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**The effectiveness of early functional occupation-based retraining therapy in a medical / surgical intensive care unit: study protocol for a single-site feasibility trial (EFFORT-ICU)**

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**STATEMENT OF COMPLIANCE**

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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**1. GLOSSARY OF ABBREVIATIONS AND TERMS**

|  |  |
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| **ABBREVIATION** | **DESCRIPTION** |
| ICU | Intensive Care Unit |
| OT | Occupational Therapist |
| PICS | Post Intensive Care Syndrome |
| ADL | Activities of daily living |
| FIM | Functional Independence Measure |
| MBI | Modified Barthel Index |
| GCS | Glasgow Coma Scale |
| RASS | Richmond Agitation and Sedation Scale |
| IQCODE | Informant Questionnaire of Cognitive Decline in the Elderly |
| HADS | Hospital Anxiety and Depression Scale |
| SF-36v2 | Short Form (36) Health Survey |
| MoCA | Montreal Cognitive Assessment |
| CAM-ICU | Confusion Assessment Method- ICU |
| HRQOL | Health related Quality of Life |
| ICUAW | Intensive care unit acquired weakness |

**2.** **STUDY AND ADMINISTRATIVE INFORMATION**

**2.1 Study Title**

The effectiveness of early functional occupation-based retraining therapy in a medical / surgical intensive care unit: a single-site feasibility trial (EFFORT-ICU).

**2.2 Funding**

The Chief Investigator has been awarded a Metro South Health Research Support Scheme Postgraduate Scholarship to pursue her doctoral studies. The Logan Hospital Occupational Therapy Department will cover all labour and equipment costs associated with the study.

**2.3 Trial Registration**

This protocol has been registered on the following registry:

Australian New Zealand Clinical Trials Registry: **XXXXXXXXX**

**3. INTRODUCTION AND BACKGROUND**

**3.1 Summary**

Admissions to intensive care units (ICUs) are increasing due to an aging population. With advances in medical care, patients are surviving an initial stay in critical care; however they are presenting with ongoing health and mental ability limitations following their stay in intensive care. Recent research has focused on the introduction of early rehabilitation within the ICU in an attempt to reduce the long-term complications regarding physical recovery and cognition. To date the exact scope and type of therapeutic care that occupational therapists can provide, as part of the multidisciplinary team, requires further investigation.

This research project will investigate how useful and effective certain occupational therapy interventions can be in influencing longer term outcomes relating to physical strength and ability to complete simple daily activities such as self-care and grooming, following an early rehabilitation program within an intensive care unit. It will also interview patients who participated in the early rehabilitation program to understand how they felt about participating and whether there are changes that can be made to make their experience more beneficial. The results of this study will help to redefine how we provide occupational therapy in the intensive care unit and may help to support a clearer and more active role for occupational therapists in future critical care settings.

**3.2 Introduction**

Patients admitted to an intensive care unit may experience a lack of control, reduction in sensory stimulation and reduced engagement in meaningful activities ([Howell, 1999](#_ENREF_15)). In addition to being subjected to intrusive interventions, this can lead to a sequelae of cognitive and physical symptoms known as post-intensive care syndrome (PICS), often accompanied by reduced long term participation outcomes ([Elliott et al., 2014](#_ENREF_9)).While physical rehabilitation and early cognitive stimulation have been shown to be effective ([Brummel et al., 2014](#_ENREF_5)), to date there remains little evidence regarding the impact of early task-specific training carried out by occupational therapists directed towards cognitive and functional engagement. It is proposed that early directed cognitive engagement and participation in simple functional therapy on a daily basis may positively impact on a patient’s length of stay in addition to minimising the long term impact of cognitive sequelae on quality of life. This study will contribute to the expanding knowledge base regarding the impact of early occupation-based purposeful activity within the critical care setting.

**3.3 Background Information**

Admissions to intensive care units within Australian hospitals have increased over the last 10 years with approximately 114 000 patients requiring a stay in an intensive care unit between 2013-2014 (Australian Institute of Welfare, 2015). Longitudinal studies on critical illness survival show that 30-80% of patients will acquire post-intensive care syndrome (PICS), a collection of complications including persistent cognitive dysfunction, acquired weakness and post-traumatic stress disorder ([Harvey & Davidson, 2016](#_ENREF_12); [Myers, Smith, Allen, & Kaplan, 2016](#_ENREF_22)). A substantial proportion of patients who survive their initial ICU stay, report significant decreases in quality of life at 6 months post admission ([Khouli et al., 2011](#_ENREF_18)) in addition to increased mortality and associated economic costs, where functional status has deteriorated since premorbid baseline ([Hashem, Nallagangula, et al., 2016](#_ENREF_13); [Rydingsward et al., 2016](#_ENREF_26)).

Early rehabilitation within critical care settings is now considered effective and feasible when carried out within a multidisciplinary approach (Sosnowski et al., 2015; Schweickert et al., 2009; [Brummel et al., 2014](#_ENREF_5)). Altering the approach to rehabilitation through functional participation may lead to further benefits. Critical care practice has not traditionally included therapeutic functional input or early self-care rehabilitation, however there is a growing need for early effective interventions addressing cognitive, physical and psychological functioning to optimise long term functioning (NICE, 2009). Recently Alvarez et al (2017) demonstrated the effectiveness of occupational therapy functional approaches towards delirium in non-mechanically ventilated patients.

There is an ongoing need for research into the feasibility and effectiveness of graded occupational based activities within the intensive care unit for patients who are mechanically ventilated. Howell (1999) provides an approach for delivering self-care tasks within the intensive care unit. Through participation within structured and graded purposeful tasks, the reticular activating system and thus the brain’s ability to interpret and respond to stimuli is challenged such that a state of sensory overload or sensory deprivation is avoided. Appropriately challenging activities leads to positive cognitive and sensory stimulation, which affects the long term participation by improving physical strength and functional ability ([Howell, 1999](#_ENREF_15)). Participation in purposeful activities and task-specific training is supported by a Cochrane review relating to stroke ([Legg, Drummond, & Langhorne, 2006](#_ENREF_21)), which found that patients who participate in occupational therapy interventions are less likely to deteriorate and more likely to gain higher levels of independence in activities of daily living. Meaningful tasks improve cortical reorganisation, which in addition to regular practice and sufficient intensity, impact significantly on recovery within the domains of self-care ([Bayona, Bitensky, Salter, & Teasell, 2005](#_ENREF_3)). While the literature often focuses on the stroke population, concepts are transferable as patients who sustain an intensive care admission have higher exposure to oxygen deprivation at the brain level, ongoing sedation and subsequent prolonged bed rest leading to weakness. Therefore, the literature strongly supports task-specific training as “training which utilizes, as its principal therapeutic medium, ordinary everyday activities which are intrinsically and/or extrinsically meaningful to the patient” ([Hubbard, Parsons, Neilson, & Carey, 2009, p. 181](#_ENREF_16)).

The aim of this research project is to explore the impact on function and patient experience of early functional occupation-based retraining, focusing on early cognitive stimulation and engagement within functional activities in mechanically ventilated patients within an intensive care setting. This will be explored through a pilot feasibility trial comparing standard care to daily targeted occupation-based therapy.

**4. STUDY OBJECTIVES**

**4.1 Research Hypothesis**

Critically ill invasively ventilated patients who participate in an early occupation-based rehabilitation program will demonstrate increases in functional ability, cognition and participation compared to those patients who receive standard medical, nursing and allied health care.

Introduction of regular occupational therapy intervention will be feasible and effective.

**4.2 Primary Objectives**

The purpose of this feasibility study is to inform future study design and add to the body of evidence regarding occupational therapy interventions within intensive care. The study is divided into 2 parts: part 1 aims to investigate the feasibility of an enhanced functional occupational therapy intervention program in a medical / surgical intensive care unit. Part 2 aims to explore the perceptions of participants and his/her significant others in relation to therapy completion. Both parts of the study are carried out concurrently.

Specifically the objectives of the early functional occupation-based activity trial are to:

PART 1:

1. To evaluate the sensitivity of a selection of functional, cognitive, physical and quality of life outcome measures in their ability to capture the effect of the early functional occupation-based activity interventions on participants and their long term outcomes.
2. To identify recruitment and consent rates from eligible participants
3. To evaluate retention rates in response to follow up procedures (attendance at interviews)
4. To test the early functional occupation-based activity intervention in terms of therapist compliance, ability to provide consistent intervention (fidelity), differentiation from current usual practice and amount of staff skill/experience required to carry out the intervention
5. To explore the effect on occupational performance at ICU and hospital discharge, and to evaluate the effect on cognitive, functional and mood factors on discharge from ICU, hospital and 3 months post discharge.

PART 2:

1. To qualitatively evaluate the perception of occupational therapy intervention on a subsection of intervention group participants and their significant others, exploring factors such as experience of participation, satisfaction with treatment content and perceived benefit of participation.

**4.4 Outcome Measures**

Patient demographic data including age, gender, date of admission to ICU, co-morbid diseases and ICU admission diagnosis and hospital discharge destination will be collected from the medical records. Severity of illness will be measured using the Acute Physiology and Chronic Health Evaluation II APACHE II scoring system ([Knaus WA, 1985](#_ENREF_19)).

Measures of ICU and hospital length of stay and duration of mechanical ventilation will be extracted from the Australia New Zealand Intensive Care Society ANZICS Adult Patient Database (APD). The following measures will be completed at the timepoints indicated in Appendix B: Table 1.

Primary Outcome Measure:

Independence within activities of daily living will be measured using the Functional Independence Measure (FIM™). The FIM will quantify the participant’s functional and cognitive status at ICU and hospital discharge, as well as at 3 months follow up from hospital discharge. This tool is validated for use in the critically ill population ([Schweickert, Gehlbach, Pohlman, Hall, & Kress, 2004](#_ENREF_28); [Zanni et al., 2010](#_ENREF_30)) and provides reliable information regarding patient functional change during rehabilitation across various hospital and community settings ([Ottenbacher, Hsu, Granger, & Fiedler, 1996](#_ENREF_23)). The FIM will be conducted within 24 hours of the expected ICU and hospital discharge or on the Friday before the expected discharge if likely to occur over the weekend. It will also be administered during the 3 month follow up session. The FIM will be performed by an occupational therapist blinded to participant assignment groups and who does not actively work on the Intensive Care Unit.

Secondary Outcome Measures:

1. The Modified Barthel Index (MBI) is used to measure functional ability and serves as a secondary measure included for its ability to detect change within self-care and functional tasks. The MBI is commonly used in hospital settings, although recent research has highlighted ceiling and reliability effects ([de Morton, Keating, & Davidson, 2008](#_ENREF_8)). However it remains highly recommended within the field of functional outcome measurement (RCP, 1992). The MBI also provides an additional source of comparison across multiple earlier critical care rehabilitation studies. The MBI will be assessed at multiple time points including allocation to intervention, ICU discharge, hospital discharge and 3 months follow up.
2. The Montreal Cognitive Assessment (MoCA) is a screening measure of cognition and assesses multiple domains of cognition including attention, memory and visuospatial relations. It is commonly used within the acute and community setting and demonstrates high criterion and convergent validity within the acute care setting ([Lam et al., 2013](#_ENREF_20)). The MoCA will be administered at discharge from ICU, hospital and 3 month follow up using alternate versions at each time point ([Costa et al., 2012](#_ENREF_7)).
3. Grip strength will be measured using a dynamometer (Jamar) ([Samosawala, Vaishali, & Kalyana, 2016](#_ENREF_27)) at discharge from ICU, hospital and 3 month follow up. Grip strength is used as a measure of Intensive Care Unit Acquired Weakness (ICUAW) and infers a relation between weakness and inability to complete functional activities independently ([Ali et al., 2008](#_ENREF_1)).
4. The Short-Form (36) Health Survey (SF-36v2™) will provide a baseline and post discharge measure of participants’ health related quality of life (HRQOL). The SF-36v2™ is a validated and reliable tool ([Brazier et al., 1992](#_ENREF_4)) and has been further validated within the ICU setting ([Chrispin, Scotton, Rogers, Lloyd, & Ridley, 1997](#_ENREF_6)). This will be completed at ICU discharge, and 3 month follow up.
5. Sedation and delirium status will be measured using the validated Richmond Agitation Sedation Scale (RASS) ([Ely et al., 2003](#_ENREF_11)) and the reliable and validated Confusion Assessment Method for ICU (CAM-ICU) ([Ely et al., 2001](#_ENREF_10)). These scores are regularly administered by nursing staff throughout a 24 hour period. RASS and CAM-ICU scores immediately prior to and following early occupation based interventions will be collected for additional analysis. RASS and CAM-ICU scores for the control group participants will be collected daily at 9am.
6. The Glasgow Coma Scale (GCS) is used to evaluate the level of consciousness in patients with neurological conditions or severe injury ([Barlow, 2012](#_ENREF_2)) and will be collected daily at 9am.
7. Hospital Anxiety and Depression Scale (HADS) is a measure of emotional distress regarding anxiety and depression. It has been validated with the use of critical care survivors ([Jutte, Needham, Pfoh, & Bienvenu, 2015](#_ENREF_17)). It will be administered at discharge from ICU, hospital and 3 month follow up.
8. The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) (short form) is a reliable and validated measure used to screen for cognitive dysfunction ([Park, 2017](#_ENREF_24)). It will be used as a screening tool for eligibility to the trial and will be completed by the participant’s substitute decision maker.

**5. STUDY DESIGN**

**5.1 Description of Study Design**

Prospective single-centre, single blinded, equally randomised controlled trial (1:1) comparing standard occupational therapy care to early occupation-based purposeful activity care. The study will be conducted in a level two adult eight bed Intensive Care Unit at Logan Hospital, Brisbane. See Appendix A: Figure 1 for trial flowchart.

**5.2 Study Procedures**

Intervention Group: Early occupation-based purposeful activity interventions will be administered based on a graded plan (according to the Richmond Agitation and Sedation Scale (RASS) and medical stability). A manualised intervention strategy will be followed to ensure consistency of approaches. The aim of the trial is to implement an early occupational performance-based and cognitive stimulation intervention, focusing in particular on the amount, structure and quality of occupation-based therapy. Interventions will be graded according to functional ability. Patients in the intervention group will receive a minimumtotal of 60 minutes daily engagement within self-care / grooming tasks adapted to current functional ability where a cognitive component will be incorporated within the functional task. Intervention activity options will be based on a leisure / premorbid lifestyle interview with relevant next-of-kin to enable appropriate activity choices for optimised participation.

Cognitive stimulation tasks incorporated within the functional tasks will be modified according to cognitive level. Cognitive tasks incorporated within functional activities will include sensory stimulation and sensory modulation, daily orientation, engagement and reflection of task performance (using judgement and insight), attention challenges through task set-up, active daily planning and goal setting, and iPad tasks impacting on or enhancing functional participation.

Functional tasks will include hand-over-hand facilitation of grooming tasks, self-care activities in the bed, bedside or bathroom, and leisure related activities.

All interventions will be delivered by the trained specialist ICU occupational therapists based on the intervention manual. Two reserve therapists whose primary caseload is not ICU will be trained to ensure all functional sessions can be completed even in absence of usual ICU staff (annual leave / unexpected absence). All occupational therapists expected to work within the ICU will be trained and familiar with the intervention manual prior to research initiation.

Control Group: The control group will receive usual occupational therapy care. At Logan Hospital an occupational therapist attends daily clinical ward rounds within the intensive care unit. Patients are identified based on clinical needs and daily prioritisation guidelines for operation within an acute hospital. Core non-functional risk remediation activities such as splinting (for example foot drop) and pressure cushion provision are provided on an immediate basis when clinical need is identified. Functional therapy is completed at the discretion of therapists and clinical caseload weighting and may be absent in most units.

**6. STUDY POPULATION**

**6.1 Inclusion Criteria**

Patients admitted to the ICU will be included if they are aged over 18 years, and are expected to require invasive mechanical ventilation for greater than 48 hours.

**6.2 Exclusion Criteria**

Patients will be excluded from the trial if:

1. Admission to ICU not requiring mechanical ventilation
2. They have been readmitted to ICU from current hospitalisation
3. They have a poor level of functional ability prior to admission ( requiring carer assistance / high dependency level in activities of daily living as measured by a Modified Barthel Index score <40)
4. Have a pre-existing severe cognitive deficit (as identified by completion of the short form IQCODE with an average score above 3.31-3.38 )
5. Have a pre-existing significant mental health disorder impacting on participation
6. A withdrawal of treatment is expected to occur within the next 24 hours or they are not expected to survive the current ICU admission
7. They live interstate and would be unable to attend the 3 month follow up
8. They are unable to communicate in English.

Patients admitted over the weekend where occupational therapy intervention cannot be immediately initiated, will continue to participate in the trial, and therapy will begin on the first working day.

**6.3 Recruitment, Randomisation and Blinding**

**Recruitment**

A consecutive sampling model will be used where all patients who meet the eligibility criteria will be invited to participate. All patients admitted to the intensive care unit will be screened for eligibility on a daily basis by research and clinical staff. Patients meeting the study criteria will be identified within 24 hours of admission by the research team. Patients who meet the criteria or their substitute decision maker will be provided with information regarding the study’s purpose and will be invited to participate in the study by an investigator. Written informed consent will be sought. Once able, the participant will be asked to provide deferred consent if the substitute decision maker initially gave consent on his or her behalf.

**Randomisation:**

Following consent, participants will be randomly allocated to either the intervention group who will receive early occupation-based activity or the control group who will receive standard occupational therapy, medical, nursing and physiotherapy care. Patients will be randomised into the intervention and control groups via computer generated numbers (<http://www.randomization.com/>) which will be sealed in consecutively numbered opaque envelopes. The production of the envelopes will be performed by research support staff who will not be involved in the interventions.

**Blinding**

It will not be possible to blind the research team or the participants to group assignment. However participant outcome measurement assessors will be blinded to participant assignment as they will be other occupational therapists who work at the hospital but not in the ICU, or with patients who have been transferred from ICU.

**6.4 Qualitative Follow Up**

Part 2 of this study includes the qualitative component and will be guided by interpretive description (Thorne, 2004) to explore the lived experience of participants receiving the intervention and the perception of family members / most involved substitute decision maker. All patients from the occupation-based therapy intervention group, will be invited to undergo in-depth semi-structured interviews targeted at exploring their experience of engaging within the early occupation-based purposeful activity program, at 3 months post hospital discharge.

Interviews will be conducted in a private, wheelchair accessible room at Logan Hospital. Funding for transport will be provided to facilitate attendance at interviews. Wheelchair accessible transport will be organised for participants who require specialist accessibility options.

**7. SAMPLE SIZE AND DATA ANALYSIS**

**7.1 Sample Size Estimation and Statistical Power**

A sample size of 30 participants has been chosen, based on recommendations regarding pilot and feasibility trials evaluating outcomes (Dobkin, 2009). Fifteen patients from the intervention group will be included within the qualitative component carried out at 3 months post discharge from hospital.

**7.2 Data Analysis Plan**

All data will be entered into a purposefully designed Excel database and exported into SPSS version 22.0 for analyses. Descriptive statistics will be used to determine the distributions of the data for the intervention and control groups and to test whether statistical assumptions for parametric tests are achieved. Groups will be compared to identify baseline differences on measures. Analyses will be performed on an intention-to-treat and per protocol method. Continuous variables that are normally distributed will be compared between the groups at each follow-up using an independent groups t-test. Effect sizes will be calculated using Cohen’s *d*. Non-parametric analysis will be conducted for continuous variables that are not normally distributed. Categorical variables will be compared with the chi-square statistic. A *p* value of 0.05 will be considered statistically significant. Where appropriate, analyses will be reported with mean differences and 95% CI. Protocol violations regarding the intervention manual strategies will be noted. Imputation will be used to correct for missing data.

Semi-structured qualitative interview data will be transcribed and analysed through thematic analysis to identify key perceptions, self-reported experience and highlight factors that may contribute to future clinical care design.

**7.3. Analysis of Session Content**

All case notes of patients seen by occupational therapy will be audited and analysed to categorise common therapeutic interventions used, and determine fidelity with respect to adherence to manualised intervention protocol. Deviations from the protocol will be reviewed. Casenotes for patients experiencing usual care will also be analysed to identify if any cross-over of groups occurred.

**8. PARTICIPANT SAFETY AND RISK MANAGEMENT**

There is no anticipated harm associated with participating in the early rehabilitation program. All occupational therapists carrying out the interventions will be trained and experienced ICU staff. Unforeseeable changes in medical condition will influence the type and content of therapy sessions and there may be a period where therapy is reduced under the guidance of the medical team until organ system stabilisation has occurred. Therapy will be initiated as soon as both medical and allied health teams identify that safe mobilisation practices can be re-implemented.

Occupational therapy staff completing the outcome measures are familiar with the complex caseload of patients and will be sensitive to the vulnerable nature of the questions and outcome measures used. Staff will invite participants to have a family member / support person present if they wish, and will cease questioning if a participant becomes distressed. Emotional and physical safety of the vulnerable participants will be their primary concern.

The qualitative interviews will be carried out by the CI who is an experienced ICU therapist and is familiar with the sensitive and vulnerable nature of the participants. It is acknowledged that asking participants to recall their time on ICU has the potential to be distressing. Questioning will cease if the participant becomes distressed, and a family member/ support person will be invited to attend should they not already be present. Participants will be provided with further information regarding community support services or organisations should they need ongoing support with coping.

**9. CONSENT AND ETHICAL CONSIDERATIONS**

Ethical approval will be sought from the Metro South Hospital and Health Service Human Research Ethics Committee (EC00167) and The University of Queensland prior to the study commencement.

**9.1 Consent**

Participants or their substitute decision maker will be invited to provide consent. Further informed consent will be sought from the substitute decision maker to act as a participant during the qualitative interviews. Eligible participants will be informed that participation in the study is voluntary and if they choose not to participate, or if they choose to withdraw from the study after consenting, this will in no way affect their normal treatment at the hospital.

The study will be explained verbally by the chief investigator or her nominated delegate. The participant or the substitute decision maker will be given the opportunity to read the information sheet and ask any questions prior to participation in the study. The participant or the substitute decision maker will be provided with a copy of the signed consent form and the information sheet and any other documentation discussed throughout the consent process.

**9.2 Confidentiality and Security**

All patient data (paper copy and secure computer files) pertaining to the study will be stored maintaining confidentiality in accordance with local legislation on privacy and the use of health data.

Confidentiality of all patient information will be safeguarded through coding mechanisms and stored in secure locked conditions with access limited to study personnel. Electronic files will be password protected. The chief investigator will maintain the confidentiality of all study documentation and / or participants, and take measures to prevent accidental or premature destruction of these documents, and prevent access to this data by any unauthorised third party.

The investigator will retain study documents for at least 15 years after the completion of the study. Study documents will be disposed of securely after 15 years – paper documents will be shredded and computerized data will be permanently erased and back-ups physically destroyed.

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**Appendix A: Figure 1: Trial Flow Chart**

All patients admitted to Logan ICU and mechanically ventilated >48 hours

Consent and randomisation

Baseline Data Collection1

Ineligible Subjects

n =

Consent declined

n =

Early Occupation-Based Retraining

n =

Daily Assessments2

Standard OT care

n =

Daily Assessments2

Patient died n =

Withdrawn n =

ICU Discharge Assessments3

n =

Hospital Discharge Assessments4

n =

3 Months Post Discharge Assessments5

n =

Patient died n =

Withdrawn n =

Lost to Follow Up n =

Baseline Data Collection1 *Short IQCODE, APACHE II, Demographics, Reported MBI, Leisure checklist*

Daily Assessments2 *CAM-ICU, GCS, RASS*

ICU Discharge Assessments3 *MBI, Grip Strength, FIM, SF-36, MoCA, HADS*

Hospital Discharge Assessments4 *MBI, Grip Strength, FIM, MoCA, HADS*

3 Months Post Discharge Assessments5 *MBI, Grip Strength, FIM, SF-36, MoCA, HADS*

Other Measures: *occupational therapy dose, intervention fidelity, case notes analysis of sessions*

Data Analysis and Dissemination

Participant and Substitute Decision maker Interviews at 3 Month Follow Up

**Appendix B: Table 1: Outcome Measure Schedule**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Measure** | **Enrolment** | **Allocation to Intervention** | **ICU Stay** | **ICU Discharge** | **Hospital Discharge** | **Follow up 90 days** |
| Eligibility Screen | x |  |  |  |  |  |
| Informed Consent | x |  |  |  |  |  |
| Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) | x |  |  |  |  |  |
| Demographic |  | x |  |  |  |  |
| APACHE II |  | x |  |  |  |  |
| Modified Barthel Index (MBI) |  | x  (Reported) |  | x | x | x |
| Grip Strength (Dynamometer) |  |  |  | x | x | x |
| Functional Independence Measure (FIM) |  |  |  | x | x | x |
| Short Form (SF-36v2) |  |  |  | x |  | x |
| Hospital Anxiety and Depression Scale (HADS) |  |  |  | x | x | x |
| Confusion Assessment Measure (CAM-ICU) |  |  | Daily |  |  |  |
| Glasgow Coma Scale (GCS) |  |  | Daily |  |  |  |
| Richmond Agitation and Sedation Scale (RASS) |  |  | Daily |  |  |  |
| Montreal Cognitive Assessment (MoCA) |  |  |  | x | x | x |
| Dose of Occupational Therapy |  |  | Daily |  |  |  |
| Intervention fidelity checking through notes audit |  |  | Daily |  |  |  |

**Appendix C: Participant and Substitute Decision Maker Interview Guide**

*Introduction:* Thank you for taking the time to meet with me to today. During this interview, I am hoping to explore how you felt and what you think about your recent stay in the intensive care unit. In particular I want to focus on the occupational therapy (or OT) sessions you had with myself or the other therapist. If you are not sure what they were exactly, that’s ok, as I will try to give some suggestions of what we may have done with you. Sometimes it can all be a blur!

There is no right or wrong answer as this interview is designed to explore your experience. With your permission, I’m going to be recording this interview so that I can go over what you said and it helps me to remember our conversation. We have an hour together to talk about your experience so there is no rush. If you want to stop at any time, you just need to let me know and we can take a break.

1. Can you tell me in your own words why you were recently admitted to the intensive care unit at Logan Hospital?
2. Can you tell me how much you remember about your stay in ICU?
3. Do you recall working with an occupational therapist (myself, Andrea, or Simone) while you were in the intensive care unit?
4. Can you tell me a little about what you may have done with us during your treatment sessions?
5. How did these sessions make you feel?
6. What did you like about the sessions, if anything? Can you describe any benefits to you of having occupational therapy while you were in ICU?
7. Was there anything you didn’t like about the OT sessions? Do you have any recommendations for what the OTs could do differently with patients in the future?
8. Overall what was your experience of working with occupational therapists in the intensive care unit?
9. Can you tell me a bit about your time after ICU, while you were on the ward?
   1. What health professions did you see?
   2. What was your daily routine like?
10. Can you tell me about your time at home?
    1. What was your routine like? What did you do?
    2. What did you find easy? What did you find difficult?
    3. Are you experiencing any ongoing concerns?