

METHODOLOGICAL PROTOCOL

Criterion validity of the Actigraph GT3X accelerometer in determination of body position and walking in hospital ward patients recovering from critical illness

Protocol details

Version 1 01/04/2016

Name, role and contact details of Chief Investigator:

Mrs Jayne Anderson

Lecturer Practitioner Physiotherapist /

Therapies Centre

Hull Royal Infirmary

Anlaby Road

Hull

HU3 5JZ

Tel: 01482 605293

PhD Student

Faculty of Health and Life Sciences

De Grey Building

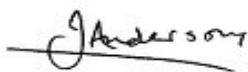
York St John University

Lord Mayor's Walk,

York

YO31 7EX

Signature



Date 12th April 2016

Study Site

Hull and East Yorkshire Hospitals NHS Trust

Castle Hill Hospital

Castle Road

Cottingham

East Yorkshire

HU16 5JQ

Hull Royal Infirmary

Anlaby Road

Hull

HU3 5JZ

Tel: 01482 605293

Study Sponsor

Mr James Illingworth

Research and Development Manager

Hull and East Yorkshire Hospitals NHS Trust

2nd Floor Daisy Building

Castle Hill Hospital

Cottingham

East Yorkshire

East Yorkshire

HU16 5JQ

Tel: 01482 461903

List of abbreviations and definitions

BMI	Body Mass Index
CI	Chief Investigator
HLS	Faculty of Health and Life Sciences
HEYHT	Hull and East Yorkshire Hospitals NHS Trust
ICU	Intensive Care Unit
ICUAW	Intensive Care Unit Acquired Weakness
IG	Information Governance
IRAS	Integrated Research Application System
LOA	Limits of agreement
UoL	University of Leeds
UK	United Kingdom
YSJU	York St John University

Background information and rationale

Physical recovery following critical illness is often complicated by profound muscle weakness, referred to as intensive care unit acquired weakness (ICUAW). ICUAW negatively impacts on the time taken to wean patients from ventilator support, precipitating significant mobility and functional impairment (Latronico et al., 2012, Latronico and Bolton, 2011, Deem et al., 2003). Functional impairment; impacting negatively on quality of life, may continue for years following discharge from hospital (Herridge et al., 2011, Cheung et al., 2006, Herridge et al., 2003).

Research has investigated how the negative effects of functional impairment may be attenuated. Early mobility interventions, commencing in the intensive care unit (ICU), including sitting over the edge of the bed, sitting to standing, bed to chair transfers and walking variable distances may reduce the severity of ICUAW (Morris et al., 2011, Schweickert et al., 2009, Needham, 2008). These interventions are safe, well tolerated and effective, even when patients are on ventilator support (Adler and Malone, 2012). This evidence supports the instigation of early activity and the development of more formal mobility protocols for those recovering from critical illness. These

methods are only effective if all members of the health care team promote activity within ICU and upon a patient's return to the ward. What is desirable therefore is the multi-disciplinary adoption of a rehabilitation 'culture' inherent within this patient population.

Research evidence suggests that a culture which encourages early activity within the ICU is not universally adopted (Berney et al., 2015, Nydahl et al., 2014, Berney et al., 2013). Absence of a rehabilitation culture within the hospital ward environment is provided from a number of observational studies. A decrease in the distances mobilised compared to those undertaken within ICU in the first 48 hours on the ward has been reported (Hopkins et al., 2012). Time delays have been described in patients undertaking the same mobility interventions that were performed within the ICU, for example getting out of bed to sit in a chair (Pandullo et al., 2015). Finally, a study reported that patients were still spending 90% of the day inactive in lying or sitting positions in the final two days prior to discharge from hospital (Borges et al., 2015). These findings persist despite evidence reporting early mobilisation attenuates neuromuscular weakness and is linked to both a reduction in readmission and death within the first year following discharge (Morris et al., 2011, Schweickert et al., 2009, Needham, 2008). What is desirable may not always be achievable however, with barriers impacting on patients' ability to resume activity upon transfer to the ward; including health care resources and time of transfer (Pandullo et al., 2015).

The last few days before hospital discharge is possibly the final opportunity patients' will access rehabilitation services administered by health care professionals. Surveys report only 27% of NHS adult ICU's across the United Kingdom (UK) have formal post discharge services for patients who have experienced critical illness (Connolly et al., 2014). Only 7% offer specific post discharge rehabilitation programmes; not all on a regular basis, with 'funding' being the most often barrier. Consequently, there is a need to ensure patients feel empowered with confidence, motivation and the physical abilities essential to continue progression of functional recovery after discharge. This is especially important where formal follow up services are not accessible.

Formal follow up services post discharge are rare (Connolly et al., 2014). This presents a need for closer monitoring of physical activity in hospital during recovery from critical illness in order to identify those requiring most support and health resource

input. This will identify those patients who although functionally able to undertake activity independently, may lack the confidence or motivation to do so. If not addressed, this may continue following discharge from hospital, negatively impacting on further functional recovery and quality of life (Herridge et al., 2011, Cheung et al., 2006, Herridge et al., 2003). Subjective methods exist for monitoring activity levels within the hospital environment but they are subject to both methodological and operational weaknesses. Whilst direct observation permits the ability to monitor and record the specific type and duration of activity being undertaken (Patterson et al., 2005), it is time consuming and not a viable option to undertake as part of a daily routine for individual patients due to resource intensity (Cheung et al., 2011). As patients become able to undertake more activity under their own volition, it may not be documented as a result of it not being witnessed. Physiotherapy or occupational therapy documentation only provides a brief snapshot of activity, with studies in other hospital populations reporting these sessions only account for 0.5 and 0.6% of the day (Patterson et al., 2005). Therefore, whilst direct observation has proved useful for research purposes (Berney et al., 2015, Patterson et al., 2005), it is not feasible as a method of activity monitoring within a busy clinical environment.

Another method of activity monitoring is patient self-report; but evidence suggests patients may fail to accurately report activity levels and abilities (Cheung et al., 2011, Prince et al., 2008, Sager et al., 1992). Self-report tools in adult populations are based on subjective feedback, show generally low to moderate correlations with more directly measured activity and may fail to register low intensity activities undertaken within 'frail' populations (Prince et al., 2008). Patients recovering from critical illness also often experience cognitive impairment affecting the ability to recall information required for self-report measures (Pandharipande et al., 2013). Both observation and self-report rely on individuals to subjectively record or remember activity undertaken. It requires those assimilating the information to consciously register that activity is being undertaken in order to capture and record it, which is not always the case (Cheung et al., 2011, Prince et al., 2008, Sager et al., 1992). This evidence suggests that both methods may be unsuitable for monitoring activity within patients recovering from critical illness. Moreover, both are prone to methodological and operational weaknesses, which may adversely affect their validity and reliability for use within this setting.

The use of technology to monitor activity levels within the hospital environment.

Due to the operational and methodological inadequacies of direct observation and patient self-report to accurately monitor activity levels within the hospital environment, other approaches must be considered. Methods of activity monitoring should be explored which relinquish the operational demands on individuals and embrace objective and quantifiable methods which demonstrate validity and reliability within a specific setting.

There is continued interest in the validation of small, wearable activity monitors to capture activity, especially in elderly hospital inpatient populations (Pedersen et al., 2013, Taraldsen et al., 2011, Culhane et al., 2004). These devices permit quantification of both the type and amount of activity undertaken though a typical day. Evidence suggests that these small dimension, lightweight, measurement devices demonstrate validity and reliability dependent on the task being analysed and where the sensors are applied (Cuesta-Vargas et al., 2010).

To date, only two studies have investigated the validity of activity monitors in quantification of purposeful activity undertaken by patients recovering from critical illness (Edbrooke et al., 2012, Winkelman et al., 2005). Both of these studies were undertaken within the ICU. No studies have investigated the validity of activity monitors to quantify activity upon return to the ward as functional ability improves. The aim of this study therefore is to investigate the validity of a specific activity monitor, the Actigraph GT3X accelerometer (Actigraph LLC, Pensacola, Florida, USA) in identifying activities and adoption of certain body postures in patients recovering from critical illness within the hospital ward environment.

The Actigraph GT3X accelerometer

One example of an activity monitor is an accelerometer, which detects movement by sensing changes in the speed and direction of acceleration, capturing it as a numerical 'count'. As movement intensity increases, there is a corresponding increase in numerical count; the higher the count, the more intensive the activity. Information on

activity is captured over a specific time period, called an epoch, which can be programmed onto the devices. An epoch can capture activity undertaken over less than a second to over a number of minutes (Actigraph, 2009). Accelerometers have the capacity to continuously capture data over a number of days if necessary, depending on the measurement modes used, for eventual download onto a computer. Data is captured in real time (as it happens), permitting the ability to identify the actual duration of activity (or inactivity) and when it occurred.

The Actigraph GT3X accelerometer contains measurement modes which quantify physical activity intensity (registering a numerical 'count'), body position via an inclinometer (lying, sitting or standing) and step count. Studies have shown good inter-instrument reliability in this particular make and model (Santos-Lozano et al., 2012). These measurement modes could permit objective, unobtrusive monitoring of all purposeful activity undertaken during the day by those recovering from critical illness in hospital. Activity may involve a postural change (sitting to standing for example), walking independently or with assistance (mobilisation) and other generalised physical activity. It could also identify where prolonged periods of inactivity are being observed, assisting in identifying individuals who may lack confidence or motivation, despite being able to undertake movement under their own volition. If used in this way, the Actigraph GT3X could assist in the effective allocation of rehabilitation resources, identifying those who may require increased input to achieve their rehabilitation goals. To date, no research has been undertaken to determine whether the Actigraph GT3X accelerometer is a valid instrument to assess body position, step count or generalised activity within a population recovering from critical illness. Despite this, recent research has used this model to objectively quantify activity levels in patients resident in the ICU, using both the inclinometer (body position) and activity count settings (Schujmann et al., 2015). The study by (Schujmann et al., 2015) placed the accelerometer on the ankle. Although manufacturer's recommend that this device is worn around the waist (Actigraph 2009), encouraging results have been found with an ankle placement, particularly in determination of step count (Korpan et al., 2015). It is important therefore to determine the validity of this particular device and its optimum body placement site within a patient population recovering from critical illness.

A feasibility study undertaken by the chief investigator (CI), as part of a PhD programme of study, determined that an ankle placement of the Actigraph GT3X accelerometer was superior to the waist for determination of body position and step count. In this study, thirty healthy adult volunteers simulated patients weakened by critical illness. They performed a movement protocol which incorporated the typical activities undertaken by patients recovering in hospital from critical illness. These included moving from lying to sitting, sitting to standing (and vice versa) and walking short distances. Video recordings were taken of each participant during the movement protocols, enabling observation of the body positions adopted and step counting during the walking activities. Video recording was used as the criterion measure for comparison against the data captured by the accelerometers worn both at the ankle and the waist. The activities detailed above are typically included within early mobility protocols which have undergone evaluation within populations experiencing critical illness (McWilliams et al., 2015, Adler and Malone, 2012, Schweickert et al., 2009). Moderate agreement ($\kappa = 0.43$, $p < 0.001$), was found between observation of video recordings of body position (lying, sitting or standing) and the inclinometer setting for the ankle placement. Fair agreement only ($\kappa = 0.21$, $p < 0.001$) was found for the waist placement. Regular misclassification of all body positions was found with the waist placement. The ankle placement identified both the lying and standing positions well. The sitting position however was only correctly identified intermittently for the ankle placement. A novel finding emerged from this research relating to the ankle placement site. When a side lying position was adopted, the ankle accelerometer inclinometer function regularly registered a '0'. The '0' setting normally corresponds to a 'not being worn' option. When a reading of '0' was recoded to the option 'side lying,' agreement improved from $\kappa = 0.43$ ($p < 0.001$) to $\kappa = 0.48$ ($p < 0.001$). This finding suggests a new way of interpreting the '0' reading of the inclinometer when worn on the ankle, which is worthy of further investigation within an actual patient population.

The inconsistency of correct determination of body position of this accelerometer model when worn around the waist has been demonstrated by other authors (Berendsen et al., 2014, Hänggi et al., 2013). The inconsistency of correct identification of the sitting position in particular was highlighted by (Hänggi et al., 2013). Other researchers have investigated ways of improving the ability to correctly classify the sitting position (Skotte et al., 2014). The study by (Skotte et al., 2014)

determined that the addition of a second Actigraph GT3X accelerometer placed on the mid-thigh yielded excellent results in detection of the sitting position. Pressure sensors in subjects' hip pockets were used as a criterion measure to classify body position.

As mentioned previously, the feasibility undertaken by the CI determined that the ankle placement was superior to the waist for recognition of step count. When walking a ten metre distance with a walking aid, using observed step count as a criterion measure the ankle placement demonstrated a mean difference -1 step, (Limits of Agreement (LOA) +3 to -5 steps) compared to the waist placement (mean difference -7 steps, LOA +9 to -23 steps). These positive findings for step count for the ankle placement are supported by a recent study cited earlier using a similar Actigraph model investigating the accuracy of step count in older adults (Korpan et al., 2015).

Defining the research question

Using the findings from the feasibility study regarding the ankle placement of the Actigraph GT3X accelerometer and the research cited suggesting improved classification of the sitting position with the addition of a thigh mounted accelerometer the following research question is proposed:

Can an Actigraph GT3X accelerometer, placed at the ankle and thigh of the same leg, accurately measure body position and walking episodes undertaken by patients recovering from critical illness in a hospital ward?

A number of study objectives evolve from this research question, assisting in the development of the methodological processes required to answer it.

1. To determine the criterion validity of the ActiGraph GT3X accelerometer in detection of body position and step count when positioned either on the mid-thigh or ankle of the same leg.
2. To establish if there is a superior single body placement site (thigh or ankle) to objectively record body position and step count within this patient population.
3. To investigate the criterion validity of the combination of thigh and ankle accelerometer inclinometer outputs to correctly determine the sitting position. This

will determine whether an algorithm can be constructed using the two inclinometer readings, which will better distinguish the sitting from the standing position.

4. To evaluate, from a user perspective, the acceptability of these devices in relation to the placement sites used. This will be achieved by asking patients to score the answer to a particular question through the use of a Likert scale. The question is:
 - How would you rate the comfort of wearing the accelerometers?

In consideration of the results from the feasibility study undertaken by the CI and research using the addition of a thigh mounted accelerometer to identify the sitting position (Skotte et al., 2014), the following hypotheses can be constructed:

Hypotheses

1. An ankle mounted Actigraph GT3X accelerometer, will accurately identify both the lying and standing positions when compared with direct observation as a criterion measure.
2. An ankle mounted Actigraph GT3X accelerometer, will capture a step count comparable to that recorded by direct observation in a population resident on a hospital ward recovering from critical illness.
3. The combination of inclinometer outputs of both the thigh and ankle placement sites will permit development of an algorithm permitting the ability to better distinguish between the sitting and standing position.
4. The ankle and mid-thigh accelerometer placement sites will be well tolerated by patients recovering on a ward from critical illness.

Subject selection and involvement

The study will invite adult hospital ward patients recovering from critical illness to wear one Actigraph GT3X accelerometer on the antero-medial mid-thigh and another on the ankle, resting above the lateral malleolus of the same leg. The accelerometers will be worn for a period of time not exceeding three hours. Each device will be attached with a single patient use broad elastic belt, secured by Velcro fastening, using a standardised placement protocol. The non – dominant leg will be the preferred placement side.

Participants will be asked to undertake a semi - structured movement protocol, consisting of low intensity movements typical of those that they will already be taking through the day. These include lying in bed, getting out of bed to sit over the side, moving from sitting to standing, sitting in a chair and walking distances that their current level of physical ability permits. The observation period will be undertaken at a time mutually agreed between the participant and the observer (the CI). Observation periods will not occur over lunchtimes or protected patient rest periods, which vary from ward to ward. Rest periods will be encouraged if required and should the participant request them.

Participants will determine the order in which they perform the movements, but as many as possible must be completed within a period not exceeding three hours. It is envisaged this will reduce bias due to order effects and enable the determination of accelerometer validity in as naturalistic conditions as possible, whilst also permitting participant autonomy.

Inclusion Criteria

- 18 years of age or above.
- Ventilated in excess of 48 hours during admission in the ICU
- Currently resident on a hospital ward (secondary care) following step down from ICU
- At a stage in recovery where individuals are able to undertake all postural transfers independently or with minimal assistance (one person only)
- Able to mobilise short distances, either independently or with assistance from a walking aid or one person
- Willing to permit application of two Actigraph GT3X accelerometer devices, one lying anteromedially around the non-dominant mid-thigh; the other resting above the lateral malleolus on the same (ipsilateral) leg. Each device weighs 27g with dimensions of 3.8cm x 3.7cm x 1.8cm.
- Participants must be willing to consent to a period of direct observation for a length of time not exceeding three hours, which will take place at a mutually agreed time. Observation will serve as the criterion measure which accelerometer data will be compared against.

Exclusion Criteria

- Unable to provide informed written consent, or unwilling to consent to a period of observation not exceeding three hours.
- Those unable to make an informed decision about participation or demonstrating an inability to interpret information or follow study instructions as a result of impaired cognitive function.
- Significant neurological or coordination impairment rendering it not possible to undertake purposeful movements independently or with minimal assistance, either of one person or with walking aids if walking.
- Unable to speak/ understand English. This research forms part of a PhD programme of study and receives no funding to enable the use of language interpreter services or translation of study documentation (e.g. information sheet and consent form) into different languages.
- Clostridium Difficile, similar infection or unmanaged urinary incontinence, due to potential contamination of the accelerometers if leakage into the internal mechanism occurs.
- Evidence/ diagnosis of peripheral vascular disease.
- Lower limb amputation
- Polytrauma which prevents the adoption of normal lying, sitting or standing postures, or placement of the accelerometers according to the placement protocol.

Recruitment of study participants

Study participants will be resident on a hospital ward within The Hull and East Yorkshire Hospitals Trust (HEYHT) sites of Castle Hill Hospital and Hull Royal Infirmary. Patients will be identified in the first instance during their stay on the ICU at either Castle Hill Hospital or Hull Royal Infirmary by senior physiotherapists responsible for the delivery of respiratory and rehabilitation services to this group. Any patients with a known period of intubation and ventilation lasting in excess of 48 hours will be highlighted as a potential participant to senior physiotherapists working on the wards where patients will be transferred to.

Potential participants will be approached for the first time near the end of their hospital stay by a senior physiotherapist from the direct care team looking after them, who will briefly explain the study intentions. For those deemed to fulfil the inclusion criteria and none of the exclusion criteria, an information sheet will be offered to the potential participant to read and discuss study participation possibly with their family and friends. There is a significant risk that patients may be discharged home if there is too much time between the initial approach and undertaking the activities. With this in mind, 24 hours only will be permitted for participants to express interest in involvement to the senior physiotherapist who supplied the study information or a physiotherapist directly involved in their care.

Patients who express interest in the study will be communicated to the CI by the senior physiotherapists directly involved in their care. The CI will only approach patients who have expressed verbally to the ward physiotherapy staff that they would like to meet with her to discuss potential involvement. The CI will arrange to meet the patient at their earliest convenience (which may be the same day), to discuss the study in more detail, providing an overview of what is required for participation and the format of the informed consent process. She will answer any further questions they may have following reading the information sheets. It will be made explicit that if they do not wish to participate in the study this will not affect their treatment in any way and they will be thanked for the interest already shown in the study. Informed consent will be collected at this meeting via a separate consent form, should the patient express a wish to participate. The CI will also sign the form as the 'person obtaining consent' at this meeting. The participant must be physically able to sign the consent form themselves prior to taking part in the study. This form will be retained by the CI, with a further duplicate copy given to the participant. A copy will also be placed in the medical notes of the participant. Together with the patient information sheet.

Once informed consent has been gained data collection will commence within 24 hours. Prior to undertaking data collection, the CI will ascertain that each participant is still physically able to undertake the movement protocol and has not suffered any deterioration in their condition. They will be asked for a final time if they still wish to participate and if so, data collection will begin.

Study procedure

Body mass index (BMI) will be calculated by using the latest weight recording (in kilogrammes) on the participants observation charts and asking participants to estimate their height, which will be converted to centimetres if given in feet and inches. Participants will wear two Actigraph GT3X accelerometers, one anteromedially around the mid - thigh and the other around the ankle of the same (ipsilateral) leg resting above the lateral malleolus. The CI will attach the accelerometers, ensuring they feel comfortable and pose no circulatory concerns. The placement sites will be checked on a half hourly basis during the data collection period. This has been recommended by the tissue viability team, to ensure the accelerometers are not compromising skin integrity or circulation. A standardised assessment form will be used for this process, which has been constructed with assistance from the tissue viability team.

The data collection period will not exceed three hours; including rest periods. Accelerometers will be removed at any time during the data collection period should a participant request this. Any data that has been collected during the time period that the accelerometers were worn prior to the request for removal will be downloaded and included within the analysis with the participant's permission.

Participants will be free to undertake the activities within the semi-structured movement protocol in any order they prefer. Whilst undertaking the movements, participants will be observed by the CI. Although there is a requirement for the CI to be able to visualise them, the actual distance that she is from the patient will be determined according to the individual's wishes. Respect for privacy and dignity will be of paramount importance. Participants will not be observed if they are using a commode, the toilet or if bathing. The accelerometer data downloaded during these periods of time will be excluded from data analysis. A digital clock with an hour, minute and second display, successfully employed within the feasibility study will be used to note the time (to the hour, minute and second) when a particular movement or postural change occurred and ended. Once a postural change ends, a further five seconds will be observed on the digital clock before the new body position is documented as complete. This is to accommodate findings from the feasibility study and subsequent manufacturers recommendations related to how the accelerometer models process information. The digital clock will be synchronised to the time setting on a laptop computer, which will also be used to activate the desired settings on both accelerometers (termed 'initialisation'). These

processes will occur immediately before the data collection period to maximise synchronisation of the digital clock with the time setting on the accelerometers. The laptop computer will not be used during data collection, only for time synchronising the digital clock and for initialising the settings onto both accelerometers. The accelerometers will be programmed to capture data every second (one second epoch).

Following completion of the data collection period, the information captured by the accelerometers will be downloaded as soon as possible onto the laptop computer. The time when a movement commenced and ceased (with the addition of five seconds to accommodate accelerometer processing), will be noted by the CI. The type of movement and body positions adopted will also be documented (lying, sitting or standing). If the movement involves walking, the CI will count the number of steps undertaken manually, entering all of the above information onto a data collection sheet. The participant will not miss any refreshments, food or any investigations and they will also be encouraged to undertake usual daily activities, e.g. reading a paper or watching the television. If the participant requests some time alone, in the case of making a phone call for example, the CI will comply, but encourage the participant to remain in the same body position. If they were sitting in a chair for example, they would be encouraged to remain seated, agreeing a time for the CI to return (e.g. fifteen minutes). Should any procedures or personal cares be necessary, the CI will respect the need for privacy and dignity and leave until they are complete. The data captured by the accelerometers during these time periods will be excluded from data analysis, as there will be no criterion measure (observation) to compare accelerometer data against.

Observational data will be collected by the CI using a data collection form specifically designed for this purpose, which will be entered into an electronic format within the IBM SPSS statistics programme (version 20) for data analysis. The CI will undertake all data collection procedures and undertake statistical analysis.

Upon completion of the period of observation the accelerometers will be removed and the skin examined for one final time. Participants will be asked to rate their views on acceptability of wearing the accelerometers at the two placement sites. They will be asked to consider the question in relation to the individual placement sites and in combination. One question will be asked:

1. How would you rate the comfort of wearing the accelerometers?

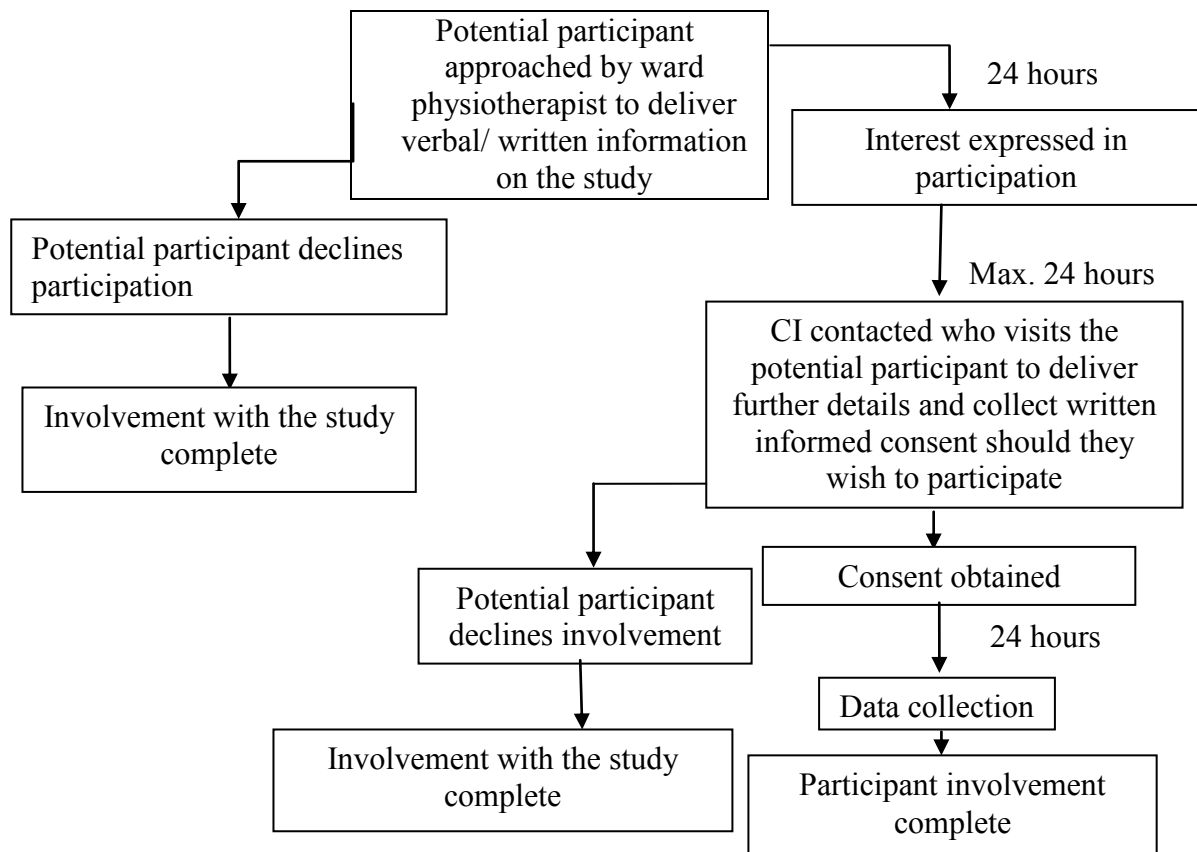
Participants will be requested to match their answer to a statement on a five-point Likert Scale which will be printed on a sheet for them:

1. Very uncomfortable
2. Somewhat uncomfortable
3. Neither comfortable or uncomfortable
4. Somewhat comfortable
5. Very comfortable

A similar method of gaining feedback from participants regarding accelerometer comfort has been used in previous studies (Kramer et al., 2013).

Participants will also be asked if they have any comments they wish to make regarding the accelerometers, which will be noted as free text should any be forthcoming.

Study format



Semi structured movement protocol

1. Lying in bed with the legs straight and the bed head set at a comfortable height as dictated by the participant
2. Lying on the left side
3. Lying on the right side
4. Moving from lying to sitting over the side of the bed
5. Sitting to standing
6. Sitting in a chair
7. Mobilising a distance determined by the functional ability of the individual participant at that point in their recovery.

N.B. The participant will be free to undertake these movements in any order they wish, but there is a requirement to undertake as many of these movements as possible within the observation period, which will not exceed three hours. The participant will be provided with a sheet to remind them of the movements required to be undertaken. This will contain a tick box so they can mark off when a particular movement was completed. If a movement is missed, the CI will encourage the participant towards the end of the observation period to undertake it.

Infection control considerations

Advice has been sought from the HEYHT Infection Control Team regarding infection control considerations when using the accelerometers with patients' resident within HEYHT. The recommendations are as follows:

1. Elastics belts must be single patient use only and fastened using Velcro
2. The part of the accelerometer that permits download to the computer should be covered with a piece of easily removable tape (e.g. 'Scotch tape') to permit the whole device to be swabbed down with a Tristel wipe following the three-hour period of data collection per participant.
3. The devices are not required to be placed in a nylon pouch prior to application.

Tissue viability considerations

Advice has been sought from the HEYHT Tissue Viability Team during construction of this methodological protocol. The inclusion and exclusion criteria have been constructed in such a way to consider those populations where placement of the accelerometers may pose additional and unnecessary risk. An assessment form has been constructed with advice from the same team to use when undertaking the half hourly assessment of skin integrity and circulation of participants during the data collection period. The Tissue viability team borrowed the accelerometers to assess whether they posed any significant risk to tissue viability and to assist in construction of the eligibility criteria for participation.

Data collection process

A data collection sheet will be populated during the data collection period. Rest periods and the positions participants adopt (e.g. lying, sitting or standing) will be recorded also.

Accelerometer data will be captured using the three different measurement modes available on the GT3X devices. Activity intensity detection is a default setting on the devices. These modes can be initialised onto the accelerometers simultaneously for eventual download onto the computer. A password protected laptop computer will be used for the initialisation of the accelerometers and subsequent data download. This laptop computer has direct remote access to the CI's personal folders on the York St John University (YSJU) virtual desktop facility, which is secure and password protected. Data files can be transferred electronically to the YSJU student virtual desktop to permit statistical analysis within SPSS.

The accelerometer settings (measurement modes) will be:

- Physical activity count (a default setting), giving a numerical score related to intensity of activity, the greater the count, the greater the acceleration of movement, hence the greater intensity
- Step count
- Inclinator for identification of body position (lying, sitting or standing)

There are only four readings the inclinometer setting on this particular device can supply, which are detailed below:

0 = Device is off (not being worn by patient)

1 = standing

2 = lying horizontally

3 = sitting upright

Sample size calculation

A sample size of 20 participants will be recruited. This sample size has 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). A sample size of 20 was also recruited in another study investigating the validity of accelerometer measurement within a hospitalised stroke population (Kramer et al., 2013). Recruiting a sample of 20 patients will permit some attrition should there be any accelerometer malfunction or decisions to withdraw, yet supply an achievable number for participant recruitment based on feedback from clinical colleagues working within the specialty.

Statistical analysis

IBM SPSS statistics (Version 20) will be used to undertake statistical analysis. Some data captured by the accelerometers is continuous and others categorical.

Categorical data

Categorical data, concerning body position (lying, sitting or standing) will be analysed using the Kappa statistic, calculating agreement between the accelerometer inclinometer data and direct observation. Each accelerometer placement site (thigh and ankle) will initially be analysed separately. Examination of the inclinometer raw data captured from both placement sites will determine whether an algorithm can be constructed using readings from both the ankle and thigh placement to improve determination of the sitting

position specifically if necessary. Direct observation will serve as the criterion measure for all the analyses.

Percentage agreement of inclinometer raw data from the thigh and ankle accelerometers with direct observation for detection of each separate body position will be calculated. A further percentage agreement analysis will be undertaken if an algorithm can be constructed for determination of the sitting position using readings from both placement sites. This algorithm will be compared against direct observational raw data identifying the sitting position only. This result will be compared against the percentage agreement of the individual placement sites in determination of the sitting position. This will assist in determination of whether the algorithm is more superior to a single placement site in determination of the sitting position.

Continuous data

Agreement between step count recorded by each accelerometer placement site and direct observation (manual counts) as a criterion measure will be determined using Bland Altman analysis with 95% limits of agreement (LOA).

Acceptance of the devices over a three-hour period

The statements within the Likert scale will be collapsed to obtain true positives (very comfortable and somewhat comfortable) and true negatives (very uncomfortable and somewhat uncomfortable). The middle category (neither comfortable nor uncomfortable) will remain a separate category. A descriptive analysis will be undertaken to investigate this particular aspect of enquiry using percentages of true positives, the middle category and true negatives. This will be presented graphically.

Any specific comments made by the patients in relation to acceptability of the devices will be included as free text within the results section. The statements will be anonymous and permission from participants will be sought regarding their inclusion within the body of the thesis or publications which may arise from it.

Ethics approval

This study has received approval from the NHS Local Research Ethics Committee (REF: XXXXX) and the Research Ethics Sub Committee, YSJU (REF: XXXXXX).

Data handling and confidentiality

All participants will be assigned a unique reference number which will be linked to personal details stored securely on paper. Any electronic data will be anonymous, bearing the unique reference number of the participant and their initials only, with no personally identifiable information included within the data files. Only the CI will have the ability access to trace data files created from accelerometry measurements to the individual participant, using their unique reference number and initials within the file name.

Any paper documentation, which may include personal data (e.g. signed consent form, personal contact details), will be kept in a locked filing cabinet within the Therapies Centre, Hull Royal Infirmary. This is shared with one other colleague, Dr. Angela Green, who is also a member of the PhD supervision team. This office is always locked when vacant. Preferred personal contact details will only be obtained at the consent phase should the participants express a desire to hear of the results.

The CI will adhere to the NHS Information Governance (IG) Toolkit Regulations, professional codes of conduct and relevant HEYHT and YSJU policies and procedures at all times. No information regarding research participants will be passed to third parties not directly involved in the research.

The identity of individual participants in the research report and any publications will remain confidential and anonymous. Data protection will conform to the Data Protection Act 1998.

Finance

This study has not received any funding from external sponsors and all accelerometry equipment and software has been supplied by YSJU. Lack of an ability to employ language interpreters, due to no external funding has necessitated the requirement to enrol only those who have a good command of the English language.

Reporting and dissemination

This study will form part of a PhD thesis, investigating the validity of a particular model of accelerometer (the Actigraph GT3X) for use as a clinical measurement tool to quantify the typical activities patients undertake on a hospital ward as they continue their recovery following critical illness.

Following data analysis, opportunities will be sought for presentation of results at National Conferences, including the University College London (UCL) annual conference 'Critical Care Update for Physiotherapists'. Abstracts are hoped to be submitted for peer review to other relevant National Conferences, including Physiotherapy UK for oral presentation/ poster presentation.

Opportunities for poster presentations, hospital service improvement conferences, YSJU or University of Leeds (UoL) conferences will also be sought. Presentation within the research seminar programme held within the Health and Life Sciences Faculty (HLS) at YSJU will also be explored, following guidance and consultation with the PhD supervision team.

Presentations via local research networks and critical care networks will be explored, together with a submission to a selected journal for peer review to consider for publication.

References

- ACTIGRAPH ENGINEERING/ MARKETING. 2009. ActiLife users manual, Document No. PUB08DOC04, Revision H, ACTIGRAPH™
- ADLER, J. & MALONE, D. 2012. Early mobilization in the intensive care unit: a systematic review. *Cardiopulmonary Physical Therapy Journal*, 23, 5-13.
- BERENDSEN, B. A. J., HENDRIKS, M. R. C., MEIJER, K., PLASQUI, G., SCHAPER, N. C. & SAVELBERG, H. H. C. M. 2014. Which activity monitor to use? Validity, reproducibility and user friendliness of three activity monitors. *BMC Public Health*.
- BERNEY, S. C., HARROLD, M., WEBB, S. A., SEPPELT, I., PATMAN, S., THOMAS, P. J. & DENEHY, L. 2013. Intensive care unit mobility practices in Australia and New Zealand: a point prevalence study. *Critical Care & Resuscitation*, 15, 260.
- BERNEY, S. C., ROSE, J. W., BERNHARDT, J. & DENEHY, L. 2015. Prospective observation of physical activity in critically ill patients who were intubated for more than 48 hours. *Journal of Critical Care*, 30, 658-663.
- BORGES, R. C., CARVALHO, C. R., COLOMBO, A. S., DA SILVA BORGES, M. P. & SORIANO, F. G. 2015. Physical activity, muscle strength, and exercise capacity 3 months after severe sepsis and septic shock. *Intensive Care Med*, 41, 1433-44.
- CHEUNG, A. M., TANSEY, C. M., TOMLINSON, G., DIAZ-GRANADOS, N., MATTÉ, A., BARR, A., MEHTA, S., MAZER, C. D., GUEST, C. B., STEWART, T. E., AL-SAIDI, F., COOPER, A. B., COOK, D., SLUTSKY, A. S. & HERRIDGE, M. S. 2006. Two-year outcomes, health care use, and costs of survivors of acute respiratory distress syndrome. *American Journal of Respiratory & Critical Care Medicine*, 174, 538-544.
- CHEUNG, V. H., GRAY, L. & KARUNANITHI, M. 2011. Review article (meta-analysis): Review of Accelerometry for Determining Daily Activity Among Elderly Patients. *Archives of Physical Medicine and Rehabilitation*, 92, 998-1014.
- CONNOLLY, B., DOUIRI, A., STEIER, J., MOXHAM, J., DENEHY, L. & HART, N. 2014. A UK survey of rehabilitation following critical illness: implementation of NICE Clinical Guidance 83 (CG83) following hospital discharge. *BMJ Open*, 4, 1.
- CUESTA-VARGAS, A. I., GALÁN-MERCANT, A. & WILLIAMS, J. M. 2010. The use of inertial sensors system for human motion analysis. *Physical Therapy Reviews*, 15, 462-473.
- CULHANE, K. M., LYONS, G. M., HILTON, D., GRACE, P. A. & LYONS, D. 2004. Long-term mobility monitoring of older adults using accelerometers in a clinical environment. *Clinical Rehabilitation*, 18, 335-343.
- DEEM, S., LEE, C. M. & CURTIS, J. R. 2003. Acquired Neuromuscular Disorders in the Intensive Care Unit. *American Journal of Respiratory & Critical Care Medicine*, 168, 735.
- EDBROOKE, L., LYTHGO, N., GOLDSWORTHY, U. & DENEHY, L. 2012. Can an accelerometer-based monitor be used to accurately assess physical activity in a population of survivors of critical illness? *Global Journal Of Health Science*, 4, 98-107.

- HÄNGGI, J. M., PHILLIPS, L. R. S. & ROWLANDS, A. V. 2013. Original research: Validation of the GT3X ActiGraph in children and comparison with the GT1M ActiGraph. *Journal of Science and Medicine in Sport*, 16, 40-44.
- HERRIDGE, M., CHEUNG, A. & TANSEY, C. 2003. One-Year Outcomes in Survivors of the Acute Respiratory Distress Syndrome. *Indian Journal of Critical Care Medicine*, 53.
- HERRIDGE, M. S., TANSEY, C. M., MATTÉ, A., TOMLINSON, G., DIAZ-GRANADOS, N., COOPER, A., GUEST, C. B., MAZER, C. D., MEHTA, S., STEWART, T. E., KUDLOW, P., COOK, D., SLUTSKY, A. S. & CHEUNG, A. M. 2011. Functional Disability 5 Years after Acute Respiratory Distress Syndrome. *New England Journal of Medicine*, 364, 1293-1304.
- HOPKINS, R. O., MILLER III, R. R., RODRIGUEZ, L., SPUHLER, V. & THOMSEN, G. E. 2012. Physical Therapy on the Wards After Early Physical Activity and Mobility in the Intensive Care Unit. *Physical Therapy*, 92, 1518-1523.
- KORPAN, S. M., SCHAFER, J. L., WILSON, K. C. S. & WEBBER, S. C. 2015. Effect of ActiGraph GT3X+ Position and Algorithm Choice on Step Count Accuracy in Older Adults. *Journal of Aging & Physical Activity*, 23, 377.
- KRAMER, S. F., CUMMING, T., CHURILLOV, L. & BERNHARDT, J. 2013. Measuring activity levels at an acute stroke ward: comparing observations to a device. *BioMed Research International*, 460482-460482 1p.
- LANDIS, J. R. & KOCH, G. G. 1977. The Measurement of Observer Agreement for Categorical Data. Biometric Society.
- LATRONICO, N. & BOLTON, C. F. 2011. Review: Critical illness polyneuropathy and myopathy: a major cause of muscle weakness and paralysis. *Lancet Neurology*, 10, 931-941.
- LATRONICO, N., TOMELLERI, G. & FILOSTO, M. 2012. Critical illness myopathy. *Current Opinion In Rheumatology*, 24, 616-622.
- MCWILLIAMS, D., WEBLIN, J., ATKINS, G., BION, J., WILLIAMS, J., ELLIOTT, C., WHITEHOUSE, T. & SNELSON, C. 2015. Mechanical Ventilation: Enhancing rehabilitation of mechanically ventilated patients in the intensive care unit: A quality improvement project. *Journal of Critical Care*, 30, 13-18.
- MORRIS, P. E., GRIFFIN, L., BERRY, M., THOMPSON, C., HITE, R. D., WINKELMAN, C., HOPKINS, R. O., ROSS, A., DIXON, L., LEACH, S. & HAPONIK, E. 2011. Receiving early mobility during an intensive care unit admission is a predictor of improved outcomes in acute respiratory failure. *The American Journal Of The Medical Sciences*, 341, 373-377.
- NEEDHAM, D. M. 2008. Mobilizing patients in the intensive care unit: improving neuromuscular weakness and physical function. *JAMA: Journal of the American Medical Association*, 300, 1685-1690 6p.
- NYDAHL, P., RUHL, A. P., BARTOSZEK, G., DUBB, R., FILIPOVIC, S., FLOHR, H.-J., KALTWASSER, A., MENDE, H., ROTH AUG, O., SCHUCHHARDT, D., SCHWABBAUER, N. & M NEEDHAM, D. 2014. Early mobilization of mechanically ventilated patients: a 1-day point-prevalence study in Germany*. *Critical Care Medicine*, 42, 1178-1186.
- PANDHARIPANDE, P. P., GIRARD, T. D., JACKSON, J. C., MORANDI, A., THOMPSON, J. L., PUN, B. T., BRUMMEL, N. E., HUGHES, C. G., VASILEVSKIS, E. E., SHINTANI, A. K., MOONS, K. G., GEEVARGHESE, S. K., CANONICO, A., HOPKINS, R. O., BERNARD, G. R., DITTUS, R. S. & ELY, E. W. 2013. Long-term cognitive impairment after critical illness. *New England Journal of Medicine*, 369, 1306-1316 11p.

- PANDULLO, S. M., SPILMAN, S. K., SMITH, J. A., KINGERY, L. K., PILLE, S. M., RONDINELLI, R. D. & SAHR, S. M. 2015. Physiotherapy: Time for critically ill patients to regain mobility after early mobilization in the intensive care unit and transition to a general inpatient floor. *Journal of Critical Care*, 30, 1238-1242.
- PATTERSON, F., BLAIR, V., CURRIE, A. & REID, W. 2005. An investigation into activity levels of older people on a rehabilitation ward: an observational study. *Physiotherapy*, 91, 28-34.
- PEDERSEN, M. M., BODILSEN, A. C., PETERSEN, J., BEYER, N., ANDERSEN, O., LAWSON-SMITH, L., KEHLET, H. & BANDHOLM, T. 2013. Twenty-four-hour mobility during acute hospitalization in older medical patients. *Journals of Gerontology Series A: Biological Sciences & Medical Sciences*, 68, 331-337.
- PRINCE, S. A., ADAMO, K. B., HAMEL, M. E., HARDT, J., CONNOR GORBER, S. & TREMBLAY, M. 2008. A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review. *Int J Behav Nutr Phys Act*, 5, 56.
- SAGER, M. A., DUNHAM, N. C., SCHWANTES, A., MECUM, L., HALVERSON, K. & HARLOWE, D. 1992. Measurement of activities of daily living in hospitalized elderly: a comparison of self-report and performance-based methods. *JOURNAL - AMERICAN GERIATRICS SOCIETY*, 40, 457.
- SANTOS-LOZANO, A., TORRES-LUQUE, G., MARIN, P. J., RUIZ, J. R., LUCIA, A. & GARATACHEA, N. 2012. Intermonitor Variability of GT3X Accelerometer. *INTERNATIONAL JOURNAL OF SPORTS MEDICINE*, 33, 994-999.
- SCHUJMAN, D., GOMES, T., DA SILVEIRA, L. T. Y. & FU, C. 2015. Quantifying physical activity levels of patients in intensive care: an objective measurement. *Physiotherapy*.
- SCHWEICKERT, W. D., POHLMAN, M. C., POHLMAN, A. S., NIGOS, C., PAWLIK, A. J., ESBROOK, C. L., SPEARS, L., MILLER, M., FRANCZYK, M., DEPRIZIO, D., SCHMIDT, G. A., BOWMAN, A., BARR, R., MCCALLISTER, K. E., HALL, J. B. & KRESS, J. P. 2009a. Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial. *Lancet*, 373, 1874-1882.
- SCHWEICKERT, W. D., POHLMAN, M. C., POHLMAN, A. S., NIGOS, C., PAWLIK, A. J., ESBROOK, C. L., SPEARS, L., MILLER, M., FRANCZYK, M., DEPRIZIO, D., SCHMIDT, G. A., BOWMAN, A., BARR, R., MCCALLISTER, K. E., HALL, J. B. & KRESS, J. P. 2009b. Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial. *Lancet*, 373 North American Edition, 1874-1882 9p.
- SKOTTE, J., KORSHØJ, M., KRISTIANSEN, J., HANISCH, C. & HOLTERMANN, A. 2014. Detection of Physical Activity Types Using Triaxial Accelerometers. *Journal of Physical Activity & Health*, 11, 76.
- TARALDSEN, K., ASKIM, T., SLETVOLD, O., EINARSEN, E. K., BJÅSTAD, K. G., INDREDAVIK, B. & HELBOSTAD, J. L. 2011. Evaluation of a Body-Worn Sensor System to Measure Physical Activity in Older People With Impaired Function. *Physical Therapy*, 91, 277-285.
- TRAPP, R. G. E. & DAWSON, B. E. 2004. *Basic & clinical biostatistics*, New York, N.Y., McGraw-Hill Education LLC.
- WINKELMAN, C., HIGGINS, P. A. & CHEN, Y. K. 2005. Activity in the chronically

