Study Title: meAsuring physiCal acTIvity leVEls in critical care: a feasibility study

Short title or acronym: ACTIVE

Protocol Number: 18IR06

Protocol Version: Version 1.0

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Funder: N/A

There are no known potential conflicts of interest

Sponsor:

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Signatures

The Chief Investigator, Principal Investigators and Sponsor have discussed this protocol. All have agreed to perform the investigation as written and to abide by this protocol except in case of medical emergency or where departures from it are mutually agreed in writing.

Chief Investigator
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Signature

Date: 01/02/2018

Participating Sites and Local Principal Investigators (PI)

Principal Investigator
Mrs Laura Jones

Signature

Date: 01/02/2018

1 Amendment History

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	1.0	27/01/18	Laura Jones	Update inclusion/exclusion criteria after external peer review. Update observation sheet to include routine turns.
2	1.0	01/02/18	Laura Jones	Update statistical analysis plan after peer review

2 Abbreviations

C&VUHB	Cardiff and Vale University Health Board
CI	Chief Investigator
CIS	Consultee Information Sheet
CRF	Case Report Form
EVD	External Ventricular Drain
GCP	Good Clinical Practice
ICP	Intracranial Pressure
NICE	National Institute for Health and care Excellence
PI	Principal Investigator
PIS	Participant/ Patient Information Sheet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
UCL	University College London
UHW	University Hospital Wales

3 Study Synopsis

Title	Measuring Physical Activity Levels in Critical Care: A Feasibility Study (ACTIVE)
Sponsor name	University College London Institute of Child Health
IRAS ID number	238464
Primary objective	To establish the feasibility of using a wearable accelerometer to measure the activity levels of patients recovering from critical illness
Secondary objective (s)	To quantify the activity levels of critical care patients on a single critical care unit
Study Design	Prospective observational study
Study Endpoints	Date of last participant's discharge from critical care
Sample Size	Target sample size: 15
Summary of eligibility criteria	Patients admitted to critical care at University Hospital Wales, Cardiff will be eligible for the study if they meet the inclusion criteria: • Age >18; • 'At risk' of physical morbidity as determined by NICE CG83 guidelines (Appendix C); • Consent or advice obtained
Intervention	Participants will wear an accelerometer device attached to their thigh and any observed activity will be recorded. There is no direct intervention.
Procedures: Screening & enrolment	All new patients admitted to the critical care unit will be screened for eligibility. Consultee advice will initially be sought before participant re-consenting when appropriate.
Baseline	Baseline demographic information recorded
Treatment period	A wearable accelerometer device will be worn for the duration of the participant's critical care admission. Any observed activity will also be recorded
End of Study	13th August 2018

Contents Table

4 Introduction

4.1 Background and Rationale

Patients admitted to critical care have a variety of life threatening conditions which require specialist care, often including a period of sedation and mechanical ventilation. As a consequence of critical illness, survivors often experience multiple sequela, including muscle weakness which leads to reduced mobility and physical function, persisting beyond discharge back into the community (Griffiths and Hall., 2010).

Guidelines for rehabilitation after critical illness (NICE CG83, 2009), enable identification of patients at risk of developing physical morbidity and provide recommendations to support the rehabilitation of these patients. Rehabilitation has been demonstrated to be safe and feasible within critical care, with traditional barriers to intervention gradually reducing (Nydahl et al., 2017). Many studies have examined rehabilitation of critically ill patients using a variety of measures, which demonstrated positive physiological and functional outcomes at various end-points, with evidence supporting early intervention (Kayambu et al., 2013). Despite this, recent studies suggest there may be disparity between the evidence supporting rehabilitation and the reality of clinical practice, with very low levels of overall physical activity demonstrated in this population (Connolly et al., 2017; Berney et al., 2015). There could be several reasons for this, but it does suggest that measurement of activity levels beyond specific exercise rehabilitation input provides a more realistic picture of a patient's physical recovery. Therefore, activity levels may be a more useful measurement of recovery than the amount of physical rehabilitation intervention or specific functional measurements.

Currently only one study in the UK (Connolly et al., 2017) has measured patient activity during critical care admission, using behavioural mapping. Although this method can provide detailed information, it does not measure patient activity continuously and is time consuming to perform. An alternative method of measuring physical activity in this population is using wearable technology, which allows continuous measurement of activity, with minimal time and resource requirements. It provides researchers and clinical staff with detailed information and, as exercise based interventions become more prevalent in critical care, research suggests wearable technology is likely to be increasingly useful to monitor progress (Verceles and Hager, 2015).

Many types of wearable device exist but few have been used in critical care. One study examined activity levels of patients within an Australian critical care unit (Beach et al., 2017) using a motion sensor armband. Although deemed to be a feasible physical activity monitor in this patient group, the motion sensor was unable to capture changes in patient position which, for this low activity population, may be an important factor. An accelerometer, which can detect changes in position, may be a more appropriate method of monitoring activity on critical care (Beach et al., 2017). Therefore, this study will aim to evaluate the feasibility of using a wearable accelerometer device to measure physical activity in patients recovering from critical illness. Those patients at higher risk of physical morbidity based on NICE guidelines (2009) will be recruited as this will allow evaluation of the device in those most likely to be minimally active and whose length of admission is more likely to be long enough to establish the feasibility of using the device within critical care.

5 Objective and purpose

Objectives	Outcome Measures/Endpoints
Primary Objective To establish the feasibility of using a wearable accelerometer to measure the activity levels of patients recovering from critical illness	Feasibility outcomes will be assessed: Wear time (hours per day) Number of days worn Number of adverse events Percentage of activities observed by nursing staff recorded by activPAL™ device. (Reasons for removal of device will be recorded if applicable)
Secondary Objectives To quantify the activity levels of critical care patients on a single critical care unit	Amount of time spent performing activity Amount of time spent sitting in chair Amount of time spent in bed

6 Study Design

6.1 Description of study design

The study will be a single-centre, prospective observational study involving patients admitted to the critical care unit at University Hospital of Wales (UHW).
The study is a feasibility study to evaluate the use of this wearable device within critical care. A priori criteria for feasibility success are recommended by the CONSORT statement extension for feasibility trials (Eldridge et al., 2010). No other study investigating the feasibility of wearable technology was identified which had pre-defined criteria for success, therefore criteria for this study were based on the results of previous studies and the recommended data needed for analysis of physical activity. A wear time of 10 hours per day and at least 3 days of data will be considered as the criteria for feasibility success.

7 Population

The study participants will be patients admitted to UHW critical care unit. It is a 33 bedded mixed unit, providing tertiary care for patients from across South and West Wales. Nursing care is provided 1:1 for level 3 care and 1:2 for level 2 care. Patients present with a wide range of medical conditions including post-surgery, polytrauma, respiratory failure and neurological injury. The severity of illness will be variable, but patients admitted to critical care will require support for at least one organ. The majority of patients are likely to be sedated and mechanically ventilated on admission to the unit or shortly afterwards. Patients who do not require mechanical ventilation may require non-invasive ventilation or support for another organ. All patients are screened by physiotherapists at admission and therapy is provided by a team of physiotherapists as part of routine care.

Approximately 125 patients are admitted to this critical care unit each month. It is estimated that approximately 70% of these patients will meet the exclusion criteria. A target sample size of 15 is deemed to be achievable and adequate to evaluate feasibility for this study with this population.

7.1 Inclusion Criteria

1. Age >18
2. 'At risk' of physical morbidity as determined by NICE CG83 guidelines (Appendix C)
3. Advice from consultee for participation and patient re-consent if appropriate for continuing participation

7.2 Exclusion Criteria

1. Age <18
2. Expected to die during admission
3. Failure to obtain consent or advice,
4. Pre-existing neuromuscular disease
5. Unable to wear activPAL™
6. Open abdomen
7. Active neurological event requiring intervention (e.g. EVD, ICP bolt)
8. Acute spinal cord injury
9. Lower extremity fractures
10. Bedbound prior to admission

The exclusion criteria (with the exception of age, pre-existing neuromuscular disease and unable to wear activPAL™) are the same criteria used by the critical care physiotherapy team to decide if a patient is or is not appropriate for rehabilitation input.

8 Study Procedures

8.1 Recruitment

Participants will be recruited from patients within the critical care unit at UHW. Screening of potential participants will be completed through routine daily reviews of patients admitted to the unit. As far as is possible this will occur in order of admission time. Every new patient admitted to the critical care unit will be screened by the principal investigator or member of the critical care research team, all of whom will be part of the direct clinical care team and as such confidentiality will be maintained in accordance with practice. Reviewing identifiable personal information will be required to identify potential participants to establish if they meet the inclusion criteria. This will be achieved through the review of patient's medical notes and their clinical presentation and will include a short assessment using the National Institute for Health and Care Excellence CG83 guidance short clinical assessment tool. This assessment is routine practice within this critical care unit. See Appendix C for details.

Potential participants who satisfy the inclusion and exclusion criteria will be recruited into the study. See section 8.2 for consent.

8.2 Informed Consent

Due to the nature of this study, the wearable device needs to be fitted within the first 24 hours following admission to critical care. This allows the feasibility of using the device to be evaluated at all stages of a patient's admission within critical care. It is likely that the patients will have undergone intubation and initiation of mechanical ventilation during this time. These patients will be sedated as part of their medical management and as such will not be able to provide consent prior to inclusion. It may not be appropriate to approach the relatives before the first measurement is taken so consent will be waived until discussed with an appropriate consultee. A consultee will be approached as soon as is appropriate, which will generally be within 48 hours after admission. A consultee will be identified after discussion with the participant's family and friends and will be approached by either the principal investigator or a member of the Critical Care research team. This will not be the first contact the consultee has with a member of the healthcare team. They will be able to advise on the presumed thoughts and wishes of the participant. Consultees will be provided with an information sheet and after an appropriate time will be asked to sign a consultee declaration form. If the consultee does not wish for the patient to be included in the study, any data previously collected will be destroyed.

Once the participant has regained capacity and is able to provide their consent they will be provided with a patient information sheet by the principal investigator or member of the critical care research team. The participant will be allowed adequate time (at least 24 hours) for consideration prior to signing a participant re-consent form. The PI or member of the critical care research team must record when the patient information sheet (PIS) has been given to the patient. If the amount of time between the PIS being given and the date of consent is less than 24 hours, the PI needs to explain the rationale for this.

If new safety information results in significant changes in the risk/benefit assessment, the consent form will be reviewed and updated if necessary and subjects will be re-consented as appropriate. Due to the nature of critical illness, it may be some time between inclusion and re-consenting. The re-consent process is to ensure that the participant is willing for the data previously collected to be used as part of the study, and that they are happy for data collection to continue. If they do not consent they will be asked if data previously collected can be used for the study or if they wish for it to be destroyed.

The PI and members of the critical care research team have all received Good Clinical Practice training. The PI has also received valid informed consent training and mental capacity act training. Members of the research team have received additional consent training and are experienced in taking consent from patients and consultees in the critical care environment.

8.3 Screening and Eligibility Assessment

Demographic information of age, medical history and diagnosis will be screened for to check against the inclusion and exclusion criteria for eligibility.

A patient's risk of developing physical morbidity will be assessed using the National Institute for Health and Care Excellence CG83 guidance short clinical assessment tool (see appendix C). If four or more of the criteria are met the patient will be determined as at risk of developing physical morbidity and will be eligible for inclusion in the study.

Participant's baseline mobility status will be checked to ensure exclusion criteria item 10 is not applicable.

No additional tests or examinations are required.

8.4 Baseline Assessments

For all recruited patients, demographic information will be recorded at critical care admission. This information will be gender, date of birth, diagnosis, ventilation status and severity of illness using the acute physiology and chronic health evaluation 2 (APACHE II) score. Length of mechanical ventilation and critical care stay will be recorded on discharge from the unit.

8.5 Data Collection

Data collection will not start until approval is received from the REC and R&D.

Participants will not be expected to do anything different to normal as part of the study except wear an activPAL™ device on their thigh for the duration of their critical care admission. This will be applied to the patient by the PI, clinical supervisor or member of the critical care research team, all of whom will be part of the direct clinical team. This will take place on the critical care unit and will not require the patient to be moved. The device will be placed on the participant's right thigh unless this is prohibited by lines, wounds or dressings when it will be placed on the left thigh. The device will not be placed on areas of skin that appear marked or broken. Fitting the device does not require any specialist training and all instructions from the manufacturer will be followed. The device will be covered in a waterproof dressing so that it will not need to be removed during routine personal care. All devices will be fully charged and calibrated prior to application.

In addition, once the device is fitted, the critical care the nursing staff looking after the participant will fill out a simple record sheet each hour during the day shift to document the participant's activity. The activity observation data collection sheet will be based on one previously used in a UK research study (Connolly et al., 2017). This data is routinely collected by physiotherapists on the unit at each therapist-patient contact but is not routinely collected hourly by the nursing staff. Recording observed activity will be performed to further explore the feasibility of the data collected from the wearable device. Once completed at the end of each shift the record sheets will be stored in the site file and transferred onto an electronic spreadsheet at the earliest opportunity. The site file will be kept in a locked office which is only accessible by the research team

A priori criteria for feasibility success are recommended by the CONSORT statement extension for feasibility trials (Eldridge et al., 2010). No other study investigating the feasibility of wearable technology was identified which had pre-defined criteria for success, therefore criteria for this study were based on the results of previous studies and the recommended data needed for analysis of physical activity. A wear time of 10 hours per day and at least 3 days of data will be considered as the criteria for feasibility success.

8.5.1 Wearable device

The activPAL™ (PAL Technologies Limited) is the chosen wearable device for collecting activity data. The device is CE marked and will be used for its intended purpose. The activPAL™ classifies an individual's activity into periods spent sitting, standing and walking. This wearable accelerometer device sticks to the participant's thigh, which may be more appropriate than the more traditional wrist watch design as critical care patients often have lines and cannulae inserted into their wrist/forearm which may preclude wearing a watch device.

No intervention is being investigated as this is an observational study. Consequently, there are unlikely to be any adverse or detrimental effects to the participant. However, it is possible the participant may experience some mild discomfort from the device on the skin. This will be monitored by the healthcare team. The device will not be placed on areas of skin that appear marked or broken. If there are any concerns the advice of tissue viability nurses will be sought. If the participant experiences discomfort and asks for the device to be removed the device will be taken off. The participant will be asked whether the data collected from the device can be used for the study or if they wish for the data to not be included in the research.

8.6 Subsequent Visits

No specific visits are required once data collection has started unless consent is withdrawn by the participant or consultee, in which case the PI or member of the research team will remove the device. If the participant has a prolonged admission (more than 14 days) The device will need to be re-charged. This takes approximately 3 hours according to manufacturer guidelines. The PI or member of the critical care research team will remove, charge and replace the device as required.

When the participant is discharged from the critical care unit the activPAL™ device will be removed from their leg. They will not be required to do anything else as part of the study. The device will be removed by the PI or member of the critical care research team. In circumstances where discharge from the unit occurs outside of normal working hours for the PI or research team the nurse looking after the patient will remove the device and store it in the research office on the critical care unit. This office will be locked.
For more information refer to the study schedule (appendix A)

8.7 Study Duration

The intended study duration is 12 weeks. Individual participants will only be involved in the study for the duration of their critical care admission. Once they are discharged from critical care no further participation is required.

8.8 Discontinuation/Withdrawal of Participants from Study

Participants are free to withdraw from the study at any time without giving a reason. This will not affect their ongoing care or treatment. Additionally, consultees may wish for participants to be withdrawn without giving a reason before they have been able to re-consent. The participant would be withdrawn from the study in this circumstance.

In circumstances where a consultee does not wish for the participant to be included in the study, any information already collected will be destroyed.

If initial consultee advice has been gained but the participant does not wish to continue at re-consenting, they will be asked if any data that has already been collected should be destroyed or if it can be used for the study.

When a participant is withdrawn from the study the wearable device will be removed and all activity observation stopped. If the participant is withdrawn due to an adverse event, the PI will arrange for follow-up visits or telephone calls until the adverse event has resolved or stabilised. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason.

The reason for withdrawal is all situations will be recorded in the CRF.

8.9 Definition of End of Study

The end of study is the date when the last participant is discharged from critical care.

9 Statistics

9.1 Statistical methods / plan of analysis

This study aims to evaluate the feasibility of using a wearable device and inform the design of a future trial, rather than to detect statistically significant differences; therefore, a formal sample size calculation has not been completed (Arain et al., 2010). The sample size needs to be suitable to allow evaluation of the feasibility parameters taking into account the likely recruitment rate (Eldridge et al., 2016). Based on previous data, it is estimated that 375 of patients will be admitted to the unit within a 12 week period and 70% are likely to meet the exclusion criteria, leaving approximately 112 eligible participants. With a minimum of five devices available and an average length of admission for 'at risk' patients of 14 days, a sample size of 15 is deemed to be achievable and adequate to evaluate feasibility.

Descriptive data (see section 5 primary outcome measures) from the activPAL™ will be summarised using tables and presented using graphs. As there is no hypothesis testing, no statistical tests will be performed. The feasibility outcomes will be compared against the a priori criteria for success.

Comparisons will be made between the activity levels detected by the wearable device, and staff-reported activity using percentage agreement. Descriptive data for the secondary outcome measures (see section 5) will be summarised using tables.

Due to the small size of the study there is no planned interim analysis.

10 Data Management

10.1 Source Documents

Source documents which will be used for completion of CRFs in this study are patient's medical notes and clinical charts. All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by their unique study identification, not by name.

10.2 Direct Access to source data / documents

Only members of the study research team and authorised representatives from the sponsor will have direct access to the source data and study documentation. All source data and study documentation will also be available to external auditors if and when required, and inspectors in the event of regulatory inspection. Access to the final data set will remain with the chief investigator

10.3 Data Recording and Record Keeping

Initial participant screening will be recorded on a paper screening log and entered onto a spreadsheet using Microsoft Excel. Demographic data for participants who are eligible and included in the study will be recorded from source documents onto a paper CRF and this information entered into a spreadsheet using Microsoft Excel. This spreadsheet will contain identifiable information, however, once enrolled in the study participants will be pseudo-anonymised. They will be assigned a unique study identification number which will be used on all other documents so that identifiable information will not be included in any other documentation.

When a participant is enrolled in the study and the wearable device fitted, the serial number of the device will be recorded against the participant identification number on an electronic Microsoft Excel spreadsheet. When the activPAL™ device is removed from the participant the data will be extracted using the software provided by PAL technologies (PAL Analysis v7.2.32, PAL Connect v7.1.2.142, PAL Viewer v1.2.2.25). The results will be entered into a spreadsheet using Microsoft Excel.

Nursing staff will complete an activity observation record chart (Appendix D) as part of the data collection process. This is based on the observation sheet developed by Connolly et al., (2017). After each shift this record sheet will be securely stored and as soon as is possible will be entered into a Microsoft Excel spreadsheet. These will be stored in the site file and kept in a locked office which is only accessible by the research team.

The software used for analysis will be Microsoft Excel and IBM SPSS statistics software. The results of the study will be analysed within Cardiff and Vale University Health Board and some pseudo-anonymised data may be analysed at University College London Institute of Child Health. Data will be transferred using an encrypted memory stick, but only pseudo-anonymised data will be transferred between sites. During data collection all electronic and hard copy data will be stored within C&VUHB.

10.3.1 Archiving

Archiving will be authorised by the Sponsor following submission of the end of study report. Essential documents will be retained for 15 years after completion of the study, according to UCL Institute of Child Health. These documents will be retained for longer if required by the applicable regulatory requirements.

11 Patient Confidentiality & Data Protection

Patient identifiable data, including initials, date of birth and NHS/hospital number will be required for the registration process. The study staff will ensure that the participants' anonymity is maintained. Confidentiality will be maintained in accordance to routine clinical practice and will be respected subject to legal constraints and professional guidelines. The participants will be identified only by a study identification number on the CRF and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act 1998, which requires data to be anonymised as soon as it is practical to do so.

Data will be stored in a secure manner and in accordance with the Data Protection Act 1998. All electronic information will be stored securely on password protected NHS computers at UHW, C&VUHB. Hard copies of CRF forms will be stored in a locked cupboard in the physiotherapy department within UHW, C&VUHB. Once the study is finished data will be kept securely for 15 years in accordance with UCL Institute of Child Health policy. After this it will be destroyed.

The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data and can be contacted at data-protection@ucl.ac.uk.

12 Project Management

The project will be overseen by two research supervisors (Dr. Harriet Shannon, UCL; Ms Ema Swingwood, Bristol Royal Infirmary) and a local clinical supervisor (Mr Paul Twose, Clinical Specialist Physiotherapist, UHW).

The project has been externally peer reviewed by Dr Matt Morgan (Honorary Senior Research Fellow, Consultant in Intensive Care Medicine & Head of Research and Development, UHW), and Dr Una Jones (Cardiff University).

13 Financial Information and Insurance

As the research is being completed as part of an MSc project no additional funding is required for this study.

Cover for negligent harm will be provided by the Great Ormond Street Hospital for Children NHS Foundation Trust through the Clinical Negligent Scheme for Trusts (CNST). No-fault compensation insurance cover for any non-negligent harm will be provided by University College London.

14 Publications Policy

All individuals who have made substantial intellectual, scientific and practical contributions to the study and the manuscript will, where possible, be credited as authors. The status of manuscripts in preparation will be reviewed by the CI and sponsor if required. In all cases where journal policies permit, all investigators who contributed to the study will be acknowledged.

Findings of this feasibility study will contribute to the development of a research project to evaluate the physical activity levels of critical care patients. They will be disseminated to the local critical care team and add to the current understanding of activity levels on critical care.

The results of the study will also be reported and disseminated as follows;

- Peer reviewed scientific journals;
- Conference presentation(s);
- Written report for submission of MSc research project

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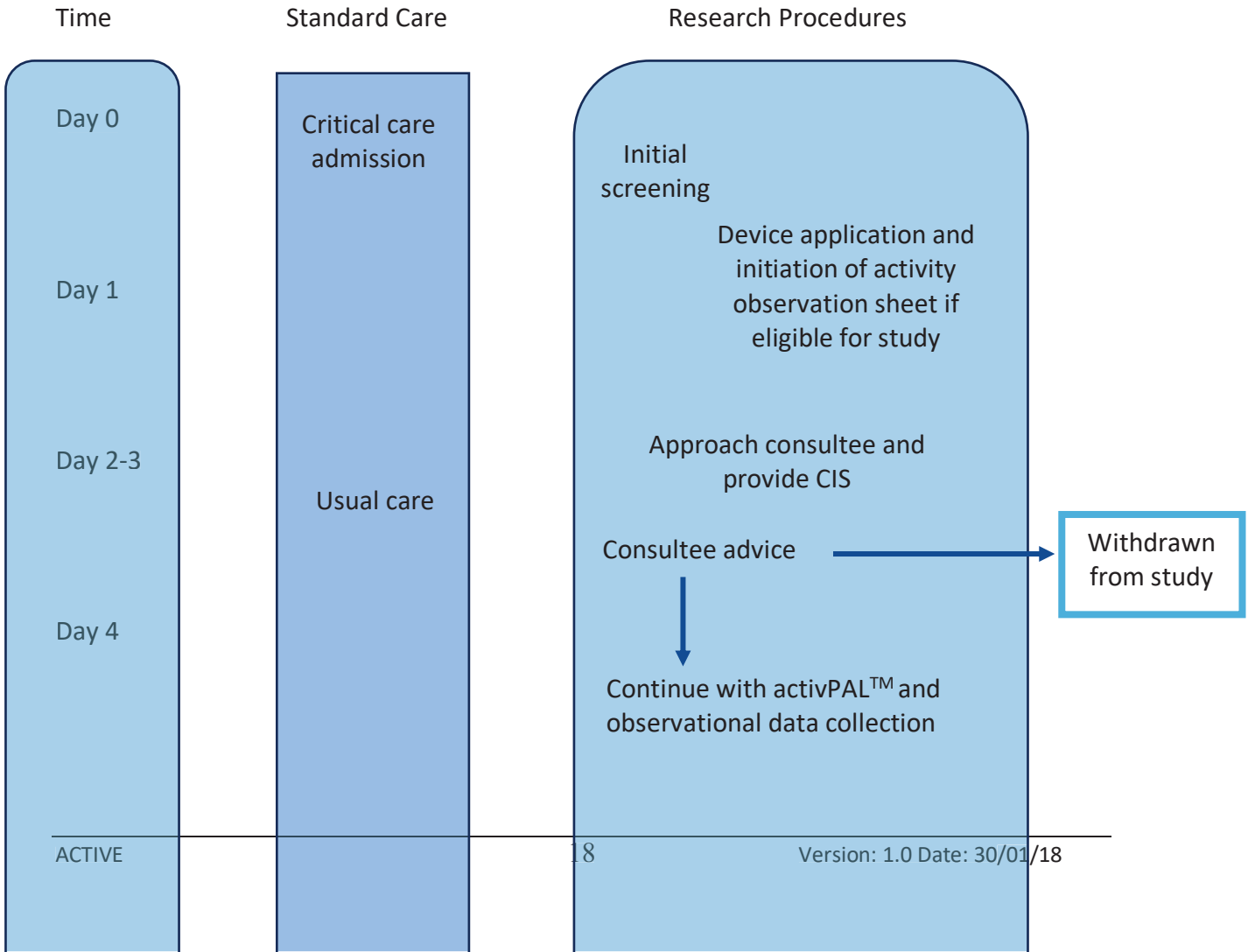
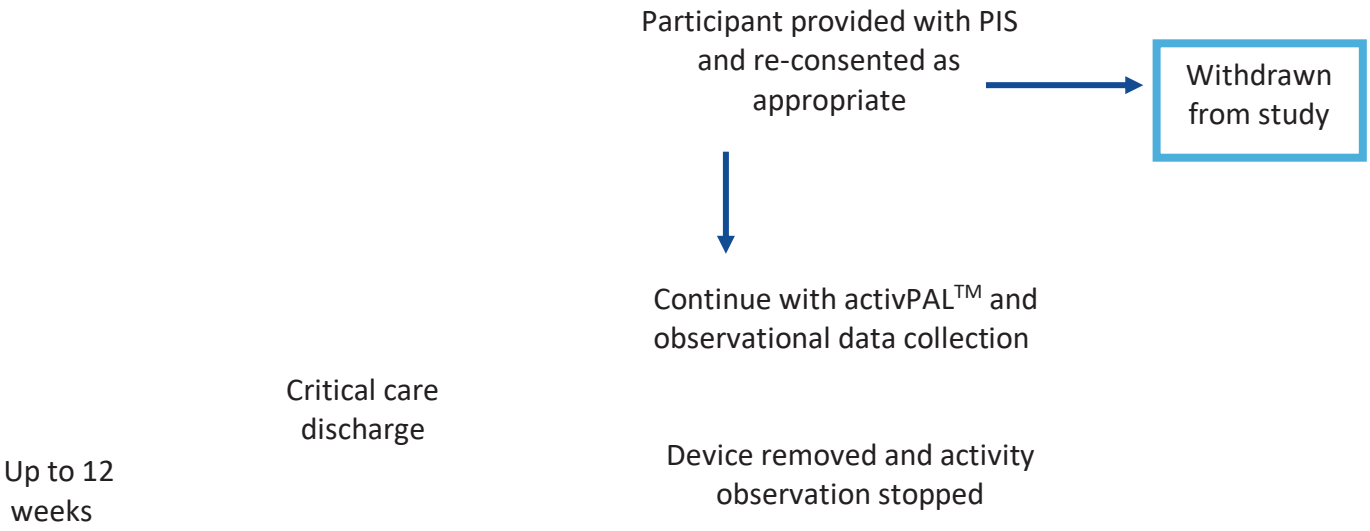
16 Appendices

16.1 Appendix A: Study Flow Chart





16.2 Appendix B: Schedule of Procedures

Procedures	Visits				
	Screening	Baseline	Within 48 hours	Within 3-4 days	Discharge
Eligibility assessment (check inclusion/exclusion criteria)	1				
Demographics	1	1			
Medical history	1	1			
Clinical assessment	1				
Approach consultee and provision of CIS			1		
Consultee advice				1	
Provision of PIS			At appropriate time when participant regains capacity to consent		
Informed consent			At appropriate time when participant regains capacity to consent		
Device application		1			
Recording of observed activity		Started at baseline and continued until discharge from critical care			
Removal of device					1

16.3 Appendix C: NICE short clinical assessment

The NICE clinical guideline 83 short clinical assessment tool will be used to identify patients at risk of developing physical morbidity which is part of the inclusion criteria for this study. Patients will be assessed as part of routine practice and those meeting 4 or more of the following criteria will be eligible for inclusion in the study.

-Unable to get out of bed independently.

-Anticipated long duration of critical care stay.

-Obvious significant physical or neurological injury.

-Lack of cognitive functioning to continue exercise independently.

-Unable to self ventilate on 35% of oxygen or less.

-Presence of premorbid respiratory or mobility problems.

-Unable to mobilise independently over short distances.

16.4 Appendix D: Activity observation recording sheet

ACTIVE [IRAS ID 238464] Ventilation status:

Study ID:

Date: Activity / Time	0700-0800	0800-0900	0900-1000	1000-1100	1100-1200	1200-1300	1300-1400	1400-1500	1500-1600	1600-1700	1700-1800	1800-1900
Routine turn/personal care												
0| Nothing/lying in bed												
0a| Purposeful upper limb movement												
1| Sitting in bed/exercises in bed												
2| Passively moved to chair												
3| Sitting over the edge of the bed												
3a| Seated position in chair												
4| Standing												
5| Transferring from bed ↔ chair												
6| Marching on the spot												
7| Walking with assistance of 2												
8| Walking with assistance of 1												
9| Walking independently with an aid												
10| Walking independently with no aid												

Please note the time and any reasons for occasions when the device had to be removed e.g. for scan, to change dressings, to charge device.