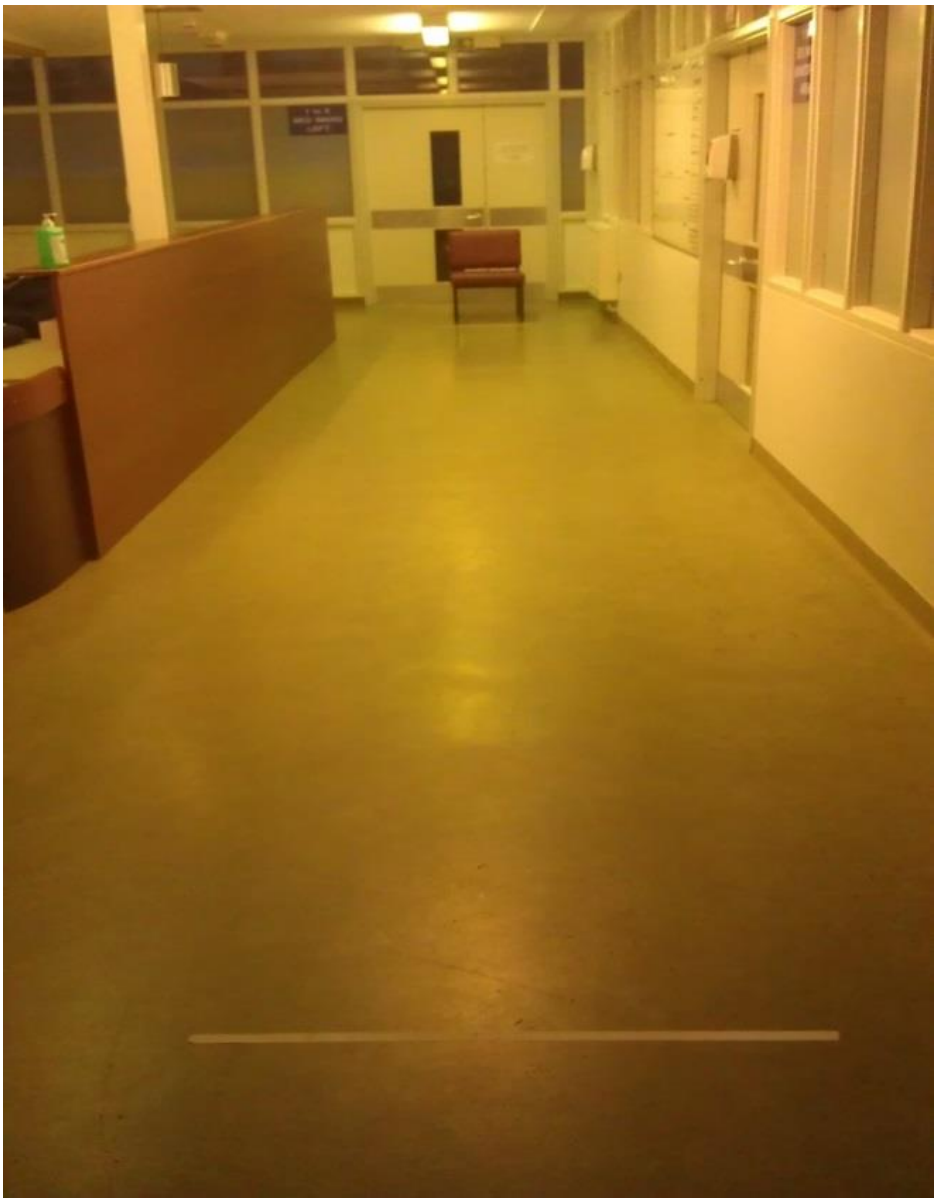
The assistant also had direct involvement with components of a movement protocol where participants were required to accept help to perform certain

postural transitions. Observed step counts were compared to ensure agreement between the CI and assistant during the ten-metre walks. If there was a discrepancy, the video would be revisited and steps recounted by both the CI and assistant to reach final determination of observed step count prior to data input and analysis. This was not eventually required for any of the 30 participants. Walking speed was determined by timing the participant from the first footfall to the time when their body crossed the line marking the end of the ten metre distance. The participant was timed using the stopwatch application of a Motorola android phone. Walking speed was calculated using the following equation:

SPEED = DISTANCE (metres) / TIME (seconds)

The ten-metre walks were undertaken within the hospital ward where the movement protocols took place. Tape was used on the floor to denote the ten-metre distance, which is shown in Figure 3.2 on page 105. A ten-metre distance was identified as the most common distance used to assess walking speed in a systematic review and meta-analysis assessing how walking speeds are calculated in clinical research (Graham et al. 2008). This is why this distance was selected.

Figure 3.2 Location where ten- metre walks were undertaken



3.8 Study Procedure

The short Physical Activity Readiness Questionnaire (PARQ) was formally completed on arrival for data collection (Bailey et al. 1976). A copy of this questionnaire is located in Appendix B9 on page 276. This standardised seven item questionnaire was originally designed to identify those who may have been at risk of injury in completing the Canadian Home Fitness Test, originally introduced to raise the levels of fitness in the Canadian populations (Bailey et al. 1976). It was tested in over 10,000 people without any serious complications and remains to this day in its seven item format. Completion of this simple questionnaire assisted in assessing that participants were physically able to

undertake the activities contained within the movement protocol, to ensure their safety and wellbeing. The level of physical function of each participant had been ascertained previously as part of the informed consent process. When the CI was initially contacted by an individual expressing interest in participation, the questions contained within the PARQ were posed to them. This prevented participants from spending unnecessary time attending for data collection if it seemed likely, upon questioning, that physical difficulties would be encountered performing the protocol movements. This short questionnaire was deemed appropriate for use within this study. Although taking a maximum of five minutes to complete, it permitted the ability to gather all the necessary information on general physical health and ability of those interested in participation. An informed decision was able to be made regarding whether undertaking the movement protocol was safe and appropriate for every individual.

Participants were required to wear two Actigraph GT3X accelerometers, one around the waist (resting above the left hip) and the other around the left ankle, resting just above the lateral malleolus. Both devices were attached by elastic belts secured by plastic clips worn on the outside of comfortable clothing.

Participants were requested to perform a series of functional movement sequences, undertaken both independently and with physical assistance. These movements comprised:

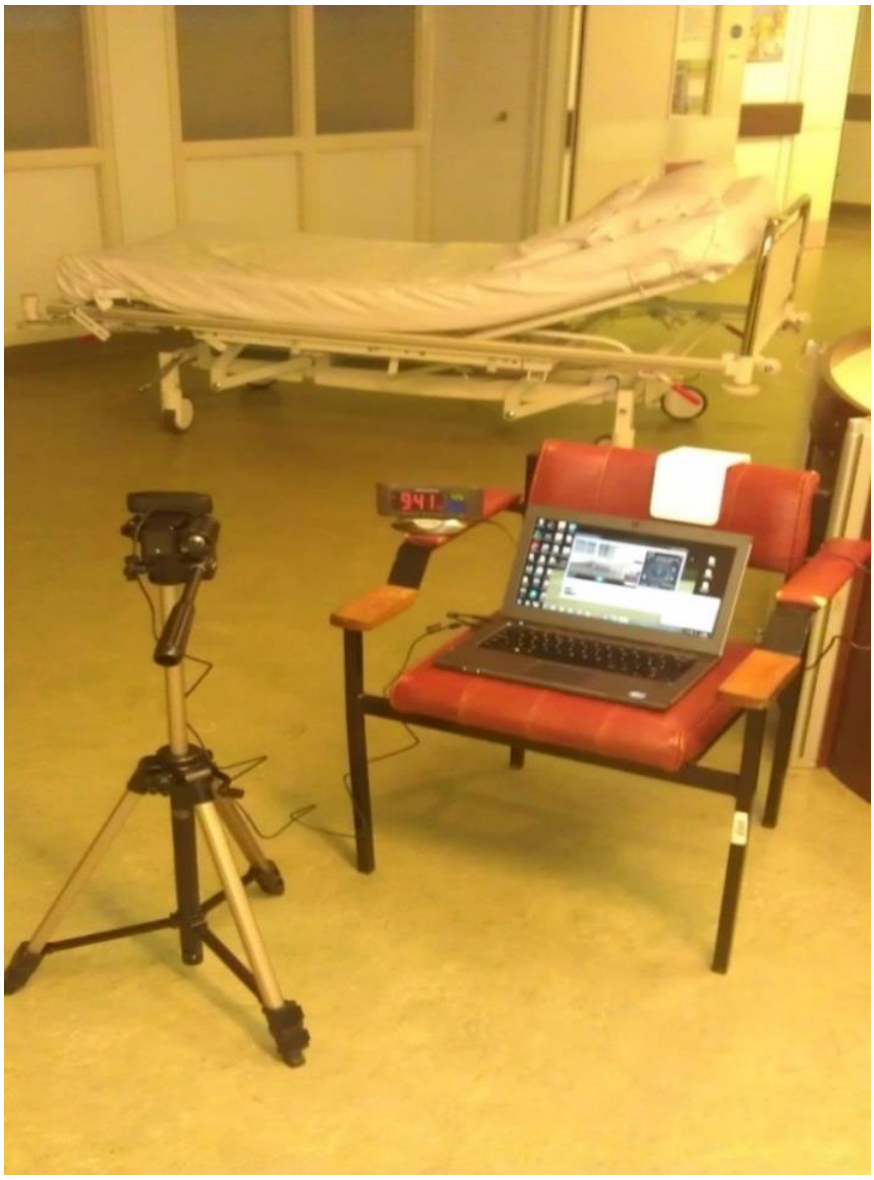
1. Lying to sitting and sitting to lying postural transfers

2. Sitting to standing and standing to sitting postural transfers

3. Undertaking four measured ten-metre distance walks with the assistance of a wheeled zimmer walking frame (WZWF) or a walking stick (WS). Two of the walks were undertaken using a WZWF and two with a WS. The length of time in between the repeated walks did not exceed two minutes, where the participants were permitted the chance to rest in a chair.

Postural transfers (lying to sitting, sitting to standing) and their reverse transitions were performed from a height adjustable hospital bed. The height was adjusted so that participants could comfortably rest their feet flat on the floor if they were sitting over the side. Each separate postural transition was repeated three times. This was included within the protocol as a method of assessing the ability of the accelerometer to generate reproducible graphical representations of the patterns of movement constructed using activity intensity (vector magnitude) counts alone. It was thought this would assist in assessment of the reliability of the accelerometers to yield similar information when exposed to the same conditions. The head of the bed was raised to simulate conditions often encountered in patients resident in hospital and to ensure participant comfort. The degree that the bed head was raised depended on each individual participant's request. The angle of the raise was not recorded. The video camera was positioned to ensure the bed; the participant and the digital clock were visible within the recording field. Figure 3.3, located on page 108 demonstrates this arrangement to assist the reader.

Figure 3.3 Arrangement of video recording equipment



3.8.1 Movement protocol

The clock was synchronised with the laptop computer which was also used to initialise the accelerometers. It was important that the clock and laptop were synchronised together first to permit an identical time to be programmed onto the two accelerometers which were worn during the movement protocol. The accelerometers were programmed to capture data every second (termed a one second epoch). Parts of the movement sequences required the participant to accept physical assistance from two health care professionals. Assistance during these particular movements was administered by the CI (a qualified

physiotherapist) and a second physiotherapist employed by HEYHT. The full movement protocol undertaken on the day of data collection is detailed below:

1. Prior to beginning the movement protocol, height and weight were measured in order to calculate BMI. The basic function of the accelerometer was explained to the participant regarding the data captured. Two accelerometers were applied over comfortable clothing, one just above the left hip (attached around the waist) and one around the left ankle, superior to the lateral malleolus, using the elastic belts and clips supplied with the devices.
2. A familiarisation phase followed, involving practical instruction on using a WZWF and WS. Instruction was also given of how to simulate a person weakened by illness and the level of contribution expected from the participant during the movement sequences which required physical assistance. Rehearsal of all the postural transitions and activities required to be performed then occurred (lying to sitting/ sitting to lying, sitting to standing/ standing to sitting and walking ten-metre lengths with either a WZWF or WS). Each separate component of the movement protocol was rehearsed once, making sure participants verbally reported that they were confident of how to undertake each of the movements. The entire rehearsal time period did not exceed 15 minutes.

Following this familiarisation and training period the participant was permitted to rest whilst the video camera was activated. This process never exceeded ten minutes. Following this, data collection commenced which is detailed below:.

3. A period (approximately one minute) of lying supine (on their back) with minimal movement was captured. This was then followed by a similar time period spent in both right and left side lying. The participant was then requested to lie supine again for approximately one minute.
4. A postural transfer with moderate physical assistance of two from lying to sitting over the edge of the bed and sitting to lying on the bed was repeated three times. Moderate physical assistance for the purposes of the study was defined as the participant physically contributing approximately 50% to the movement (UK FIM and FAM, Version 2.2, October 2010), with the remaining 50% provided by help from the CI and

assistant. It was considered that performing each transfer included within the movement protocol three times would increase the possibility of them being performed in a similar way with subsequent repetitions. It was also felt that if the number of repetitions was increased from three, participants may have become fatigued due to the number of different transfers being undertaken overall, followed by the ten-metre walks. Previous opportunity to practice all transfers had also occurred during the instruction phase prior to data collection. In between each transfer a stationary period of no less than 25 seconds was employed. The participant was encouraged to remain as still as possible.

5. The same postural transfers were performed, but without any physical assistance (i.e. the participant undertook the movement independently). Participants were encouraged to perform the transfers at a slower pace than they possibly would normally undertake them. Encouragement was given to perform each movement as similarly as possible.
6. The postural transfers of sitting to standing and standing to sitting from the bed were repeated three times with physical assistance of two.
7. The same postural transfers were undertaken independently, at a slower pace than participants were likely to have normally performed them. Encouragement was given again to perform each movement as similarly as possible.
8. Participants walked a measured ten-metre distance twice with a WZWF, then twice with a WS. Rests were offered between walks, with chairs placed at both ends of the ten-metre distance for this purpose. Rest periods did not exceed two minutes and their duration was participant determined.
9. Participants were asked to verbally feedback regarding the comfort of the accelerometers at their respective placement sites and if they impeded movement in any way. They were asked ‘How comfortable did you find the accelerometers to wear?’ They were also asked ‘Did you feel they affected your ability to undertake any of the movements at all?’
10. The movement protocol was complete and the accelerometers were removed. The CI assessed both the individual accelerometer placement

sites for evidence of blanching, skin breakdown or redness immediately following their removal.

11. Participants were offered refreshments following completion of the movement protocol.

3.9 Data analysis

Observation through the use of video recordings functioned as the criterion measure. Accelerometer data was compared against the video recordings of all purposeful movements performed. No data for any participant was required to be excluded from analysis as a result of a malfunction of the accelerometers or video camera. No participants withdrew consent at any point during or following data collection or refused to repeat any aspects of the movement protocol where necessary. All camera recordings were successfully saved onto the laptop computer and time stamped on a second by second basis. This was achieved either manually using the alarm clock within the camera's field of vision for the bed movements or the time stamp directly from the motion sensor setting on the camera for the ten- metre walks with the walking aids. Camera recordings were compared with the synchronised time stamping on the accelerometers on a second by second basis for all postural transitions performed on the bed. The CI undertook all aspects of data input and analysis.

Accelerometer data was downloaded immediately following the data collection period for each participant onto the same laptop computer used to capture the camera footage. The devices were not programmed to switch off, hence data continued to be collected even after their removal if they were moved. Downloading immediately after removal from participants' ensured minimal extra data was captured other than that which was to be directly involved in data analysis. During the download of accelerometer data, an Excel file was generated, creating a time stamped spread sheet of data captured from all the measurement modes which had been programmed onto the accelerometers during the initialisation period. Data was captured on a second by second basis. An example of a typical Excel spread sheet is shown in Table 3.2 on page 112.

Table 3.2 Excel data spread sheet created following accelerometer download

---------- Data File Created By ActiGraph GT3X (low frequency extension) ActiLife v4.2.0 Firmware v4.1.0 ----------							
Serial Number: MAT2A40099973							
Start Time 13:00:00							
Start Date 06/02/2015							
Cycle Period (hh:mm:ss) 00:00:01							
Download Time 14:02:32							
Download Date 06/02/2015							
Current Memory Address: 33480							
Current Battery Voltage: 4.17 Mode = 45							

Date	Time	Activity	Activity (Horizontal)	3rd Axis	Vector Magnitude	Steps	Inclinometer
########	13:08:00	0	0	0	0	0	3
########	13:08:01	0	0	0	0	0	3
########	13:08:02	0	2	0	2	1	3
########	13:08:03	11	34	26	44.19275959	1	3
########	13:08:04	13	13	28	33.49626845	2	3
########	13:08:05	28	53	11	60.94259594	1	3
########	13:08:06	41	69	52	95.63472173	2	3
########	13:08:07	10	10	53	54.85435261	0	3
########	13:08:08	0	0	19	19	0	3
########	13:08:09	0	0	0	0	0	1
########	13:08:10	0	0	5	5	0	1
########	13:08:11	5	15	31	34.79942528	1	1
########	13:08:12	0	1	1	1.414213562	0	1
########	13:08:13	0	0	0	0	0	1

The choice of statistical analysis was dependent on the data outputs generated by the different measurement modes, with some being categorical and others numerical. All data was analysed using IBM SPSS statistics (version 20). Data analysis, depending on how the data presented, is now described.

3.9.1 Inclinometer (body position) recording

Data output by the accelerometers was categorical. The accelerometers recorded one of four numbers every second, depending on how they interpreted body position at any given time. These numbers were:

0 The accelerometer was not being worn

1 Participant was standing

2 Participant was lying

3 Participant was sitting

This data was contained within final column of the Excel spread sheet (see Table 3.2 on page 112). A new column was created containing the results of body position analysis following observation of the video recordings for each participant, using the same second by second time stamp. Observations of the postures of lying, sitting or standing were coded identically using the same 0 to 3 numbers as described previously. A change in body position (e.g. from lying to sitting) was only recorded after the movement was complete. As the data was categorical, a Kappa (κ) analysis was undertaken to measure agreement between accelerometer data and observational data. Data from the accelerometers and observation for each participant were accumulated and entered into a single analysis. This was performed for both the waist and ankle accelerometer. A total of 50,193 seconds (13.94 hours) of time synchronised data from the accelerometers and observation was compared in each analysis.

The κ statistic not only calculates the level of agreement between two categorical measurements, but also agreement that would have occurred by chance (Rigby 2000). IBM SPSS statistics (version 20) terms the calculated level of agreement between two measures as ‘count’ and agreement that would have occurred by chance as ‘expected count’. A count higher than that expected by chance indicates that agreement between two measurements did not occur by chance alone. A number which is lower than that calculated for chance suggests agreement between two measures is worse than chance and the measures do not agree. The strength of agreement between two measures depends on the κ value calculated following analysis of the data (Landis and Koch 1977). The κ value ranges used for this study are shown in Table 3.3 on the page 114 (Landis and Koch 1977). This type of analysis was undertaken independently for both the ankle and waist accelerometer data, to ascertain if there was a superior placement site which yielded better results for recognition of lying, sitting and standing.

Table 3.3 Kappa value ranges (Landis and Koch 1977)

< 0.00	'Poor' agreement
0.00-0.20	'Slight' agreement
0.21-0.40	'Fair' agreement
0.41-0.60	'Moderate' agreement
0.61-0.80	'Substantial' agreement
0.81- 0.99	'Almost perfect' agreement

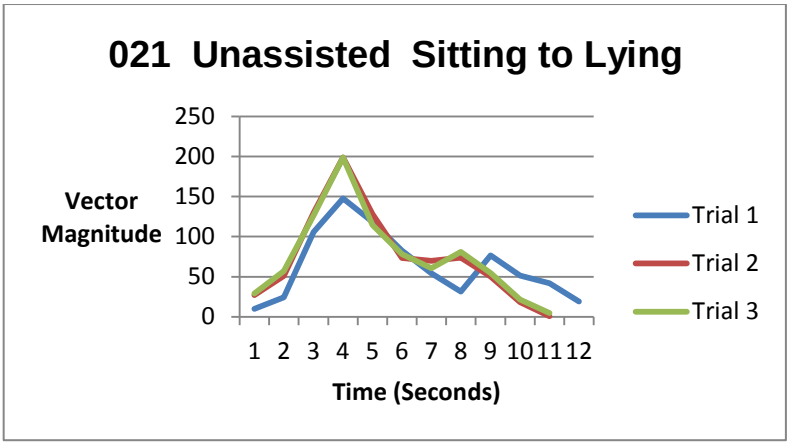
3.9.2 Physical activity intensity count

Each postural transition within the movement protocol was undertaken three times. Data derived from the vector magnitude recording from the ankle and waist mounted GT3X accelerometers was extracted to construct a set of graphs. The vector magnitude reading was found in the sixth column of the Excel spread sheet, shown in Table 3.2 on page 112. This numerical figure is derived from the accelerations captured by all three axes of measurement. Vector magnitude readings are thought to provide a more comprehensive estimate of sedentary and active periods than a single vertical axis alone (Trost et al. 2005). The GT3X also uses the vector magnitude readings to inform the inclinometer output, assigning a 0, 1, 2, or 3 accordingly (John and Freedson 2012).

The second by second vector magnitude readings from commencement to completion of each of the three identical movements within each postural transition were plotted to construct a line graph. This process was performed individually for both the ankle and waist placement sites. The three lines produced for each postural transition were superimposed onto the same chart to look for similarity in their contours. An example of one of the graphs produced using this methodology is found in Figure 3.4 on page 115. The example shown was constructed for the postural transition of sitting to lying when performed without assistance. This graph was constructed using data from the ankle placement. It demonstrates the consistency in the contours of

the lines produced, suggesting that similar data was being captured for each of the three repeated movements for each postural transition.

Figure 3.4 Line graph constructed for the postural transition of unassisted sitting to lying (ankle accelerometer)



This process was undertaken to assess accelerometer reliability. This was performed individually for all participants, to control for slight variations in the ways the assisted and independent postural transitions might have been undertaken between participants, with each individual serving as their own control (Bland 2010). This was a novel and visual method of assessing the reliability of the accelerometers to capture data during the various postural transitions. This proposed method was looked on favourably when discussed with statistical experts. The systematic review revealed no other study had attempted to investigate the reliability of accelerometer measurement during postural transitions, highlighting the originality of this analysis, including its methodology.

A descriptive analysis was also undertaken to explore the second by second vector magnitude activity intensity counts produced during every postural transition. This accessed the same data used to construct the line charts. The overall intensity of each postural transfer was calculated by combining the activity intensity counts captured during each second from commencement to completion. As each postural transfer contained within the movement protocol was undertaken three times by each of the 30 participants, 90 separate scores

were calculated for each postural transition. The mean, SD, 95% CI and range were calculated for both the waist and ankle accelerometer. This method also investigated the consistency of vector magnitude readings for particular postural transfers between all participants.

Histograms were constructed for each separate assisted and unassisted postural transfer to explore the range and frequencies of intensities calculated. This assisted in further understanding the variability in intensity scores achieved for each postural transfer performed. All transfers included were likely to be undertaken by those recovering from critical illness during a typical day. This analysis furthered understanding of whether activity type in those recovering from critical illness could be determined by intensity count alone. A previous study, identified within the systematic review had initially intended to investigate this aspect but had encountered difficulties due to the limited activities undertaken within patients who were resident within the ICU (Winkelman et al. 2005).

3.9.3 Step count

The data captured by the accelerometers for quantification of step count was numerical (continuous). This data was compared with observed step count determined by observation which functioned as the criterion measure. Two ten-metre walks were completed with a WZWF and two with a WS. Investigation of agreement between accelerometer determined step count and observed step count for the ten-metre walks was undertaken using Bland Altman analysis (Giavarina 2015), assessing the mean difference between accelerometer data and observed step count and 95% limits of Agreement (95% LOA). Finally, test-retest reliability of accelerometer determined step counts undertaken during the repeated walks with a WZWF was calculated to determine the Intraclass Correlation Coefficient (ICC) and 95% Confidence Interval (95% CI). The same analysis was undertaken with the two repeated walks using a WS to understand the correlation between the two sets of data captured for each walk. Both the waist and ankle accelerometer underwent investigation separately. This particular method of analysis was employed to permit

comparison with the results of the study by Edbrooke et al. (2012). Edbrooke et al. (2012) undertook a very similar analysis of reliability for quantification of step count when recorded at the ankle using the AMP 331 accelerometer.

3.10 Results

3.10.1 Patient demographic data

Table 3.4 below presents the mean, SD and range for participants' age, body weight, height and BMI. Shapiro Wilk analyses determined the continuous variables of age, weight, height and BMI to be normally distributed ($p > 0.05$ for all variables). The categorical variable of sex is expressed as absolute numbers and percentages.

Table 3.4 Demographic Variables

Variable	Mean (± SD, range), *n* (%)
Age	58.8 (± 6.8, 43-73)
Sex	Male 19 (63%) Female 11 (37%)
Body Weight (kg)	80.7 (± 11.9, 57-107)
Height	174 (± 8.6, 158-188)
BMI	26.5 (± 3.2, 20.9-36.5)

BMI = Body Mass Index

3.10.2 Repeatability of measurements for all postural transfers

Vector magnitude readings captured every second from the beginning to the end of each postural transfer were plotted to construct line graphs. As there was variability in how individual participants performed the various postural transfers, each participant served as their own control. All postural transitions were repeated three times, creating three separate plots which were superimposed over each other. Similarity in the shapes of the three lines was interpreted as evidence that the accelerometers were consistent in capturing similar information.

3.10.2.1 Lying to sitting and sitting to lying transfers

Figure 3.5 on page 120 presents a complete set of graphs constructed for the lying to sitting/ sitting to lying postural transfers for a participant, in this case using data captured from the waist accelerometer. Graphs constructed for both assisted and independent transfers are shown. The first graph (assisted lying to sitting postural transfer), shows an initial spike of activity followed by a period of no activity (contour falls to a vector magnitude of 0), then a further smaller spike of activity. All three plots demonstrated similar intensity and shape, suggesting consistency of data captured by the accelerometer. This graphical representation accurately describes how the postural transfer was executed.

The initial spike of activity occurred as the participant was assisted from the supine (lying on the back) to a side lying position. Participants remained static in the side lying position for a number of seconds whilst the CI and assistant changed their position to permit completion of the transfer from side lying to sitting over the side of the bed. The final smaller spike in activity corresponds with this final component of this particular transfer. This double spike of activity was clearly evident in a number of the line charts constructed for this movement. The proximity of the two spikes to each other was dependent on the period of time spent in a static position, where the CI and assistant altered their position to enable the next stage of the transition (side lying to sitting). Some periods of static activity were shorter than others, hence bringing two spikes of activity closer together. This highlighted the usefulness of the choice of this novel methodology to assess the reliability of the accelerometers to capture similar information when movements were repeated.

Although the contours of the line charts created for each individual participant demonstrated similarities such as those described above, there were also distinct differences in some contours between participants. This was possibly due to the subtle modifications required to enable assisted transfers for each participant, depending on their body shape for example, or preferences of individuals in how transfers were undertaken independently. Hence, the decision to use each participant as their own control appeared to be justified.

The similarities of the shapes of the three lines within each graph are demonstrated in Figure 3.5 on page 120, suggesting the waist accelerometer was consistently capturing similar information during all the three repeated movements.

Figure 3.6 on page 121 presents a complete set of graphs for sitting to lying and lying to sitting postural transfers using data captured from the ankle placement of the same participant. Similar characteristics to those found in the waist placement were present in a number of the line charts constructed for the assisted lying to sitting postural transition, with spikes of activity separated by a periods of no activity. Other plots suggested that ankle activity during sitting to lying and lying to sitting transfers was more variable, even during the three repeated movements by individual participants.

Figure 3.5 **Complete set of line graphs constructed for the postural transfers of lying to sitting/ sitting to lying for a single participant (waist accelerometer).**

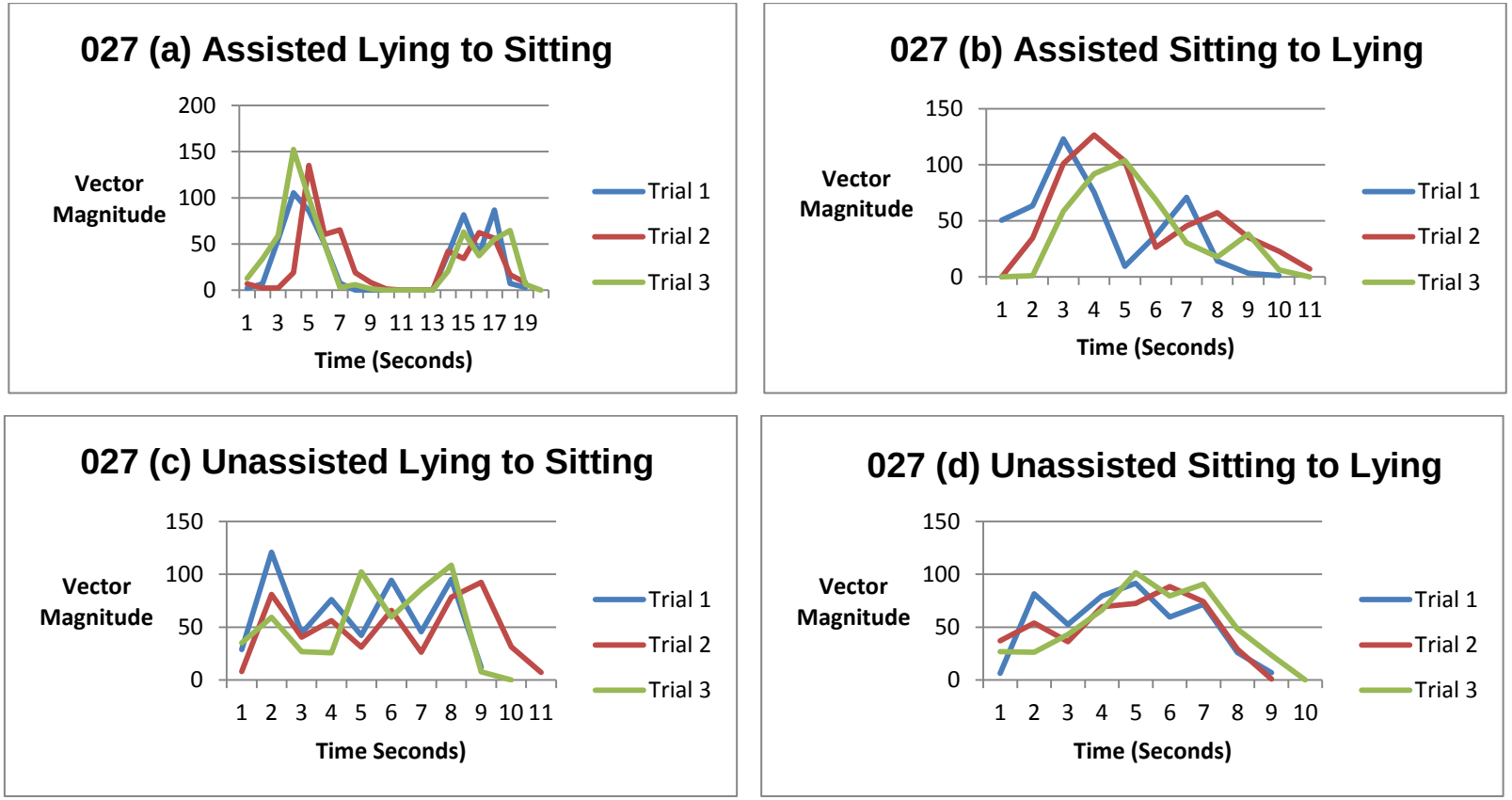
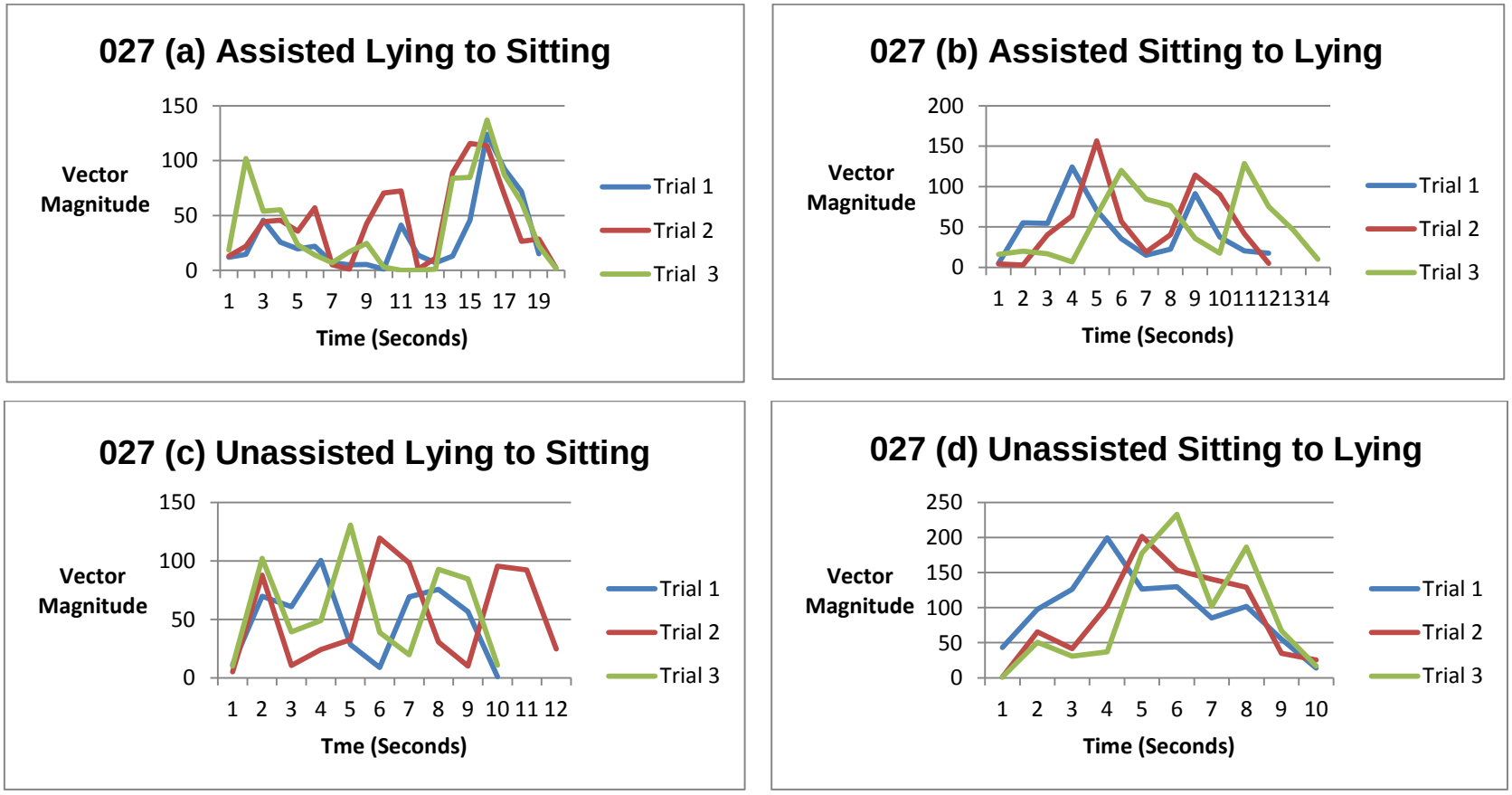


Figure 3.6 Complete set of line graphs constructed for the postural transfers of lying to sitting/ sitting to lying for the same participant (ankle placement).

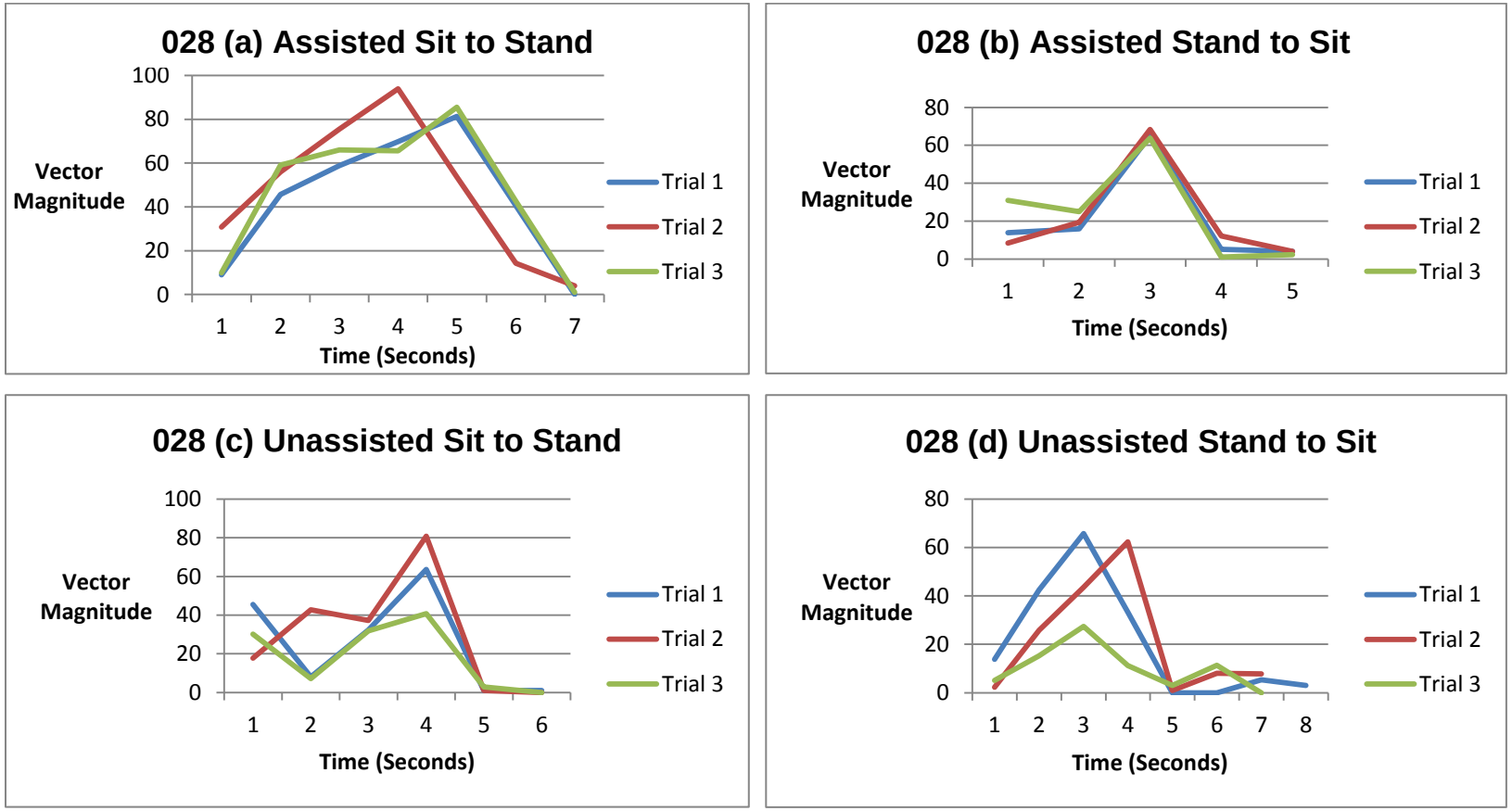


3.10.2.2 Sitting to standing and standing to sitting transfers

The waist placement captured vector magnitude readings for sitting to standing and standing to sitting transfers for all 30 participants. Figure 3.7 on page 123 presents a complete set of graphs constructed for these transfers for a participant, demonstrating the similarity in the shapes of the three lines produced following plotting of the vector magnitude data captured during repeated movements. Graphs could not be constructed for the ankle placement as a vector magnitude reading often failed to be captured when the postural transfers were undertaken either with assistance or independently. This happened on 17 out of 90 occasions for assisted sit to stand, 45 out of 90 occasions for assisted stand to sit, 37 out of 90 occasions for unassisted stand to sit and 43 out of 90 occasions for unassisted stand to sit transfers. Although other transfers did record vector magnitude readings, these often did not exceed ten counts throughout the entirety of the transfer.

The regularity of the failure of the ankle accelerometer to capture any or minimal activity intensity count readings for these particular transfers is clearly evident in the histograms constructed demonstrating the frequency of different activity intensity readings for these particular transfers (assisted and unassisted). These can be viewed in Appendix B11, with the sitting to standing transfers and their reverse commencing on page 283. The failure of the ankle placement to consistently capture activity intensity readings during sitting to standing and standing to sitting postural transfers suggested it was not a valid placement site for identification of these particular transfers using activity intensity readings alone.

Figure 3.7 Complete set of line graphs constructed for the postural transfers of sitting to standing/ standing to sitting for a single participant (waist accelerometer)



3.10.3 Descriptive analysis of the vector magnitude data for postural transitions

The second by second vector magnitude data used to construct the line graphs was explored using descriptive statistics and histogram production. This was undertaken for both the waist and ankle accelerometer data. Table 3.5 below presents the mean, 95% CI, SD and range of scores of the 90 vector magnitude intensity readings captured by the both the waist and ankle accelerometer for all postural transfers undertaken.

Table 3.5 Mean (95% CI), SD and range of vector magnitude scores captured by the accelerometers during all postural transitions (waist and ankle shown)

Postural Transfer	Mean Vector Magnitude Reading (95% CI), SD and range (Waist)	Mean Vector Magnitude Reading (95% CI) , SD, and range (Ankle)
Assisted Lie to Sit	409.7 (381.2 - 438.2), ± 136.0, 122.8 - 753.4	439.4 (409.6 - 469.1), ± 142.1, 130.0 - 865.0
Assisted Sit to Lie	356.3 (328.1 - 384.5), ± 134.8, 128.2 - 815.2	503.2 (467.5 - 538.9), ± 170.2, 215.6 - 939.2
Unassisted Lie to Sit	578.1 (538.8 - 617.3), ± 187.4, 227.5 - 1103.1	566.6 (522.5 - 610.8), ± 210.9, 269.5 - 1243.5
Unassisted Sit to Lie	476.1 (448.3 - 504.0), ± 132.9, 251.8 - 830.1	762.4 (730.7 - 794.1), ± 151.4, 355.3 - 1274.8
Assisted Sit to Stand	309.1 (289.4 - 329.0), ± 94.4, 83.4 - 580.5	12.0 (8.5 - 15.6), ± 17.0, 0 - 120.5
Assisted Stand to Sit	93.1 (78.4 - 107.7), ± 70.0, 1 - 284.7	4.8 (2.4 - 7.1), ± 11.3, 0 - 94.0
Unassisted Sit to Stand	172.3, (155.8 - 188.9), ± 78.9, 15.64 - 467.4	8.7, (5.6 - 11.7), ± 14.6, 0 - 79
Unassisted Stand to Sit	189.6, (167.2 - 212.0) ± 106.9, 24.7 - 668.8	12.1, (4.1 - 20.1), ± 38.3, 0 - 261.1

The SD and range of vector magnitudes calculated for each postural transfer highlighted the inconsistency in intensities captured by either placement site for all the transfers within the protocol. This variability was clearly visible in the histograms charting the frequency of scores of a particular intensity. Appendix B10 (page 277) presents the histograms for the waist placement, whilst Appendix B11 (page 281) contains those created for the ankle. Of particular note are the histograms constructed for the ankle placement for the movements of sitting to standing and standing to sitting (both assisted and unassisted). The ankle failed to capture any vector magnitude reading during the majority of these particular postural transfers so could not be used to quantify this movement. Given the wide variability in the range of intensities captured by both placement sites for all postural transfers, with some intensities shared by more than one type of transfer, difficulty would be encountered identifying a particular postural transfer by its vector magnitude intensity alone.

3.10.4 Recognition of body position using the inclinometer setting

A κ analysis evaluated the strength of agreement between the accelerometer inclinometer readings and video recordings for identification of the body positions of lying, sitting and standing. Separate analyses were undertaken for both the waist and ankle accelerometer. The waist accelerometer regularly misclassified all body positions, with a value of $\kappa = 0.21$ ($p < 0.001$), indicating only fair agreement with the observations taken from the video recordings (Landis and Koch 1977). The ankle accelerometer identified both the lying and standing positions well, but only intermittently identified sitting correctly, with a value of $\kappa = 0.43$ ($p < 0.001$), indicating moderate agreement (Landis and Koch 1977). Appendix B12 (page 285) and B13 (page 286) detail the results of the κ analyses undertaken for the waist and ankle accelerometer respectively.

Following the κ analyses, the raw data captured from the inclinometer function of both the waist and ankle accelerometers was explored. The observational data recorded following viewing of the video recordings was also accessed during this phase of the analysis. Both were viewed together to ascertain

whether any interesting findings were worthy of note or further investigation. Notable findings pertaining to each isolated site (ankle or waist) are now described.

3.10.4.1 Waist accelerometer

The waist accelerometer frequently misinterpreted the lying position as sitting, capturing an inclinometer reading of ‘3’ (sitting) instead of ‘2’ (lying). Data analysis revealed 7133 seconds of data was incorrectly identified by the waist accelerometers as sitting when the participant was in fact lying. The total amount of time spent in lying (whether supine or side lying) recorded from observation was 20,815 seconds, hence over a third of this period was incorrectly identified as sitting by the accelerometers. Evidence of this is found in Appendix B12 on page 285. The head of the bed was always raised according to participant preference and comfort, reflecting conditions often encountered within a ward situation. This arrangement may have accounted for the misinterpretation of lying as the sitting position due to the slight inclination of the trunk, giving the impression that a sitting or semi recumbent position was being adopted, not a supine position. The raise of the bed head was determined by the participant to ensure their comfort. The angle of the bed head raise was not recorded as a variable. When participants turned into side lying from this position, the inclinometer often correctly identified the lying position, changing from a ‘3’ (sitting) to ‘2’ (lying). The readings of ‘1’ (standing) and ‘3’ (sitting) were also often reversed, compared to what was actually observed from the video recordings. Table 3.6 on page 127 presents evidence of this particular finding, detailing a sample of raw data, comparing waist accelerometer readings against observed positions. During sitting activities, the bed was at a height that permitted the feet to rest flat on the floor for each individual participant. The height was not recorded as a variable.

Table 3.6 Example from an Excel spread sheet demonstrating the misinterpretation of the sitting ('3') and standing ('1') position of the waist accelerometer

Time	Observed position	Waist Accelerometer	Description of activity occurring
10:06:57	3	1	Sitting over the edge of the bed
10:06:58	3	1	
10:06:59	3	1	
10:07:00	3	1	
10:07:01	3	1	Third trial of assisted sit to stand commenced
10:07:02	3	1	
10:07:03	3	1	
10:07:04	3	1	
10:07:05	3	1	
10:07:06	3	1	
10:07:07	1	1	Third trial of assisted sit to stand complete
10:07:08	1	1	
10:07:09	1	1	
10:07:10	1	1	
10:07:11	1	1	
10:07:12	1	1	
10:07:13	1	3	Waist accelerometer reversing sitting and standing identification
10:07:14	1	3	
10:07:15	1	3	
10:07:16	1	3	
10:07:17	1	3	

Following a postural transition, a delay in recognition of a change in body position was encountered by both the waist and the ankle accelerometers compared to observation. The bold black arrow within Table 3.6 above highlights this delay. Identification of a postural change (in this example sitting to standing) occurred seven seconds later than the actual observed postural change. Although this delay was almost always present within the raw data of the waist and ankle placement, its length was not consistent. The waist accelerometer demonstrated a mean delay of 9 seconds (SD 3.3; range 0-22 seconds); whilst the ankle placement showing a mean delay of 10 seconds (SD 3.6; range 4-25 seconds).

Communication with the manufacturers' technical team explained that the firmware version of this particular model of accelerometer calculates the

inclination every second. Five consecutive seconds of a different inclination state are necessary before a change in body position is recorded in the epoch data. As one second was used as the epoch setting for this study, it would take approximately five seconds for a postural change to be detected in the data. The findings of this study, although concurring with the feedback from the manufacturers in relation to a delay encountered when recognising a change in body position, found a longer delay in some datasets than that quoted by the manufacturer's representatives.

3.10.4.2 Ankle accelerometer

The ankle accelerometer showed a similar delay in recognition of a change in body position which was described above. Visual analysis of video recordings confirmed the ankle accelerometer identified both the supine lying and standing positions well. The sitting ('3') or standing ('1') position was never misinterpreted as the lying position ('2'), taking into account the delays in the accelerometers recognising a change in body position. The sitting position however was only intermittently identified correctly. This body position was either interpreted correctly as sitting ('3') or incorrectly as standing ('1').

Further visual analysis revealed another interesting finding. As participants turned from supine lying (lying on the back) to side lying, the inclinometer reading regularly changed from a '2' to a '0'. Following turning back into supine, the inclinometer resumed a reading of '2'. Where this finding was not evident, the accelerometer continued to read '2', still correctly identifying that the participant was in a lying position, though not specifically side lying. Evidence of this finding is demonstrated within an extract of raw data in Table 3.7 on page 129. Further evidence of the delay in recognition of a change in body position compared to observational analysis is also demonstrated. This is highlighted again by a bold vertical arrow. The horizontal arrow demonstrates the change in inclinometer reading from '2' to '0' upon turning into the side lying position. This finding was not evident in any of the raw data yielded from the waist accelerometer placement site, being unique to the ankle placement only.

Table 3.7 Example from an Excel spread sheet demonstrating the inclinometer interpreting the side lying position as '0' with the ankle placement

Time	Observed position	Ankle Accelerometer	Description of activity occurring
09:55:00	2	2	Lying on back
09:55:01	2	2	Protocol turn onto right side commenced
09:55:02	2	2	
09:55:03	2	2	
09:55:04	2	2	
09:55:05	2	2	
09:55:06	2	2	
09:55:07	2	2	
09:55:08	2	2	
09:55:09	2	2	
09:55:10	2	2	Protocol turn onto right side complete
09:55:11	2	2	
09:55:12	2	2	
09:55:13	2	2	
09:55:14	2	2	
09:55:15	2	2	
09:55:16	2	0	
09:55:17	2	0	
09:55:18	2	0	

According to the manufacturers inclinometer settings, '0' denotes that the subject is 'not wearing' the accelerometer (Actigraph Engineering/ Marketing 2009). When '0' was reclassified as 'side lying', less than three minutes of data with a reading of '0' did not correspond with the side lying position. Three minutes were all contained (consecutively) within the raw data of a single participant. This was the only time period which suggested the accelerometer was not capturing any data at that time. There was no other evidence of the ankle accelerometer failing to capture inclinometer data. A '0' reading corresponded with a side lying position in 29 participants, even evidenced in

some participants during the relatively brief periods of time (seconds) spent in side lying when preparing for the second stage of the assisted lying to sitting postural transfer.

3.10.5 Percentage agreement between observation and ankle accelerometer data of lying, sitting and standing positions.

Using data captured from the ankle, percentage agreement between accelerometer data and direct observation for identification of lying, sitting and standing positions was calculated. The decision to only analyse ankle accelerometer data was based on the results of the initial κ analysis. The waist accelerometer was found to regularly misclassify lying, sitting and standing positions. The ankle placement accurately identified both lying and standing positions. It only intermittently identified the sitting position correctly, often misinterpreting this posture as standing. Based on the finding in 29 of the 30 participants that the '0' reading was predominantly captured during a side lying position, any '0' reading was recoded as a lying position ('2'). Recoded ankle accelerometer data from all participants was combined and compared against its time stamped observational data. Table 3.8 below presents the results of the percentage agreement analysis between the ankle accelerometer and observation in identification of lying, sitting and standing. Excellent results were found for identification of the body positions of lying and standing. Fair agreement (Landis and Koch 1977) was observed for identification of the sitting position.

Table 3.8 Percentage agreement between the ankle accelerometer and observation in identification of lying, sitting and standing postures.

Body position	Percentage agreement between direct observation and ankle accelerometer
Lying	90.7%
Sitting	31.9%
Standing	99%

3.10.6 Bland Altman analysis comparing step count quantified by accelerometry to observed step count.

Bland Altman analyses were undertaken for the two walks undertaken first using a WZWF and then a WS. Each walk was analysed separately. Analyses were performed both for the waist and ankle accelerometer placement sites.

3.10.6.1 Waist placement.

The mean difference (95% LOA) between observed step count and steps quantified by the waist accelerometer when using a WZWF was 9.77 steps (-11.91 to 31.45 steps) for walk one and 9.3 steps (-15.34 to 33.94 steps) for walk two. The mean difference between the waist accelerometer and observed step count for the ten-metre walks undertaken with the WS was 8 steps (-15.60 to 31.6 steps) for walk one and 8 steps (-16.7 to 32.7 steps) for walk two.

3.10.6.2 Ankle placement.

The mean difference (95% LOA) between observed step count and steps quantified by the ankle accelerometer when using a WZWF was 1.93 steps (-11.81 to 15.67) for walk one and 2.97 steps (-12.49 to 18.43 steps) for walk two. The mean difference between the ankle accelerometer and observed step count for the ten-metre walks undertaken with the WS was 2.1 steps (-15.27 to 19.53 steps) for walk one and 2.5 steps (-19.33 to 24.33 steps) for walk two.

Participants undertook the walks at a variety of speeds, ranging from 0.17m/s to 0.64m/s. They were instructed to walk at a pace likely to be slower than their usual speed. On closer inspection of the walking speeds calculated for the outliers located within the Bland Altman analyses the greatest discrepancies between accelerometer derived step count and observation occurred when walking speed was less than 0.3m/s. The waist accelerometer failed to record any steps when walks were undertaken with the WZWF at speeds of 0.17-0.19m/s. The ankle accelerometer also underestimated step count by the

greatest amount at similar speeds during walks with the WZWF, although still recorded a step count.

Differences between step counts recorded by accelerometers at both placement sites compared to direct observation were much smaller in those who walked at speeds of greater than 0.3m/s during all walks, regardless of walking aid used. Table 3.9 below presents a sample of the raw data captured by the both the waist and ankle accelerometers taken from the first walk performed with the WZWF. Three slowest walking speeds of less than 0.3m/s and three speeds of greater than 0.3m/s are shown as demonstration of evidence for the findings and observations detailed above. Note the waist accelerometer also encountered some difficulty capturing steps at greater speeds (participant 2).

Table 3.9 Example of the discrepancy between observed step count and step count recorded by the ankle and waist accelerometer at slow speeds (first wheeled zimmer walking frame walk shown as an example)

Participant number	Speed (three lowest and three highest)	Observed step count	Waist accelerometer step count	Ankle accelerometer step count
8	0.17m/s	33	0	12
4	0.18m/s	36	0	12
6	0.19m/s	30	0	15
25	0.41m/s	21	21	19
1	0.53 m/s	17	19	17
2	0.55m/s	25	1	24

Based on the findings following initial Bland Altman analysis and subsequent closer investigation of the raw data, further Bland Altman analyses were undertaken for participants who undertook walks at speeds of greater than 0.3 m/s. Step counts captured by the waist and ankle accelerometers were

compared against observed step count to assess agreement. The results of these analyses are found in Table 3.10 below. The mean differences and 95% LOA were considerably smaller for the ankle placement than the waist placement for all walks undertaken, both for the WZWF and the WS walk. The 95% LOA calculated for the WZWF exhibited a tendency to be wider however for the WZWF walks than the WS walks for the ankle accelerometer, suggesting a tendency for greater diversity between the steps counts identified by the ankle accelerometer and that determined through observation. All mean differences however between the ankle accelerometer and observed step counts were less than 1 step. The results suggested the ankle accelerometer was superior to the waist placement for determination of step count at speeds of greater than 0.3m/s when using any walking aid. Due to these encouraging results, justification for further investigation within populations recovering from critical illness who are likely to walk at slower speeds in the initial stages of recovery using this placement site was provided.

Table 3.10 Mean differences in step count recorded by accelerometry (waist and ankle) and direct observation in all walk tests undertaken at speeds greater than 0.3m/s.

Walk type	Number of participants (*n*)	Mean difference between waist accelerometer and direct observation (95% LOA)	Mean difference between ankle accelerometer and direct observation (95% LOA)
WZWF WALK 1	*n* = 18	-6.72 steps (-24.83 to 11.39 steps)	-0.28 steps (-5.98 to 5.42 steps)
WZWF WALK 2	*n* = 21	-6.30 steps (-25.91 to 13.23 steps)	-0.95 steps (-9.89 to 8.00 steps)
WS WALK 1	*n* = 26	-5.12 steps (-21.09 to 10.85 steps)	0.27 steps (-4.51 to 5.05 steps)
WS WALK 2	*n* = 24	-6.58 steps (-22.63 to 9.47 steps)	- 0.63 steps (-4.69 to 3.43 steps)

WZWF = Wheeled zimmer walking frame WS = Walking stick

3.10.7 Reliability of the step count measurement mode

An ICC (95% CI) analysis (two way random, absolute agreement) was undertaken to compare the step counts captured by the accelerometers during walks one and two for both walking aids at any speed. This was performed separately for the ankle and waist accelerometers. Table 3.11 below shows the results of this step count reliability test.

Table 3.11 Results of ICC (95% CI) for step count reliability

Walk Type	ICC (95% CI) Waist Accelerometer	ICC (95% CI) Ankle Accelerometer
WZWF	0.97 (0.94 - 0.99)	0.92 (0.81 - 0.96)
WS	0.96 (0.92 - 0.98)	0.92 (0.84 - 0.96)

WZWF = Wheeled zimmer walking frame WS = Walking stick

The results of this analysis suggested both the waist and ankle accelerometer were consistently quantifying step count at all walking speeds, demonstrating a very strong correlation (British Medical Journal 2017), even when the 95% CI was taken into consideration. Despite good evidence of reliability of the waist accelerometer it was clear at a variety of speeds that it was not demonstrating validity when compared against the criterion measure (observation from video recordings). This was demonstrated in Table 3.9 on page 132. Undertaking an analysis such as this was a useful learning experience. It demonstrated that whilst an instrument of measurement may demonstrate reliability, other investigations are necessary to evaluate its validity (Sullivan 2011).

Test-retest types of reliability investigation rely on being able to eliminate or minimise any changes between repeated tests in order to compare them (Sullivan 2011). Whilst every effort was made to repeat the tests as identically as possible, this was not always achieved. Some participants walked slightly faster or slower between the two walks using either the WZWF or WS. This caused a slight variation in the step counts recorded during some repeated

walks, both for observation and step count quantified by accelerometers. The ICC and 95% CI was calculated using the data collected during both walks. Despite the slight variations between walks (of which the greatest was 9 observed steps for one participant) the results of correlational analysis still represented a very strong correlation for test-retest reliability for either site.

3.10.8 Accelerometer comfort

No participant noted any discomfort from wearing the accelerometers at either placement site. There was no evidence of skin breakdown, non- blanching redness or reports of paraesthesia (‘pins and needles’) caused at any placement site. There were no reports of any movements being impeded by the presence of the accelerometers. No participant wore the devices for longer than one and a half hours.

The main findings of the feasibility study were:

- Similarities between the contours of the lines constructed using vector magnitude readings captured for a specific postural transfer suggested the waist accelerometer placement site was consistently capturing similar data during each of the three repeated movements (per postural transfer) for the individual participants
- Considerable variability in the shape of the three contours even during the three repeated movements for individual participants suggested ankle activity during postural transfers was more variable
- Vector magnitude readings were often not captured at all for both sitting to standing and standing to sitting transfers from the ankle placement
- Similarities between vector magnitude readings for different postural transfers were evident for both waist and ankle placement sites, meaning difficulties would be encountered identifying a specific postural transfer by knowledge of its vector magnitude intensity reading alone
- The waist accelerometer frequently misinterpreted the lying position as sitting, possibly due to the slight inclination of the trunk due to the bed head being raised for participant comfort

- The waist accelerometer correctly identified a lying position when participants adopted a side lying position
- The waist accelerometer often reversed the body positions of sitting and standing, identifying sitting as standing and standing as sitting. This was possibly due to the individual's posture and degree of pelvic tilt. A more anterior tilt of the pelvis, whether in sitting or standing may have been more likely to be identified as a standing position. A predominantly posterior tilt of the pelvis may have precipitated a sitting position to be recorded by the waist accelerometer as standing
- The ankle accelerometer correctly identified lying and sitting on greater than 90% of occasions
- The ankle accelerometer often misclassified sitting as standing, only correctly identifying the sitting position on 31.9% of occasions
- A mean difference of 5 to 7 steps was calculated when waist accelerometer step count data was compared to observed step count, with wide 95% CI. This was regardless of whether a WZWF or a WS was used
- A mean difference of less than one step in step count was calculated when ankle accelerometer step count data was compared to observed step count, with considerably narrower 95% CI compared to the waist accelerometer placement. This was again regardless of whether a WZWF or a WS was used
- Both accelerometer placement sites were well tolerated, based on participant feedback related to comfort

3.11 Discussion

This feasibility study investigated the ability of the Actigraph GT3X accelerometer to identify body position, postural transition and step count. This initial study invited an age matched healthy population who received instruction in simulation of activities typically undertaken by patients recovering in hospital from critical illness. An electronic bed, identical to those occupied by patients within the ward setting was used. A movement protocol was performed on the bed included turning into side lying, lying supine, moving from lying to sitting

and moving from sitting to standing. The reverse of these postural transitions was also undertaken. All postural transition movements were performed both with physical assistance and independently. Participants also walked two ten-metre distances with a WZWF, followed by two ten-metre distances with a WS.

The inclinometer, activity intensity and step count measurement modes of the Actigraph GT3X accelerometer were investigated to assess their ability to capture and quantify movements undertaken as part of the protocol. Two placement sites were investigated; above the hip, worn around the waist (the manufacturer's recommended position) and the lateral aspect of the ankle. Video recordings functioned as the criterion measure against which accelerometer data was compared. This study is the first to assess the validity of this particular accelerometer model mounted at any body placement site specifically during activities typically undertaken by those recovering from critical illness. Recent research has used this particular make and model, mounted on the ankle to directly quantify activity within this population (Schujmann et al. 2015a, Schujmann et al. 2015b). Hence, there is a requirement to investigate the validity of this device and provides support for the rationale of the choice of model and placement sites chosen for this study.

The results following data analysis of this feasibility study will now be discussed. Both placement sites are considered and the discussion section is organised in a similar order to which data analysis was presented.

3.11.1 Inclinometer (body position) recording

The waist placement site regularly misclassified all body positions of standing, sitting and lying. The fair level of agreement ($\kappa = 0.21$, $p < 0.001$), calculated for recognition of body position for this placement site concurs with another study which reported a similar value ($\kappa = 0.29$, $p < 0.001$) when investigating the inclinometer function of the GT3X to identify lying, sitting and standing postures (Berendsen et al. 2014). Activities undertaken within the study by Berendsen et al. (2014) were not typical of those recovering from critical illness. Over half of

the time spent in sitting was misclassified as standing in three out of the five healthy participants who undertook a movement protocol under laboratory based conditions (Berendsen et al. 2014). The feasibility study also identified that the waist placement regularly misclassified sitting as standing and vice versa. This could potentially give an overestimation of time spent in upright (standing) positions, suggesting individuals were engaging in activity for longer periods in the day when in reality they were adopting more sedentary postures (sitting). This frequent misclassification of all positions would not enable the ability to be able to accurately quantify time spent in sedentary positions (lying or sitting) or provide the opportunity to differentiate between lying and sitting postures. Raising the angle of the bed head, often seen in the hospital setting is likely to precipitate the misclassification of lying as sitting. This was evidenced within the feasibility study.

Berendsen et al. (2014) reported a substantial amount of time spent in lying was misclassified as a ‘0’ (non-wear) by the GT3X mounted at the waist, with some non-wear readings also captured during sitting. They found 98.1% of non-wear time was classified during lying, with 1.7% and 0.2% of non-wear time classified during sitting and standing respectively. The Kappa analysis within this feasibility study also revealed that virtually all readings of ‘0’ captured at the waist were encountered during either lying or sitting, evidenced in Appendix B12, found on page 285.

The waist placement frequently misclassified the lying position as sitting. It is postulated this was due to the head of the bed being raised. Participants adopted a more semi-recumbent position, causing the accelerometer to capture a sitting position due to the slightly elevated position of the trunk. The head of the bed is often raised within the hospital environment to discourage the adoption of supine lying postures, which could lead to the development of post-operative pulmonary complications, particularly within surgical populations (Cassidy et al. 2013). The consistent findings between the feasibility study and Berendsen et al. (2014) suggest a waist placement of GT3X, which is the manufacturers recommended placement site is not valid for identification of

lying, sitting and standing during typical activities undertaken by a population recovering from critical illness. As a result, accurate identification of postural transitions between these positions would not be possible.

The non-wear ‘0’ reading was also encountered within data captured by the ankle accelerometer. It was rarely captured however in any position other than the side lying position. A ‘0’ was registered on the ankle accelerometer data even during the brief periods of side lying during the assisted lying to sitting transfer, which permitted the two physiotherapists to prepare for moving the participant from side lying to sitting over the edge of the bed. These findings suggested the ankle accelerometer was consistently capturing the same number for this position. This was especially true when the accelerometer lay directly underneath the participant, for example during left side lying. Other periods of side lying were captured as lying (‘2’). This finding was consistent in 29 out of 30 participants, suggesting this was an important finding and that consideration should be given to a recoding of a ‘0’ reading to a ‘2’ for lying for this particular placement site. Further research is required to substantiate this finding. When a ‘0’ reading was recoded to a ‘2’ denoting the lying position, the ankle placement correctly identified the lying and standing positions on 91% and 99% of occasions, respectively.

The ankle placement only correctly identified the sitting position on 32% of occasions, often misinterpreting this position as standing. On closer inspection of the videos, it appeared correct recognition of the sitting position was most often captured when participants sat in a position where knee flexion was less than 90° (with the legs resting out in front of them for example). If the knee was visibly resting at 90° (the feet resting flat on the floor) a standing position was captured. Although the ankle placement accurately identified the standing position, it also regularly misinterpreted the sitting position as standing. Therefore, if this placement site captured a standing position, there was a possibility that this was a misinterpretation of the sitting position.

The systematic review, reported in Chapter 2, commencing on page 23, identified a number of studies which reported excellent results for discrimination between lying, sitting and standing positions when two identical accelerometers were placed in combination on the ankle and thigh of the same leg (Pedersen et al. 2013; Brown et al. 2008). It is postulated that placement of an Actigraph GT3X accelerometer in combination on the thigh and ankle of the same leg may also permit the ability to differentiate between the positions of standing and sitting by the construction of an algorithm. The different position of the thigh limb segment during both postures (horizontal during sitting, vertical during standing) could make this distinction possible.

A standing position is unlikely to be captured at the thigh during sitting. It is postulated that a lying (‘2’) posture would most likely be captured due to the horizontal position of this limb segment during adoption of this posture (Bassett et al. 2014). This could permit distinction between sitting and standing postures. This postulation is worthy of further investigation in future research projects using the GT3X. Given the encouraging results of the ankle placement in identification of both lying and standing postures, the data captured by a thigh mounted placement, placed in combination would only be required to differentiate between sitting and standing on occasions where the ankle placement captured a standing (‘1’) position.

Another study has concurred that a single ankle placement cannot differentiate between sitting and standing and thus cannot identify postural transitions between these two positions (Fortune et al. 2014). Given the problems with misclassification of the sitting position as standing, the postural transfers of lying to sitting may not always be correctly identified. The addition of a second thigh mounted Actigraph GT3X, solely for differentiation between sitting and standing may permit distinction between all postures, thus enabling the correct identification of all postural transitions. Patient compliance and comfort from wearing multiple units would require consideration in future research studies, especially if they were being worn for a number of hours during the day (Fortune et al. 2014; Atallah et al. 2011).

3.11.2 Physical activity intensity count

The vector magnitude readings captured by both the waist and ankle accelerometers during all postural transitions performed on the bed were plotted to form line graphs. Each transition was repeated three times, permitting the construction of three lines, which were all drawn onto the same chart. The similar contours of the three lines within the charts suggested the accelerometers were capturing similar information during the three repeated movements. The differences in the contours of the lines within the charts created for individual participants, suggested variability in how movements were undertaken between participants. The wide range in overall vector magnitude readings calculated for each individual transfer for all 30 participants, evidenced by the histograms found in Appendix B10 and B11, commencing on page 277 (waist placement) and 281 (ankle placement) suggested difficulty would be encountered identifying a particular transfer by its vector magnitude intensity (activity intensity) alone. Furthermore, the similar intensities captured for different postural transfers further confound the ability to identify a specific postural transfer by its intensity alone.

The systematic review identified one study, undertaken within an ICU, where the authors intended to investigate whether activity type could be determined by its activity intensity alone (Winkelman et al. 2005). This was unable to be achieved due to the paucity of different types of activity undertaken within this environment other than passive movements and rolling in the bed. The feasibility study, presented here in Chapter 3 has highlighted the difficulties encountered by using this technique in isolation to identify specific typical activities generally undertaken by patients recovering from critical illness.

3.11.3 Step count

The ankle placement site was superior to the waist placement for the ten metre walks taken with a WZWF and a WS respectively at speeds of greater than 0.3m/s. This was evidenced by the mean difference between the step counts captured by the accelerometers and by direct observation being much smaller for the ankle placement. All mean differences were less than one step. The

95% LOA were also much smaller for the ankle compared to the waist at these speeds. This finding was evident in both the walks undertaken using a WZWF and a WS, respectively. At walking speeds of less than 0.3m/s the ankle and waist mounted accelerometers both encountered difficulties identifying step count. The waist placement site failed to capture a single step during walks of less than 0.2m/s using a WZWF. The ankle failed to identify greater than 50% of observed steps at these very slow speeds also.

Webber et al. (2014) initially reported that the accuracy of step count quantification through the use of hip mounted activity monitors decreases when walking aids were used. Later research undertaken by Webber and St John (2016) suggested movement of placement site from the hip to the ankle, determined the validity of accelerometers such as the GT3X+ in hospitalised populations who walked at slow speeds, often using walking aids. The feasibility study found the GT3X mounted above the hip (around the waist) encountered difficulty quantifying step count during walks either with a WZWF or WS. Results were superior for the ankle placement, therefore, concurring with Webber and St John (2016) and Webber at al. (2014).

A systematic review and meta-analysis determined usual walking speed to be 0.46m/s in acute care settings for hospitalised adults of 70 years of age and over (Peel et al. 2013). It is important that laboratory based investigation or any simulated environment seeks to capture similar speeds to the eventual chosen populations when assessing the validity of accelerometers to quantify step count. However, uncertainty remains regarding what usual walking speed may be for patients recovering from critical illness. Further research is encouraged to ascertain this, to assist in future studies investigating the validity of accelerometers in patients recovering from critical illness. This is especially true in studies which may enrol healthy populations who simulate walking activities and speeds typically adopted by this patient population.

This study concurs with other studies identified within the systematic review which determined the ankle placement to be valid in determination of step

count in hospitalised populations who walked at slow speeds (Webber and St John 2016: Edbrooke et al., 2012). However, the GT3X was not able to accurately detect step count at speeds of less than 0.3m/s at either placement site. Webber and St John (2016) used a similar model in their study produced by the same manufacturer of the GT3X, called the GT3X+.

Studies using an ankle mounted Actigraph GT3X+ model in slow gait speed populations have reported an increased accuracy of step count at slow walking speeds when the LFE filter was activated (Webber and St John, 2016, Korpan et al. 2015). Both these studies found superior results when the Actigraph accelerometers were worn around the ankle compared to the hip. Error values of 19 to 97% were found when the accelerometer was worn around the hip and the LFE was not activated (Webber and St John 2016). In contrast, the ankle placement encountered absolute percentage errors of less than 3% when the LFE algorithm was activated. The feasibility study, which also activated the LFE data filter, also found the ankle placement superior to the hip (worn around the waist) for determination of step count at slow speeds.

The ankle placement demonstrated validity in quantification of step count at speeds of greater than 0.3m/s, considerably less than the 0.46m/s gait speed determined in older acutely hospitalised populations following systematic review and meta-analysis (Peel et al. 2013). The findings of this feasibility study and two further studies which have investigated almost identical Actigraph accelerometers support continued investigation of these models to quantify step count in populations likely to walk at slower speeds. Further research is also required to determine the effect of the LFE filter on possible overestimation of step count, for example in those who may fidget in the chair, due to its increased sensitivity (Webber and St John 2016, Feito et al. 2015).

The thigh mounted uniaxial activPAL accelerometer was not found to be valid in determination of step count when patients walked at speeds of < 0.47m/s (Taraldsen et al. 2011). Similar results were reported in another study which investigated this model and placement site in a population likely to walk short

distances at slow speed (advanced cancer) (Skipworth et al. 2011). The distances chosen by both authors to evaluate step count was small (six metres and five metres respectively), though not uncommon in studies of this type (Graham et al. 2008). The thigh placement was not investigated within the feasibility study; therefore, comparisons cannot be made with other studies which used this placement site to determine whether the actual placement site, not the accelerometer was the cause for the disappointing results. The studies above have highlighted, however, how body placement site can impact on the ability of an accelerometer to quantify step count (Webber and St John 2016).

3.11.4 Reliability of step count quantification

Both walks undertaken with either a WZWF or WS were repeated in order to evaluate consistency in the way the accelerometers interpreted step count on each walk. Although every effort was made to minimise variability between repeated walks this was not always successfully achieved. This led to some repeated walks not quite possessing the same number of observed steps that the accelerometers were quantifying. Despite this, strong correlations were found for test-retest reliability for both the waist and ankle placements, with the waist placement demonstrating slightly superior results. Data analysis in this way permitted direct comparison to the results of ICC (95% CI) analysis for test-retest reliability within the study by Edbrooke et al. (2012) for an ankle placement specifically. Edbrooke et al. (2012) reported an ICC (95% CI) of 0.99 (0.99-1.0) for reliability of the AMP 331. In comparison the feasibility study reported 0.92 (0.81-0.96) when using a WZWF and 0.92 (0.84-0.96) when using a WS.

Whilst both results (WZWF and WS) still demonstrated very strong correlations, the results reported by Edbrooke et al. (2012) not only reported a higher ICC (0.99) but very small 95% CI (0.99-1.0). It is difficult to directly compare the studies for a number of reasons. Firstly, although distance was measured in the study by Edbrooke et al. (2102), walking speed was not determined. It cannot be ascertained therefore whether similar walking speeds were undertaken during the study by Edbrooke et al. (2012) and the feasibility study. Secondly,

although five participants used a walking aid in the study by Edbrooke et al. (2012), 15 did not and were able to walk independently with no aid. Clearly, the majority of participants had a good degree of physical function, especially considering the maximum distance undertaken (and repeated) was 50m. This is surprising considering the location of where the research was performed (within the ICU).

3.12 Strengths and Limitations

This feasibility study has expanded the evidence base investigating the validity of the Actigraph GT3X to identify body position and quantify step count when taken at slow walking speeds. Although laboratory based, it attempted to capture a range of walking speeds likely to be encountered within clinical populations recovering from critical illness. Participants, although healthy, were age matched to a population admitted onto the various ICU establishments locally. This was considered a strength considering that research suggests individuals undertake postural transitions and movement differently in different decades of life (Mount et al. 2006, Ford-Smith and VanSant 1993). Identical equipment to that used by patients recovering from critical illness, including hospital issue beds and walking aids were employed during the movement protocol. Each participant underwent a period of training to simulate a patient weakened by critical illness, adopting lying, sitting and standing postures and undertaking postural transfers both independently and with physical assistance from two qualified physiotherapists. These two types of conditions would be encountered as a matter of routine within the clinical environment, depending on a patient's level of physical function at a given time.

Both physically assisted and independent postural transfers were undertaken three times in order to investigate the ability of the accelerometers to capture movement when it was repeated in as identical manner as possible. The vector magnitude intensity counts captured each second during the transfer were plotted on a graph for each of the three identical movements, producing three lines. These were visually examined to assess their similarity. No studies were identified within the systematic review which investigated the reliability of the

accelerometers to quantify postural transition using a test-retest design. As a result, this can be considered a strength of this study, commencing the process of investigation of this particular aspect. However, it is acknowledged that reliability was not actually quantified in the form of a correlational analysis for example. Investigation is encouraged in this area and, therefore, is also considered a limitation of this study.

Finally, this study continued investigation which was not able to be completed by other authors investigating the use of accelerometry within populations recovering from critical illness (Winkelman et al. 2005). They intended to determine if activity type, for example transferring from lying to sitting over the side of the bed, could be determined by the activity intensity counts captured by accelerometers alone. The feasibility study found wide variability in the intensity counts captured by all postural transfers, with some intensity counts shared by more than one postural transition, which would make determination of a particular activity type based solely on activity intensity count difficult.

This study also has certain limitations. Although most postural transfers and adoption of body postures were included within the movement protocol, other typical activities were not. One of these activities would be sitting in a chair by the side of the bed for a period of time. The only sitting activity investigated was that which occurred during sitting over the side of the bed. Inclusion of this activity would have made the movement protocol a considerably longer process for those who kindly agreed to participate, especially considering the time that had already been devoted to taking part. Future research will aim to include this important activity, directly within populations recovering from critical illness in order to assess the ability of the accelerometers to correctly identify the adoption of the sitting posture in a chair.

Another limitation was the enrolment of a healthy population who simulated a population experiencing critical illness. This study sought to explore how the accelerometers may behave during performance of typical activities undertaken by those recovering from critical illness. It was an opportunity to develop further

ideas, seek feedback from participants regarding accelerometer comfort and whether they were felt to impede movement in any way. The study findings and further postulations that arose following this initial investigation and undertaking of the systematic review were intended to inform the methodology for a further study. This will be explored in Chapter 4 in a study which enrolled a patient population, recovering from critical illness on a hospital ward.

3.13 Conclusions and future recommendations

The following conclusions were reached after undertaking of this feasibility study. Findings are linked to the research questions posed within introductory Chapter 1, which are revisited at this point.

To what extent can the Actigraph GT3X accelerometer quantify the functional activity (postural changes between lying, sitting and standing) typically undertaken by hospital inpatients recovering from critical illness?

The ankle mounted accelerometer placement site was superior to the waist placement site in recognition of body position in healthy subjects who simulated patients' recovering from critical illness. Whilst the waist accelerometer regularly misclassified all body positions of lying, sitting and standing, the ankle placement only regularly misclassified the sitting position. The sitting position was regularly mistaken as the standing position by the ankle placement. As a result recognition of the postural transfers lying to sitting and sitting to standing would encounter difficulty from an isolated ankle placement. Placement of a second identical model on the thigh may permit the ability to discern between sitting and standing, based on the data synthesised as part of the systematic review and assimilation of the findings within the feasibility study. This is worthy of further investigation, given the excellent results for detection of lying and standing for the ankle placement.

The wide range of vector magnitude intensities recorded by both the ankle and waist accelerometers during all postural transfers means that it cannot be recommended that activity intensity be used to identify a particular activity

being undertaken (e.g. transferring from lying to sitting over the side of the bed). This is further supported based on the findings that certain intensity readings were shared by different activities.

To what extent can this accelerometer model quantify step count in populations recovering from critical illness when compared with observed step count?

Although not strictly undertaken within a population recovering from critical illness, attempts were made to simulate slow walking speeds typical of this population using walking aids likely to be used. This study was the prequel to a study that would eventually invite this hospitalised patient group, thus informing formulation of future study methodology. An ankle placement was superior to a waist placement for quantification of step count when undertaken at speeds of greater than 0.3 m/s over short distances (e.g. ten-metres). At speeds of less than 0.3m/s, both the ankle and waist placement did not demonstrate validity. Step count demonstrated reliability in both the waist and ankle placement. Future studies should aim to evaluate typical walking speeds of those recovering from critical illness from all stages of the rehabilitation continuum. This will assist in ascertaining the typical walking speeds undertaken by this population at certain points of their recovery, for example within ICU, upon transfer to the ward and following discharge. Walking speeds would then be able to be accurately simulated, particularly if healthy individuals are simulating this patient group within a laboratory setting.

What are the optimum body placement sites in which to position the Actigraph GT3X in order to identify lying, sitting, standing postures and step count in populations recovering from critical illness?

This study revealed that the waist was not the optimum site to identify posture or step count during activities typical of this population. It also revealed that whilst the ankle identified lying and standing postures well, further investigation is necessary to determine a possible second placement site, in combination with the ankle placement, which will successfully discern sitting from standing. If this can be achieved, identification of all postural transfers can be enabled. Future studies should enrol an actual patient population and investigate

whether placement of a second accelerometer on the thigh, in combination with the ankle will improve the ability to correctly determine the sitting position. Accelerometer comfort and acceptability should also receive consideration, especially when applying multiple devices.

Is the Actigraph GT3X accelerometer valid in detection of body position and step count in a population recovering from critical illness?

This remains undetermined as an actual population of this type was not enrolled in this feasibility study. Nevertheless, this study permitted exploration of the GT3X in identification and quantification of typical activities undertaken by this patient group. Progression of thought and assimilation of knowledge from both the feasibility study and systematic review resulted in the construction of the research methodology for another study, undertaken directly within a ward based population recovering from critical illness. This is now presented in Chapter 4.

Chapter 4

Validity study

4.1 Introduction

The systematic review, presented in Chapter 2, concluded that a variety of commercial and custom made accelerometers have undergone investigation of their validity or reliability in identification of body position or purposeful movement within acute or critically ill hospitalised adults. However, only two of the 15 articles included enrolled populations recovering from critical illness (Edbrooke et al. 2012; Winkelman et al. 2005). Whilst one study investigated quantification of step count (Edbrooke et al. 2012), the other determined the validity of an accelerometer to quantify both the frequency and duration of activity performed (Winkelman et al. 2005). Both studies were undertaken within the ICU. No studies were identified where accelerometer validity was investigated within this population directly in a hospital ward environment. Therefore, the systematic review revealed a gap in the knowledge base. Despite this dearth of evidence of validity investigation in this particular setting, accelerometers have been used with patients recovering from critical illness to quantify time spent in lying, sitting or standing postures and walking in the final few days of hospital stay, prior to discharge from the acute setting (Borges et al. 2015).

The feasibility study, reported in Chapter 3, determined that an Actigraph GT3X accelerometer placed in isolation on the ankle correctly identified both lying and standing positions on greater than 90% of occasions, where any ‘0’ (not wearing) inclinometer readings were recoded to a ‘2’ (lying) readings. However, it only correctly identified the sitting position on 32% of occasions, often misinterpreting sitting as standing. Correct determination of the sitting position appeared dependent on the position adopted by the lower leg on which the ankle accelerometer was positioned. These findings were discussed in section 3.11.1 found on page 137 of Chapter 3. Further investigation is required to discover if there is a method of discerning sitting from standing. A possible

solution may be the addition of a second GT3X placed on the thigh, in combination with the ankle. This combination has demonstrated validity in identification of lying, sitting and standing postures in older hospitalised populations (Pedersen et al. 2013; Brown et al. 2008).

The feasibility study also reported that there was less than one step mean difference between the step count determined by a single GT3X mounted on the ankle when compared to observed step count for all ten-metre walks undertaken using a WZWF or WS at speeds of greater than 0.3 m/s. Considerably narrower 95% LOA were also calculated compared to a waist placement for all walks undertaken. These findings were presented in Table 3.10 in Chapter 3, found on page 133. Assimilation of the findings from both the systematic review and the feasibility study, focussing in particular on the encouraging results for determination of step count and body position regarding the ankle placement, permitted refinement of ideas and the development and undertaking of a further study which is presented within this chapter.

Reporting of the study, commencing from the introduction is in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement checklist for cross sectional studies. STROBE is an international initiative endorsed by a growing number of biomedical journals (www.strobe-statement.org). STROBE was developed in collaboration with epidemiologists, methodologists, statisticians, researchers and journal editors to ensure 'the correct conduct and dissemination of the results obtained from observational studies'. This checklist was previously used to report the results of another study which investigated the validity of another commercial accelerometer model to quantify step count in a population recovering from critical illness (Edbrooke et al. 2012).

4.2 Background and Rationale

Evidence of increasing interest has emerged regarding the use of both Actigraph GT3X and GT3X+ models within populations recovering from critical

illness. Knowledge of this has arisen from a variety of sources. The first source concerned an email contact received from a team of clinical researchers based in Canada expressing interest in the subject matter contained within this thesis. Researchers within this team had obtained a summary of the study presented within this chapter. This summary was freely available within the public domain, prepared as part of the requirements for the NHS Ethics application, requested by the Health Research Authority (HRA). A link to this summary is found below:

http://www.hra.nhs.uk/news/research-summaries/validity-of-an-actigraph-accelerometer-following-critical-illness/

This direct contact from other researchers provided evidence of the relevance and importance of the choice of subject matter contained within this thesis. More importantly it provided evidence that other clinicians and researchers working within critical care were also considering the use of this particular accelerometer model to quantify purposeful activity. Furthermore, searches undertaken within the clinical trials database ClinicalTrials.gov revealed another study where the feasibility and validity of using the Actigraph GT3X+ within a medical and surgical population resident on ICU was being investigated (ClinicalTrials.gov identifier: NCT02263716).

The study described within the ClinicalTrials.gov database (ClinicalTrials.gov identifier: NCT02263716) intended to investigate the feasibility of wearing the GT3X+ at three isolated placement sites, namely the wrist, hip (around the waist) and ankle. This was in preparation for a future study aiming to measure activity levels of 300 ICU patients, with evaluation of physical and cognitive function three and 12 months later. The investigators planned to use the activity intensity count measurement mode to quantify physical function. An email communication (NE Brummel 2017, personal communication, 29th March) reported that only two placement sites were being used in this later study (wrist and ankle) as the waist placement regularly became soiled when positioned on patients in ICU. Patients' resident on a ward may have surgical wounds following abdominal surgery, precipitating the risk of soiling a waist placement site also, accompanied by possible discomfort from wearing an elastic belt around the waist. This further supported the decision not to use the waist

placement site any further, based on the results of the feasibility study and a patient comfort perspective.

Discovery of the interesting research project detailed in the previous paragraph emphasised the importance of continuing to regularly search clinical trials databases and undertake literature searches. Adoption of this practice permitted continued identification of any more recent studies, providing opportunity to expand knowledge further within similar subject areas or yield the potential for future collaborative work on an international scale through the development of communication links and encouragement of mutually beneficial dialogue. Furthermore, it also ensured that studies that were to be undertaken as part of the PhD continued to be novel, innovative and original. Maintenance of channels of communication with a number of authors identified from journal articles and clinical trials databases has greatly assisted with progression of thought within the PhD thesis, leading to the synthesis of the projects within it.

Emergence of research undertaken within hospitalised populations recovering from critical illness using the Actigraph GT3X accelerometer supports both the rationale and justification for the creation of this thesis (Schujmann et al. 2015a; Schujmann et al. 2015b). This is especially true when the choice of body placement site (the ankle) was similar. The feasibility study determined that there was inconsistency in the ability of an ankle mounted GT3X to correctly identify the sitting position, although it correctly identified both lying and standing positions on greater than 90% of occasions. It was postulated that the inconsistency of the ankle placement to correctly identify the sitting position was due to variability in the way participants adopted this position. During sitting, when the ankle wearing the accelerometer was resting at 90°, with the foot and heel flat on the floor, sitting was often misinterpreted as standing. This was attributed to the similar position of the ankle during standing. However, if the feet were resting out in front of the participant (though still in contact with the floor) or the knees flexed beyond 90° the sitting position was correctly interpreted due to the way the accelerometer was inclined either forwards or backwards during adoption of these positions.

A similar model, the Actigraph GT3X+, has been investigated in acutely admitted older populations, also using a lateral ankle placement, similar to that used in the feasibility (Webber and St John 2016). Their investigation yielded encouraging results for quantification of step count in populations who characteristically walk at slow speeds of < 0.46m/s, with an ankle placement performing better than the manufacturer's recommended site of the waist. This finding concurred with another study investigating the validity of the same model, also using an ankle placement in an older community dwelling population, some of whom used walking aids and some who walked independently (Korpan et al. 2015). Participants within this study however, did not walk at such slow speeds (≥ 0.8m/s).

Webber and St John (2016) and Korpan et al. (2015) reported that the GT3X+ was valid in the quantification of step count in older populations when the low frequency extension (LFE) filter was activated. The findings from these studies support activation of the LFE filter on Actigraph models for quantification of step count in populations likely to walk at slow speed, which would include older people and those recovering from acute or critical illness. Furthermore, these later findings supported the decision to activate the LFE filter within the feasibility study, especially considering the range of walking speeds encountered within it (0.17m/s to 0.55m/s). Therefore, the feasibility study findings have augmented the evidence base supporting activation of the LFE filter within Actigraph accelerometer models to capture steps undertaken at slow speeds.

Assimilation of research evidence from other studies, the results of data synthesis from the systematic review and feasibility study findings precipitated the formulation of another methodological protocol for a further study. This study aimed to investigate the validity of the Actigraph GT3X in identification and quantification of both body position and step count in a hospital ward based population recovering from critical illness. Information concerning how the findings from these previous investigations informed the development of this protocol is presented in Table 4.1 on page 155.

Table 4.1 Findings which informed development of a further methodological protocol

Finding	Source	Assimilation of finding into next study
Use of the LFE filter within Actigraph models maximises the ability to capture step count during walking at slow speeds	Webber and St John (2016) Korpan et al. (2015) Findings from feasibility study	Employ the use of the LFE filter on the GT3X to capture step count within a population likely to walk at slow speed (those recovering from critical illness)
Ankle placement of the Actigraph GT3X / GT3X+ is superior to the waist for determination of step count in populations who walk at slow speed	Webber and St John (2016) Korpan et al. (2015) Findings of feasibility study	Continue investigation of the ankle placement within a clinical population
An ankle mounted GT3X correctly identifies lying and standing positions with > 90% accuracy, but is inconsistent in correctly interpreting the sitting position (32% accuracy)	Findings of feasibility study	Investigate whether a combination of placement sites improves the ability to correctly interpret the sitting position.
Placement of a GT3X+ model on the thigh is superior to the waist placement in determination of the sitting position Accelerometers placed in combination on the ankle and thigh have demonstrated validity in determination of lying, sitting and standing	Feasibility study Systematic review findings Skotte et al. (2014) Pedersen et al. (2013) Brown et al. (2008)	Investigate whether a combination of an ankle and thigh GT3X placement improves the ability to identify the sitting position by development of an algorithm using accelerometer data from both the thigh and ankle
Studies investigating accelerometry validity in quantification of purposeful movement within populations recovering from critical illness have only been conducted within the ICU	Systematic review findings Edbrooke et al. (2012) Winkelman et al. (2005)	Investigation of the validity of the GT3X within those recovering from critical illness residing within a hospital ward

The purpose of this study was to investigate whether body position and step count could be captured by the Actigraph GT3X accelerometer in a ward based population recovering from critical illness. Based on the encouraging findings for identification of lying, standing and step count from the feasibility study, the lateral aspect of the ankle was selected for continued investigation. A new body placement site was also evaluated, which was the anteromedial aspect of the thigh. This site was chosen based on findings from the systematic review, interpretation of further research findings (Skotte et al. 2014) and the undertaking of some fieldwork investigation.

Previous studies had suggested that this combination of placement sites demonstrated validity in determination of lying, sitting and standing positions (Pedersen et al. 2013, Brown et al. 2008). It was this finding that precipitated the decision to undertake some fieldwork investigation to explore how this combination of placement sites interpreted sitting and standing positions in particular. The intention of this investigation was to understand whether an algorithm could be developed to assist in successfully distinguishing between these two postures. It was hypothesised that data from the thigh placement would only be required to detect whether a sitting or standing posture was being adopted when the ankle placement identified a standing posture. However, investigation of this placement site in isolation to identify body position could also be determined as part of this study.

The systematic review determined that whilst thigh mounted models were determined to be valid in recognition of sedentary behaviours (lying or sitting), they could not discern between both of these postures (Taraldsen et al. 2013; Godfrey et al. 2010). However, in the clinical setting this may be all that is required, identifying prolonged periods of adoption of sedentary postures or when people are in upright positions, suggesting they are standing. Therefore, investigation of whether the GT3X when placed in isolation on the thigh identified postures in a similar way was considered useful. It would augment the evidence base for thigh mounted accelerometers generally within

hospitalised populations and potentially increase the choice of models to select for clinical use if it demonstrated validity.

Fieldwork explored the data captured simultaneously by GT3X accelerometers positioned at both the thigh and ankle during adoption of sitting and standing positions, assisted by the use of video recordings to compare the data against. This fieldwork was undertaken independently by the CI following completion of the feasibility study and was undertaken within a therapies gymnasium within HEYHT. An interesting finding emerged, suggesting that differentiation between sitting and standing positions was possible using a simple algorithm. Readings provided by both accelerometers were used to permit identification of each individual posture. During adoption of a sitting posture, the anteromedially positioned thigh accelerometer predominantly identified a lying position, also correctly capturing a sitting position on occasion. The lying position was predominantly interpreted at this placement site during sitting due to the horizontal position of the thigh during adoption of either posture (Bassett et al. 2014). Fieldwork also determined that the thigh placement often correctly identified the standing posture. Using this data, a simple algorithm was developed to undergo investigation within the study. The algorithm is presented in Table 4.2 below:

Table 4.2 Differentiating between sitting and standing using the thigh/ ankle algorithm

Body position	Thigh inclinometer reading	Ankle inclinometer reading
Standing	1	1
Sitting	2 or 3	1

Investigation was required to determine whether determination of the sitting position could be improved by interpreting the accelerometer readings from both the ankle and thigh, specifically when the ankle captured a reading of

standing. Following this essential fieldwork, it was possible to construct the following study objectives.

4.3 Study objectives

The study objectives were:

1. To determine the validity of the inclinometer inherent within the Actigraph GT3X accelerometer to identify lying, sitting and standing when placed in isolation on the non-dominant thigh or ankle in a ward based patient population recovering from critical illness. The non-dominant leg was chosen as manufacturers of other ankle mounted models (Actical) recommend that they are worn on the non-dominant leg (Hager et al. 2015).
2. To investigate the validity of a combination of thigh and ankle Actigraph GT3X inclinometer readings to correctly distinguish between standing and sitting, using an algorithm constructed during preparatory fieldwork.
3. To determine the validity and intermethod reliability of the step count mode within the Actigraph GT3X accelerometer to quantify step count when placed in isolation on the non-dominant thigh or ankle of the same population.
4. To evaluate from a user perspective, the acceptability and comfort of the placement sites used.

Following the formulation of study objectives, hypotheses were constructed. These were based on the postulations developed using the findings from the systematic review, the feasibility study and other research articles identified during additional literature searches.

4.4 Hypotheses

1. An ankle mounted Actigraph GT3X would accurately identify both the lying and standing position (greater than 90% accuracy) when compared against direct observation as a criterion measure. This would suggest

that results were comparable with the feasibility study and the accelerometers were consistent in their interpretation of these particular positions.

2. An ankle mounted Actigraph GT3X will capture a step count comparable to that recorded by direct observation, with a mean difference of less than one step with a narrow 95% LOA (-5 to +5 steps). This result would reflect similar readings to that captured by walks of speeds greater than 0.3m/s undertaken within the feasibility study when the ankle accelerometer was worn.

3. The combination of inclinometer outputs of both the antero-medial thigh and ankle placement sites would improve identification of the sitting position compared to an isolated ankle placement.

4. Both the ankle and mid-thigh placement sites chosen would be tolerated well by patients recovering on a ward from critical illness.

4.5 Materials and Methods

4.5.1 Study design and setting

The study was observational, prospective and exploratory in design (Black 1996). It was undertaken on hospital wards within an acute NHS Trust hospital. As patients' condition improved, the potential existed to be discharged from the ICU to a wide variety of different ward based specialties within the Trust, distributed across two main hospital sites. This was dependent on the patient's specific pathology and medical requirements at the time. As a result of this, permission was sought (and granted) from the Divisional Nurse Managers from all specialities within the Trust to enter the wards within their respective sections to undertake the research, should a participant have been identified who fulfilled the eligibility criteria and had been discharged to the ward they were responsible for. Information regarding how potential participants were identified and the consent process is discussed in section 4.5.2 on page 160.

Once patients were identified and informed consent was gained, accelerometer data was collected in a single session, not exceeding three hours in total. This

time period was selected to decrease the risk of participants withdrawing from the study due to a dislike of being observed constantly. Evidence of this was reported within a study by Brown et al. (2008), included within the systematic review in Chapter 2. The first of twenty participants was recruited and underwent data collection in September 2016. The last participant was recruited and underwent data collection in April 2017.

4.5.2 Participants and recruitment

The study invited hospital ward based patients who had been discharged from the ICU due to significant improvement in their condition. All ward based physiotherapy staff responsible for delivery of physiotherapy services as members of the direct care team received instruction concerning the study's eligibility criteria. Potential participants were identified by these members of the clinical team. They also communicated initial details of the study to patients who fulfilled the eligibility criteria. The CI did not approach any participant in the first instance to deliver study details. This was considered inappropriate and unethical, possibly increasing the risk of participants feeling compelled to participate due to the CI's desire to achieve the target sample size.

In addition to delivering brief study details, the ward based physiotherapy teams also supplied an invitation letter and information sheet for potential participants to read and discuss with their families. The information sheet is found in Appendix C1 on page 287. Participants were approached when recovery had progressed to a point where they were either independent or requiring minimal assistance to undertake postural transfers or mobilise. Due to the possibility of patients being discharged on account of the degree of physical recovery achieved, only 24 hours was permitted for participants to express interest in involvement in the study. If interest was expressed, the ward physiotherapists contacted the CI. The CI then visited the ward, often on the same day that contact had been made by the ward teams. Further details were offered and any questions were answered regarding participation. The format of the informed consent process was also discussed. It was made explicitly clear that if they did not wish to participate this would not affect their

treatment in any way. Regardless of their participation or not, individuals were always thanked for the interest they had initially shown in the study.

4.5.3 Sample size

A recruitment target of 20 participants was set. This sample size had been used in previous research investigating the validity of a different accelerometer model to quantify gait parameters in patients recovering from critical illness (Edbrooke et al. 2012). They predicted that 12 subjects were necessary based upon alpha = 0.05 (significance level), beta = 0.9 (power) and a correlation of *r* = 0.75, categorised as a good to excellent correlation (Trapp and Dawson 2004). This sample size was also used in a population resident in the ICU to investigate the validity of accelerometry to quantify the frequency and intensity of movement (Winkelman et al. 2005). Twenty participants were also recruited in another study investigating the validity of accelerometer measurement within a hospitalised stroke population (Kramer et al. 2013).

It was also recognised that this patient group had experienced a very distressing time and although progressing well with their recovery, they were still weak. A sample size of 20 was considered a realistic and achievable target, taking into account the possibility that some patients who were eligible may have just not felt physically able to undertake this type of study. Time constraints of undertaking a PhD were also taken into consideration.

4.5.4 Eligibility criteria

Table 4.3, following on page 162 details the inclusion criteria potential participants had to satisfy if they were to undertake the study. The rationale for each of these considerations is also included.

Table 4.3 Eligibility criteria

Inclusion criteria	Rationale
18 years of age or above.	Ethical and logistical considerations (only adult intensive care units on either Trust site)
Ventilated in excess of 48 hours during the ICU stay	Duration of ventilation considered prolonged, used as a standard comparable with other studies investigating early mobilisation and recovery within critically ill populations (Hodgson et al. 2015) .
Resident on a hospital ward (secondary care) following step down from ICU	No study to date has investigated the validity of accelerometry outside the ICU, within a hospital ward environment
At a stage of recovery where all postural transfers are able to be undertaken independently or with minimal assistance (one person only)	At a stage where a wider variety of postural transfers are able to be captured using accelerometers. Greater opportunity to capture a broad range of different activities compared to previous studies (Winkelman et al. 2005)
Able to mobilise short distances, either independently or with assistance from a walking aid or one person	Permits chance to also investigate quantification of step count, thus investigating whether these devices could also be used to identify episodes of mobility (walking)
Willing to permit application of two Actigraph GT3X accelerometers, one lying anteromedially around the non-dominant thigh; the other resting above the lateral malleolus on the same (ipsilateral) leg.	Data downloaded from the accelerometers relating to registration of body position and step count was to be investigated
Willing to consent to a period of direct observation for a length of time not exceeding three hours.	Observation was the criterion measure chosen to compare the accelerometer data against

4.5.5 Exclusion criteria

Participants were excluded if they were unable to provide written informed consent or had significant cognitive impairment adversely impacting on the ability to understand study information or follow a movement protocol. Patients unable to undertake postural transfers or walking activities independently or with minimal assistance due to significant neurological impairment were also not eligible. This particular exclusion criterion was also present in a study by Connolly et al. (2015), who investigated the effect of an exercise based rehabilitation programme post discharge for survivors of critical illness. As the validity study presented within this chapter also required participants to undertake gentle exercise with minimal or no assistance in order to investigate the validity of the accelerometers, it was considered appropriate to include this exclusion criteria. Participants unable to speak or understand English were excluded as the study received no funding to permit the use of interpreter services. Patients with peripheral vascular disease or lower limb amputation were also not eligible. This exclusion criterion was also applied to the study by Connolly et al. (2015). As the accelerometers were positioned around the lower limbs, attached by elastic broad bands, it was considered inappropriate to place the accelerometers on individuals with known lower limb circulatory deficiencies to decrease the risk of any further circulatory compromise. Any patients with confirmed Clostridium Difficile, similar infection or unmanaged urinary incontinence were unable to participate, due to possible contamination of the accelerometers. Finally, any patients with polytrauma preventing adoption of conventional lying, sitting or standing postures, or placement of the accelerometers according to the protocol were unable to participate.

4.5.6 Ethical approval

Ethical approval was obtained from the NHS Research Ethics Committee and Health Research Authority (REF: 16/EM/0210 198965). Please see Appendix C3 on page 291 for this documentation. The YSJU Research Ethics Committee also reviewed the study and granted approval (REF: 129091178_Anderson_15052016). A copy of this documentation is found in Appendix C4 on page 296. This study was deemed appropriate for

proportionate review by the NHS Research Ethics Committee, whose favourable opinion deemed the submission to be of ‘very high quality’. The study posed minimal risk to those being invited to participate. Participants were to be performing activities as part of a movement protocol that they would already be undertaking as part of their normal day.

4.5.7 Informed consent

Written informed consent was obtained if the patient agreed to participate following the discussion with the CI. Due to the risk of patients being discharged before data collection could take place, informed consent was often obtained at the same time the CI discussed the study with the patient. The CI countersigned the consent form and an identical signed copy of the consent form was given to the participant. This document contained the contact details of the CI had they wished to discuss any details of the study following their involvement. The participant was required to be physically able to sign the consent form and understand all the study information. The consent form used is found in Appendix C2 on page 289.

4.6 Data sources/ measurement

4.6.1 Actigraph GT3X accelerometer

Two Actigraph GT3X accelerometers, identical to the devices employed within the feasibility study were worn by participants. Three identical devices were loaned from a University supply mentioned previously in section 3.7.1 on page 100 of Chapter 3. This permitted the ability to switch the sites where a particular model was placed (ankle or thigh) to decrease the risk that the results obtained were specific to one particular GT3X model. This could have been a potential confounding factor had the same GT3X model been placed consistently at the same placement site. The dimensions and measurement modes inherent within this model have been described earlier within this thesis (section 3.7.1 on page 100). The accelerometers were positioned on the anteromedial aspect of the thigh and on the lateral aspect of the ankle of the ipsilateral (same) leg. Accelerometers were positioned on the non-dominant leg where possible to capture body position and step count readings. The devices

were only required to be worn for a maximum of three hours. The non-dominant leg was chosen as manufacturers of other ankle mounted models (Actical) recommend that they be worn on the non-dominant leg (Hager et al. 2015).

Brown et al. (2008), who also used this same placement combination, transferred the accelerometers on a daily basis to the contralateral leg, therefore using both legs for data collection. No analyses were undertaken to investigate whether there was any difference between accelerometer data captured from both legs. The accelerometers in the study by Brown et al. (2008) were worn for seven consecutive days, or until the patient was discharged, whichever came sooner. This was a considerably longer data collection period, which Brown et al. (2008) felt could have posed an increased risk of skin irritation from the devices. Therefore, Brown et al. (2008) checked the skin integrity of participants on a daily basis to ensure there were no signs of irritation. It was not deemed necessary to alternate the accelerometers between each leg for the considerably shorter duration of the data collection period for the validity study presented in this chapter (3 hours). Although Brown et al. (2008) applied the accelerometers for seven days, participants were actually only observed over two consecutive days for two hour periods at a time, during the first three days of enrolment in the study, comparing accelerometer data on body position to direct observation which functioned as a criterion measure. Up to six two hour observation periods were undertaken during this time. The duration of each individual observation period was therefore similar to the period of observation undertaken during the validity study presented in this chapter.

The LFE filter was initialised onto the accelerometers to maximise the devices ability to capture low intensity movement, including slow speed walking (Webber and St John, 2016, Korpan et al. 2015, Cain et al. 2013). The epoch setting was identical to the feasibility study, set at one second. The same measurement modes were initialised onto the accelerometers, namely activity count (triaxial), step count and inclinometer (for identification of body position). Accelerometers were attached using broad elastic belts secured with Velcro.

Placement sites were assessed every half hour by the CI to ensure the devices and their attachment method was not compromising skin integrity or circulation. A standardised assessment form was developed for this process, following advice received by the tissue viability nursing team for the hospital Trust (see Appendix C5 on page 297). A new copy of the assessment form was completed for each individual assessment. A new elastic belt was used for each participant, with new Velcro fasteners. Devices were wiped with a Tristel wipe after data collection was complete with each participant. This infection control advice was obtained from the HEYHT Infection control committee, who approved the research.

4.6.2 BMI

BMI was calculated by using the latest recording of the participant's weight by nursing staff responsible for delivery of care. This was identified from observation charts. This information was either present at the end of the participant's bed, or available to view electronically via tablet computers. Participants were asked how tall they were, which was converted into metres where necessary. BMI was manually calculated and electronically verified using the following calculation:

BMI = Weight (kg) / Height in metres $(m)^2$ (NHS Choices 2015)

BMI data was collected to understand if a representative sample of the population had been captured who were not all a similar BMI. Shapiro-Wilk analysis confirmed BMI data was normally distributed ($p = 0.93$).

4.6.3 Semi structured movement protocol

A semi-structured movement protocol was designed which encompassed all the typical activities patients recovering from critical illness within a hospital ward would undertake. These movements were agreed by consensus between the CI and clinical physiotherapy colleagues who were part of the direct care team. A meeting with seven clinical leads responsible for the delivery of physiotherapy services to those who were recovering from critical illness and the CI (also a clinical lead physiotherapist) achieved this consensus. They

included representation from general surgery, cardiothoracic surgery, critical care, vascular surgery and neurosurgery. The semi-structured movement protocol consisted of a number of activities, all of which were encouraged to be completed during a single period of direct observation, which was undertaken by the CI. Table 4.4 below details the postural transfers and activities which formed the movement protocol, for which accelerometer data was captured. The angle of the bed head was not measured as a variable and was determined according to patient comfort.

Table 4.4 Semi-structured movement protocol

Activity or postural transfer
Lying on the back in bed with the bed head raised slightly to ensure patient comfort
Lying on the left side (as comfort permitted)
Lying on the right side (as comfort permitted)
Moving from lying to sitting over the side of the bed
Sitting to standing
Sitting in a bedside chair
Mobilising a self-selected distance determined by the functional ability of the individual

Participants were free to undertake the activities in any order they preferred and were supplied with a sheet containing the movements that were required to be undertaken (please see Appendix C6 on page 298). This documentation was useful as an aide memoir to ensure no activity included within the protocol was omitted. Participants were able to mark the activities as complete once they had been performed and move onto the next movement of choice. Rest periods were permitted in between the activities undertaken. The duration of these was completely determined by the patient. The CI never rushed the participants to move onto the next protocol activity.

4.6.4 Direct observation

Direct observation was the criterion measure of choice for which accelerometer data was compared against during the data collection period where participants undertook the semi-structured movement protocol. Observation periods were planned to never exceed three hours. This was felt necessary to avoid observer fatigue and to prevent participants feeling uncomfortable due to lengthy periods of time being watched which had been reported in previous studies (Brown et al. 2008). The CI undertook all observation periods, noting the time that a change in body position occurred (lying, sitting or standing) and the position adopted. The duration of time spent in a certain position was also noted. Step count was manually counted by the CI for an agreed duration of time during walking activities which the participant felt was achievable. The duration of time normally agreed was 30, 40, 50 or 60 seconds.

Time synchronisation between direct observation and accelerometer data was achieved by employing the same Precision^{TM} radio controlled alarm clock used within the feasibility study (Model AP004: Peers Hardy Group, Precision House, Starley Way, Birmingham International Park, BIackenhill Lane, Solihull). Synchronisation of time (to the second) was achieved using the same laptop used in the feasibility study prior to initialisation of the accelerometers and their subsequent attachment.

4.6.5 Accelerometer comfort

Upon completion of the data collection period, participants were asked to rate their views on the acceptability of wearing the accelerometers at the two placement sites. The question asked was:

How would you rate the comfort of wearing the accelerometers?

Participants were asked to consider the question in relation to the individual placement sites and the combination of placement sites, in order to understand if there may be one site that was not as acceptable as the other. They were

requested to choose a statement on a five-point Likert Scale, which was printed on a sheet for them. The statements were:

1. Very uncomfortable

2. Somewhat uncomfortable

3. Neither comfortable nor uncomfortable

4. Somewhat comfortable

5. Very comfortable

4.7 Data analysis

The statistical package 'International Business Machines, Statistical Package for the Social Sciences' (IBM SPSS) (Version 20) was used to undertake statistical analysis. Shapiro Wilk analyses determined whether descriptive data were normally distributed or not. This informed how this data should be analysed and presented in the results section. Descriptive data included age, BMI, length of ventilation, ICU length of stay and overall hospital length of stay. The data captured by the accelerometers was categorical or numerical (continuous) in nature. Categorical data consisted of inclinometer readings for body position (lying, sitting or standing). These were explained previously in Chapter 3 in section 3.9.1, commencing on page 112 of this PhD thesis. Quantification of step count by the accelerometers yielded numerical data detailing the steps detected by the accelerometers on a second by second basis.

4.7.1 Categorical data

Categorical data concerning identification of body position (lying, sitting or standing) was analysed using the Kappa statistic (κ). The κ value ranges determined by Landis and Koch (1977) to indicate the strength of agreement between accelerometer data and observation were identical to those used in the feasibility study. These were previously reported in Chapter 3, located in Table 3.3, found on page 114.

Agreement between accelerometer data and observation was calculated based on categorisation of patients being in one of three positions (lying, sitting or standing) throughout the duration of the data collection period. Each participant was analysed separately. This method had been used previously in a similar study by Brown et al. (2008). Brown et al. (2008) calculated a median κ value using the values for κ reported for each individual participant in identification of time spent in one of each of the same body positions. By adopting this method for the validity study presented in this chapter, statistical analyses could be undertaken as soon as data was collected and entered for the first participant. Separate analyses were undertaken for the ankle and thigh placements. A further analysis was undertaken using ankle accelerometer data alone, recoding a '0' (not wearing) to a '2' (lying). The feasibility study reported in the previous Chapter 3 had revealed that a '0' was most often captured at the ankle during the adoption of a side lying position.

Another κ analysis was undertaken to determine whether the algorithm was superior to an isolated ankle or thigh placement for differentiation between sitting and standing. The algorithm was presented in Table 4.2 on page 157. For this particular analysis, data from the ankle was predominantly interpreted. Thigh placement data was only accessed when a reading of standing had been identified at the ankle during a particular epoch. If the thigh accelerometer captured either a sitting or lying position for the identical epoch, a sitting position was recorded. If the thigh interpreted a standing position for that particular epoch, concurring with the ankle placement, a standing position was recorded. Any '0' readings from the ankle accelerometer were also recoded to a '2' prior when performing this particular analysis also.

Having completed analysis for identification of the three distinct positions of lying, sitting and standing, a final analysis was performed. Data from the thigh placement only was categorised in a similar way to how other thigh mounted models, such as the activPAL quantify body position, namely lying (or sitting) and standing (Taraldsen et al. 2011). If direct observation captured a lying or sitting position, as long as the thigh placement captured one of these positions

during the same epoch, thigh data was classed as agreeing with observational data. Although not differentiating between lying and sitting, identification of time spent in sedentary postures would be enabled if it was determined to be valid, using a thigh placement alone.

Percentage agreement between times spent in lying, sitting and standing positions compared to observation for the isolated ankle and thigh placement sites were also calculated. This method of descriptive analysis had been undertaken previously within another study identified within the systematic review (Pedersen et al. 2013). A similar analysis was undertaken using the algorithm, where data from both the thigh and ankle accelerometers were used to differentiate between sitting and standing, where the ankle had captured a standing position. As previously for the κ analysis, any '0' readings for the ankle were also recoded to a '2'. This analysis would determine whether percentage agreement was superior for identification of the specific positions of lying, sitting and standing when data from both placement sites in combination was employed. A final percentage agreement analysis was performed for the thigh placement alone, when both lying and standing were collapsed together, interpreting data in a similar manner to other thigh mounted accelerometer models, including the activPAL (Taraldsen et al. 2011). Presentation of the results for all these analyses can be found on pages 176 to 182.

4.7.2 Continuous data

Agreement between step count recorded by each accelerometer placement site in isolation and direct observation was determined using Bland Altman analysis with 95% LOA (Giavarina 2015). Absolute percentage error (APE) between accelerometer quantified steps and observed steps was also calculated. The same formula employed in the study by Taraldsen et al. (2011) was used to calculate APE. This formula was (accelerometer data for step count – observed data for step count) / observed data for step count) x 100. This was calculated for each walk undertaken by all participants where steps were counted. An intraclass coefficient (95% CI) analysis was undertaken (two way random, absolute agreement) to evaluate intermethod reliability between accelerometer

determined step count (both the ankle and thigh individually) and observed step count. This particular analysis has been undertaken within another study evaluating intermethod reliability between accelerometer derived step count and observed step count in a population with rheumatoid arthritis (Larkin et al. 2016). The results of data analysis for quantification of step count are presented on pages 182 to 186.

4.7.3 Device comfort and acceptance

The statements within the Likert scale constructed for participants to rate the comfort of accelerometers (both in isolation and combination) were tabulated. True positives were classed as ‘very comfortable’ and ‘somewhat comfortable’. True negatives were classed as ‘very uncomfortable’ and ‘somewhat uncomfortable’. The middle category (neither comfortable nor uncomfortable) remained separate. A descriptive analysis was undertaken for this aspect of data analysis. Specific comments made by patients related to the acceptability of the devices were noted. All statements were anonymous and permission was granted to include them within the thesis or any publications arising from the research. This aspect of data analysis is presented on page 186.

4.8 Results

4.8.1 Participants

Twenty four ward based patients recovering from critical illness were identified as eligible for participation by the ward based physiotherapists directly responsible for their care. Following delivery of brief study details by these staff, four patients declined participation. Reasons for declining included involvement in other studies already, generally being low in mood and not feeling physically ready to undertake the activity level required within the study. All patients had been assessed as eligible for participation by ward physiotherapy staff and deemed to be at a stage in their recovery that the undertaking of the physical requirements of the study was achievable.

The activities included within the movement protocol were already being undertaken as a matter of routine by all patients who were approached. Those who declined participation were not approached again regarding participation by the direct care team and continued regular physiotherapy input as part of their rehabilitation. Twenty patients consented to participate in the study. This meant that the sample size was successfully achieved. All twenty participants who consented completed the entire movement protocol and all data collected both from observation and the accelerometers was able to undergo data analysis. There was no missing data for any participant.

4.8.2 Descriptive characteristics

Table 4.5 on page 174 details the descriptive characteristics of the 20 study participants. The mean age ± SD of participants was 62.3 ± 11.5 years. Sixteen participants (80%) wore the accelerometers on the left leg and four wore them on the right leg (20%) following confirmation of which leg was non - dominant. Shapiro Wilk analyses revealed that both age and BMI were normally distributed ($p = 0.93$ and $p = 0.29$ respectively). Ventilation period, ICU length of stay (LOS) and hospital LOS were not normally distributed ($p = 0.003$, $p = 0.004$ and $p = 0.025$, respectively). The demographics for these particular variables are therefore presented as the median and interquartile range (IQR).

Table 4.5 Characteristics of the study population

Characteristic	Mean ± SD (range), median (IQR) or *n* (%)
Age (years)	62.3 ± 11.5 (39 - 82)
Male	13 (65%)
BMI	25.9 ± 6.1 (16.9 – 38.3)
Ventilation period (days)	15.0 (5.50, 36.0)
ICU LOS (days)	21.0 (8.25, 42.75)
Hospital LOS (days)	35 (17.25, 64.75)

BMI = Body Mass Index

Table 4.6 below details the level of assistance required to mobilise and the frequency of each.

Table 4.6 Level of assistance required to mobilise patients in the ward

Level of assistance	Frequency
Independent (no assistance)	6
Hand held assistance of one	3
One walking stick	4
Wheeled zimmer walking frame	5
Three wheeled walking frame	1
Two Fischer sticks	1

Table 4.7 on page 175 details the reasons for admission to ICU for all 20 participants. No participants were required to be withdrawn and no adverse incidents occurred during any data collection period.

Table 4.7 Reasons for intensive care unit admission

Participant ID	Reason for admission to the ICU
001	Sepsis following cholecystitis
002	Polytrauma*
003	Cardiac surgery
004	Ischaemic bowel
005	Cardiac surgery
006	Cardiac surgery
007	Polytrauma*
008	Pneumococcal pneumonia
009	Cardiac surgery
010	Insertion of palliative tracheostomy
011	Collapse, seizure, respiratory failure
012	Pancreatitis and sepsis
013	Community acquired pneumonia
014	Asthma – life threatening bronchospasm
015	Polytrauma*
016	Community acquired pneumonia
017	Anaphylaxis and sepsis
018	Ruptured aortic aneurysm
019	Community acquired pneumonia
020	Sepsis

***** Presentation of particular polytrauma did not require exclusion from the study

Twenty direct observation periods were undertaken by the CI, one single period for each participant. Although a ceiling of three hours was permitted to complete the movement protocol, no participant required this length of time. A Shapiro-Wilk analysis confirmed the duration of observation period was normally distributed ($p = 0.27$), with a mean ± SD length of 53.5 ± 13.9 minutes.

4.8.3 Results following data analysis

4.8.3.1 Identification of body position

Agreement between accelerometer data and observation based on participants' adoption of one of three positions (lying, sitting or standing) during the movement protocol was analysed. Five separate Kappa (κ) analyses were undertaken:

1. Thigh GT3X in isolation
2. Ankle GT3X in isolation
3. Ankle GT3X in isolation, recoding any '0' (not wearing) reading to '2' (lying)
4. As 3 but also using the algorithm created using data captured from the thigh and ankle in combination to distinguish standing from sitting specifically where the ankle had identified a standing position.
5. Thigh GT3X in isolation, collapsing identification of lying or sitting postures together.

Shapiro Wilk analyses confirmed that some of the ranges of individual participant κ values for the five analyses were normally distributed whilst others were not. A median κ value (IQR) was calculated for all separate analyses to permit comparison between them, which are presented in Table 4.8 on page 177. This method of analysis enabled comparison with other studies which had also calculated a median κ value for an ankle and thigh combination in recognition of body position, although no IQR was reported (Brown et al. 2008). The full dataset of κ values calculated for individual participants for each of the five analyses can be viewed in Appendix C7 on page 299.

Table 4.8 Median κ values (IQR) calculated for identification of body position for all analyses undertaken

Analyses undertaken	Median (IQR) κ value
Thigh GT3X in isolation	0.21 (0.14, 0.36)
Ankle GT3X in isolation	0.63 (0.51, 0.85)
Ankle in isolation, recoding '0' (not wearing) to '2' (lying)	0.68 (0.58, 0.86)
Ankle in isolation, recoding '0' (not wearing) to '2' (lying) + algorithm, viewing data from the thigh placement to distinguish between sitting and standing on occasions where the ankle had identified a standing posture	0.94 (0.90, 0.98)
Thigh in isolation collapsing lying and sitting together (i.e. recognition of lying/ sitting and standing)	0.95 (0.84, 0.98)

Nineteen out of 20 participants (95%) had κ values indicating almost perfect agreement (Landis and Koch 1977) for the ankle + algorithm analysis (all $p < 0.001$). Substantial agreement was calculated for the remaining participant within this particular analysis, with $\kappa = 0.73$ ($p < 0.001$). Collapsing lying and sitting together when viewing thigh placement data in isolation also performed excellently, with 18 of 20 participants (90%) having a κ value also indicating almost perfect agreement (all $p < 0.001$). The remaining two participants (10%) had κ values indicating substantial agreement (both $p < 0.001$). Therefore, these two methods were superior to the other methods of measurement investigated in recognition of body position.

The thigh placement in isolation was poor in recognition of each of the distinct positions of lying, sitting and standing, with a median (IQR) value of 0.21 (0.14, 0.36). This indicated only fair agreement according to the ranges specified by Landis and Koch (1977). This was not an unexpected finding due to the same horizontal positon of the thigh during adoption of both lying and sitting postures

(Bassett et al. 2014). As a result, the sitting position was frequently misinterpreted as lying.

Further analysis was undertaken to determine percentage agreement between time spent in specific lying, sitting and standing postures quantified by accelerometer data compared to direct observation. This was again undertaken for every individual participant and performed for all five different measurement methods analysed during the κ analyses, previously presented in Table 4.8 on page 177. Median (IQR) percentage agreement was then calculated using the results of analysis of individual participants. Accelerometer data and observational data were compared on an epoch by epoch (second by second) basis. Shapiro Wilk analyses revealed the results of percentage agreement were all abnormally distributed. Evidence of this is provided in Appendix C8 on page 300. As a result the median (IQR) values for percentage agreement were reported. Tables 4.9 to 4.13 commencing below and finishing on page 180 present the results of these analyses.

Table 4.9 Thigh GT3X in isolation

Body position	Median (IQR) percentage of agreement between accelerometer and observation
Lying	94.0 (79.5, 98.8)
Sitting	4.0 (1.0, 18.5)
Standing	91.0 (86.3, 98.0)

Table 4.10 Ankle GT3X in isolation

Body position	Median (IQR) percentage of agreement between accelerometer and observation
Lying	91.5 (73.0, 99.0)
Sitting	72.5 (47.3, 85.0)
Standing	99.5 (94.5, 100.0)

Table 4.11 Ankle GT3X, recoding a '0' (not wearing) reading to '2' (lying)

Body position	Median (IQR) percentage of agreement between accelerometer and observation
Lying	99.0 (96.0, 100.0)
Sitting	72.5 (47.3, 85.0)
Standing	99.5 (94.5, 100.0)

Table 4.12 Ankle placement, recoding a '0' (not wearing) reading to '2' (lying) and algorithm

Body position	Median (IQR) percentage of agreement between accelerometer and observation
Lying	99 (96.0, 100.0)
Sitting	99 (98.0, 99.0)
Standing	87.5 (79.8, 98.0)

Table 4.13 Thigh accelerometer, collapsing lying and sitting together

Body position	Median (IQR) percentage of agreement between accelerometer and observation
Lying/ sitting	98 (93.3, 99.0)
Standing	91 (86.3, 98.0)

4.8.3.2 Thigh placement in isolation

Although the thigh placement in isolation performed well in recognition of time in either lying or standing postures, recognition of time spent specifically in sitting was poor, with a median (IQR) percentage agreement of only 4% (1.0, 18.5). The thigh placement predominantly misclassified sitting as lying, accounting for the poor result for the correct identification of time spent in the sitting position. This was most likely due to adoption of a similar horizontal position of the thigh during both postures (Bassett et al. 2014). When data captured for both lying and sitting was collapsed for the thigh placement in isolation, an excellent median (IQR) percentage agreement of 98% (93.3, 99.0) was achieved.

The findings suggest that a single Actigraph GT3X accelerometer mounted on the anteromedial thigh demonstrates validity in determination of time spent in lying/ sitting and standing postures when the inclinometer is initialised. The results of the κ analysis for this measurement method also supported its validity with a median (IQR) κ value of 0.95 (0.84, 0.98). An isolated thigh GT3X placement cannot differentiate between the postures of lying and sitting, hence it cannot be considered valid in determination of the three distinct postures of lying, sitting and standing.

4.8.3.3 Ankle placement in isolation

Recoding of a ‘0’ reading to a ‘2’ for the ankle placement in isolation improved recognition of time spent in lying, increasing the median (IQR) percentage

agreement from 91.5% (73.0, 99.0) to 99.5% (96.0, 100.0). The median (IQR) agreement percentage of time spent in standing and lying positions was greater than 90% for both postures, supporting the first hypothesis (hypothesis number 1) detailed in section 4.4 on page 158. Identification of sitting was less successful, with lower median percentage agreement (72.5%) and a considerably wider IQR (47.3, 85.0). Similar to the findings within the feasibility study, the ankle regularly misinterpreted the sitting position as standing. This accounted for the lower percentage agreement for this placement site in isolation compared to recognition of lying and standing positions. Due to the inconsistency of correct identification of sitting, the GT3X when mounted in isolation on the ankle for recognition of time spent in lying, sitting or standing positions was not considered to be valid.

4.8.3.4 Ankle + algorithm measurement method

Recognition of the sitting position greatly improved when the algorithm was used on occasions where the ankle mounted GT3X had identified a standing position. The algorithm relied on viewing both the ankle and thigh data captured for the same epochs of time. When used, median percentage agreement for time spent in sitting improved from 72.5% to 99%, with a considerably narrower IQR, thus supporting the third hypothesis (hypothesis 3), found in section 4.4, commencing on page 158. However, use of the algorithm caused the median percentage of agreement for identification of time in standing to fall. Whilst the ankle in isolation identified time in standing with a median (IQR) percentage of agreement of 99.5% (94.5, 100.0), use of the algorithm produced a median (IQR) percentage of agreement of 87.5% (79.8, 98.0). Although percentage agreement was high for identification of standing when data was captured in isolation at the ankle, it was often incorrectly categorising sitting as standing. This was because it encountered difficulty distinguishing between the two postures. When the algorithm was used, the incorrect misclassification of sitting as standing was virtually eliminated.

Median (IQR) percentage agreement of time spent in lying also remained excellent at 99% (96.0, 100.0) by incorporating the recoding of ‘0’ to ‘2’ for

ankle accelerometer data. Although the percentage agreement for time spent in standing fell when the algorithm was used, as a result of the thigh misclassifying standing as sitting on occasion, this misclassification never occurred during walking activities. Almost perfect agreement was also determined between accelerometers and observation for this method (Table 4.8). For these reasons, the combination of two GT3X accelerometers positioned on the anteromedial thigh and lateral aspect of the ankle of the non-dominant leg was considered valid in determination of time spent in lying, sitting and standing postures. Validity was dependent on use of the algorithm, accessing thigh accelerometer data when the ankle captured a standing position and recoding ankle data where a '0' reading was recoded as '2' (lying).

4.8.3.5 Quantification of step count

Bland Altman analyses (with 95 % LOA) determined the mean difference in step count between observed steps and accelerometer quantified steps. Absolute percentage error (APE) for accelerometer derived step count was also calculated for each participant. Some participants performed more than one walk where step were counted. Step count was analysed for 31 walks in total. Table 4.14 shows the results of Bland Altman analyses undertaken for the thigh and ankle placement sites in isolation. The ankle was superior to the thigh for determination of step count when compared to observed steps counted, with a mean difference of less than one step and considerably narrower 95% LOA.

Table 4.14 Bland Altman analyses of step count of thigh and ankle placement sites

Accelerometer placement site	Mean difference (95% LOA)
Thigh	-17.7 steps (5.23 to -40.63 steps)
Ankle	-0.84 steps (2.2 to -3.88 steps)

Scatterplots were constructed for both placement sites. No outliers were present within the plot constructed for the ankle. One outlier was identified for

thigh placement. Figure 4.1 below and 4.2 on page 184 present the scatterplots constructed for the thigh and ankle accelerometer derived step count, respectively.

Figure 4.1 Scatterplot for thigh placement

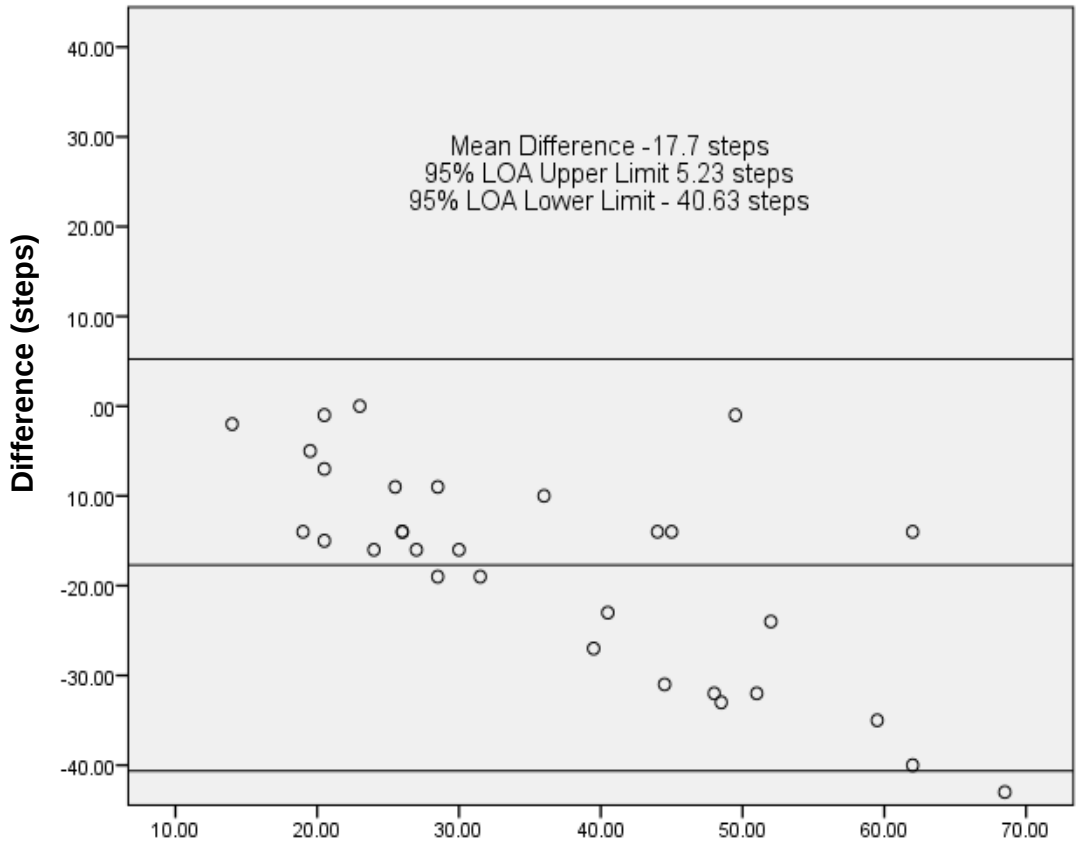
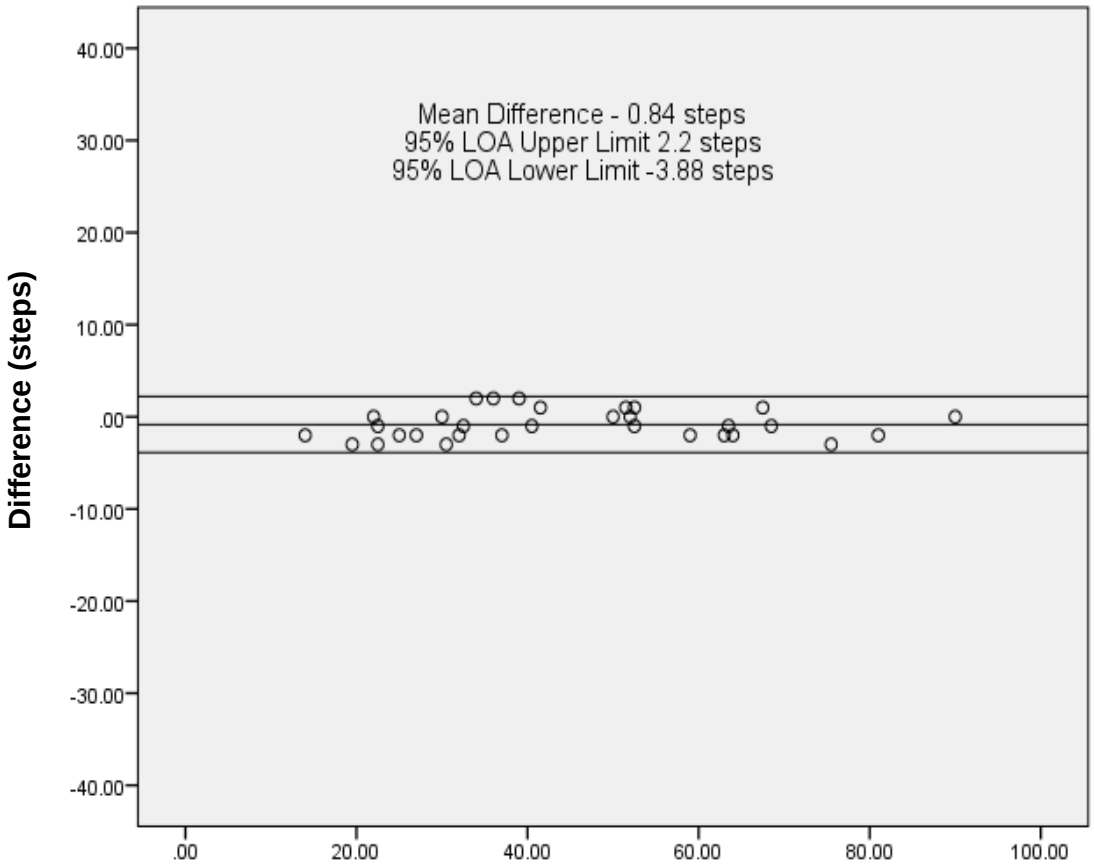


Figure 4.1 shows that the thigh placement almost always underestimated step count, with a considerably larger mean difference and wider 95% LOA than resulted with the ankle placement. However, unlike the waist placement in the feasibility study, the thigh placement never failed to register a step count. On three occasions the thigh accelerometer quantified step count with only one or two steps differences compared with observed step count. On one occasion, step count was actually identical for both the thigh accelerometer and observation. All of these walks were undertaken using walking aids, namely a single walking stick or a wheeled zimmer walking frame. This suggested the use of a walking aid was not the reason why the thigh placement significantly underestimated many of the walks undertaken by the participants.

Figure 4.2 Scatterplot for ankle placement



The ankle placement was superior to the thigh in quantification of step count. This is evidenced by the scatter plots presented above, detailing the narrow 95% LOA for the ankle placement compared to the thigh. The similar scales constructed for both scatterplots for the differences in step count between observed and accelerometer quantified step count clearly highlight this. Mean differences in step count (-17.7 steps for the thigh and -0.84 steps for the ankle) for all walks undertaken also demonstrate the superiority of the ankle placement site. The ankle accelerometer overestimated step count in seven out of 31 walks (23%). In the other 24 walks, the ankle slightly underestimated step count on 19 occasions and correctly quantified step count on 5. These findings for the superiority of the ankle accelerometer placement compared to the thigh in quantification of step count supported the hypothesis 2, found in section 4.4 commencing on page 158, which was constructed prior to commencement of the validity study. This particular hypothesis was constructed following assimilation of the findings from the systematic review.

4.8.3.6 Calculation of absolute percentage error for thigh and ankle accelerometer derived step count

Shapiro Wilk analyses determined the range of percentage error calculated for individual participants in determination of accelerometer derived step count was normally distributed for the ankle (p = 0.211). However, the range calculated for the thigh was not normally distributed (p = 0.001). For this reason median (IQR) percentage error is reported for both placement sites. It was possible with some participants to count steps taken during more than one walk, producing more than 20 sets of data which were able to undergo analysis. The actual number of individual walks which were analysed was 31. Multiple walks undertaken by the same participant were not identical meaning they could not be compared with each other for consistency. Table 4.15 below presents the median (IQR) APE for accelerometer derived step count for the thigh and ankle placements.

Table 4.15 Median (IQR) APE for accelerometer derived step count for thigh and ankle placement

Accelerometer placement site	Median (IQR) APE for accelerometer derived step count
Thigh	- 42.4% (-50.0, -27.0)
Ankle	- 2.4% (-5.3, 0)

The thigh placement demonstrated a considerably higher median APE compared to the ankle (- 42.4% compared to - 2.4%), with a much wider range of APE values within the IQR than for the ankle. The greatest APE calculated for the thigh placement was an underestimation of step count of 54%, where a walk was undertaken with a WZWF. The smallest APE (0%) was calculated during a walk with a WS, where the thigh identified an identical step count when compared against observation. However, in another walk undertaken by the same participant of the same duration (30 seconds), an APE of 42% was calculated. This suggested it was not consistently quantifying steps in a similar way.

4.8.3.7 Intermethod reliability analysis

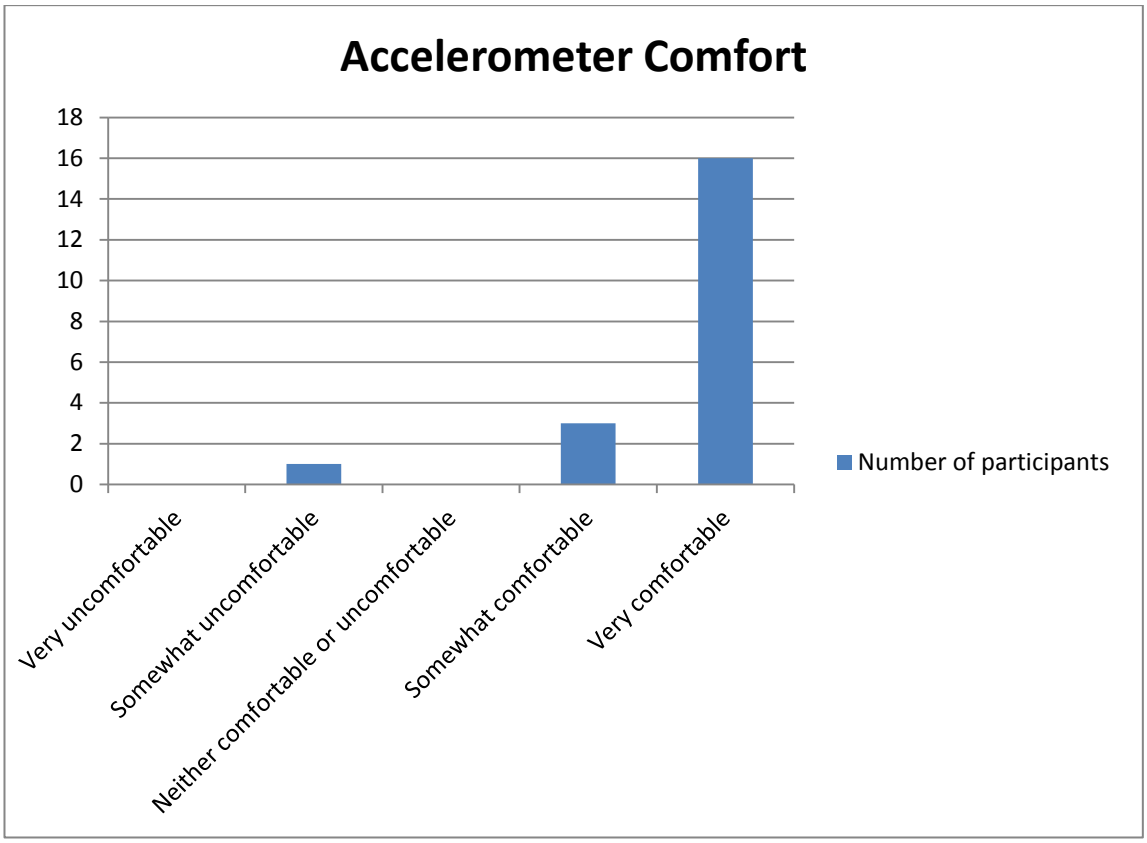
The ankle placement was strongly correlated with observational step count (ICC 0.99, 95%CI 0.99 - 1.0) (British Medical Journal 2017). A moderate correlation (British Medical Journal 2017) was determined for the thigh placement, with a broad range of values calculated for the 95%CI (ICC 0.46, 95%CI -0.10 - 0.78).

Based on the results obtained, the ankle was considered accurate in recognition of step count, regardless of whether participants walked independently or with assistance. It also demonstrated reliability. The thigh was not considered valid for quantification of step count within ward based populations recovering from critical illness due to the wide discrepancies between observed and accelerometer derived step count, variability in the way steps were quantified by the thigh placement during repeated walks by the same participant, the high APE values calculated and the results of the intermethod reliability analysis.

4.8.3.8 Accelerometer comfort

Nineteen out of the 20 participants (95%) reported that the accelerometers were either somewhat comfortable or very comfortable. Sixteen participants rated the accelerometers in combination or isolation as very comfortable, whilst three rated them as somewhat comfortable. One participant found the accelerometers caused some discomfort, classing both of them as somewhat uncomfortable. This participant wore the accelerometers for the least duration of time. Upon questioning they were unsure regarding why they felt the accelerometers to be uncomfortable, but felt it was likely that they would not be able to wear them for a full day. Other comments made by the participants included “I didn’t realise I was wearing them’”, “I didn’t know they were on”, “I couldn’t feel them” and “Very, very comfortable”. Figure 4.3 on page 187 presents the results of accelerometer comfort rating.

Figure 4.3 Accelerometer comfort rating by participants



4.9 Discussion

4.9.1 Key results with reference to study objectives

This study investigated the validity of the Actigraph GT3X accelerometer in identification of lying, sitting and standing positions and step count in a ward based population recovering from critical illness. The inclinometer inherent within this accelerometer model was used to identify body position and the step count mode was used to quantify step count. Accelerometer data was compared against observation, which functioned as the criterion measure. Two placement sites were investigated, namely the anteromedial thigh and the lateral aspect of the ankle. The key findings will now be discussed in relation to the study objectives specified earlier in this chapter on page 158. Each objective is discussed within its own dedicated section.

4.9.1.1 Objective one

‘To determine the validity of the inclinometer inherent within the Actigraph GT3X accelerometer to identify lying, sitting, standing when placed in isolation on the non-dominant thigh or ankle in a ward based patient population recovering from critical illness’.

The ankle was superior to the thigh for identification of the distinct positions of lying, sitting and standing. The thigh placement regularly misinterpreted the sitting position as lying, most likely due to the similar horizontal position of the thigh during both postures, similar to the findings and conclusions of Bassett et al. (2014). Other thigh mounted commercial models such as the activPAL do not differentiate between lying and sitting postures, interpreting body position as lying/ sitting or standing (Taraldsen et al. 2011). When data from the thigh mounted GT3X was analysed using a similar classification, a median (IQR) value of $\kappa = 95$ (0.84, 0.98) was calculated for time spent in these postural groupings. An excellent median percentage agreement (IQR) of 98% (93.3, 99.0) was determined for recognition of lying/ sitting, with 91% (86.3, 98.0) agreement for standing.

The results for the thigh mounted GT3X compare favourably with other studies which have investigated percentage agreement for recognition of lying/sitting and standing using the thigh mounted activPAL (Ryan et al. 2008). Ryan et al. (2008) reported an overall agreement compared with direct observation of 97% in a population who experienced chronic back pain. In the clinical setting, a decision must be made regarding whether there is a requirement to distinguish between lying and sitting postures, or whether identification of a sedentary posture (lying or sitting) will suffice. If identification of all three distinct postures (lying, sitting and standing) is required, a single thigh mounted GT3X would not be suitable.

The ankle placement identified both lying and standing positions well, with a median percentage agreement of greater than 90% for both positions. Median

percentage agreement for identification of sitting was considerably better for this placement site compared to the thigh placement (4% versus 72.5%). Although better at identifying the sitting position compared to the thigh, the ankle still regularly misclassified sitting as standing. Similar findings also emerged from the feasibility study. Furthermore, as with the feasibility study, a ‘0’ (not wearing) reading continued to be consistently obtained during adoption of a side lying position from the ankle sited GT3X. When every ‘0’ captured by the ankle accelerometer was recoded to a ‘2’ (lying) a median percentage agreement of 99% resulted for recognition of time spent in lying, with a very narrow IQR (96.0-100.0). This demonstrated that a ‘0’ reading was almost always captured during lying as percentage agreement for identification of both sitting and standing remained unchanged.

The finding that ‘0’ readings were most often captured during adoption of a lying position concurs with another study reported in the feasibility study, albeit when the GT3X was worn at the waist (Berendsen et al. 2014). They reported 98.1% of non - wear time (‘0’), was captured during lying. This finding suggests that the similar readings identified were not likely to be as a result of an anomaly with the specific GT3X models used within the study. Furthermore, three identical GT3X accelerometers were loaned for the duration of the study. It was not always the same model placed at the same site, suggesting all models were interpreting body position in a similar way. This provides further evidence to support the recoding of ‘0’ (not wearing) readings to ‘2’ (lying) within this population when the GT3X is worn on the ankle to estimate time spent in lying, sitting and standing positions.

When the GT3X was placed anteromedially on the thigh the inclinometer also generated a ‘0’ reading during adoption of a side lying posture, suggesting it was behaving in a similar manner. However, some ‘0’ readings were encountered during sitting when the GT3X was mounted on the thigh. This suggests a recoding of the thigh data, changing a ‘0’ to a 2 would still lead to postural misclassification, in particular misclassification of sitting as lying. It could be argued however, that if lying and sitting were grouped together, as

described previously, this misclassification would not apply. Any misclassification of sitting as lying would be immaterial due to the grouping of both postures together, classifying both as ‘sedentary’.

4.9.1.2 Objective two

‘To investigate the validity of a combination of thigh and ankle Actigraph GT3X inclinometer readings to correctly distinguish between standing and sitting, using an algorithm constructed during preparatory fieldwork’.

The ankle data was predominantly used in this analysis, only using thigh placement data when the ankle captured a reading of ‘1’ (standing). The data captured at the thigh for the identical epoch during these time periods was also accessed to enable interpretation of the algorithm, which was previously presented in Table 4.2 on page 157. Also, based on the superior results identified for percentage agreement in identification of time spent in lying for the ankle placement, the reclassification of ‘0’ (not wearing) to ‘2’ (lying) was also incorporated into this measurement method.

The methods of data analysis used (percentage agreement and calculation of the median κ and IQR) have been used in previous studies investigating an ankle and thigh combination (Pedersen et al. 2013; Brown et al. 2008). Undertaking both statistical (κ analyses) and descriptive analyses (percentage agreement) permitted direct comparison with the results of data analyses from the studies by Pedersen et al. (2013) and Brown et al. (2008). The positive findings from the validity study for identification of lying, sitting and standing postures using a combination of an ankle and thigh accelerometer placement concur with the findings of Pedersen et al. (2013) and Brown et al. (2008). As a result, further evidence supporting this combination of placement sites in determination of lying, sitting and standing postures has emerged using an accelerometer model which has not previously undergone investigation of its validity within hospitalised patients.

Using the algorithm and reclassifying ankle accelerometer ‘0’ readings to a ‘2’ determined a median κ score of 0.94, with a very small IQR (0.90, 0.98) in identification of all three distinct postures. These findings are similar to Brown et al. (2008), who reported a median κ value of 0.92 (no IQR reported). This further supports the validity of this combination of placement sites for determination of time spent in one of the three positions of lying, sitting or standing. Furthermore, the IQR for the median κ value of 0.94 indicated minimal variability in the κ values calculated for each individual participant compared to other measurement methods investigated. The median κ value of 0.94 indicated almost perfect agreement with observation for categorisation of time spent in lying, sitting or standing (Landis and Koch, 1977).

Several steps are required before interpretation of body position can be achieved using the GT3X when the algorithm and reclassification of ‘0’ to ‘2’ are employed simultaneously. These are as follows:

1. Downloading of both thigh and ankle accelerometer data to produce separate Excel files (an example of which can be found in Table 3.2 on page 112 of Chapter 3).
2. Copying of the inclinometer data column for the thigh data to enter next to the inclinometer data for the ankle placement, ensuring time stamped epochs are synchronised.
3. Reclassification of any ‘0’ readings to ‘2’ for ankle inclinometer data needed

Only at this point can data analysis commence. These processes are unlikely to take longer than five minutes if data was downloaded on a daily basis. Any reclassification of ‘0’ to ‘2’ readings would easily be achieved using the find and replace option within the Excel toolbar. Although relatively brief, a busy clinician may encounter difficulty finding sufficient time to download accelerometer data for every individual patient under their care. Furthermore, data would still then require interpretation. Whilst this may be achievable for the researcher undertaking this activity as part of data analysis, the clinician may experience difficulty in devoting time to this activity on a day to day basis for individuals

under their care. However, they may find this method useful when undertaking audits of the regularity of activity undertaken by patients under their care, assisting in understanding if there are certain times of the day when patients tend to adopt prolonged periods of sedentary activity. This may assist in employing effective rehabilitation resources at times of the day when patients are identified as being least active.

When considering all of the individual κ values calculated using this particular measurement method, 19 out of 20 participants (95%) returned a κ value indicating almost perfect agreement, ranging from 0.87 to 0.99 (all $p < 001$). The remaining participant recorded a κ value of 0.73 indicating substantial agreement ($p < 0.01$). This particular participant was observed to predominantly lie on the bed with both hips and knees flexed. When the raw data was revisited for the periods of time when this posture was adopted, both the thigh and ankle accelerometer often captured a sitting position (inclinometer readings of '3' and '3'). The participant was actually adopting a lying posture on the bed, but lying on their back with the hips and knees bent (i.e. crook lying).

Participants were not instructed to lie on their back in bed in any particular way. It was hoped this would introduce some variability into how this position was adopted and encourage a more naturalistic setting in order to understand how the accelerometers behaved. Unfortunately, variability within this population regarding how this particular positon was adopted was limited. This may have been related to the population who participated in the study or was indicative of this population generally. Nevertheless, this was an interesting finding. However, due to only a single participant adopting this posture, further investigation to understand if this specific position could be identified by viewing the thigh data also when the ankle recorded a reading of '3' (sitting) was not possible. Pedersen et al. (2013) were able to identify this 'knees bent' position with a percentage agreement of 99.72%, with sitting only being identified during adoption of this position on 0.28% of occasions. The methods used to identify the different body postures were different between the study within this thesis and the study by Pedersen et al. (2013).

Identification of standing when ankle data was viewed in isolation produced a median (IQR) value of 99.5% (94.5, 100.0). However, within this range, the ankle was not only correctly identifying the standing position, but also regularly misinterpreting sitting as standing. When the algorithm was employed, median (IQR) percentage of agreement in identification of time in standing fell to 87.5% (79.8, 98.0). This was because on a number of occasions, when the algorithm was being employed to discern between sitting and standing, the GT3X placed on the thigh was capturing a reading of '3'(sitting) when the ankle was actually correctly capturing a standing position ('1'). Following the rules of the algorithm, this combination of accelerometer readings meant that the position of sitting had to be documented. This provides an explanation for why the median percentage agreement for the time spent in a standing position decreased upon employment of the algorithm.

It is postulated that participants, when standing stationary (i.e. not walking) may have periodically transferred their body weight away from the leg wearing the accelerometer. This might have caused the knee to flex slightly. A reading of standing would still be captured at the ankle if the foot remained flat on the floor. This postulation is supported by observation of the data for the thigh returning to a '1' (standing position) when patients started to take steps again, as weight began to be evenly distributed between each lower limb again. A '3' (sitting position) was never recorded at the thigh when steps were being taken. Correct identification of the standing position was almost always achieved when steps were being taken. This could potentially be a very useful finding for clinical and research purposes, which may provide indication of when patients are actually mobilising.

Use of descriptive analysis to calculate percentage agreement between time spent in lying, sitting and standing positions has been undertaken in other studies which investigated a combination of the ankle and thigh placement (Pedersen et al. 2013). Pedersen et al. (2013) also constructed an algorithm to determine lying, sitting and standing positions using this combination of placement sites which underwent cross validation. A different accelerometer

model was investigated. Numbers of participants who underwent investigation during the cross validation process were small (*n* = 6) which may limit the external validity of the study findings. The validity study reported within this chapter enrolled a larger sample size (*n* = 20). This sample size has been used in other studies investigating accelerometer validity within critical care populations (Edbrooke et al. 2012; Winkelman et al. 2005). Edbrooke et al. (2012) predicted a sample size of 12 subjects was required, based on alpha = 0.05, beta = 0.9 and a correlation of 0.75 (good to excellent reliability), basing their calculations on work by Portney and Watkins (1993). Winkelman et al. (2005) selected a sample size of 20 to allow for sufficient power to 'detect congruence' between accelerometers and direct observation with Bland-Altman plots, using 'medcalc' statistical software. Employing a similar data analysis for the validity study to that undertaken by Pedersen et al. (2013) permitted direct comparison between the two investigations.

Pedersen et al. (2013) reported 89.6% agreement between observation and algorithm data for recognition of standing. The validity study reported a median agreement of 87.5% for identification of standing. Interestingly, they also reported that standing was identified as sitting on 10.4% of occasions when employing the algorithm. Moreover, they too reported that during walking, correct recognition of the standing position using the algorithm improved to 96.49%. This concurrence in findings suggests that different accelerometer models demonstrate similarities in the way they captured data when positioned in a combination of placement sites at the ankle and thigh.

Further similarities between the study reported within this chapter and the study by Pedersen et al. (2013) were evident regarding identification of sitting. Pedersen et al. (2013) reported agreement of 95.3% and 98.6% for recognition of sitting in a chair and sitting on the bedside respectively. This study within this chapter did not differentiate between sitting on the side of the bed or sitting in a chair but calculated a median percentage agreement of 99% for recognition of the sitting position generally when using the algorithm, capturing data simultaneously from the thigh and ankle. Furthermore, the IQR was extremely

narrow (98.0, 99.0), indicating little variability between participants for identification of this position. Comparatively, the ankle placement alone could only achieve 72.5% agreement with observed adoption of the sitting posture, with a much wider IQR (47.3, 85.0). This again provided support that the algorithm, based on readings from accelerometers placed in combination at the thigh and ankle of the same leg was superior at identifying the sitting position.

The findings of this validity study suggested the algorithm was valid in identifying the sitting position. It permitted differentiation between standing and sitting where the ankle accelerometer captured a reading of standing. However, by using the algorithm, some sacrifice of recognition of the standing position resulted. Clinicians should be aware of this and decide whether this loss of accuracy for identification of standing is clinically acceptable. This may apply in cases where patients may not yet be able to walk but are practising sit to stand transfers, to gain an idea of the number of times during the day that they are practising this transfer as part of their rehabilitation. Clinicians should also be aware that when patients commence walking activities, any misclassification of standing as sitting appears to resolve. This may prove useful, indicating that patients are engaging in activities that involve walking.

4.9.1.3 Objective three

‘To determine the validity and reliability of the step count mode within the Actigraph GT3X accelerometer to quantify step count when placed in isolation on the non-dominant thigh or ankle of the same population’.

The ankle was found to be superior to the thigh placement for quantification of step count, demonstrated by a smaller mean difference (-0.84 steps compared to -17.7 steps) and narrower 95% LOA (2.2 to -3.88 steps compared to 5.23 to -40.63 steps). These findings were regardless of whether participants walked independently or with assistance from a walking aid or a single person. The ankle placement also demonstrated excellent intermethod reliability (ICC 0.99,

95%CI 0.99 - 1.0). The thigh placement demonstrated moderate correlations (British Medical Journal 2017) when compared to observed step count (ICC 0.46, 95%CI -0.10 - 0.78).

These findings for both the ankle and thigh placement sites concur with findings from other studies identified during construction of the systematic review. Edbrooke et al. (2012) concluded that a different commercial accelerometer model when mounted on the ankle was valid in determination of step count in a population recovering from critical illness. Mean differences in step count were remarkably similar, with Edbrooke calculating 0.92 steps and the validity study calculating a mean difference of 0.84 steps for the ankle placement. The 95% LOA were also similar, with Edbrooke et al. (2012) calculating - 3.27 to 5.11 steps for the ankle and the validity study calculating - 3.88 to 2.2 steps for the same placement site. A further study also investigated the ankle placement in a population likely to walk at slow speed, opting to choose the Actigraph GT3X+ (Webber and St John 2016). Mean differences in step count between accelerometer determined and observed steps were again less than one step, with ‘narrow’ 95% LOA. Intermethod reliability was also investigated by Webber and St John (2016), with an ICC of 0.94 and 95% CI of 0.870 to 0.969 being determined. The findings suggested the GT3X+ was valid and reliable in quantification of step count when positioned on the ankle in a hospitalised older population who walked at slow speed.

Another study also concurred with the findings from the study undertaken within this chapter for the thigh placement (Taraldsen et al. 2011). Taraldsen et al. (2011) determined that a thigh placement was not valid in determination of step count in populations who walked at speeds of less than 0.47m/s (older medical inpatient and acute stroke admissions). A systematic review by Taraldsen et al. (2012) also reported that the APE between accelerometer quantified steps and observed steps calculated for participants walking at slow speed was 40.3%, with a considerable underestimation of steps. This compared favourably with the results from the study in this chapter, where a median (IQR) APE value of -42.4% (- 50.0, - 27.0) was calculated. The ankle placement had a median

(IQR) APE of - 2.4% (- 5.3, 0) suggesting considerably less error was being encountered when the ankle accelerometers were quantifying step count. This APE figure was very similar to that determined by Webber and St John (2016) for an ankle placement, who reported less than 3% APE.

The GT3X mounted on the ankle overestimated step count on 23% of the walks undertaken where step count was counted. Webber and St John (2016) warned that activation of the LFE in Actigraph models may cause these models to overestimate steps undertaken. An overestimation of ≤ 3 steps was demonstrated by the ankle accelerometer in the validity study undertaken within this chapter. Due to this small difference in step count from observed step count, the clinical significance of this difference is questionable. The same conclusions regarding these small differences in step count were reached by Edbrooke et al. (2012).

4.9.1.4 Objective four

‘To evaluate from a user perspective, the acceptability and comfort of the placement sites used’.

Both accelerometer placement sites were reported to be comfortable in 95% of participants. Only one participant in the study reported that they felt somewhat uncomfortable, although were unspecific regarding the reasons why. Based on these findings, the placement sites for the GT3X of the ankle and anteromedial thigh appear acceptable to patients and when worn for a maximum of 99 minutes did not appear to pose any major skin integrity risk on average.

4.10 Limitations

This validity study was not undertaken within a naturalistic setting, choosing instead to incorporate a semi structured movement protocol. However, all activities were identical to those most likely to be undertaken as a matter of routine within patients recovering from critical illness. Brown et al. (2008) highlighted some difficulties of undertaking a validity study of this kind within a completely naturalistic environment. When a κ analysis was undertaken to

determine agreement between accelerometer data and observation for the proportion of time spent in lying, sitting or standing positions, nine participants data had to be withdrawn. Close observation of the data revealed that these participants constantly adopted a lying position, rendering κ analysis unable to be undertaken on these particular participants. Rather unintentionally, this also highlighted the importance of monitoring activity within hospitalised patients. Due to the inclusion of a semi-structured movement protocol within the validity study, there were no incidences of the adoption of one single posture. All 20 sets of accelerometer data captured at the thigh and ankle were able to be included in the κ analyses, albeit a sample size still smaller than Brown et al. (2008), despite the withdrawal of nine participants (n = 38).

Another limitation was the inability to understand if a particular method of mobilisation affected the ability of the accelerometers to capture step count (for example whether independent or with assistance). There was considerable variability in the type of walking aid used when required (please see Table 4.6 on page 174). Whilst six participants walked independently with no aid, their walking speeds were visibly slow. All patients did not walk a pre-measured distance, but were encouraged to walk at a comfortable pace and stop when they felt the need to rest. When patients stopped, the timing of the walk was ceased at the next multiple of ten of the second. For example, if someone walked for 27 seconds and stopped, timing continued until 30 seconds. Step count walks were always commenced at the start of a new minute or 30 seconds into a minute. This method was deemed more manageable and memorable for the observer to record the time when walking started and ceased. This was entered into the observer documentation, whilst the patient was permitted chance to rest, remaining in standing.

Walking speed could not be calculated as distance was not pre-determined; with participants walking distances that they felt were manageable. It could be argued that this approach encouraged a more naturalistic feel to the study methodology. It empowered the patient to make decisions about how far they could manage, thus respecting ethical considerations such as participant

autonomy. The paths patients took when walking were not always in a straight line, moving from their bays onto a corridor for example or moving to pass other patients or visitors. Patients often did not feel they could repeat the walk in an identical manner, hence only undertaking one walk where steps were counted. This method did not permit an intramethod reliability analysis to be performed to see if the accelerometers were consistent in their ability to quantify step count. Therefore, the lack of intrareliability investigation is considered a limitation of the study presented within this chapter. However, intermethod reliability was undertaken within the validity study, determining that the ankle placement demonstrated excellent reliability (ICC 0.99 95%CI 0.99 – 1.0), whilst moderate correlations were reported for the thigh placement (ICC 0.46, 95%CI -0.1 – 0.78).

Both the study reported within this chapter and the feasibility study in Chapter 3 encountered similar findings from the ankle placement when participants moved from supine into a side lying position. On these occasions, the inclinometer reading changed from a ‘0’ (not wearing) to a ‘2’. Three GT3X models were loaned in order to complete the studies. Several factors suggest that the ‘0’ reading was not an anomaly from a single accelerometer used in the study. Despite alternating the GT3X model used at a particular placement site, the ‘0’ reading was still encountered when patients turned into side lying, from lying supine on the bed. Furthermore, Berendsen et al. (2014) reported 98.1% of ‘0’ reading were encountered during lying activities when using the same model. Evidence was provided within this chapter demonstrating how improvement of recognition of the lying position was achieved when a ‘0’ reading was reclassified to a ‘2’ (Table 4.11 on page 179).

In the clinical setting, difficulties may be encountered ascertaining whether the ‘0’ readings really were related to patients adopting a lying position or simply that the GT3X devices had been removed. This is considered a further limitation of the research. However, a method of differentiation may be possible. If the device were resting within a locker, it would be unlikely that any activity count would be quantified by any of the axes of measurement. If the

device was attached to the patient, even small alterations in body position, e.g. a move to establish comfort, moving up the bed, turning onto their side, reaching to their bedside table, would produce some quantification of activity due to the devices being moved, detecting resultant acceleration forces. This could possibly be a method of differentiating between the devices not actually being worn or the '0' reading identifying a lying position. This postulation requires substantiation. Confirmation that the GT3X devices are being worn could also form part of the routine observations taken by nursing staff at regular intervals during the day, also incorporating tissue viability checks of skin areas underneath the accelerometers.

The maximum time that participants wore both accelerometers was 99 minutes with a mean wear time of 58.55 minutes (SD 16.85, range 30-99 minutes). Assessment of comfort was based on the devices being worn for a relatively limited period of time. It remains unknown how comfortable and acceptable the accelerometers would have been if worn for the entire day and whether they posed any significant risk to skin integrity. Interestingly, comfort was an aspect given consideration by Webber and St John (2016), who only compared daily step count from the Step Watch 3.0 mounted at the ankle and a waist mounted GT3X+ accelerometer. They decided not to place a further GT3X+ on the other ankle, despite this placement site being superior to the waist in quantification of step count during a hallway walk. The authors felt that an accelerometer resting on the lateral aspect of each ankle would preclude participants from lying on their side if they so wished, suggesting they had concerns about potential threats to skin integrity or participant comfort due to the pressure exerted by the devices. Having one ankle free of an accelerometer permitted participants to lie on this side if they wanted to. This is an important consideration and should receive attention in future studies.

A final limitation is the absence of representation of some specialities that often require critical care support, including the neurosurgical population, including patients who have suffered traumatic brain injury, possible sub-arachnoid haemorrhage or have undergone surgery for debulking or removal of space

occupying lesions (brain tumour). This is particularly worthy of consideration in populations who may present with hemiplegia, making the undertaking of normal gait patterns difficult or impossible. Further research is recommended to understand how this arrangement of accelerometers may behave when interpreting lying, sitting or standing positions in this population due to the possibility of adoption of unconventional postures, sometimes requiring considerable physical support to maintain them. Furthermore, other studies have suggested that accelerometers quantify steps with less error when mounted on a non-affected limb in cases where patients have a hemiplegic or single limb pathology (Taraldsen et al. 2011). Further research is necessary to verify which lower limb accelerometers should be mounted upon to produce least error in quantification of step count.

4.11 Generalisability (external validity)

Table 4.7 on page 175 demonstrated the wide variety of original presenting complaints of the patients who kindly gave informed consent to participate. Participants comprised both medical and surgical specialties. Surgical specialties included both cardiac and general surgery. This variability assisted in enhancing the generalisation of the study findings within populations recovering from both acute and critical illness. It does not focus on a single patient population. Critical care is not speciality specific; a patient from any speciality could deteriorate to a point where support within a critical care environment was necessary. The study aimed to consecutively recruit all patients who satisfied the inclusion criteria for enrolment, which ultimately permitted recruitment of participants from a wide range of specialities. Although, there are still some groups (for example neurology or neurosurgical population) where further research is necessary to understand how the accelerometers may behave when applied.

4.12 Interpretation of findings (conclusion)

As in Chapter 3, the research questions are revisited again in order to understand how knowledge has progressed in order to answer them. Important

considerations, especially for the clinician regarding use of the GT3X, have also undergone further consideration within this chapter. Each question will be considered separately.

To what extent can the Actigraph GT3X Accelerometer quantify the functional activity (postural changes between lying, sitting and standing) typically undertaken by hospital inpatients recovering from critical illness?

This study has increased the evidence base concerning the validity of placement of accelerometers in combination on the ankle and thigh for identification of time spent in lying, sitting and standing postures. A median (IQR) κ value of 0.94 (0.90, 0.98) was calculated when compared to direct observation. This concurs with findings by other authors (Brown et al. 2008) who also positioned different accelerometer models in the same ankle and thigh combination, reporting a median agreement with observation of κ = 0.92. Identification of all distinct postures should enable recognition of all transitions between them. However, validity of the GT3X when using this combination of placement sites is dependent on a number of parameters:

1. Two accelerometers are placed in combination on the anteromedial thigh and lateral aspect of the ipsilateral ankle of the non- dominant leg.
2. Data captured from the ankle placement is predominantly viewed for determination of body position. However, where ankle accelerometer data captures a reading of '1' (standing), thigh data for the identical epochs of time must be viewed in conjunction with ankle data. Differentiation between sitting and standing using the combination of data captured by both the ankle and thigh is possible by referring to the algorithm presented in Table 4.2 on page 157 of this chapter.
3. Where a '0' (not wearing) reading is captured by the ankle, this must be recoded to a '2' (lying)

Whilst this may be useful for research or audit purposes, the clinician must decide whether the processes required in preparation of the data for analysis and subsequent interpretation can be incorporated into a normal working day for individual patients.

To what extent can this accelerometer model quantify step count in populations recovering from critical illness when compared with observed step count?

The GT3X was determined to be valid in quantification of step count when positioned on the ankle, with a mean difference in step count compared to observation of less than one step (- 0.84 steps), with very narrow 95% LOA (2.2 to -3.88 steps). The GT3X demonstrates strong correlations (British Medical Journal) when compared to observed step count when worn on the ankle in patients recovering from critical illness (ICC 0.99, 95%CI 0.99 – 1.0). It has concurred with findings from other research regarding the validity of ankle mounted accelerometers in quantification of step count, both within a critical care population and other hospitalised populations who walk at slow speeds (Webber and St John 2016; Edbrooke et al. 2012).

What are the optimum body placement sites in which to position the Actigraph GT3X in order to identify lying, sitting, standing postures and step count in populations recovering from critical illness?

A combination of an ankle and thigh placement is the optimum placement site for the GT3X for identification of lying, sitting and standing postures. However, researchers and clinicians must be aware that due to the way data is interpreted using an algorithm; there is a tendency for periods of standing to be misinterpreted as sitting. This resolves when patients are engaging in walking activities. This study positioned both accelerometers on the non-dominant leg, although other studies alternated the leg used (Brown et al. 2008). Therefore, further exploration is recommended to understand if placement of the GT3X on any leg produces similar results which would increase the options available regarding placement. Investigation should also include evaluation of whether both accelerometers are required to be placed on the ipsilateral leg, or whether they can be positioned on opposite legs.

The study also determined that an isolated anteromedial thigh placement was valid in detection of lying or sitting postures and standing positions with a median (IQR) κ value of 0.95 (0.84, 0.98). Whilst this placement in isolation could not differentiate between lying and sitting, this level of detail may suffice if

being used within the clinical environment. This would still permit identification of time spent in sedentary postures and time spent standing. The clinician may find this method of placement more feasible to use on a day to day basis, requiring no interpretation of an algorithm or reclassifying of ankle accelerometer data. However, if differentiation between lying and sitting was clinically necessary, the ankle and thigh combination of placement sites would be required, using the parameters detailed previously. This arrangement would also permit quantification of step count by accessing the ankle accelerometer data only. The ankle was determined to be the optimum placement site compared to the thigh in quantification of step count.

Is the Actigraph GT3X Accelerometer valid in detection of body position and step count in a population recovering from critical illness?

Validity of the Actigraph GT3X in detection of lying, sitting and standing postures within this population is dependent on the use of an algorithm (detailed in Table 4.2 on page 157 of this chapter), interpreting inclinometer data from two devices placed in combination, one at the thigh and the other at the ankle. Reclassification of inclinometer ‘0’ (not wearing) settings to ‘2’ (lying) settings for the ankle placement is also necessary. An anteromedial thigh placement demonstrated validity in identification of sedentary (lying or sitting) postures and standing in isolation. It cannot discern between lying and sitting postures. The ankle placement is valid and reliable in step count during walks of short distance and duration undertaken by this population within the hospital ward environment. A thigh placement was not found to be valid in detection of step count in this patient group.

In addition, further exploration is required to understand if there is any risk to skin integrity from prolonged wear time of GT3X accelerometers on the thigh or ankle. Evaluation of comfort should also form part of these investigations to understand from a user perspective how acceptable they would be if worn for the entire day. In the clinical setting, assessment of skin integrity underneath where the accelerometers are positioned could form part of the routine observations undertaken by nursing staff. This would assist in decreasing the

risks of accelerometers causing pressure damage. Collaborative ventures between clinicians, researchers and manufacturers in the future will assist in the development of accelerometer models which are not only accurate but also pose minimal risk to skin integrity and are comfortable to wear.

At this point in the thesis, all the studies undertaken as part of the PhD have been reported within their respective chapters. The following chapter will begin the process of synthesising the components of the thesis to demonstrate evidence of the contribution each study made to answer the research questions.

Chapter 5

Synthesis

5.1 Introduction

This PhD thesis has reviewed and augmented the evidence base concerning the validity of accelerometry to quantify purposeful activity within the hospital setting. It commenced investigation of the validity of the Actigraph GT3X accelerometer in identification and quantification of low intensity purposeful activity typically undertaken by hospitalised patients recovering from critical illness. This research is timely, both concerning the choice of accelerometer model and the patient population investigated. The GT3X has been used to quantify purposeful activity within a hospitalised critically ill population without undergoing prior investigation of its validity within this patient group (Schujmann et al. 2015a; Schujmann et al. 2015b).

Whilst it was appropriate to present all aspects of each individual study within dedicated chapters, this format did not permit a collective assimilation of the findings. This chapter aims to address this in order to demonstrate how the projects, although distinct, were interrelated. The studies receive consideration in the order they are presented in the thesis. Synthesis in this way provides a platform leading to the concluding chapter.

5.2 Systematic review chapter

This initial project constructed an evidence base which explored previous research investigating the validity and reliability of accelerometry to quantify purposeful activity in adult hospitalised patients. The populations selected included adults admitted to hospital acutely and the critically ill. Both of these patient groups were considered likely to undertake movement of low intensity, at slower speeds compared to healthy individuals. No other systematic review had focussed on this combination of patient populations, highlighting the originality if this work. Completion of the systematic review enhanced understanding of whether this technology, originally designed for application in

bridgework, dynamometers and aircraft (Walter 1997), possessed the ability to quantify the purposeful activities likely to be undertaken by them. It is only since the 1980's that interest in the use of accelerometer based activity monitors to quantify physical activity levels in free living environments for research purposes developed for large scale epidemiological studies (John and Freedson 2012).

Studies were identified where accelerometer validity was investigated to determine activity intensity or identification of rest and activity patterns (Choquette et al. 2008; Nagels et al. 2007; Winkelman et al. 2005; Bisgaard et al. 1999). Only one of these enrolled a population recovering from critical illness (Winkelman et al. 2005). It intended to investigate whether specific activity type, such as transferring over the side of the bed, could be determined by the activity intensity count it generated alone. Lack of opportunity to undertake a varied selection of activities beyond passive movements and turning within the bed meant this was unable to be determined. Therefore, the ability to determine specific activities using activity intensity counts alone required further investigation. Knowledge gained from the study by Winkelman et al. (2005), particularly as it was conducted with critically ill people, assisted in formulation of the research methodology for the feasibility study. Investigation was included within it to determine whether specific activities, for example moving from lying to sitting, could be determined by quantification of activity intensity alone.

No studies have investigated the validity of any accelerometer with critically ill people to quantify adoption of specific postures (lying sitting or standing). However, a number of studies investigated the validity of accelerometry measurement for this purpose within hospitalised older adult populations (Pedersen et al. 2013; Taraldsen et al. 2011; Brown et al. 2008; Culhane et al. 2004). They reported that combinations of placement sites, including the ankle and thigh or ankle and sternum successfully differentiated between these positions, using commercial or custom made accelerometers. However, a desire still remained to understand how the GT3X quantified the typical

purposeful activity undertaken by patients recovering from critical illness when positioned at a single site. If all purposeful activity undertaken undertaken by this patient group could be quantified by a single accelerometer this may prove more acceptable to patients. Research suggests that placement of accelerometers at multiple sites adversely affects compliance to wear them (Fortune et al. 2014; Atallah et al. 2011).

Ankle mounted accelerometers demonstrated validity in quantification of step count within acute or critically ill populations (Webber and St John 2016; Edbrooke et al. 2012). Another study, identified during further literature searching also supported the ankle placement in community dwelling individuals post stroke (Klassen et al. 2016). Less than 10% error was found when an accelerometer (the Fitbit One) was worn around the ankle for all walking speeds between 0.4 and 0.9m/s. However, when positioned at the waist, the same model failed to record a single step in a number of participants at speeds of 0.3 to 0.5m/s, with greater than 10% error up to 0.8m/s. This finding highlighted the importance of determining optimum placement sites for accelerometers which have demonstrated validity.

Only one study within the systematic review investigated the validity of a waist mounted accelerometer to quantify step count (Webber and St John 2016). Webber and St John (2016) concluded that a waist mounted Actigraph GT3X+ with the LFE setting initialised was similar to an ankle mounted Step Watch 3.0 in quantification of daily step count in hospitalised older people. No study investigated the ability of an isolated waist mounted device to interpret body position within acute or critically ill populations. Furthermore, no studies were identified which investigated an isolated ankle placement to gain understanding of its ability to interpret body position within the same patient groups.

The validity of accelerometry measurement to quantify purposeful activity has not been investigated within a ward based population recovering from critical illness. In response to identification of this knowledge gap, identified as a result of completing the systematic review, subsequent studies within the thesis

focussed on assessment of validity of an accelerometer in quantification of typical activities that would be undertaken by this patient group. Justification for the selection of the Actigraph GT3X accelerometer as the model of choice to investigate was provided as other studies had used this model to quantify time spent in lying, sitting and standing positions within the ICU, without evidence of its validity within this setting (Schujmann et al. 2015b). The manufacturers of the GT3X recommend that it is worn in isolation around the waist, above the hip in order to quantify activity intensity, body position and step count (Actigraph 2009). However, Schujmann et al. (2015b) chose to position the GT3X around the ankle. This knowledge assisted in the final choice of isolated placement sites to investigate and the subsequent development of a research protocol for the feasibility study, which is now discussed.

5.3 Feasibility study

The feasibility study positioned the GT3X at two isolated placement sites, around the waist above the hip and the lateral aspect of the ankle. The first site was recommended by the manufacturer to quantify all aspects of purposeful activity. The second site was chosen for two reasons. The superiority of this placement site in quantification of step count undertaken at slower speeds was concluded within the systematic review. Secondly, this was the site used by Schujmann et al. (2015b) when quantifying time spent in lying, sitting and standing within the ICU. Both of these aspects of purposeful activity were to be investigated as part of the feasibility study, to determine the ability of the GT3X to quantify these parameters when mounted in isolation around the waist or ankle.

The thigh was not chosen as a single placement site to investigate for this particular study due to knowledge gained from the systematic review of its inability to distinguish between lying and sitting postures (Rowlands et al. 2014; Taraldsen et al. 2011; Godfrey et al. 2010). One of the feasibility study's aims was to understand whether the distinct positions of lying, sitting and standing could be identified when a GT3X was mounted in an isolated placement site during typical activites undertaken by patients recovering from critical illness.

These were described previously in Table 1.1 on page 16 of Chapter 1. Construction of a movement protocol ensured all these activities would be undertaken, maximising the opportunity to investigate how the inclinometer (which interpreted lying, sitting and standing positions) and step count measurement modes within the GT3X interpreted them.

The decision to enrol a healthy population for this particular study was an ethical consideration. Participants received face to face training immediately prior to data collection on how to simulate patients weakened due to critical illness. Activities were repeated as part of accelerometer reliability investigations. Repeating a number of activities in a time limited period was thought to be too physically demanding for those recovering from critical illness, It was possible that this would have resulted in some patients being withdrawn from aspects of data analysis due to a refusal to repeat activities. This was encountered in one study included within the systematic review. One within the ICU refused to repeat a walk of known distance, leading to his or her withdrawal from a reliability analysis (Edbrooke et al. 2012).

Schujmann et al. (2015b) used an ankle mounted Actigraph GT3X to quantify time spent in lying, sitting and standing postures with hospitalised critically ill people, using an algorithm that had not been validated directly within this population. Furthermore, its development was based on numerical activity intensity count ranges quantified by an accelerometer placed at the hip, not the ankle, corresponding with metabolic equivalent (MET) levels determined for specific activities in other populations (Freedson et al. 1998). It was not originally developed to specifically identify body position. The algorithm categorises activity as sedentary, light, moderate or vigorous according to the counts per minute (CPM) quantified by accelerometry. Sedentary activity is defined as any activity registering less than 100 counts per minute (CPM), suggesting lying or sitting postures are being adopted.

As both lying and sitting are both classified as sedentary activity, it was unclear how Schujmann et al. (2015b) distinguished between these two postures using

this algorithm method alone to quantify time spent in specific body positions. The study did not state the inclinometer mode was initialised as the data it yields was not used as part of the algorithm developed by Freedson et al. (1998). Therefore, the validity of the Actigraph GT3X inclinometer setting to differentiate between lying, sitting and standing postures within populations recovering from critical illness had not yet been investigated. The feasibility study was the first to embark on this investigation, using the placement sites previously described, again emphasising the originality of this project also.

Typical postural transfers likely to be undertaken by populations recovering from critical illness produced a wide range of activity intensity counts. This variability was present even within individuals when transfers were repeated, regardless of whether it was undertaken with assistance or independently. Of particular note was the repeated finding of the inability of the GT3X when placed on the ankle to identify any activity intensity during the postural transfers of sitting to standing and standing to sitting. This result concurred with other authors who have investigated the intensity of activity occurring around the ankle using accelerometers during postural transitions of sitting to standing and the reverse (Fortune et al. 2014; Che-Chang and Yeh-Liang 2010).

Fortune et al. (2014) postulated that the acceleration generated at the ankle during the postural transitions of sitting to standing and the reverse transition were too low to be detected as movement, hence not quantifying any activity when an accelerometer was placed in this location. The feasibility study findings supported this theory, with the GT3X often failing to register any activity intensity at the ankle during these particular transitions. Histograms, presented in Appendix B11 on page 281, detailing the frequency of specific activity intensity values calculated for all sit to stand and stand to sit transfers recorded at the ankle highlighted this finding. Many of these particular transitions did not register a single count from the ankle sited accelerometer. These findings, therefore, cast uncertainty on how this specific postural transfer could have been quantified and identified as activity that led to a change in posture in the study by Schujmann et al. (2015b).

An activity intensity (vector magnitude) count was captured by the waist accelerometer placement during all postural transitions undertaken as part of the movement protocol in the feasibility study. This finding was consistent with other studies, reporting the waist as the optimum placement site for quantifying activity during whole body movements (Fortune et al. 2014; Che-Chang and Yeh-Liang 2010). Despite this, the range of activity counts generated from the GT3X at the waist or ankle (where counts were generated) were widely dispersed, even within individuals repeating the same transfer. Furthermore, vector magnitude activity counts recorded during different postural transitions were often similar. As a result, it was concluded that it would be difficult to identify a specific transfer or adoption of a specific posture (lying, sitting or standing) from the activity count it generated alone.

The feasibility study concluded that an ankle mounted Actigraph GT3X accelerometer was superior to the waist for identification of lying, sitting or standing positions using the inclinometer setting. This was rather surprising, especially considering that the manufacturers recommended the waist placement, resting above the hip. The waist placement regularly misclassified all body positions, often mistaking the lying position as sitting. It was postulated that this was due to the inclination of the hospital bed back rest used during the movement protocol. Raising the back rest to a position which was comfortable for each participant raised the trunk slightly. It is likely that this semi-recumbent position caused the GT3X positioned at the waist to register a sitting position. The waist placement also regularly misinterpreted the sitting and standing position, often reversing both postures. Other studies have also reported this finding when using the GT3X in the same position, due to the similar inclination of the hip during adoption of both of these positions (De Vries et al. 2011; Parkka et al. 2006).

An interesting finding for the ankle placement emerged during data analysis as part of the feasibility study. The inclinometer reading regularly changed from a ‘2’ (lying) to ‘0’ (not wearing) position once the participant moved from lying on their back (supine) into a side lying position. This was encountered in 29 of 30

participants, even changing to a ‘0’ during the short side lying phase when a lying to sitting assisted transfer was performed. A ‘0’ reading was hardly ever recorded during adoption of sitting or standing postures by the ankle placement during the movement protocols undertaken by any participant. This finding was considered significant and novel. As a result, further investigation of this aspect was incorporated into the study methodology for the final study to investigate the effect of recoding a ‘0’ setting to a ‘2’ (lying position) when the GT3X was worn on the ankle, classifying both side lying and supine lying postures as ‘2’ (lying). This analysis would investigate whether this recoding further improved recognition of the lying position in particular.

Although the ankle placement was superior to the waist in recognition of body position, it still regularly misinterpreted the sitting position, often misclassifying sitting as standing. It was postulated that this was due to the variability in the position of the lower leg during the movement protocol; evident during adoption of the sitting position. If participants sat with their legs out in front of them, the ankle accelerometer tilted posteriorly, correctly identifying the sitting position. However, if participants’ feet were flat on the floor with the ankles at right angles to the foot during sitting, the ankle accelerometer rested in an upright position, causing sitting to be interpreted as standing. Therefore, a need was presented to develop a method of differentiating between sitting and standing using the GT3X, specifically when the ankle placement interpreted the standing position in order to successfully discern between the two postures. Here, findings from the systematic review were revisited.

A combination of a thigh and sternum placement demonstrated validity in discerning between lying, sitting and standing postures (Skipworth et al. 2011; Taraldsen et al. 2011; Culhane et al. 2004). However, this combination of placement sites may not be universally appropriate within populations recovering from critical illness, for example those who have undergone cardiac surgery due to the presence of a wound, monitoring leads or pacing wires. Two studies were identified where a combination of an ankle and thigh placement were found to be valid in differentiation between lying, sitting and standing

postures (Pedersen et al. 2013; Brown et al. 2008). Upon assimilation of the findings by both Pedersen et al. (2013) and Brown et al. (2008), it was considered that this combination of placement sites was more appropriate for those recovering from critical illness, which was the chosen population for the purposes of this PhD thesis. Assimilation of these findings assisted in the choice of placement sites to investigate in the final validity study which was presented in Chapter 4 of this thesis. These sites were the thigh and ankle, in combination and isolation.

The predominant role of the thigh mounted GT3X, positioned on the same non-dominant leg as the ankle GT3X was to investigate if this combination permitted discrimination between sitting and standing postures, in situations where the ankle site identified a standing position. However, it was also considered an opportunity to investigate how effective an anteromedial thigh placement of the GT3X in isolation was in detection of lying, sitting, standing postures and step count. This enabled the ability to compare its output with other thigh mounted models which had undergone investigation of their validity in interpretation of body position or step count within hospitalised populations (Taraldsen et al. 2011; Godfrey et al. 2010).

The feasibility study determined the ankle placement to be superior to the manufacturers recommended site (worn around the waist, above the hip) for quantification of step at walking speeds walking greater than 0.3m/s. These results concurred with the systematic review findings regarding the superiority of ankle mounted accelerometers for step count detection at slower walking speeds, which also compared waist and ankle placement sites (Webber and St John 2016). Furthermore, concurrence with another study which had compared waist and ankle placements for step count detection during slow speed walking in a functionally impaired population was found (Klassen et al. 2016). The natural progression of investigation was to assert this positive finding for the ankle placement to quantify step count within an actual population recovering from critical illness. Only then could it be confirmed that an Actigraph GT3X

accelerometer mounted in isolation on the ankle was valid in determination of step count within this patient group.

The findings from the feasibility study precipitated the decision not to include any further investigation related to identifying activity type from activity intensity readings alone. Instead, attention was focussed on developing a methodological protocol that continued investigation of the validity of the inclinometer and step count settings of the GT3X directly within a population recovering from critical illness. It was felt that these particular measurement modes would produce information which would be particularly clinically meaningful, due to the nature of data captured (body position and step count), should they demonstrate validity. They would also be more likely to mean more to patients if they were able to access this information themselves.

5.4 Validity study

This study was the first to investigate the validity of any accelerometer within a population recovering from critical illness resident on a hospital ward. Progressing directly onward from the feasibility study it investigated whether the addition of a second GT3X accelerometer, positioned on the anteromedial aspect of the thigh in combination with the identical ankle placement used previously improved identification of the sitting position. Only the inclinometer measurement mode was used to identify body position. If the ability to detect sitting could be improved by accelerometers placed in combination compared to an isolated ankle placement it would enable discrimination between lying, sitting and standing postures. As a result, identification of both lying to sitting and sitting to standing postural transitions would also be enabled.

As a result of field work investigation it was found that during sitting activities, the inclinometer of the thigh mounted GT3X captured readings of a ‘2’ (lying) or ‘3’’ (sitting). Using this data, it was possible to investigate the validity of an algorithm to determine whether the combination of readings returned from the ankle and ipsilateral thigh placement could improve recognition of the sitting

position, specifically on occasions where the ankle recorded a reading of ‘1’ (standing). During field investigations the thigh placement often captured a reading of ‘1’ during standing, suggesting it was correctly determining this posture. It was felt that the ability to distinguish between the two postures of sitting and standing would be further enhanced by this. The algorithm constructed to guide discrimination between sitting and standing, interpreting data captured by both the thigh and ankle placements is presented again in Table 5.1 below.

Table 5.1 Differentiating between sitting and standing using the thigh/ ankle algorithm

Body position	Thigh inclinometer reading	Ankle inclinometer reading
Standing	1	1
Sitting	2 or 3	1

The validity of this algorithm underwent investigation, comparing accelerometer data against direct observation of body position. Inclinometer data for each participant was analysed separately in this study in order to understand how consistently the accelerometers identified body position. Hospitalised participants performed typical activities that they would undertake throughout the course of a day, included within a semi structured movement protocol. They could execute these activities in any order they wished, resting in between. This arrangement introduced variation in the order in which activities were undertaken representing a more naturalistic environment compared to the more regimented movement protocol used in the feasibility study. Adoption of a particular posture for a period of time (the duration of which was decided by the participant) provided opportunity to see if the accelerometers continued to capture inclinometer data during a period of little or no movement.

Skotte et al. (2014) reported the potential difficulties of maintaining activation of the inclinometer function of Actigraph models when a prolonged period of inactivity occurred, although they were not specific about the duration of these periods. This may cause the inclinometer to capture readings of ‘0’ (not wearing) mistakenly believing it has been removed. The authors reported that 5% of inclinometer data during 8 hour recording periods was registered as ‘0’ (not worn) by the accelerometers, noting that this reading was often returned when prolonged periods of inactivity were encountered. Therefore, despite the prolonged adoption of sedentary postures (of a non-specific duration), 95% of readings throughout the eight hour recording period were not registered as a ‘0’.

Accelerometers are unlikely to pose any privacy or dignity issues which accompany other methods of activity monitoring such as direct observation. Observation over lengthy periods is resource intensive and clearly poses privacy and dignity issues. Moreover, self-report tends to only moderately correlate with more objective means of activity monitoring (Cheung et al. 2011). The ability to self-report activity may also be difficult for some individuals recovering from critical illness due to persisting cognitive impairment (Pandharipande et al. 2013). Given that 95% of inclinometer data was captured successfully during an eight hour period by Skotte et al. (2014), this method still appears superior to observation and self-report, especially considering its unobtrusive nature.

The validity study also investigated the thigh and ankle placements in isolation to evaluate their individual abilities to identify lying, sitting and standing postures and quantify step count. The feasibility study reported encouraging findings for the ankle placement in identification of lying and standing postures and step count. These findings supported continued investigation of the validity of this placement site directly within a population recovering from critical illness. The disappointing results for the waist placement both for interpretation of body position and step count precipitated the decision not to continue further investigation of the validity of this placement site.

5.5 Limitations of the research

This PhD has increased the evidence base concerning investigation of the validity of accelerometry to quantify purposeful movement within hospitalised patients recovering from critical illness. It has also commenced investigation of the validity of one commercially available accelerometer model, the Actigraph GT3X accelerometer for identification of body position and quantification of step count. Although certainly a useful expansion to a developing evidence base, several limitations of the research exist, which are now considered.

5.5.1 Determination of daily step count using the GT3X

The feasibility study, presented in Chapter 3 investigated the ability of the GT3X to quantify step count over short distances (ten metres) during slow speed walking. A healthy population was enrolled who were age matched to the local population admitted onto the ICUs within HEYHT throughout 2012. Participants received instruction on how to simulate a patient weakened by critical illness. In the validity study presented in Chapter 4, ward based hospitalised adult patients recovering from critical illness was enrolled. Participants were permitted to self-determine walking distances, whilst having their step count recorded. Distances achieved were not recorded. Encouraging results emerged regarding an ankle placement to quantify step count undertaken at slow speed for both studies. However, it remains undetermined whether the steps undertaken during a whole day by this population would be as accurate. Further study is required to investigate this, with consideration given to the choice of criterion measure to use. If its validity can be determined over longer durations when worn at the ankle, this device could function as a criterion measure in future studies investigating the validity of other step count monitoring technologies within this population for full day step count.

5.5.2 Ability of the GT3X inclinometer to identify prolonged adoption of lying, sitting or standing postures

The maximum duration of wear time for patients within the validity study was 99 minutes, with a mean of 58.55 minutes (SD 16.85, range 30-99 minutes).

Adoption of a single posture, for example lying or sitting did not exceed 30 minutes. It therefore remains unclear whether the inclinometer setting would continue to capture a correct reading of body position beyond this time period, without the device thinking it is not being worn if no movement was being detected. This would register a ‘not wearing’ reading of ‘0’ on the inclinometer. For the purposes of the studies within this thesis the ‘0’ reading was recoded as lying (‘2’) due to the consistent finding when worn on the ankle of a ‘0’ being recorded when the participant turned in a side lying position. This recoding greatly improved agreement between inclinometer readings and those captured through observation in recognition of the lying position. A ‘0’ reading was captured by three different GT3X models which were alternated at the ankle between participants during the final study. As a result it is unlikely the finding was an anomaly specific to an individual device.

One final limitation is consideration of the effect of any fixed flexion deformities in the lower limbs and the effect this may render on the correct determination of body position captured by the inclinometer function of the GT3X. All patients consecutively enrolled in the final study did not have any evidence of fixed flexion deformities in the lower limbs. Therefore, it remains unknown how the inclinometer function may capture information in those who may walk with a degree of fixed flexion in the hip or knee. This may cause the thigh placement in particular to read a sitting position, or the ankle placement to read a sitting position due to the inclination of the accelerometers. This may precipitate an incorrect interpretation of the standing position as sitting. This was not explored within this thesis due to all patients not experiencing any fixed flexion deformity but is certainly worthy of consideration in future investigations using this device.

The healthy population enrolled within the feasibility study performed typical activities likely to be undertaken throughout the day by those recovering from critical illness. Other aspects still required investigation, however, such as how the accelerometers interpreted the sitting position whilst patients sat in a standard hospital issue bedside chair. This activity had not been included within the movement protocol. Therefore, this required inclusion and investigation

within the final study in order to encompass all possible activities this population may perform. Synthesis of the data from the validity study led to the formulation of conclusions, which lie within the next chapter that draws the thesis to a close.

5.6 Assimilating the findings to reach a conclusion

This chapter has permitted opportunity to demonstrate how the PhD progressed using the findings generated from the individual studies within it. It also highlighted the usefulness of field work and the desire to maintain a strong clinical focus throughout the individual projects. Each separate study resulted in assimilation of knowledge and synthesis of data which assisted in progression of the evidence base, which informed construction of subsequent studies. The concluding chapter which follows summarises the key findings. Recommendations for the clinical application of the GT3X are also discussed. Optimum placement sites are suggested based on the findings of studies undertaken as part of this PhD process. Future recommendations for research are also suggested.

Chapter 6

Conclusion

6.1 Introduction

This thesis has responded to the finding that there is limited evidence regarding the validity of accelerometry to quantify purposeful movement in hospitalised patients recovering from critical illness. It commenced investigation of a commercial model, the Actigraph GT3X, in a ward based population, following their discharge from the ICU. This work is the first to investigate the validity of any accelerometer within this population directly within a hospital ward environment. A systematic review completed as part of this PhD determined that previous studies have investigated accelerometer validity only within the confines of the ICU (Edbrooke et al. 2012; Winkelman et al. 2005). Justification for the choice of model was found in a study which quantified patient activity within the ICU using the Actigraph GT3X, without prior investigation of its validity within this setting (Schujmann et al. 2015). Therefore, the research projects undertaken within this PhD are the first to commence investigation of the validity of this particular model within this population, highlighting the originality of this PhD thesis. A variety of measurement modes were investigated including activity intensity (via its vector magnitude reading), inclinometer (to identify body position) and step count.

Evidence of continued interest in the use of accelerometers to quantify purposeful activity in hospitalised adults following critical illness has been identified within clinical trials databases. A study is planning to investigate the feasibility and validity of the Actigraph GT3X+ to quantify the intensity of activity undertaken by patients in the ICU (ClinicalTrials.gov identifier: NCT02263716). This model is produced by the same manufacturer as the GT3X and also possesses activity intensity, inclinometer and step count measurement modes. The results of this study (when available) and the findings of this PhD will continue to expand the evidence base concerning the validity of accelerometry to quantify purposeful movement within this patient group.

The research questions, originally posed on page 22 within Chapter 1 of this PhD thesis will now be revisited in section 6.2. The summary of findings and conclusions arising for each question are reported, ultimately leading to assimilation of a set of clinical recommendations regarding the application of the Actigraph GT3X within populations in the early stages of recovery from critical illness to quantify purposeful activity. Placement sites and recommendations are based on the data synthesised during the various research projects within the thesis. How these findings have contributed to the current literature is also discussed. Recommendations for future research, both with this particular model and generally regarding accelerometry with critically ill people to quantify purposeful movement are also proposed. These recommendations will serve to stimulate development of ideas for the formulation of future research projects. This thesis will then draw to a close, ending with a personal message from a patient contained within a letter. It reveals the impact of critical illness and its effect on both the patient and their loved ones. It also highlights the importance to patients of returning to pre illness levels of activity. This further emphasises the importance of development of unobtrusive methods to demonstrate to patients that progress really is being made, assisting in providing motivation and encouragement.

6.2 Research questions

6.2.1 Question 1

How has investigation of the validity of accelerometry measurement been undertaken in acute or critically ill hospitalised adults and what have these studies concluded?

Studies investigating the validity of accelerometry to quantify purposeful movement have predominantly been undertaken within acutely admitted older patients. The variety of all hospitalised patient populations investigated within the systematic review were reported in Table 2.5, found on page 46 in chapter 2. Two studies have investigated the validity of accelerometry measurement in patients recovering from critical illness to determine the frequency and duration of activity and to quantify step count (Edbrooke et al. 2012; Winkelman et al. 2005). No studies had investigated the validity of accelerometry measurement

to specifically identify lying, sitting or standing postures within this patient group prior to construction of this thesis.

Combinations of accelerometer placement sites, including the thigh and ankle, and thigh and sternum, permit differentiation between lying, sitting and standing postures (Pedersen et al. 2013; Taraldsen et al. 2011; Brown et al. 2008; Culhane et al. 2004). This has been achieved using measurement modes inherent within individual specific accelerometer models. A number of commercial accelerometers have demonstrated validity in determination of step count when worn around the ankle in populations likely to walk at slow speeds. These include both acutely admitted older populations and those recovering from critical illness (Webber and St John 2016; Edbrooke et al. 2012).

Ankle mounted models have demonstrated reliability in quantification of step count (Edbrooke et al. 2012). The feasibility study, undertaken as part of this PhD thesis also determined that an ankle mounted Actigraph GT3X was reliable in quantification of step count undertaken at slow speed, when 10m walks were undertaken with a WZWF or WS. The ankle placement also demonstrated intermethod reliability within the final validity study, undertaken directly within a ward based hospitalised population recovering from critical illness. Whilst some investigation of accelerometer reliability was included within this PhD thesis, both for identification of step count and activity intensity, further work is necessary to truly understand the reliability of the Actigraph GT3X within the context of the purposeful activities which were undertaken within this PhD.

6.2.2 Question 2

To what extent can the Actigraph GT3X accelerometer quantify the functional activity typically undertaken by hospitalised adults recovering from critical illness?

The inclinometer within the Actigraph GT3X can identify lying and standing postures when positioned on the ankle with greater than 90% accuracy respectively when compared against observed body position. Recoding of any

‘0’ (not wearing) readings from the ankle inclinometer to a ‘2’ (lying) position further improves the level of accuracy for interpretation of the lying position. This finding was present from both the feasibility study and final validity study which enrolled hospitalised adult patients. An ankle placement cannot consistently identify the sitting position correctly, often misinterpreting this as standing. The application of a second GT3X on the anteromedial aspect of the thigh of the same leg permits differentiation between these two postures. This is achieved by viewing the inclinometer data captured by both placement sites when a standing position is identified by the ankle placement in order to permit differentiation.

The reading captured by the thigh placement will confirm whether a sitting or standing position is being adopted. If the thigh placement captures a reading of ‘2’ (lying) or ‘3’ (sitting), when the ankle placement identifies a ‘1’ (standing), a sitting position is most likely being adopted. If the thigh and ankle placements both capture a reading of ‘1’, then a standing posture is most likely being adopted. Using this method of interpretation, lying, sitting and standing postures can be differentiated. Therefore, typical functional activities likely to be undertaken by patients recovering in hospital from critical illness including postural transfers (e.g. moving from lying to sitting over the side of the bed) can be identified.

When the Actigraph GT3X is placed in isolation on the anteromedial thigh it cannot differentiate between lying and sitting postures. However, if identification of time spent in sedentary (lying or sitting) or standing postures if clinically sufficient, a GT3X mounted in isolation on the anteromedial thigh has demonstrated validity.

6.2.3 Question 3

To what extent can this accelerometer model capture step count in hospitalised adults recovering from critical illness?

An Actigraph GT3X accelerometer, when mounted on the lateral aspect of the non-dominant ankle is valid in quantification of step count in ward based

patients recovering from critical illness during the final days of hospital stay. The feasibility study and validity study also determined this placement site to be reliable.

Although a waist placement was also determined to be reliable in the feasibility study, it was not found to be valid in step count quantification, often failing to record a single step at speeds of less than 0.3 m/s. Considerably wider 95% LOA and mean differences between observed step count and accelerometer derived step count were also found at this placement site compared to the ankle. A thigh placement in isolation was not valid or reliable in determination of step count in ward based populations recovering from critical illness, with over 50% error calculated in some participants.

6.2.4 Question 4

What are the optimum body placement sites in which to position the Actigraph GT3X in order to capture specific aspects of activity or adoption of body postures in hospitalised adults recovering from critical illness?

This PhD thesis has determined the following accelerometer placement site recommendations to capture specific aspects of activity within hospitalised adult patients recovering from critical illness. These recommendations are now presented in Table 6.1 on page 226.

Table 6.1 Recommendations for placement of the Actigraph GT3X accelerometer depending on preferred recognition of activity type

Activity type	Recommended placement
Quantification of time spent in lying, sitting and standing postures including recognition of postural transitions	Ankle and thigh in combination NB: Thigh data only necessary for differentiation between sitting and standing postures.
Identification of standing and adoption of sedentary (lying or sitting) postures, including their duration.	Thigh placement only
Step count only, as evidence of periods of activity (mobilising)	Ankle placement only

6.2.5 Question 5

Is the Actigraph GT3X Accelerometer valid in detection of body position and step count in a population recovering from critical illness?

Validity of the Actigraph GT3X in detection of lying, sitting and standing postures within this population is dependent on the use of an algorithm (first described in Table 4.2 on page 157). This requires interpretation of inclinometer data from two identical GT3X models placed in combination. One is positioned anteromedially on the non-dominant thigh, the other placed on the lateral aspect of the ankle of the ipsilateral leg. Recoding of inclinometer ‘0’ (not wearing) settings to ‘2’ (lying) settings for the ankle placement is also necessary. An isolated anteromedial thigh placement demonstrated validity in identification of sedentary (lying or sitting) postures and standing. However, it cannot discern between lying and sitting postures. An ankle placement was valid and reliable in step count during typical walks of short distance and duration undertaken by this population within the hospital ward environment. A

thigh placement was not found to be valid or reliable in detection of step count in this patient group.

6.3 Implications of study findings

Based on the outcomes of the studies within this PhD thesis potential future clinical uses for the Actigraph GT3X can be proposed. These suggestions also take into consideration findings from previous studies which have investigated similar models produced by the same manufacturer within hospitalised populations likely to walk at slow speed or undertake activity which is of low intensity. These studies were identified as a result of the systematic review undertaken.

The use of the Actigraph GT3X could quantify periods of time patients' spent in bed during the day, or the regularity and duration of periods of mobilisation undertaken. This could enable the clinician to build up a picture of individual patient's activity levels, identifying those who may still require regular encouragement from the rehabilitation team, despite having regained the ability to undertake activity independently. Sharing this information with the wider multidisciplinary team, including medical and nursing staff, means all members of the MDT can be made aware of those who may not be very active. Encouragement and support to mobilise throughout the whole day can be provided by all members of the health care team.

This device could also be used for audit purposes to determine if there are specific times of the day when patients appear more active (or inactive). This could be the morning, afternoon or evening for example. The ability to capture and analyse this information would yield useful information regarding the effective allocation and delivery of rehabilitation resources at times when it appears patients spend lengthy periods in sedentary postures.

Sharing the data captured by the step count measurement mode of the Actigraph GT3X with patients individually could also provide motivation and

encouragement. Goals could be agreed between therapist and patients to achieve a particular daily step count. This could provide the necessary encouragement for patients to increase the regularity of episodes of mobilisation in order to achieve their goal. This may be only a small increase to aim for, yet still feeling like progress is being made. Increasing the regularity of physical activity would decrease the adoption of lengthy periods of sedentary behaviour. Evidence suggests that the use of technology to capture step count can provide the motivation necessary to undertake exercise (Martin et al. 2010). A systematic review analysed the results of eight RCTs which enrolled hospital outpatients (277 patients in total). They determined following 'meta-regression analysis' that outpatient pedometer users significantly increased their physical activity by 2491 steps compared to control groups (95% CI 1098 - 3885 steps per day, $p < .001$), with accompanying significant decreases in systolic blood pressure and BMI (Bravata et al. 2007). The outpatient populations investigated had an average age of 49 years and 85% of patients' enrolled were female. It remains unknown whether similar findings would result in acute or critically ill inpatient populations, especially considering the majority of inpatient populations identified during the systematic review within this thesis were considerably older.

Encouragement to mobilise from all members of the MDT will assist in helping patients to achieve their target step count. Adoption of the use of accelerometers to encourage activity within the hospital ward environment may assist in decreasing the episodes of prolonged adoption of sedentary postures reported in some studies (Borges et al. 2015). Objective proof of regular activity and achievement of progressively increasing target step counts could be shared with the patient, providing evidence of improvement in physical function. Provision of the Actigraph GT3X to quantify step count beyond discharge from the acute hospital setting in those recovering from critical illness may prove beneficial. If step count only is being captured, there would only be the requirement to wear a single accelerometer.

Continuation of activity monitoring within those recovering from critical illness is worthy of consideration, especially with the lack of specialist rehabilitation facilities for patients who are recovering from critical illness (Connolly et al. 2014). Even where access is available to rehabilitation services post discharge, the addition of accelerometers could complement these valuable resources. The use of this technology could serve as an additional motivator to undertake physical activity, which can be monitored by health care professionals responsible for delivery of the post discharge services.

Based on initial evidence of its validity in quantification of step count in those recovering from critical illness, it is possible that an ankle mounted GT3X could be used as a criterion measure for future studies investigating the validity of other activity monitoring technology. In this instance, the GT3X would function as a research tool, possibly during validity investigation of other activity monitoring technologies which connect to smartphones. Smartphones may prove a popular choice in the future if their validity is ascertained due to the immediacy of feedback they give, without the need for computer download and further interpretation. However, comparison with a criterion measure that has proven validity itself within a specific clinical setting is essential.

6.4 Recommendations for future research

Further investigation into the validity of an ankle mounted Actigraph GT3X to capture daily step count within populations recovering in hospital from critical illness is recommended. Larger sample sizes of critical care patients, encompassing those who may walk with a degree of fixed flexion in the hip or knee are also recommended, especially to investigate the effect of fixed flexion deformities on the inclinometer readings captured by both the thigh and ankle. Investigation is also required into how the inclinometer function behaves when lengthy periods of adoption of certain postures are encountered, to understand if minimal movement leads the accelerometers to believe they are not being worn. Populations should include not only those patients resident in ICU, but also on the ward in order to gain understanding of how accelerometers quantify purposeful activity through the entire hospital stay.

Investigation of the reliability of the GT3X to quantify typical activities undertaken by those recovering from critical illness and step count was commenced within this thesis. However, further investigation of reliability is recommended. The systematic review revealed possible difficulties of undertaking reliability investigation within this population (Edbrooke et al. 2012). The requirement to repeat movements in a test-retest research design may precipitate patient withdrawal if they refuse to perform a particular activity twice. Attempts to investigate the reliability of accelerometry measurement and avoid refusal to undertake repeated movements were made in the feasibility study, where a healthy population were recruited. The study by Edbrooke et al. (2012) was the only study identified in the systematic review which investigated accelerometer reliability in quantification of step count. This finding may be due to the difficulties faced by researchers to devise methods of investigation that are likely to be acceptable to hospitalised participants.

6.5 Self-reflection

Entry onto a PhD programme of study from a Graduate Diploma was an enormous undertaking, requiring positivity and self-belief. Support and encouragement from academic, clinical and senior management staff greatly assisted the confidence to embark on this path, moving from a predominantly clinically orientated background into academia. The five years of study have seen the unexpected loss of a parent, devastating last minute disappointments requiring seeking of new premises in which to undertake the feasibility study necessitating amendments to NHS ethics applications, many late nights and equally numerous early mornings. In contrast, it has also seen many moments to celebrate including yearly positive review meetings and successful abstract submissions for poster presentations at Conferences. Most recently acceptance of an article based on the systematic review for publication within a peer reviewed Journal has demonstrated that this PhD thesis possesses work of publishable quality (Anderson et al. 2018).

An understanding and acceptance has been gained that the world of research is one of positive and negative experiences. Dwelling on disappointment leads

to a spiral of negativity and lack of progress. Focussing on positives increases productivity, which has seen the thesis move forward to a point where it could be submitted. Acquisition of knowledge in undertaking literature searches has meant that these skills have been used to advise clinical colleagues who are entering the world of research. The ability to act on constructive feedback has greatly improved academic writing skills, evidenced in acceptance of the article for publication recently (Anderson et al. 2018).

No longer are the results sections of journal papers read in an instant due to an inability to understand any of the statistics. Whilst it cannot be said that a statistical genius has emerged, an ability to interpret specific methods of statistical analyses has certainly developed, especially those which were included within the various studies in the PhD. Interpreting what lies beneath a statistically significant result has been one of the most exciting advances in knowledge gained. Aspects of this knowledge acquisition can be put to good use with clinical colleagues during journal club sessions, especially if similar methods of statistical analysis are included within the chosen papers to those used during the PhD.

Mature students often have other responsibilities that require consideration. Retention of clinical commitments (including weekends), children of GCSE and A level ages and a house in need of urgent repair made balancing of work and home life challenging. This occasionally led to feelings of loss of control, which negatively impacted on both motivation and output. However, as progress was made and each study was completed, it became easier to see what had been achieved, rather than what there was still left to do. Adoption of this method of viewing progress was a hugely positive step and one that will certainly be recommended and encouraged in future researchers who embark on a PhD.

6.6 Concluding words

Construction of this thesis has been both mentally and physically taxing, requiring tenacity, determination and the will to succeed. Ironically, all of these

experiences and attributes will be encountered or required by those recovering from critical illness. Critical illness is painful and emotionally challenging, both for those experiencing it and their families and loved ones. The following extract is a letter which was received in 1997. Patients and family names have been removed to maintain anonymity. The words conveyed are personal and endearing; instrumental in fuelling a desire to follow a career path specialising in the rehabilitation of this very needy population. It delivers a message of hope, determination and courage. It is a fitting tribute to those who have experienced critical illness and offers words of encouragement for patients of the future. Although this letter brings the thesis to an end, the determination and desire to discover ways of enhancing the patient experience and optimising recovery following critical illness continues.

"Dear Jayne

Remember me? I was the liver transplant patient at the end of last year who labelled you 'a big bully'. You were always dragging me out of bed to do stupid things like climbing stairs or exercise biking!! I always tried to resist but invariably lost! (you were bigger and stronger than I was). I've looked for you the last two times I've been to clinic but once you were on another ward and the second time you were on holiday for a few days. I only come now every six weeks.

I'm sat outside in this glorious spring sunshine amidst daffodils, having a cup of coffee thinking how wonderful life is. Unfortunately I'm not yet back to tramping the Derbyshire hills and dales (the 'Brasher' boots are still in the cupboard!) but I'm slowly getting there. I'm aiming to walk 3 or 4 miles shortly, round a local reservoir and woods when the bluebells and wood anemones are in full bloom. Take comfort Jayne that all your efforts were not totally in vain.

I often think about you all, including the entire physio's, doctors, nurses and domestic staff. It was a horrendous time for me (and XXXX) and we both fully

appreciate how much easier it was made by all your kindnesses and cheerful and willing ways to help.

Sorry I don’t know your surname but I don’t think I ever knew it, you were always known to me as “oh no, not Jayne again!” Our best wishes to you all and if ever you’re in the Peak District with an hour to spare call in and see us.

With Love

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Appendices

Appendix A Systematic review

A1 CASP cohort study checklist (version 31st May 2013)

12 questions to help you make sense of cohort study

How to use this appraisal tool

Three broad issues need to be considered when appraising a cohort study:

- **Are the results of the study valid?** **(Section A)**
- **What are the results?** **(Section B)**
- **Will the results help locally?** **(Section C)**

The 12 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions.

There is some degree of overlap between the questions, you are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

These checklists were designed to be used as educational tools as part of a workshop setting

There will not be time in the small groups to answer them all in detail!

(A) Are the results of the study valid?

Screening Questions

1. Did the study address a clearly focused issue? ❒ Yes ❒ Can't tell ❒ No

HINT: A question can be 'focused' In terms of

- The population studied
- The risk factors studied
- The outcomes considered
- Is it clear whether the study tried to detect a beneficial or harmful effect?

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2. Was the cohort recruited in an acceptable way? ❒ Yes ❒ Can't tell ❒ No

HINT: Look for selection bias which might compromise the generalisibility of the findings:

- Was the cohort representative of a defined population?
- Was there something special about the cohort?
- Was everybody included who should have been included?

Is it worth continuing?

Detailed questions

3. Was the exposure accurately measured to minimise bias?

❒ Yes ❒ Can't tell ❒ No

HINT: Look for measurement or classification bias:

- Did they use subjective or objective measurements?
- Do the measurements truly reflect what you want them to (have they been validated)?
- Were all the subjects classified into exposure groups using the same procedure

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4. Was the outcome accurately measured to minimise bias?

❒ Yes ❒ Can't tell ❒ No

HINT: Look for measurement or classification bias:

- Did they use subjective or objective measurements?
- Do the measures truly reflect what you want them to (have they been validated)?
- Has a reliable system been established for detecting all the cases (for measuring disease occurrence)?
- Were the measurement methods similar in the different groups?
- Were the subjects and/or the outcome assessor blinded to exposure (does this matter)?

5. (a) Have the authors identified all important confounding factors? ❒ Yes ❒ Can't tell ❒ No

List the ones you think might be important, that the author missed.

(b) Have they taken account of the confounding factors in the design and/or analysis? ❒ Yes ❒ Can't tell ❒ No

List:

HINT: Look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

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6. (a) Was the follow up of subjects complete enough? ❒ Yes ❒ Can't tell ❒ No

(b) Was the follow up of subjects long enough? ❒ Yes ❒ Can't tell ❒ No

HINT: Consider

- The good or bad effects should have had long enough to reveal themselves
- The persons that are lost to follow-up may have different outcomes than those available for assessment
- In an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort?

(B) What are the results?

7. What are the results of this study?

HINT: Consider

- What are the bottom line results?
- Have they reported the rate or the proportion between the exposed/unexposed, the ratio/the rate difference?
- How strong is the association between exposure and outcome (RR,)?
- What is the absolute risk reduction (ARR)?

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8. How precise are the results?

HINT: Look for the range of the confidence intervals, if given.

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9. Do you believe the results?

❑ Yes ❑ Can't tell ❑ No

HINT: Consider

- Big effect is hard to ignore!
- Can it be due to bias, chance or confounding?
- Are the design and methods of this study sufficiently flawed to make the results unreliable?
- Bradford Hills criteria (e.g. time sequence, dose-response gradient, biological plausibility, consistency)

(C) Will the results help locally?

10. Can the results be applied to the local population? ❒ Yes ❒ Can't tell ❒ No

HINT: Consider whether

- A cohort study was the appropriate method to answer this question
- The subjects covered in this study could be sufficiently different from your population to cause concern
- Your local setting is likely to differ much from that of the study
- You can quantify the local benefits and harms

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11. Do the results of this study fit with other available evidence? ❒ Yes ❒ Can't tell ❒ No

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12. What are the implications of this study for practice?

HINT: Consider

- One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making
- For certain questions observational studies provide the only evidence
- Recommendations from observational studies are always stronger when supported by other evidence

A2 Data collection form (systematic review)

DATA COLLECTION FORM FOR FULL TEXT REVIEW OF ARTICLES CATEGORISED AS 'INCLUDE' OR 'UNCLEAR' FOLLOWING REVIEW OF TITLE/ TITLE AND ABSTRACT

Reference ID number…… Reviewer Initials …… Date: …… …..

ORGANISATIONAL ASPECTS	
Title	
Author (s)	
Year	
Journal	
Source (Database)	
Page numbers/ issue/ volume	
Country of origin	
Study type	
Research question	
Short description of study objectives	

PATIENT CHARACTERISTICS		
Patient population by speciality (e.g. ICU inpatient survivors, acute medical admissions, oncology)		
Gender (%)	Male = % Female = % Undisclosed = %	Gender reported? Yes No (Please circle)
Age	**Range:** **……**	(Please tick) Mean ……..... Median …….. SD …… IQR ……
Sample size	***n* = ……**	**Was power achieved?** YES NO NOT STATED
Drop out from sample Reasons for drop out		

DATA EXTRACTION SPECIFIC TO ACCELEROMETER ('INTERVENTION')	
Accelerometer make and model	
Accelerometer placement site(s)	HIP ANKLE WRIST OTHER (STATE) ……..
Method of attachment of accelerometers to the body e.g. elastic belt etc.	
Single accelerometer placed or a combination of accelerometers identifying movement?	SINGLE COMBINATION

DATA EXTRACTION SPECIFIC TO ACCELEROMETER ('INTERVENTION')	
Comparison of one accelerometer placement site against another?	YES NO
Duration of active recording time for which accelerometer data was collected	
Accelerometer measurement modes used (e.g. step count, activity count, activity frequency count)	
Epoch length e.g. 1 second etc. (Please enter as 'not stated' if not evident clearly within the paper)	
Patient tolerance of the device	
Infection control measures/ precautions undertaken regarding placement of the accelerometer(s)	

Any further comments related to questions within 'intervention' subgroup headings e.g. ambiguity, something you feel requires contact and clarification with the study author(s)?

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COMPARATOR	
Does the study involve the use of a comparator at all?	YES NO
Was the accelerometer being compared against itself (i.e. test – retest design)	YES NO
Was the accelerometer being compared against another reference measure e.g. observation? (PLEASE STATE BEING AS SPECIFIC AS POSSIBLE)	YES NO CRITERION REFERENCE MEASURE:

Any further comments related to questions within 'comparator' subgroup headings e.g. ambiguity, something you feel requires contact and clarification with the study author(s)?

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SPECIFIC ASPECTS RELATED TO METHODOLOGICAL DESIGN	
Was a specific 'movement protocol' incorporated into the study design where participants performed a set regime of movement? (PLEASE STATE MOVEMENT PROTOCOL)	YES NO COMMENTS:
Was there a very specific accelerometer placement protocol? (PLEASE STATE)	YES NO COMMENTS
Was 'spontaneous' movement captured as it occurred? (PLEASE EXPLAIN HOW THIS WAS UNDERTAKEN E.G. WITHIN THE WARD ENVIRONMENT ETC)	YES NO COMMENTS:
Was physically assisted movement captured other than that undertaken using a walking aid (e.g. zimmer frame or walking stick?)	YES NO COMMENTS

Any further comments related to 'specific aspects related to methodological design' section e.g. contact/ clarification with authors necessary?

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OUTCOME	
What statistical methods have been used to undertake psychometric analysis? (PLEASE STATE THE SPECIFIC STATISTICS UNDERTAKEN)	
Results of statistical analysis to include actual p – values etc	
Study conclusion related to validity and reliability of accelerometer within movement/ activity domains of the methodological design and inpatient population	

Any further comments related to questions within 'outcome' subgroup headings e.g. ambiguity, something you feel requires contact and clarification with the study author(s)?

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IF YOU HAVE CEASED REVIEW OF THIS ARTICLE AND CHOSEN TO EXCLUDE IT FROM THE SYSTEMATIC REVIEW, PLEASE DETAIL YOUR REASONS WHY:

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Website that the form was developed from:

http://chmg.cochrane.org/sites/chmg.cochrane.org/files/uploads/Template-Data%20Extraction-CHMG.pdf

Accessed originally [21st October 2013]

Appendix B Feasibility study

B1 Flyer for feasibility study

York St John University

Hull and East Yorkshire Hospitals NHS Trust

ARE YOU AGED OVER 18?

Volunteers required (no upper age limit)

Getting up and getting going!

I am seeking volunteers to help with a PhD research project. You would need to wear two small movement sensors, about the size of a digital watch, which will measure your activity during getting out of bed, standing up and walking. Participation would take about one and a half hours, commencing **October 2014** at **Ward 7, Castle Hill Hospital, Castle Road, Cottingham, East Riding of Yorkshire HU165JQ**. For more information please contact:

Mrs. Jayne Anderson on 01482 605293 or jayne.anderson@hey.nhs.uk

Many thanks for your time and initial interest

Jayne Anderson Grad. Dip. Phys. MCSP
Lecturer Practitioner Physiotherapist, Respiratory Care, Hull and East Yorkshire Hospitals Trust

PhD Student, Faculty of Health and Life Sciences, York St John University

Version 3: 20th September 2014

B2 Poster submission at HEYHT Innovation Day

Hull and East Yorkshire Hospitals NHS
NHS Trust

York St John University

Are we preparing people adequately for discharge? Encouraging physical activity in hospital

Jayne Anderson
Lecturer Practitioner Physiotherapist Hull and East Yorkshire Hospitals Trust
PhD Student York St John University

What the evidence tells us.....

'Older acutely hospitalised medical patients with walking ability spent 17 hours a day of their 'in hospital' time in bed' [1]

'Of 61 participants who walked 100ft on their last day of an intensive care unit stay, 14 did not walk at all on the first full day back on the ward , 22 walked less than 100ft and 25 ambulated 100ft or more' [2]

'Total time spent standing up (not necessarily walking) in the first four days following upper abdominal surgery:

3 minutes on day 1, 8.2 minutes on day 2, 7.6 minutes on day 3 and 34.4 minutes on day 4' [3]

The undesirable effects of inactivity

- Respiratory complications
- Increased risk of deep vein thrombosis
- Increased length of hospital stay
- Pressure sores
- Decreased motivation and low mood

PhD research currently underway by the physiotherapy department, Hull and East Yorkshire Hospitals NHS Trust

What type and patterns of daily activity undertaken by patients recovering from critical illness during their first few days back on the ward from the intensive care unit lead to greatest improvement in physical function?

Can we determine the type and pattern of daily physical activity patients undertake using accelerometry (movement sensor) data alone?

The Actigraph GT3X Accelerometer

Actigraph GT3X data

Time	Activity	Steps	Inclinometer
13:43:05	0	0	2
13:43:10	0	0	2
13:43:15	0	0	2
13:43:20	0	0	2
13:43:25	14	0	2
13:43:30	204	0	2
13:43:35	0	0	3
13:43:40	0	0	3
13:43:45	0	0	3
13:43:50	0	0	3
13:43:55	0	0	3
13:44:00	0	0	3

The future...maybe?

Collaboration between the NHS and industry to further develop programmable technology to alert patients and hospital staff of prolonged inactivity and the need for a position change. Also to encourage those capable of independent ambulation to meet individually tailored physical activity targets.

[1] Pedersen M.M, Bodilson A.C, Petersen J et al., Twenty-four-hour mobility during acute hospitalization in older medical patients. J Gerontology A Biol Sci Med Sci. 2013 March; 68(3): 331-337.
[2]. Hopkins, R.O, Miller III R.R, Rodriguez L et al. Physical therapy on the wards after early physical mobility in the intensive care unit. Physical Therapy 2012; 92 (12): 1518-1523
[3] Browning L, Denehy L, Scholes R.L. The quantity of early upright mobilisation performed following upper abdominal surgery is low: an observational study. Australian Journal of Physiotherapy 2007; 53: 47-52

B3 Information sheet

York St John University

Hull and East Yorkshire Hospitals NHS Trust

CRITERION VALIDITY AND RELIABILITY OF THE ACTIGRAPH(TM) GT3X ACCELEROMETER IN MEASUREMENT OF BODY POSITION, POSTURAL TRANSITION AND WALKING WITH AND WITHOUT ASSISTANCE: A FEASIBILITY STUDY.

PARTICIPANT INFORMATION SHEET

Introduction

I am undertaking a research project as part of a PhD, investigating the use of an accelerometer (movement sensor) to measure body position (lying, sitting or standing), postural transition (lying to sitting or sitting to standing and vice versa) and step count (walking). The PhD is registered with York St John University (YSJU) /University of Leeds and is being supervised by Professor Howard Hall, Professor of Sports and Exercise Psychology, Dr. Samantha Yoward, senior lecturer, school of physiotherapy, both within the Faculty of Health and Life Sciences, YSJU and Dr. Angela Green, Clinical Lead Research Therapist, Therapies, Hull and East Yorkshire Hospitals NHS Trust. The study has received ethical approval from the YSJU Research Ethics committee (REF: UC/25/2/14/JA) and the NHS Research Ethics Committee (REF: 14/NI/1023).

What is the purpose of this research?

The movements and activities described above are typically undertaken by patients recovering from critical illness in hospital. This study will investigate the possibility of using an accelerometer to record the functional activity that patients who have experienced critical illness undertake through the day during their initial stages of recovery. It is thought this might help in assessing the progress being made, assisting in understanding when the time is right to plan discharge from hospital and when patients feel confident to continue to progress rehabilitation at home.

Do you have to take part?

Your participation in this study is entirely voluntary. You would be free to withdraw at any stage, without any explanation of your reasons to the research team.

What will you need to do in the project?

You would need to wear comfortable clothing (e.g. 'T' shirt and jogging trousers or shorts) to allow placement of two small pain free accelerometers (movement sensors), attached by small elastic belts around your waist (near the hip) and around your ankle, each one weighing 27g. You would wear the accelerometers on the outside of your clothes. You will be asked to perform and repeat the movements described earlier. Some of the movements will be undertaken with help from two physiotherapists employed by Hull and East Yorkshire Hospitals NHS Trust (one of them Jayne Anderson, the chief investigator), like how a patient who is weak is assisted in hospital by the health care professionals involved in their care. You would receive full instruction on how to act like a patient who is weakened. Four ten-metre length walks will be performed using either a walking stick or a wheeled walking aid ('zimmer' frame). We would need you to agree to have your movements' recorded by a video camera, for which a medical technician may be present. These video recordings would be viewed only by the chief investigator, the physiotherapists helping during the movement sequences or the research supervision team named above. You would need to commit approximately one and a half hours of your time in a single session, attending **Ward 7, Castle Hill Hospital, Castle Road, Cottingham, East Riding of Yorkshire. HU16 5JQ.**

Version 5, Date: 20th September 2014

York St John University

Hull and East Yorkshire Hospitals NHS Trust

Why have you been invited to take part?
We are looking for healthy adult volunteers willing to be taught how to act like someone who is weak, making getting out of bed, standing up and walking a few steps harder to perform. Ideally we are looking to recruit adults above the age of 55, but anyone over the age of 18 is welcome to take part. If travelling by car you would need to pay a hospital car parking charge of £2.50, if you do not have a valid hospital parking permit.

You must not have any balance or coordination problems and be able to perform the above movements independently, accepting help from physiotherapists to perform some of them. It will be useful to know any medication you take to help us make sure it is safe for you to take part. We would also complete a short questionnaire to check that you can manage to undertake these activities, record your height, weight and date of birth and note whether you are right or left handed.

What are the potential risks to you in taking part?
There are no anticipated risks from participation in this study. You will receive full training on how to 'act out' the movements regularly undertaken by patients who are weakened by illness and how to use the walking aids. The lying to sitting and sitting to standing movements would be performed from a hospital bed within a side room on Ward 7, to try to help things feel as realistic as possible for you.

What happens to the information in the project?
Your identity in the research report and any publications will remain confidential and anonymous. Research data and any of your personal details will be stored on a password protected computer or in locked filing cabinets within an office at the Therapies Centre, Hull Royal Infirmary, which is always locked when no one is there. The video recordings will be downloaded directly onto a password protected computer. Only the immediate research team will have access to your personal details. Protection of all data will strictly conform to the Data Protection Act 1998 and relevant Trust policies.

What happens next?
If you are interested, you could talk this study over with friends, family or your GP. If you have any questions, please don't hesitate to contact the chief investigator, Jayne Anderson using the details below. You would need to complete, sign and return the accompanying consent form in the stamped addressed envelope supplied. A further week would follow upon receiving it; allowing you to change your mind if you wish. We would contact you then, to arrange your attendance at Ward 7, Castle Hill Hospital. If you have decided not to take part, thank you very much for taking the time to read this information sheet.

Best wishes

Jayne Anderson (Chief Investigator) Grad. Dip. Phys. MCSP.
Lecturer Practitioner Physiotherapist, Hull and East Yorkshire Hospitals NHS Trust
PhD Student, Faculty of Health and Life Sciences, York St John University
jayne.anderson@hey.nhs.uk
Direct Line: 01482 605293

Version 5, Date: 20th September 2014

B4 Consent form

York St John University

Hull and East Yorkshire Hospitals NHS Trust

RESEARCH CONSENT FORM

Name of Researcher(s)
Jayne Anderson (PhD student/ Chief Investigator), supervised by Professor Howard Hall, Dr. L. Samantha Yoward and Dr. Angela Green.
Title of study
CRITERION VALIDITY AND RELIABILITY OF THE ACTIGRAPH(TM) GT3X ACCELEROMETER IN MEASUREMENT OF BODY POSITION, POSTURAL TRANSITION AND WALKING WITH AND WITHOUT ASSISTANCE: A FEASIBILITY STUDY.

Please read and complete this form carefully. If you would like to participate, ring the appropriate responses and sign and date the declaration. If you would like any more information, don't hesitate to ask. Please return this form in the stamped addressed envelope supplied.

- I have had the study satisfactorily explained to me by the chief investigator and had the opportunity to read the information sheet (Version 5, dated 20th September 2014). **YES / NO**

- I understand that the research will involve:
  - Wearing comfortable clothing, permitting placement of two Actigraph™ GT3X accelerometers (movement sensors) by elastic belts, on the outside of my clothes, above the hip and ankle, each weighing 27g.
  - Repeating the movements of lying to sitting, sitting to standing and vice versa and walking four x ten-metre distances with either a walking stick or a wheeled walking frame ('zimmer' frame), while the accelerometers record the activity I undertake.
  - Receiving instruction on how to act like a patient who is weak, requiring physical assistance from others to undertake some of the movement sequences above.
  - The use of video to record the movements of lying to sitting, sitting to standing (and vice versa) and walking with a walking stick or wheeled zimmer walking frame. This will be undertaken with assistance from a medical technician and viewed only by the chief investigator, research team or the physiotherapists assisting in the movements. **YES / NO**

- I understand that I may withdraw from this study at any time without having to give any explanation. **YES / NO**
- I understand that all information about me will be treated in strict confidence and I will not be named in any written work. **YES / NO**

Version 5, Date: 20th September 2014

York St John University

Hull and East Yorkshire Hospitals NHS Trust

- I understand that you will be discussing the progress of your research with the immediate supervision team named above. **YES / NO**

- I give my consent to participate in this research study and have been given a copy of this consent form for my own information, containing the full contact details of the chief investigator, should I require them. **YES / NO**

Name of participant	Date	Signature

Name of person obtaining consent	Date	Signature

Preferred method of contact:

E-mail: .....

Telephone: .....

Postal address: .....

.....

.....

.....

Chief Investigator contact details
Jayne Anderson Grad. Dip. Phys. MCSP
Lecturer Practitioner Physiotherapist/PhD Student
Therapies Centre
Hull Royal Infirmary
Anlaby Road
Hull
HU3 2JZ
Tel: 01482 605293 (Direct Line)

jayne.anderson@hey.nhs.uk

Version 5, Date: 20th September 2014

B5 Demographic data collection form for feasibility study

Name of participant……..

PRINT NAME……..

Date of birth ……..

Gender FEMALE MALE

Height (cm)……

Weight (kg)……..

Body Mass Index ($kg.m^{-2}$)……

Are you right or left handed RIGHT LEFT

Unique reference number (to be assigned)……..

Date…….

B6 YSJU Ethics approval letter

York St John University

Jayne Anderson
PhD Student
Faculty of Health & Life Sciences

Lord Mayor's Walk
York YO31 7EX
T: 01904 624624
F: 01904 612512
www.yorksj.ac.uk

Dr Simon Rouse
Associate Professor
Chair of Research Ethics
Direct Line 876901
e-mail: s.rouse@yorksj.ac.uk

25 February 2014

Dear Jayne

RE: REPRODUCIBILITY OF AN ACTIVITY MONITOR TO MEASURE FUNCTIONAL MOVEMENT

REF: UC/25/2/14/JA

I can confirm that your IRAS application (title above) has been peer reviewed by the research ethics committee of the university and, after minor corrections, has been approved.

Yours sincerely

Cc Dr Sam Yoward, Professor Howard Hall

B7 Copy of NHS Ethics approval letter

HSC Business Services Organisation

Office for Research Ethics Committees Northern Ireland (ORECNI)

Customer Care & Performance Directorate
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn
Co. Antrim BT28 1TW
Tel:+44 (0) 28 9260 3107
www.orecni.hscni.net

HSC REC B

26 June 2014

Mrs Jayne L Anderson
Lecturer Practitioner Physiotherapist, Respiratory Care
Hull and East Yorkshire Hospitals NHS Trust
Therapies Centre
Hull Royal Infirmary, Anlaby Road
Hull, East Yorkshire
HU32JZ

Dear Mrs Anderson

Study title: **CRITERION VALIDITY AND RELIABILITY OF THE ACTIGRAPH(TM) GT3X ACCELEROMETER IN MEASUREMENT OF BODY POSITION, POSTURAL TRANSITION AND WALKING WITH AND WITHOUT ASSISTANCE: A FEASIBILITY STUDY.**
REC reference: **14/NI/1023**
IRAS project ID: **147297**

Thank you for your letter of 25 June 2014, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Miss Jan Daley, .

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [FLYER]	2	31 March 2014
Covering letter on headed paper [Covering letter]	1	03 June 2014
Covering letter on headed paper [Covering letter]		24 June 2014
Covering letter on headed paper		26 June 2014
GP/consultant information sheets or letters [GP letter]	1	19 June 2014
IRAS Checklist XML [Checklist_11062014]		11 June 2014
IRAS Checklist XML [Checklist_25062014]		25 June 2014
Letters of invitation to participant [Participant invitation letter]	1	31 March 2014
Other [CV Dr Angela Green]	1	15 May 2014
Other [Further supporting letter YSJU ethics]		28 May 2014
Other [CV Dr Samantha Yoward]	1	03 February 2014
Other [Good Clinical Practice e-learning certificate]	1	28 February 2014
Other [York St John ethics approval]	1	25 February 2014
Participant consent form	4	26 June 2014
Participant consent form [Research consent formClinical Skills Facility]	1	31 March 2014
Participant information sheet (PIS)	4	26 June 2014
REC Application Form [REC_Form_11062014]		11 June 2014
Referee's report or other scientific critique report [PhD transfer report]	1	25 September 2013
Research protocol or project proposal	4	26 June 2014
Response to Request for Further Information [Covering email]		26 June 2014
Summary CV for Chief Investigator (CI) [CV Jayne Anderson, NRES Format]	1	15 May 2014
Summary CV for supervisor (student research) [Professor Howard Hall CV February 2014]	1	05 May 2014
Validated questionnaire [Physical Activity Readiness Questionnaire]	1	31 March 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol

- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/NI/1023	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Jan Daley

pp Dr Anne Moorhead
Vice Chair, HSC REC B

Email: prs@hscni.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Mr James Illingworth*

B8 Copy of continued approval from the NHS Research Ethics Committee following notification of minor amendment - change of study location

HSC Business Services Organisation

Office for Research Ethics Committees Northern Ireland (ORECNI)

Customer Care & Performance Directorate
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn
Co. Antrim BT28 1TW
Tel:+44 (0) 28 9260 3107
www.orecni.hscni.net

HSC REC B

20 October 2014

Mrs Jayne L Anderson
Lecturer Practitioner Physiotherapist, Respiratory Care
Hull and East Yorkshire Hospitals NHS Trust
Therapies Centre
Hull Royal Infirmary, Anlaby Road
Hull, East Yorkshire
HU32JZ

Dear Mrs Anderson

Study title:	**CRITERION VALIDITY AND RELIABILITY OF THE ACTIGRAPH(TM) GT3X ACCELEROMETER IN MEASUREMENT OF BODY POSITION, POSTURAL TRANSITION AND WALKING WITH AND WITHOUT ASSISTANCE: A FEASIBILITY STUDY.**
REC reference:	**14/NI/1023**
Amendment number:	**Minor Amendment #1**
Amendment date:	**02 October 2014**
IRAS project ID:	**147297**

Thank you for your letter of 02 October 2014, notifying the Committee of the above amendment.

The amendment has been considered by the Chair.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received
The documents received were as follows:

Document	*Version*	*Date*
Covering letter on headed paper		27 September 2014
Notice of Minor Amendment		02 October 2014

Other [Flyer]	Version 3	20 September 2014
Participant consent form	Version 5	20 September 2014
Participant information sheet (PIS)	Version 5	20 September 2014
Research protocol or project proposal [Methodological Protocol]	Version 5	20 September 2014

Statement of compliance
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

14/NI/1023: Please quote this number on all correspondence

Yours sincerely

Jane Keenan

Miss Jane Keenan
REC Manager

E-mail: recb@hscni.net

Copy to: *Mr James Illingworth*

B9 Physical Activity Readiness Questionnaire (PARQ)

Physical Activity Readiness Questionnaire	YES	NO
Has your doctor ever said you have a heart condition and that you should only do physical activity recommended by a doctor?		
Do you feel pain in your chest when you do physical activity?		
In the past month, have you had chest pain when you were not doing any physical activity?		
Do you lose your balance because of dizziness or do you ever lose consciousness?		
Do you have a bone or joint problem (for example back, knee or hip) that could be made worse by a change in your physical activity?		
Is your doctor currently prescribing medication for your blood pressure or heart condition?		
Do you know of any other reason why you should not do any physical activity?		

If any of the answers to the above is yes, please comment

……

……

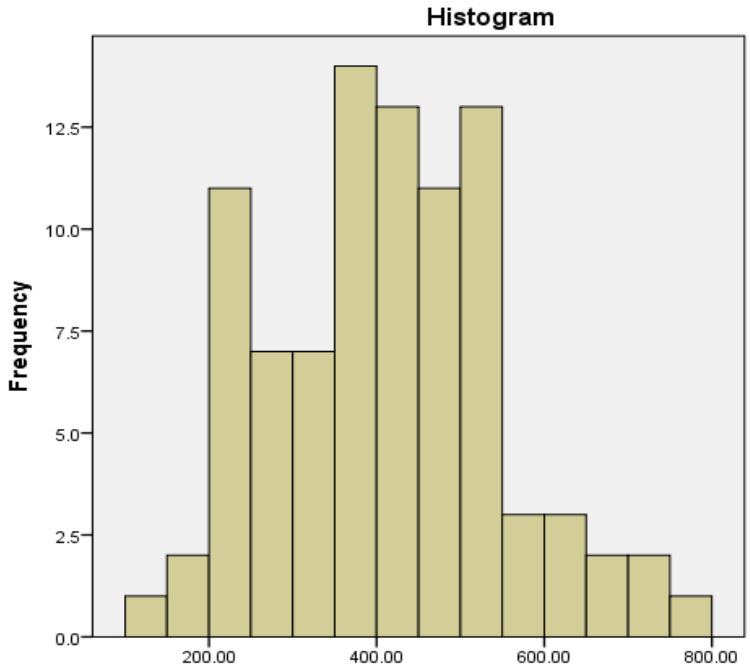
……

……

Signed ……

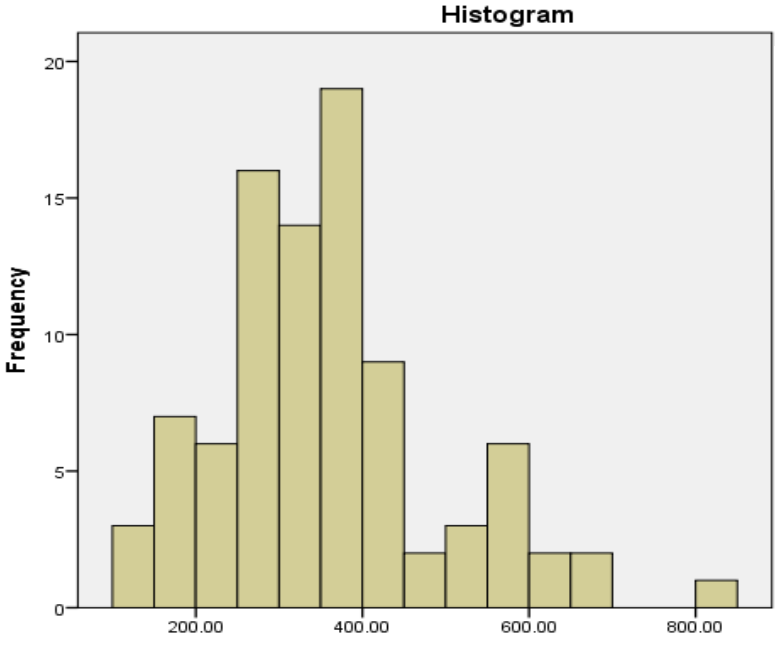
B10 Frequency of vector magnitude intensity readings for all postural transfers (waist accelerometer)

Assisted lying to sitting



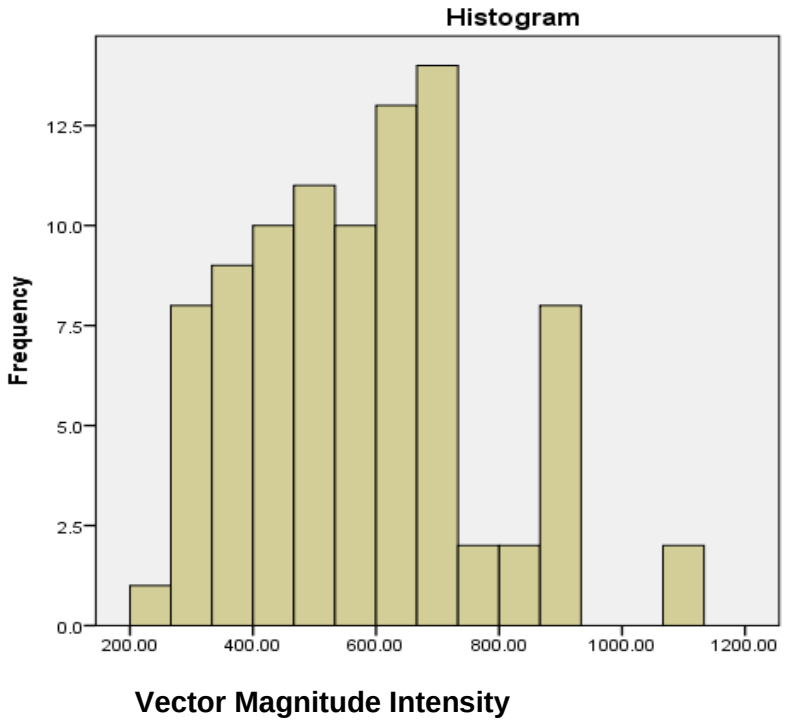
Mean = 409.75
SD = 135.99
n = 90

Assisted sitting to lying



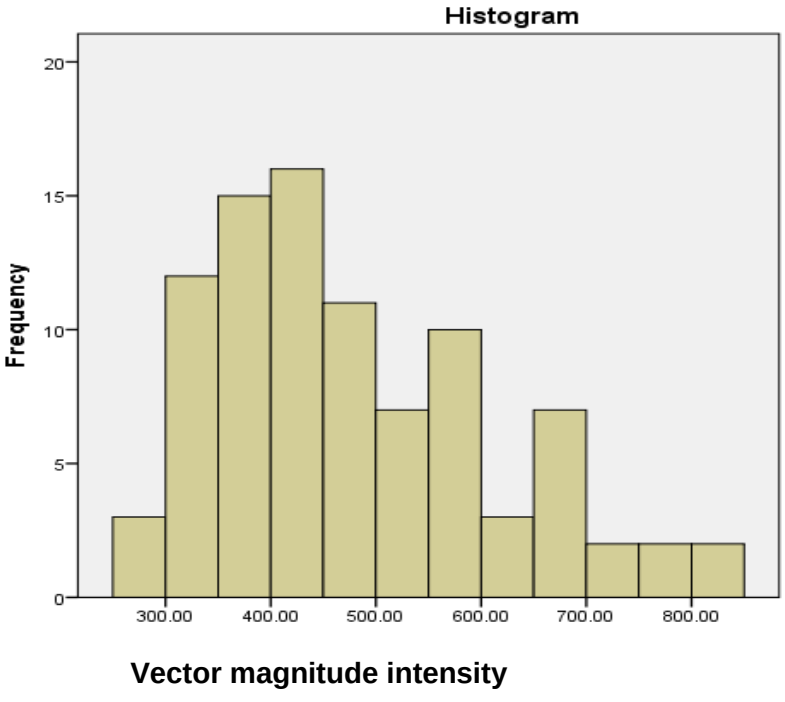
Mean = 356.29
SD = 134.84
n = 90

Unassisted lying to sitting



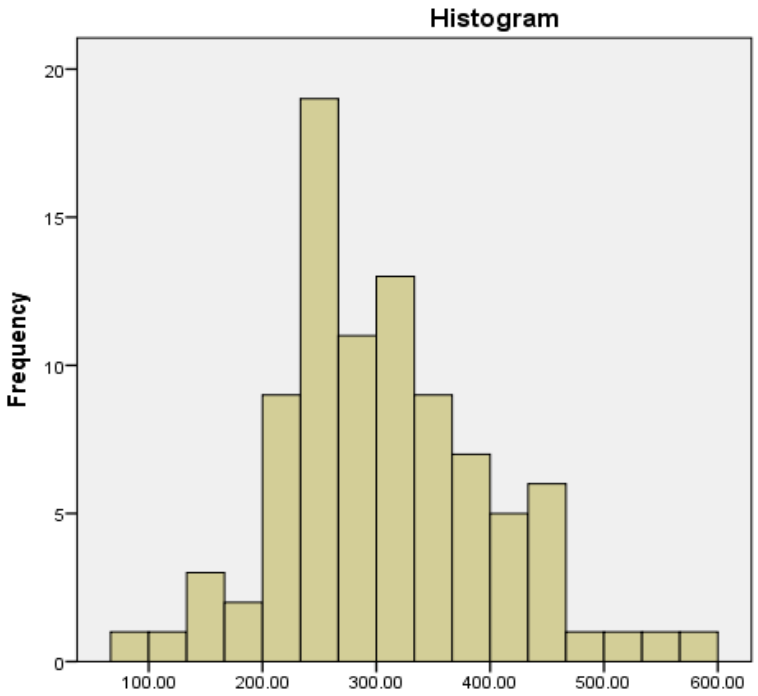
Mean = 578.07
SD = 187.42
n = 90

Unassisted sitting to lying



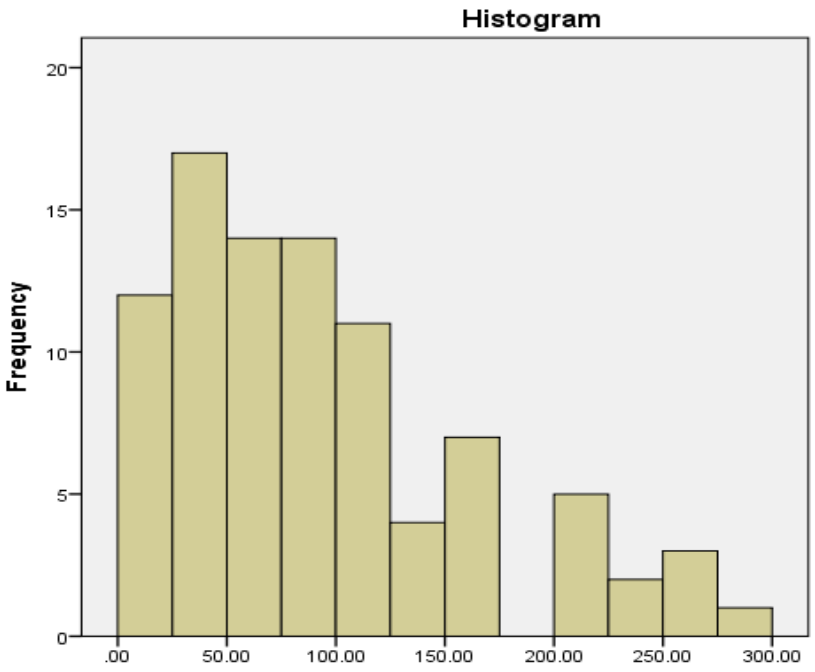
Mean = 476.14
SD = 132.89
n = 90

Assisted sitting to standing



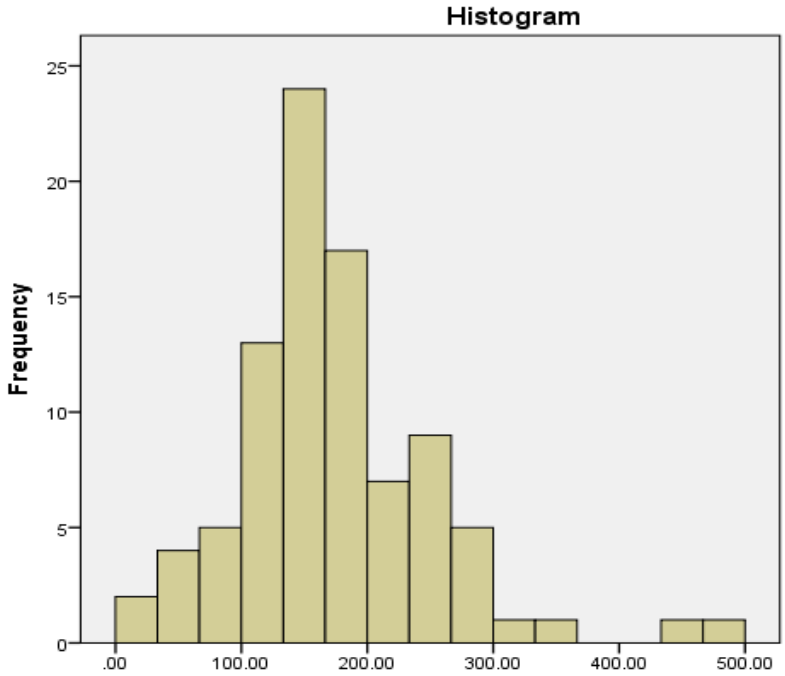
Mean = 309.18
SD = 94.37
n = *90*

Assisted standing to sitting



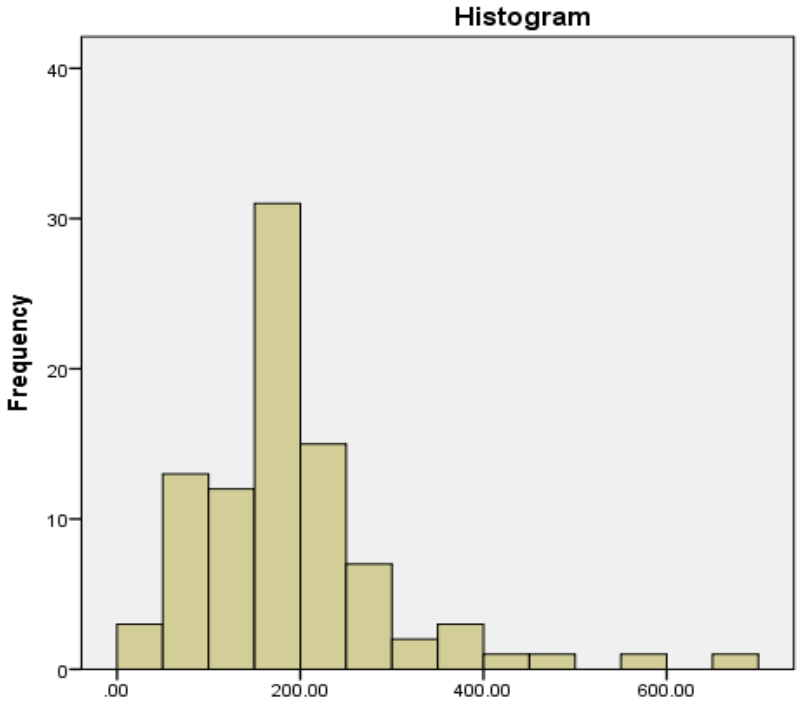
Mean = 93.07
SD = 70.00
n = 90

Unassisted sitting to standing



Mean 172.35
SD = 78.86
n = 90

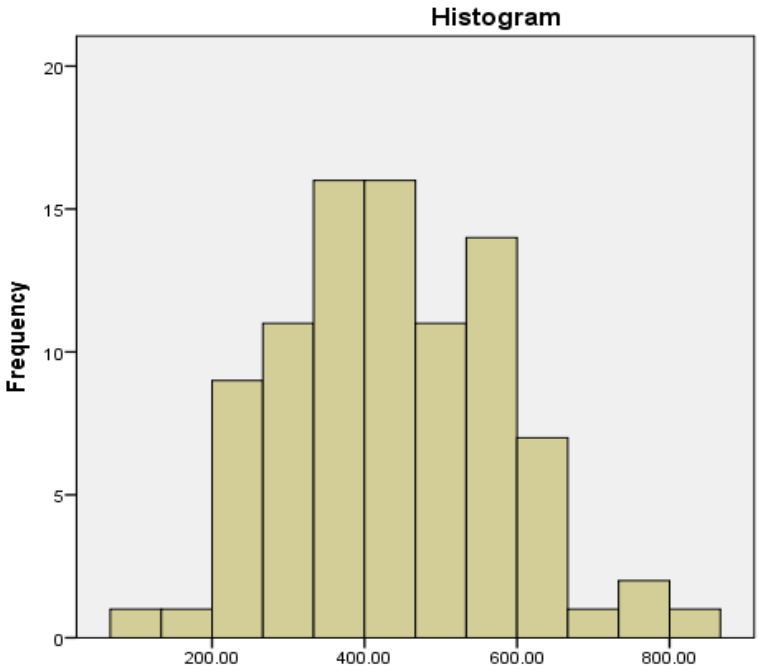
Unassisted standing to sitting



Mean = 189.57
SD = 106.85
n = 90

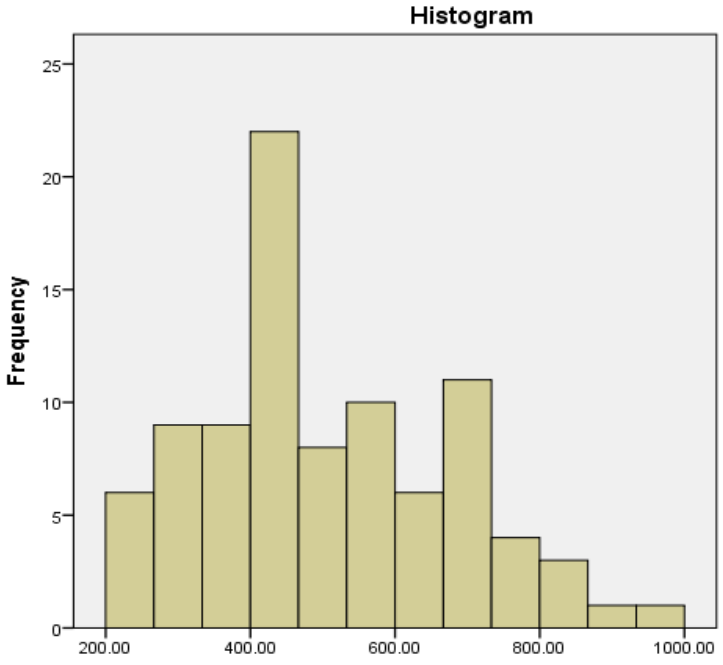
B11 Frequency of vector magnitude intensity readings for all postural transfers (ankle accelerometer)

Assisted lying to sitting



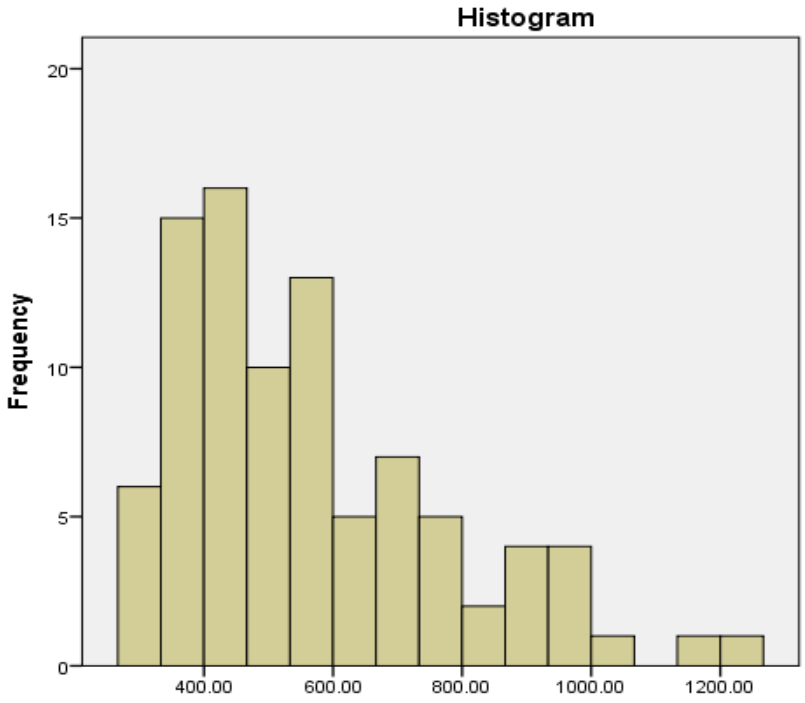
Mean = 439.37
SD = 142.14
n = 90

Assisted sitting to lying



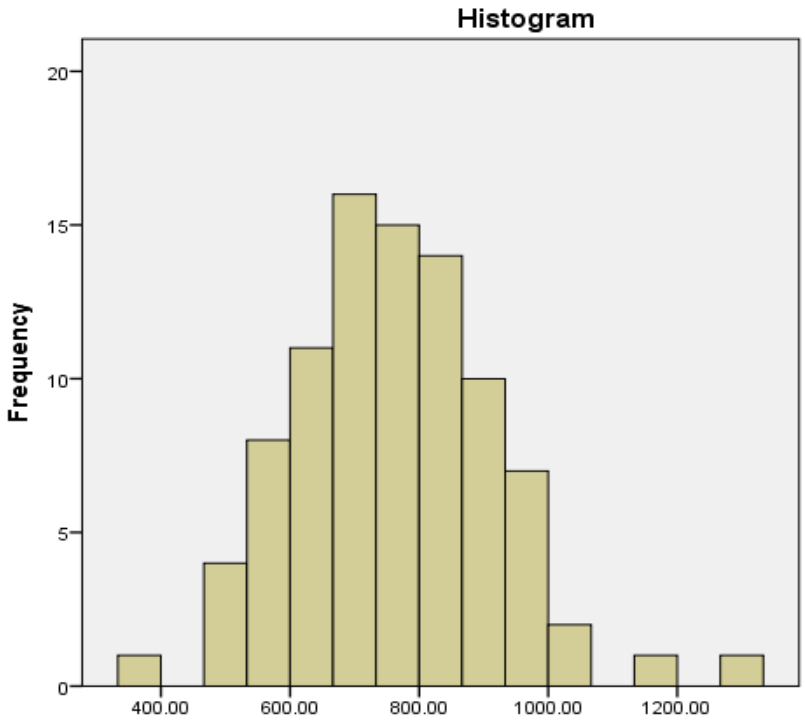
Mean = 503.20
SD = 170.24
n = 90

Unassisted lying to sitting



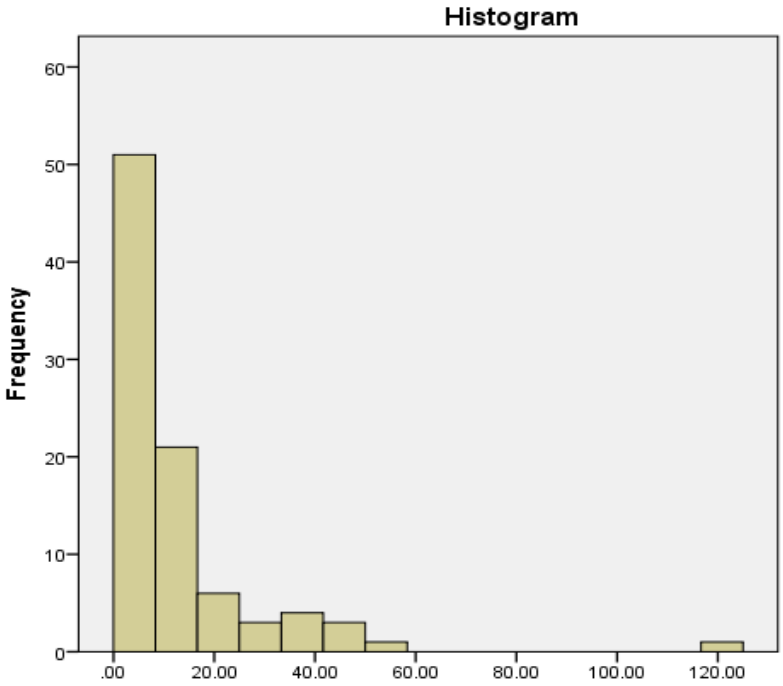
Mean = 566.62
SD = 210.87
n = 90

Unassisted sitting to lying



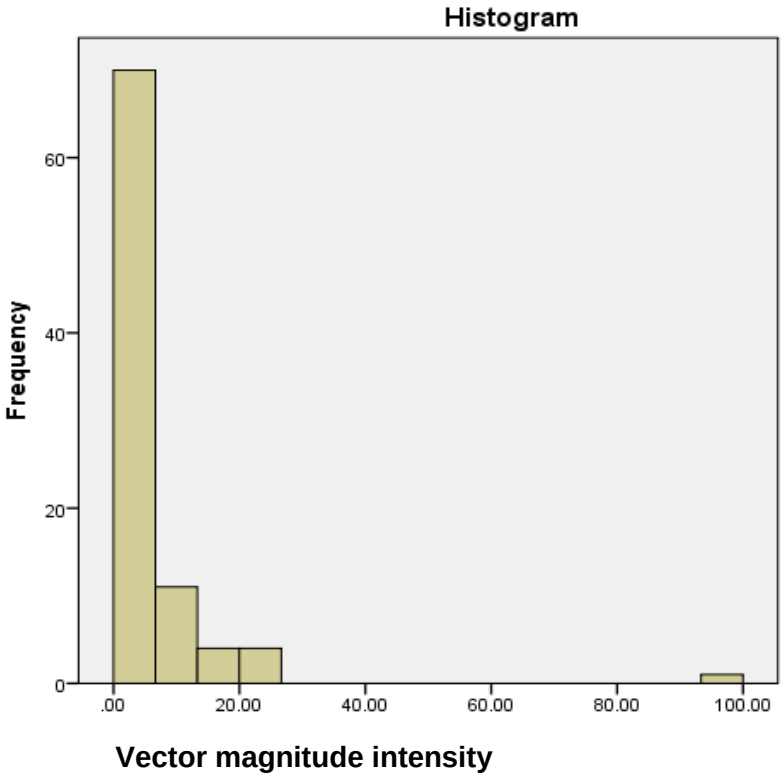
Mean = 762.41
SD = 151.41
n = 90

Assisted sitting to standing



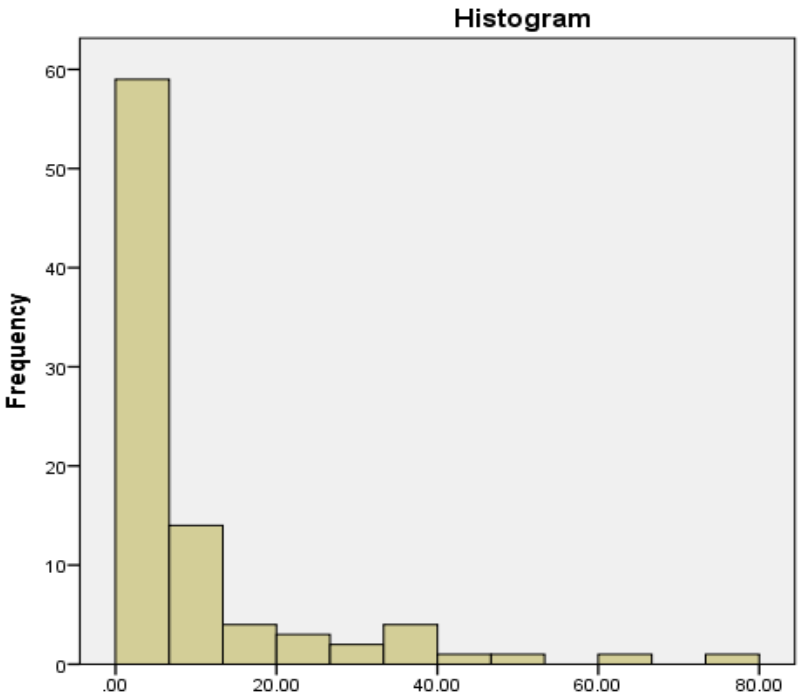
Mean = 12.02
SD = 17.02
n = 90

Assisted standing to sitting



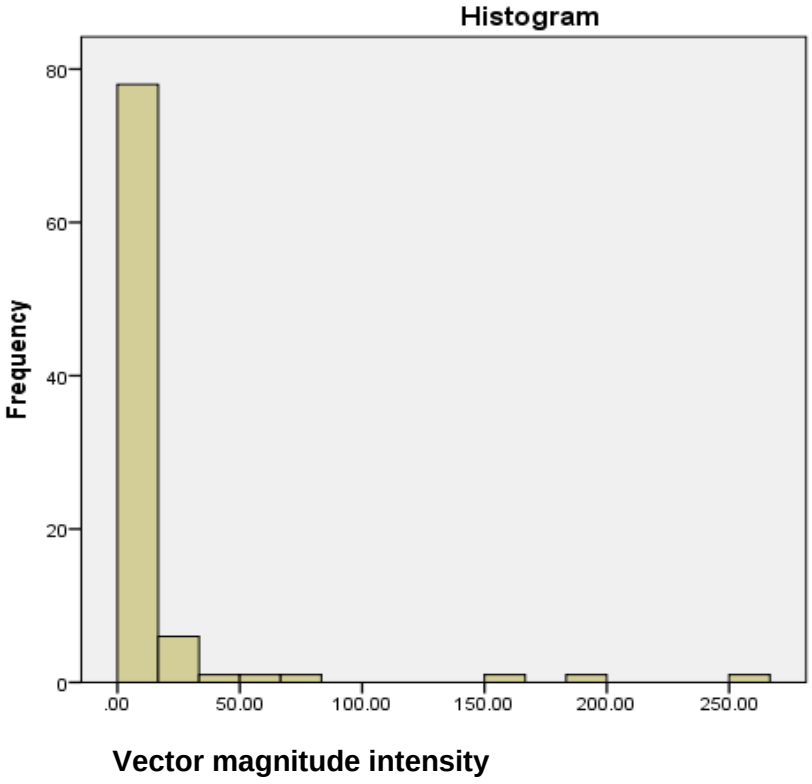
Mean = 4.78
SD = 11.29
n = 90

Unassisted sitting to standing



Mean = 8.66
SD = 14.61
n = 90

Unassisted standing to sitting



Mean 12.09
SD = 38.30
n = 90

B12 Results of κ analysis for waist accelerometer (feasibility study)

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
WaistAccel * Observation	50193	100.0%	0	0.0%	50193	100.0%

WaistAccel * Observation Crosstabulation

			Observation			
			Not wearing	standing	Lying	Sitting
WaistAccel	Not wearing	Count	2	0	1625	250
		Expected Count	.1	290.6	778.4	808.0
	Standing	Count	0	3042	1464	10913
		Expected Count	.6	2386.9	6394.2	6637.2
	Lying	Count	0	2	10593	587
		Expected Count	.4	1731.0	4637.2	4813.4
	Sitting	Count	0	4726	7133	9856
		Expected Count	.9	3361.5	9005.2	9347.4
Total		Count	2	7770	20815	21606
		Expected Count	2.0	7770.0	20815.0	21606.0

Symmetric Measures

		Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Measure of Agreement	Kappa	.211	.003	72.740	.000
N of Valid Cases		50193			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

B13 Results of κ analysis for ankle accelerometer (feasibility study)

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
AnkleAccel * Observation	50193	100.0%	0	0.0%	50193	100.0%

AnkleAccel * Observation Crosstabulation

			Observation			
			Not wearing	standing	Lying	Sitting
AnkleAccel	Not wearing	Count	2	0	2257	144
		Expected Count	.1	372.0	996.5	1034.4
	Standing	Count	0	7654	1676	14895
		Expected Count	1.0	3750.1	10046.1	10427.9
	Lying	Count	0	2	16143	1083
		Expected Count	.7	2666.9	7144.4	7415.9
	Sitting	Count	0	114	739	5484
		Expected Count	.3	981.0	2627.9	2727.8
Total		Count	2	7770	20815	21606
		Expected Count	2.0	7770.0	20815.0	21606.0

Symmetric Measures

		Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Measure of Agreement	Kappa	.428	.002	175.140	.000
N of Valid Cases		50193			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Appendix C Validity study

C1 Information sheet

York St John University

Hull and East Yorkshire Hospitals NHS Trust

Criterion validity of the Actigraph GT3X accelerometer in determination of body position and walking in hospital ward patients recovering from critical illness

PARTICIPANT INFORMATION SHEET

Introduction

I am undertaking a research project as part of a PhD to investigate whether an activity monitor (called an accelerometer) can correctly identify body positions (lying, sitting or standing) and walking undertaken by patients recovering on a hospital ward following a stay in the Intensive Care Unit (ICU). The PhD is registered with the University of Leeds and is being conducted at York St John University (YSJU) under the supervision of Professor Howard Hall, Dr. Samantha Yoward, from the Faculty of Health and Life Sciences and Dr. Angela Green, Lead Clinical Research Therapist, Hull and East Yorkshire Hospitals NHS Trust. The study has undergone ethical scrutiny and has received ethical approval from the NHS Research Ethics Committee (IRAS ID 16/EM/0210 198965).

What is the purpose of this research?

Typical activities undertaken by patients recovering on a hospital ward following discharge from the ICU include lying on the back in bed, turning onto one side, getting out of bed, standing up, sitting in a chair and walking (to the bathroom for example). This study will investigate if a single activity monitor, called an accelerometer, or combination of two identical accelerometers can correctly identify these activities and the time they occurred. By doing this research in hospital with patients who have spent some time in ICU we hope to identify those who need more help to increase their confidence and strength in order to become more active.

Do you have to take part?

You are under no obligation to participate. Your participation in this study is entirely voluntary. You would be free to withdraw your consent to participate at any time, without explaining your reasons and without any adverse effect on your medical care.

What will you need to do in the project?

If you agree to participate, you will be asked to wear two accelerometers on the same leg (preferably your non-dominant leg). One is worn around the mid-thigh and the other around the ankle, attached by an elastic belt with Velcro fastening. Each accelerometer weighs 27g and is about the size of a digital watch. They can be worn over the white stockings you may be wearing at the moment. You will be asked to undertake a series of movements including lying in the bed, turning onto your side, getting out of bed, getting back into bed, moving from your bed to sit in a chair, standing up and walk a distance no further than what you have achieved so far in your recovery. You can perform these activities, which will be written on a sheet of paper to help you, in any order you wish. They do not have to be taken immediately after each other, giving you a chance to rest between each movement if you wish. The chief investigator (Jayne Anderson), who is a qualified physiotherapist, will stay with you on the ward while you perform the movement routine, recording the time you undertook a particular movement, what the movement was and how long you stayed in a particular position before moving on to another movement. It is not anticipated that involvement in the study will last any more than two or three hours. You will not miss any refreshments and can still undertake your usual routines e.g. reading a paper. If there is a movement that you still need assistance with, physiotherapy or nursing staff will give you the help you need.

York St John University

Hull and East Yorkshire Hospitals NHS Trust

Why have you been invited to take part?
We aim to invite patients who have spent some time on ICU during their stay, in particular those like you, who spent at least a couple of days on a ventilator whilst they were there. We are investigating a way of monitoring how active you are as you continue to recover on the ward.

In order to participate in the study, you must not have any balance, coordination or longstanding circulatory problems in your legs and you must be able to perform the movements within the routine independently or with minimal assistance from only one person. You will also need to be able to sign your own name on a consent form. It does not matter if you are still using a zimmer frame, stick or hand held assistance to walk. We would need to collect information on your height, current weight and date of birth. If you decide you would like to take part, we will ask your permission to notify your GP and any other doctor who might be treating you.

What are the potential risks to you in taking part?
There are no anticipated risks from participating in this study. The chief investigator will spend a maximum of three hours with you recording your activity, allowing you time to rest alone in between the movements, so you do not feel uncomfortable or pressurised by her presence. You will continue to have your routine observations (e.g. pulse, temperature, blood pressure). Any investigations that might have been organised (e.g. an x ray) since arranging to spend time together will not be cancelled and if possible the monitoring period can be rescheduled if you would still like to take part. Your privacy and dignity will always be respected and you will not be observed when using the bathroom or during washing and dressing.

In the event of any queries, concerns or complaints in relation to any aspect of this study please contact the patient experiences service (PALS). PALS provides confidential, on the spot advice and support to patients, carers, relatives and users of health services, helping them resolve any concerns they have.

Patient Experience Service
1st Floor
Alderson House
Hull Royal Infirmary
Anlaby Road
Hull
HU3 2JZ

Telephone: 01482 875875 Ext. 3065 (Castle Hill Hospital)
Ext. 5508 (Hull Royal Infirmary)

E mail: PALS: pals@hey.nhs.uk

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Hull and East Yorkshire Hospitals NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

C2 Consent form

York St John University

Hull and East Yorkshire Hospitals NHS Trust

RESEARCH CONSENT FORM

Name of Researcher(s)
Jayne Anderson (PhD student/ Chief Investigator), supervised by Professor Howard Hall, Dr. L. Samantha Yoward and Dr. Angela Green.
Title of study
Criterion validity of the Actigraph GT3X accelerometer in determination of body position and walking in hospital ward patients recovering from critical illness

Please read and complete this form carefully. If you would like to participate, please initial the box after each response and sign and date the declaration at the end of the consent form.

Patient ID……. Initials …….. Date of Birth ……..

Please initial each response

- I have had the study satisfactorily explained to me by the chief investigator and had the opportunity to read the information sheet dated……. (Version……) ☐

- I understand that the research will involve:
  - Wearing two Actigraph GT3X accelerometers (activity monitors) secured with elastic belts, one on the mid - thigh and the other on the ankle of the same leg, each weighing 27g.
  - Completing a set of movements and body positions that I would usually perform during the day including lying on my bed, turning on my side, getting out of bed and getting back into bed, sitting in a chair, moving from my bed to my chair and taking a walk. I am free to perform these movements and body positions in any order I choose. I will be supervised by the chief investigator (Jayne Anderson, also a qualified physiotherapist) whilst I perform these movements, who will note each movement undertaken and the time when I start and finish them.
  - Providing feedback of my view of how comfortable the accelerometers (activity monitors) were to wear. ☐
- I understand that I am free to withdraw from this study without having to give any explanation. ☐
- I understand that all information about me will be treated in strict confidence and I will not be identified in any presentations or written work, which will include a PhD thesis or journal publications. ☐

York St John University

Hull and East Yorkshire Hospitals NHS Trust

- I understand that Jayne Anderson, the chief investigator will discuss the progress of the research with her supervision team named above. ☐
- I understand that anonymous data collected during the study may be discussed with individuals from the PhD supervision team, regulatory authorities or the NHS Trust where it is relevant to my taking part in this research. I give my permission for these individuals to have access to these data. ☐
- I give consent for my GP, or any other doctor treating me to be notified of my participation in the study. ☐
- I give my consent to participate in this research study and have been given a copy of this consent form for my own information, containing the full contact details of the chief investigator and main supervisor. ☐

Name of participant	Date	Signature

Name of person obtaining consent	Date	Signature

Preferred method of contact if you would like to read a summary of the study results:

E-mail: .....

Telephone: .....

Postal address: .....

.....

.....

Chief Investigator Contact Details
Jayne Anderson Grad. Dip. Phys. MCSP
Lecturer Practitioner Physiotherapist/PhD Student
Therapies Centre
Hull Royal Infirmary
Anlaby Road
Hull
HU3 2JZ
Tel: 01482 605293 (Direct)
jayne.anderson@hey.nhs.uk

Main Supervisor Contact Details
Professor Howard Hall
Chair in Sports Related Studies
De Grey Building,
York St John University
Lord Mayor's Walk
York
YO317EX
Tel: 01904 876302 (Direct)
h.hall@yorksj.ac.uk

Version 1, Date: 1st April 2016

C3 Copy of NHS Ethics approval letter (validity study)

NHS
Health Research Authority
East Midlands - Nottingham 1 Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

11 May 2016

James Illingworth
Research and Development Office
Office 13
2nd Floor
Daisy Building
Castle Hill Hospital
Castle Road
Cottingham
East Yorkshire
HU16 5JQ

Dear James Illingworth

Study title:	**Criterion Validity of the Actigraph GT3X Accelerometer in Determination of Body Position and Walking in Hospital Ward Patients Recovering from Critical Illness**
REC reference:	**16/EM/0210**
IRAS project ID:	**198965**

The Proportionate Review Sub-committee of the East Midlands - Nottingham 1 Research Ethics Committee reviewed the above application on 10 May 2016.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mr George R. Martin, NRESCommittee.EastMidlands-Nottingham1@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

Other general comments

The PR Sub-Committee agreed the application was of a very high quality and commended the engagement of patient user groups in the design of the study. The Members also acknowledged that the applicant clearly spent a long time putting the application together and thoroughly considered the care given to participants in the process.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper [Criterion Validity of the Actigraph GT3X acclerometer in determination of body position and walking in hospital ward patients recovering from critical illness. Covering letter]		22 April 2016
GP/consultant information sheets or letters [GP letter]	1	01 April 2016
GP/consultant information sheets or letters [Consultant Letter]	1	01 April 2016
Interview schedules or topic guides for participants [Movements to be performed (Participant movement guide)]	1	01 April 2016
IRAS Application Form [IRAS_Form_27042016]		27 April 2016
IRAS Application Form XML file [IRAS_Form_27042016]		27 April 2016
IRAS Checklist XML [Checklist_27042016]		27 April 2016
Letter from statistician [Communication with statistician]		03 February 2016
Letters of invitation to participant [Participant invitation letter]	1	01 April 2016
Other [GCP training certificate]		17 February 2016
Other [Tissue Viability Checklist]	1	01 April 2016
Other [Evidence of e mail communications from the Charity ICU steps]		03 February 2016
Other [Guidance for Clinical Staff]	1	01 April 2016
Other [Participant Data Collection Form 1]	1	01 April 2016
Other [Data Collection Sheet: Movement Protocol]	1	01 April 2016
Other [Likert Scale for patients to rate accelerometer comfort]	1	01 April 2016
Other [HRA Statement of Activities Document]	Template Version 4	30 March 2016

Other [HRA Schedule of Events]	Template 2	19 April 2016
Participant consent form [Criterion Validity of the Actigraph GT3X acclerometer in determination of body position and walking in hospital ward patients recovering from critical illness]	1	01 April 2016
Participant information sheet (PIS) [Criterion Validity of the Actigraph GT3X acclerometer in determination of body position and walking in hospital ward patients recovering from critical illness]	1	01 April 2016
Research protocol or project proposal [Criterion Validity of the Actigraph GT3X acclerometer in determination of body position and walking in hospital ward patients recovering from critical illness]	1	01 April 2016
Summary CV for Chief Investigator (CI) [CURRICULUM VITAE: JAYNE ANDERSON GRAD.DIP.PHYS. MCSP]	2	12 April 2016
Summary CV for student [CURRICULUM VITAE: JAYNE ANDERSON GRAD.DIP.PHYS. MCSP]	2	12 April 2016
Summary CV for supervisor (student research) [Curriculum Vitae Howard Kingsley Hall]		27 February 2014
Summary CV for supervisor (student research) [Curriculum vitae: Louise Samantha Yoward]	2	12 April 2016
Summary CV for supervisor (student research) [Curriculum Vitae Dr Angela Green]	2	12 April 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow Chart Detailing Study Format]	1	01 April 2016

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

16/EM/0210	**Please quote this number on all correspondence**

Yours sincerely

P.P. Gmcb

Dr Carl Edwards
Chair

Email: NRESCommittee.EastMidlands-Nottingham1@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers"

Copy to: *Sponsor - Mr James Illingworth, Hull and East Yorkshire Hospitals Trust*

C4 YSJU Ethics approval letter (validity study)

York St John University

Faculty of Health and Life Sciences
Lord Mayor's Walk YORK YO31 7EX
Tel: (01904) 876734
Fax: (01904) 876500

Nathalie Noret
Chair of Faculty of Health & Life Sciences Research Ethics Committee
Direct Line 876311
E-mail: n.noret@yorksj.ac.uk

15 May 2016

Dear Jayne

RE: Criterion validity of the Actigraph GT3X accelerometer in determination of body position and walking in hospital ward patients recovering from critical illness

REF: 129091178_Anderson_15052016

The research ethics committee has approved, without reservation, the above research ethics submission of 15 May 2016.

Yours sincerely

N. Noret

C5 Standardised assessment form developed for assessing skin integrity whilst accelerometers were worn

TISSUE VIABILITY CHECKLIST **PARTICIPANT ID ……**

TIME ACCELEROMETERS APPLIED	TIME ACCELEROMETERS REMOVED

TIME OF ASSESSMENT	

ASSESSMENT	COMMENTS (ANKLE)	COMMENTS (THIGH)
Assess skin for pallor, significant indentation, non blanching redness or any skin breakdown around accelerometer site		
Any evidence of paraesthesia (e.g. pins and needles) in the toes		
Action		

Additional comments

……

……

……

……

C6 Movements required to be undertaken as part of the semi-structured movement protocol

York St John University

Hull and East Yorkshire Hospitals NHS Trust

MOVEMENTS TO BE PERFORMED

We would like you to perform <u>all of these</u> movements during the period when you are wearing the accelerometers. You can choose to do them in any order you please.

MOVEMENT	PERFORMED (please tick)
Lying on your back on the bed (the bed head can be raised, you do not have to lie flat)	
Turning onto and lying on your left side	
Turning onto and lying on your right side	
Moving from lying on your bed to sitting over the side of it (from your back or your side)	
Standing up from sitting on your bed	
Moving from the bed into your chair	
Sitting in your chair	
Going for a walk	
Moving from sitting on your bed to lying down (on your side or your back)	

Version 1, Date: 1st April 2016

C7 Individual κ values for agreement between inclinometer and direct observation of lying, sitting and standing postures

Participant ID	Thigh GT3X	Ankle GT3X	Ankle GT3X recoding '0' to '2'	Ankle + algorithm	Thigh collapsing lying and sitting
001	0.21	0.78	0.80	0.94	0.98
002	0.16	0.86	0.86	0.99	0.96
003	0.17	0.91	0.91	0.99	0.99
004	0.49	0.61	0.61	0.99	0.99
005	0.14	0.59	0.59	0.87	0.91
006	0.41	0.86	0.86	0.94	0.95
007	-.09	0.50	0.50	0.73	0.98
008	0.03*	0.54	0.54	0.87	0.97
009	-0.01**	0.55	0.69	0.92	0.76
010	0.64	0.83	0.89	0.98	0.97
011	0.38	0.86	0.86	0.90	0.84
012	0.20	0.88	0.88	0.91	0.85
013	0.23	0.53	0.53	0.88	0.83
014	0.21	0.38	0.47	0.96	0.88
015	0.17	0.44	0.59	0.94	0.97
016	0.15	0.49	0.66	0.95	0.82
017	0.84	0.42	0.57	0.98	0.98
018	0.11	0.81	0.81	0.94	0.90
019	0.30	0.64	0.65	0.94	0.77
020	0.30	0.74	0.94	0.98	0.95

* $p = 0.045$, ** $p = 0.092$, all other κ values $p < 0.001$

C8 Results of Shapiro-Wilk analyses for percentage agreement between inclinometer and observation for lying, sitting and standing postures (five different measurement methods)

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
ThighLying	.276	20	.000	.816	20	.002
Thighsitting	.289	20	.000	.677	20	.000
ThighStanding	.210	20	.021	.890	20	.027
Anklelying	.224	20	.010	.818	20	.002
AnkleSitting	.150	20	.200*	.898	20	.037
AnkleStanding	.336	20	.000	.614	20	.000
Ankle0is2lying	.289	20	.000	.586	20	.000
Ankle0is2Sitting	.150	20	.200*	.898	20	.037
Ankle0is2Standing	.336	20	.000	.614	20	.000
Algorithmlying	.289	20	.000	.586	20	.000
AlgorithmSitting	.294	20	.000	.848	20	.005
AlgorithmStanding	.147	20	.200*	.881	20	.019
Thigh23sittinglying	.244	20	.003	.816	20	.002
Thigh23Standing	.210	20	.021	.890	20	.027

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Appendix D Record of achievements during the course of the PhD

10th-11th October 2014: Physiotherapy UK Conference and trade exhibition. International Convention Centre, Birmingham

Successful abstract submission for a poster presentation titled 'Quantification of critical illness survivors' physical activity patterns using accelerometry: from narrative review to feasibility study'.

10th November 2014: 9th Annual Research Methodologies Conference, York St John University

Successful abstract submission for platform presentation titled 'Quantifying the functional activity of patients recovering from critical illness'

16th November 2015: 10th Annual Research Methodologies Conference, York St John University

Successful abstract submission for platform presentation titled 'Quantifying activity undertaken by patients recovering from critical illness: results from a feasibility study'

11th-12th November 2016: 4th European Congress of the European Region of the World Confederation for Physical Therapy (ER-WCPT), ACC Liverpool

Successful abstract for poster presentation titled 'Criterion validity of an ankle or waist mounted Actigraph GT3X accelerometer in measurement of body position and step count'

This work was shortlisted for the ER-WCPT Congress 2016 outstanding poster award within the Practice in a digital age – Quantitative research theme.

1st August 2017

Acceptance of an article created from the systematic review chapter for publication in the Journal Clinical Rehabilitation titled 'Validity and reliability of accelerometry in identification of lying, sitting, standing or purposeful activity in adult hospital inpatients recovering from acute or critical illness: a systematic review.'

ANDERSON, J. L., GREEN, A. J., YOWARD, L. S. & HALL, H. K. 2017. Validity and reliability of accelerometry in identification of lying, sitting, standing or purposeful activity in adult hospital inpatients recovering from acute or critical illness: a systematic review. *Clin Rehabil***,** Aug 1:269215517724850. doi 10.1177/0269215517724850 [Epub ahead of print]