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| **protocol** |
| Feasibility of a patient- and family-mediated intervention to improve functional ability following recovery from critical illness |
| Version Number: 2  Date: 18/11/2020 |
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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 stipulations of this protocol, the conditions of the ethics committee approval, the NHMRC *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018*, and the NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2018)*. If the project is a clinical trial, it will comply withthe *Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)*. |

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## Background

Improvements in clinical management of critically ill patients has resulted in a mortality reduction for critically ill patients; however improved survivorship can also result in significant and longstanding impairment following recovery. More than 50% of survivors exhibit intensive care unit-acquired weakness (ICU-AW) at discharge and half will have a cognitive, mental or physical problem at one year.[1](#_ENREF_1) The consequences of ICU-AW are considerable and include extended intensive care and hospital stays, increased healthcare-related costs and mortality, and impaired physical function and quality of life.

Weakness and reduced physical function have a substantial impact on activities of daily living (ADLs), an outcome of high importance to patients and their families. Two fundamental care practices (nutrition and exercise) may contribute to improved physical recovery. Optimal energy and protein intake in critical illness are associated with fewer complications, lower mortality and perceptions of faster recovery. Similarly, exercise interventions, such as bed exercises and mobilisation, are safe and have been shown to reduce the length of ventilation and ICU stay while also improving physical function.[2](#_ENREF_2) It is suggested that to maintain optimal muscle mass, strength and physical function, the combination of nutrition and exercise may have the greatest impact on the physical recovery of survivors of critical illness.[3](#_ENREF_3)However, evidence-practice gaps exist in relation to both optimising nutrition and facilitating exercise during the critical illness and recovery phases, with gaps in hospital processes (including limited mobilisation and inadequate nutrition intake) accounting for the majority of disability observed post-hospitalisation.[4](#_ENREF_4)

Given that functional recovery and ability to independently resume ADLs is of high importance to patients and their families, it is important to support their participation in optimising nutrition and exercise during, and following recovery from, critical illness. Partnering with family members of critically ill patients has been shown to improve outcomes for both the patient and the family member. Specifically, partnering with families has been shown to reduce family members’ incidence of anxiety, depression and other psychological symptoms long-term.[5](#_ENREF_5) Our work to date suggests that families are willing and able to partner with health professionals in promoting nutrition and exercise in the ICU and during hospital-based recovery, provided they are furnished with the necessary knowledge and skills. However, the optimal way to engage families in the role they can and want to play, and how best to capacitate them as advocates and partners in care while helping them maintain their own wellbeing, is unknown.

## Study Objectives

### Research Question and Aims/objectives

The broad aim of the study is to demonstrate that supporting active patient and family engagement in nutrition and exercise (active mobilisation and rehabilitation) during recovery from critical illness will result in better patient- and family-centred outcomes compared with usual care.

Before we can assess these long-term patient- and family-centred outcomes we need to evaluate, in a Phase II trial, the feasibility, intervention acceptability and short-term effectiveness, which is the specific aim of the study proposed here.

Primary research question (Phase II trial)

Is it feasible to undertake a randomised, controlled trial of a patient- and family-mediated intervention to improve nutrition intake and exercise of adult patients recovering from critical illness?

Secondary research questions:

In critically ill patients at increased nutritional risk and with risk factors for ICU-acquired weakness, does a patient- and family-mediated intervention to improve nutrition intake and exercise during recovery from critical illness result in:

* Improved protein and energy intake and increased duration of active mobilisation and rehabilitation throughout hospitalisation;
* An increase in the extent to which family members are engaged in caring or advocating for their family members; and
* A better experience of patient participation?

Co-primary research questions (Phase III trial):

In critically ill patients at increased nutritional risk and with risk factors for ICU-acquired weakness, does a patient- and family-mediated intervention to improve nutrition intake and exercise during recovery from critical illness result in improved physical function?

In family members of critically ill patients at increased nutritional risk and with risk factors for ICU-acquired weakness, does a patient- and family-mediated intervention to improve nutrition intake and exercise during recovery from critical illness result in a decrease in psychological stress (anxiety, depression and PTSD) and increase satisfaction?

### Hypothesis

We hypothesise that the trial will be feasible (as determined by ability to recruit 80% of eligible participants, retain 70% of participants to 6-month follow-up, achieve 90% intervention fidelity and collect 75% of all outcome measures) and the intervention acceptable to patients, family members and health professionals as determined by the Theoretical Framework of Acceptability questionnaire.

We also hypothesise that the trial will result in improvements in short-term outcomes including nutrition adequacy and exercise throughout the hospital stay.

## Methodological Approach

A phase II, mixed methods, open-label, randomised, clinical trial of a patient- and family-mediated intervention to improve functional recovery following critical illness compared with usual care.

### Study Sites/Settings

Gold Coast University Hospital intensive care unit (ICU) and inpatient medical and surgical wards.

### Study Population

All patients ≥18 years of age admitted to ICU with a projected duration of ICU dependency of >72 hours OR patients with two or more organ failures will be eligible to participate. Patients not expected to benefit will be excluded, including those who: are expected to die or for whom life-sustaining treatments will be withdrawn in ICU; are not ambulating independently prior to ICU admission (use of a gait aid permitted); have lower extremity injury or impairments (e.g. stroke) that prevent them walking prior to hospital discharge; have pre-existing primary severe systemic neuromuscular disease resulting in severe weakness (e.g. Myasthenia Gravis); are hospitalised for >5 days before ICU admission; or are expected to be transferred to another health care facility prior to hospital discharge.

Family members of eligible patients will include both relatives and close friends who know the patient well and either live with, or are involved in, the ongoing care of the patient provide support and/or with whom the patient has a significant relationship. Family members must be ≥18 years old, be expected to visit the patient regularly (≥3 times/week) and be able to communicate in English (verbally and in writing).

### Recruitment/ Selection

Newly admitted patients will be screened daily against the inclusion/exclusion criteria by an experienced research assistant. If the patient is eligible and also has a family member who is eligible to participate, the family member will be approached in person by the research assistant to provide consent. Following consent, randomisation will occur via the randomisation function within REDCap. The allocation table will be created by a researcher external to the study team. The system will confirm eligibility and use a computer-generated randomisation schedule, allocating patients 1:1 to either the intervention or control group by the method of permuted blocks of random, undisclosed size. The randomisation system has a robust audit trail and will maintain concealment of future allocations.

A study sample size of 50 patients (25 per group) will be recruited, which is a sample size like other feasibility studies.

### Consent

Patients and their family member are both participants in this study. An information sheet and consent form will be presented to the family member by a research assistant. All questions will be answered at that time and if the family member needs more time to consider participation the research assistant will return at a later predetermined time.

Patients in ICU are highly dependent on medical care and unable to give direct consent and are entitled to participate in research where it is likely that the research will lead to increased understanding or improvements in their care. Due to the nature of the patient population in ICU often patients are unable to provide initial consent to participate. In this circumstance following principles of Good Clinical Practice (GCP), consent from eligible family members will be obtained within 96 hours following ICU admission. Consent will be sought from the patient if or when they are able to do so. Participants will be able to withdraw their consent at any time throughout the study by contacting the research team or GCHHS HREC department.

### Risk Mitigation Procedures

The research team anticipates there are minimal risks associated with this trial. The primary aim intervention is premised on developing capacity of patients and families to engage and partner with health professionals. The intervention involves active patient and/or family engagement and could potentially increase fatigue or stress. We have experience with delivering similar interventions and have developed strategies to assess for and mitigate against these potential risks.

Data collected to assess the performance of physical activity include:

* 1. 6-minute walk test: is a low-risk, submaximal exercise test commonly used to assess exercise tolerance. This test will be performed by a trained healthcare professional, with the ability to assess and maintain patient safety during testing.
  2. Strength tests of upper and lower body which include active participation of patients include the Medical Research Council sum-score (manual strength of six muscle groups – shoulder abduction, elbow flexion, wrist extension, hip flexion, knee extension, ankle dorsiflexion – is evaluated bilaterally); Short Physical Performance Battery (measure balance, walking speed, and rising from a chair); Functional Status Score for ICU (assesses patient assistance required to roll in the bed, sit up from the supine position, stand from the sitting position, sit up at the side of the bed, assistance to walk/wheel); hand grip strength and quadriceps force. These tests used are low risk tests and will be performed by a trained healthcare professional, with the ability to assess and maintain patient safety during testing.
  3. Additional self-report measures of physical or functional performance, quality of life, psychological response, family satisfaction, family engagement or patient participation are collected through self-report or by proxy report (from the family). None pose a risk greater than fatigue. Strategies will be used to assess the patient and/or their family during completion of these instruments with adjustments made to accommodate individual requirements.
  4. For the phone call follow up at 6-months, the highest risk we foresee is inconvenience for participants, and participants can withdraw from the interview at any time.

### Participant Withdrawal Procedures

Participants will be able to withdraw their consent at any time throughout the study by contacting the research team or GCHHS HREC department.

### Study Procedure (Intervention)

The intervention is based on the OPTICS nutrition intervention, which has been systematically evaluated over the past 5 years.[6](#_ENREF_6),[7](#_ENREF_7),[8](#_ENREF_8) We have augmented the intervention to incorporate aspects of exercise and mobility throughout critical illness recovery because it is suggested that nutrition and exercise in combination may have the greatest impact on physical recovery of survivors of critical illness.[3](#_ENREF_3) The intervention is premised on developing capacity of patients and families to engage and partner with health professionals; thus our education focuses on capacitating the patient and family to interact with health care providers and encourage them to ask questions about the nutrition and exercise being received by the patient. We use a variety of dissemination methods including face-to-face education, written information and video clips,[9](#_ENREF_9),[10](#_ENREF_10) which reinforce information provided (exercise videos to be developed as part of this grant) and also provide an exemplar of engagement between patients/families and health care providers in the ICU[11](#_ENREF_11) and following transfer to the ward.[12](#_ENREF_12),[11](#_ENREF_11) During face-to-face education the ‘teach back’ method[13](#_ENREF_13) will be used to allow for assessment of information comprehension. Intervention components and timing are detailed in Table 1.

Table 1: Intervention components

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|  | Nutrition | Mobilisation |
| ICU | Nutrition risk assessment by dietitian with results communicated to the clinical team verbally and in the medical record | A pre-admission level of function assessed by the Clinical Frailty Scale[14](#_ENREF_14) and the Pre-ICU baseline FSS-ICU[15](#_ENREF_15) with data obtained from the patient or proxy |
|  | Face-to-face education focusing on nutrition support strategies and progression of exercise and mobility in the ICU | |
|  | Touch points during ICU admission by the dietitian to communicate nutrition goals and nutrition adequacy | Touch points during the ICU admission by the physiotherapist to communicate exercise/mobility progression to the family as per the ICU Mobility Scale.[16](#_ENREF_16) |
| Preparation for discharge | Provide patient (if able) and families with information about current nutrition status (nutrition support, eating by mouth, swallowing difficulty), nutrition the patient can expected on the ward. | Provide patient (if able) and families with information about the plan for exercise progression on the ward. |
|  | Introduction of a nutrition and exercise diary to be completed by the family (or patient, if able) to record the patient’s nutrition intake for each meal. | |
|  | Setting of exercise and nutrition-related goals and monitoring/follow-up plan for home | |
|  | Information reinforced through viewing of the ward-based video which is specific to nutrition after discharge. | Information reinforced through viewing of the ward-based video which is specific to exercise and mobility on the ward. |
| Ward | Nutrition care plan for the ward developed by the ICU and ward dietitians and communicated to the patient and family | Exercise and rehabilitation plan for the ward developed by the ICU and ward physiotherapist and communicated to the patient and family |
|  | Handover between ICU/Ward dietitians and physiotherapists | |
|  | Provide 2 or more Oral Nutrition Supplements per day (approximately 400 kcal/day)[17](#_ENREF_17) |  |
| Prior to hospital discharge | Ward dietitian to work with patient and family to develop a nutrition plan for implementation after hospital discharge which will be provided in writing. | Ward physiotherapist to work with patient and family to develop an exercise plan for implementation after hospital discharge which will be provided in writing. |

### Outcome Measures

For the purpose of this Phase II study, we are evaluating process measures and more proximal (short-term) outcomes (Table 2).

Table 2 Process and short-term outcomes

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| **Process Measures** | |
| Feasibility | Percentage of eligible participants recruited to the study |
|  | Percentage of recruited participants who remain in the study for 6-month follow |
|  | Time taken to complete outcome assessment |
|  | Compliance with intervention components |
|  | Number of patients able to engage in the intervention |
| Acceptability | Assessed using the theoretical framework of acceptability (TFA)[18](#_ENREF_18) which consists of seven component constructs: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy. |
| **Short-term outcome measures** | |
| Nutrition | Nutrition adequacy in ICU |
|  | Nutrition adequacy on the ward (3-day calorie count) |
|  | Consumption of oral nutrition supplements |
| Exercise | Type and frequency of exercise in ICU |
|  | Duration of mobilisation on the ward (via activity tracker) |
|  | Time to achieve functional milestones: sitting out of bed, standing, mobilising with assistance and mobilising independently |

For a Phase III study our patient outcome measures would be functional status and we will follow the recommendations from a recent expert consensus statement[3](#_ENREF_3) (Table 3). As part of feasibility assessment these data will be collected in the Phase II study.

**Table 3: Patient Outcome Measures**

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| **Functional Status** | | |
| *Timing* | *Outcome measure* | *Description* |
| At or before hospital discharge | 6-minute walk distance | **The 6MWT** is a reliable, valid, responsive measure of physical function[19](#_ENREF_19) for survivors of acute respiratory failure Implementation of the test will be based upon the 2014 ATS standards, with adaptation, as needed, for the in-patient setting and ICU survivor population.[20](#_ENREF_20) To be used as primary outcome measure for future Phase III trial. |
| Muscle strength | **The Medical Research Council (MRC) Scale**: overall strength using MRC sum-score evaluated via standardised “manual muscle testing” with each of 12 muscle groups assessed using a 6-point MRC scale[21](#_ENREF_21) and summed to a total score (range: 0-60).[22-29](#_ENREF_22) |
| **Quadriceps force**: measured via hand-held dynamometry (HHD)[30](#_ENREF_30),[31](#_ENREF_31) for of both lower extremities. Each will be scored by, averaging the results of 3 trials.[32](#_ENREF_32),[33](#_ENREF_33) |
| **Hand grip strength**: measured via isometric hand grip strength via a hydraulic hand dynamometer performed bilaterally as per American Society of Hand Therapist guidelines[34](#_ENREF_34) and evaluated using normal values.[35](#_ENREF_35) |
| **Short Physical Performance Battery**: measures balance, walking speed, and rising from a chair.[36-42](#_ENREF_36) |
| **Functional Status Score for ICU (FSS-ICU)**: a 5-item, 35-point assessment of bed mobility, transfers, and ambulation.designed for ICU patients.[29](#_ENREF_29),[43](#_ENREF_43),[44](#_ENREF_44) and was designed and validated specifically in ICU patients evaluated 8-point Functional Independence Measure (FIM) response scale used throughout rehabilitation assessments,[45-48](#_ENREF_45) and is responsive to change during recovery for ICU patients.[29](#_ENREF_29),[44](#_ENREF_44),[49](#_ENREF_49),[50](#_ENREF_50),[44](#_ENREF_44),[49](#_ENREF_49),[51-54](#_ENREF_51) |
| Patient Preferences for Patient Participation | **The Patient Preferences for Patient Participation tool** (The 4Ps) was developed to aid clinical dialogue and to help patients to 1) depict, 2) prioritise, and 3) evaluate patient participation with 12 pre-set items reiterated in the three sections. The 4Ps has reasonable validity and is suggested for use to increase general knowledge of patient participation.[55](#_ENREF_55),[56](#_ENREF_56) |
| At 6 mo post hospital discharge (to be collected by phone) | Health-related quality of life | **EQ-5D-5L** it a descriptive system comprising five dimensions (mobility, self-care, usual activity, pain/discomfort, anxiety/depression) and is suitable for patients with inattention and fatigue,[57](#_ENREF_57),[58](#_ENREF_58) recommended for use in ICU survivors.[59](#_ENREF_59),[60](#_ENREF_60) |
| **Short Form-36** (SF-36) is a set of generic, coherent and easily administered quality-of-life measures and is valid and reliable across a variety of patient groups, including ICU survivors.[61](#_ENREF_61),[62](#_ENREF_62) |
| Physical function status | **Katz activities of daily living (ADL) Index**[63](#_ENREF_63) is designed to assess functional status as a measurement of a person’s ability to perform ADLs independently. The KATZ ADL Index has established internal consistency (α=0.87-0.94) and content, construct, predictive and convergent validity.[64](#_ENREF_64) |
| **Lawton’s Instrumental ADL**[65](#_ENREF_65) scale was developed to assess more complex activities (termed “instrumental activities of daily living”) necessary for functioning in community settings (e.g., shopping, cooking, managing finances). There is considerable evidence for its reliability and concurrent validity.[66](#_ENREF_66) |
| Mental health | **The Hospital Anxiety and Depression Scale** is a 14-item scale (7 items relate to anxiety and 7 to depression). Each item on the questionnaire is scored from 0-3 (total score 0-21 for anxiety/depression). Reported cut points are 8/21 for anxiety or depression. The HADS-A has a specificity of 0.78 and a sensitivity of 0.90. The HADS-D has a specificity of 0.79 and a sensitivity of 0.83.[67](#_ENREF_67) |
| **IES-Revised** is a 22-item self-report measure (for DSM-IV) that assesses subjective distress caused by traumatic events.[68](#_ENREF_68) |

For a Phase III study our family outcome measures would include (Table 4).

**Table 4: Family outcome measures**

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| **Timing** | **Outcome measure** | **Description** |
| At or before ICU discharge | Satisfaction | **Family Satisfaction with the ICU Revised (FS-ICU24R)**[69](#_ENREF_69),[70](#_ENREF_70) is a 24-item survey generated from conceptual frameworks of patient satisfaction, quality end-of-life care, research on needs of critically ill families, literature on family satisfaction with medical decision making, existing validated satisfaction surveys. |
|  | Family engagement | The **Family Engagement Survey** has been developed by PI Heyland. Content and face validity have been established and the instrument is currently undergoing assessment of construct validity. |
| At ICU admission, ICU discharge and 6 months | Anxiety | Hospital Anxiety and Depression, anxiety subscale.[67](#_ENREF_67) |
| Depression | Hospital Anxiety and Depression, depression subscale.[67](#_ENREF_67) |
| Post-traumatic stress disorder | IES-Revised[68](#_ENREF_68) |
| At ICU admission and 3 months after ICU discharge | Quality of life | SF-36 is the most frequently used measure of quality of life for informal caregivers of ICU survivors.[71](#_ENREF_71) |
| Complicated grief (administer to bereaved relatives only) | Inventory of Complicated Grief–Revised[72](#_ENREF_72) |

### Data Collection

In addition to outcome data specified in Tables 2-4, for patients we will collect demographic data including admission type, diagnosis, comorbidities, sex, age, height, weight, APACHE II score,[73](#_ENREF_73) SOFA score,[74](#_ENREF_74) length of hospital stay prior to ICU admission, number of hospital and ICU admissions in the last 12 months, Functional Comorbidity Index[75](#_ENREF_75), the Charlson Comorbidity Index,[76](#_ENREF_76),[77](#_ENREF_77) postcode and living status. From family members we will collect further patient-related data including physical function domain of the SF-36, nutrition risk using the malnutrition screening tool, and clinical frailty score.

Nutrition-specific information will be collected, including nutrition prescription and intake throughout hospitalisation. In ICU the total amount of energy or protein received from either EN or parenteral nutrition (PN), inclusive of propofol, will be divided by the amount prescribed in the baseline assessment and expressed as a percentage for patients in all groups, scoring endpoints used in prior studies.[78](#_ENREF_78),[79](#_ENREF_79),[80](#_ENREF_80)On the ward, we will use visual estimation of plate waste (validated measure of estimating energy and protein intake) and observe intake of oral nutritional supplements for three days, from all study patients, in order to determine total estimated energy and protein intakes. A dietitian will calculate patients’ individual, disease-specific estimated energy and protein requirements. Nutritional adequacy on the ward will be determined by expressing energy/protein intakes as a percentage of estimated energy/protein requirements where meeting ≥75% of requirements is considered adequate.[81](#_ENREF_81),[82](#_ENREF_82)

Mobility-specific data will include the number and type of physiotherapy sessions while in ICU, physiotherapy sessions while on the ward, number of steps, distance and minutes of activity (measured with fitbit versa Lite) and family assistance with physiotherapy sessions or mobility throughout hospitalisation.

Family demographics will include age, sex, education, relationship to patient, living with the patient, postcode, education, employment, general health, and preference for participating in the physical care of their family member.

### Data Storage and Confidentiality

Data will be stored in a manner which complies with the NHMRC guidelines.

### Data Analysis and Statistical Considerations

Consistent with the primary aim of this study, which is to evaluate study procedures and intervention fidelity, we have selected a total sample for this trial of 50 patients (25 per group), a sample size similar to other feasibility studies.[7](#_ENREF_7),[8](#_ENREF_8),[83](#_ENREF_83) GCUH ICU currently admits more than 1800 patients annually and approximately 1/3 remain in ICU more than 3 days (n=594) suggesting we will have a reasonably large pool of potential participants, to which other inclusion criteria can be applied.

The feasibility outcomes will be described as rates with 95% confidence intervals. Reasons for loss-to-follow-up and non-compliance will be tabulated. Prior to analysis, all missing data and improbably values will be checked against source data. To include data from all randomised patients, as per the intention-to-treat principle, we will assign decedents a lower value than all survivors (e.g. -1) for the 6MWT, quadriceps force and handgrip strength. Where patients are unable to complete these tests, they will receive a score of 0. The MRC Scale and Short Physical Performance Battery incorporate a score for non-attempt enabling data to be collected from all patients at hospital discharge.

### Translation to Changes in Clinical Practice

Marshall, Heyland, Tobiano and Roberts are currently undertaking the first ever randomised controlled trial of family engagement in the context of critical illness. With their extensive track record of research in the context of person-centred care, critical illness and nutrition, they are well placed to influence both practice change and policy. Their learning from this work will be applied in this trial. Through their work we will be better placed to understand how to best support families to develop capacity to engage with heath providers in the delivery of evidence-based care that is known to improve patient outcome. In keeping with Standard 2 of The Australian Commission on Safety and Quality in Healthcare, we are developing strategies to create a person-centred health system where patients and their families are partners in care and involved in the development and design of quality health care.

We anticipate that our work will help to dispel some of the myths about family engagement that currently exist in the acute care context. This will support better enactment of principles of person-centred care. Longer-term, if our Phase II trial is considered feasible, this study will help provide important feasibility data that is necessary for securing future competitive research funding in Australia and overseas.

We will disseminate the findings of our research to the community, to health professionals, researchers and policy makers to promote the uptake of person-centred care in Australia.

### Timeline

January – October 2020: Study Start Up (ethics, governance and development of study materials)

November 2020 – May 2022: Recruitment. We anticipate recruiting approximately 2-3 eligible patients each month because our inclusion criteria is designed to identify only those patients for whom we believe the intervention may be of benefit.

June 2022: Completion of data collection

July-September 2022:

### Budget

**Infrastructure and Equipment – amount requested $2,985.00**

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| **Item** | **Quantity** | **Year** | **Justification** | **Unit cost** | **Total cost** |
| Trundle Wheel | 1 | 1 | Required to measure distance for 6MWT | $50 | $50 |
| Stopwatch | 1 | 1 | Required for timing of 6MWT | $20 | $20 |
| Tape measure | 1 | 1 | Required for Short Physical Performance Battery | $20 | $20 |
| Microfet push digital dynamometer | 1 | 1 | Required for assessment of quadriceps strength | $2145 | $2145 |
| Fitbit Versa | 3 | 1 | Required to assess physical activity on the ward | $250 | $750 |

**Human Resources Costs 9 – amount requested $114,429**

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| **Position/ Justification** | **Year** | **Detail** | **Hourly rate#** | **Hours** | **Total cost** |
| *Project manager* -  Provide overall study management including study start up (ethics, governance and development of study materials, RA training), data entry, cleaning, and preliminary analysis. This position requires a senior clinician who can independently lead the conduct of the study and supervise research assistants. He/she will be required to hold GCP certification and have experience in managing clinical trials. | 1 | Based on experience with similar studies we anticipate 3 hours/week will be required for each year of the study 3 hours/week x 52 weeks = 156 hours per year | $59.98 |  | $9,357 |
| 2 | $61.48 |  | $9,590 |
| 3 | $63.20 |  | $9,859 |
| Research assistant –  Will assist with screening and baseline data collection. | 1 | Screening (1 hour/day 5 days/week x 52 weeks = $15,594)  Consent (2 hours per participant x 10 participants = $1200)  Collection of patient and family demographic data (1 hour per participant x 20 participants = $1200 | $59.98 | 300 | $16,794 |
|  | 2 | Screening (1 hour/day 5 days/week x 52 weeks = $15,985  Consent (2 hours per participant x 20 participants = $2,460)  Collection of patient and family demographic data (1 hour per participant x 40 participants = $2,460) | $61.48 | 340 | $20,905 |
|  | 3 | Screening (1 hour/day 5 days/week x 52 weeks = $16,432  Consent (2 hours per participant x 20 participants = $2,528)  Collection of patient and family demographic data (1 hour per participant x 40 participants = $2,528) | $63.20 | 340 | $21,488 |
| Research assistant –  Will assist with intervention delivery. In our experience this takes approximately 3 hours per patient (25 intervention patients/families) | 1 | 5 participants x 3 hours = $900 | $59.98 | 15 | $900 |
|  | 2 | 10 participants x 3 hours = $1,845 | $62.48 | 30 | $1,845 |
|  | 3 | 10 participants x 3 hours = $1,896 | $63.20 | 30 | $1,896 |
| Outcome assessment (patient) – based on experience time required to collect outcome data is 6MWT (1h); MRC (30m); Quadriceps and hand grip strength (1h); FSS-ICU (30m); 4P tool (30m), total of 3.5h per patient | 1 | 10 participants x 3.5 hours/participant = $2,099 | $59.98 | 35 | $2,099 |
| 2 | 20 participants x 3.5 hours/participant = $4,374 | $62.48 | 70 | $4,374 |
| 3 | 20 participants x 3.5 hours/participant = $4,424 | $63.20 | 70 | $4,424 |
| Outcome assessment (family) – based on experience it will take approximately 1.5 hours per participant to collect outcome data | 1 | 10 participants x 1.5 hours/participant = $900 | $59.98 | 15 | $900 |
|  | 2 | 20 participants x 1.5 hours/participant = $1,874 | $62.48 | 30 | $1,874 |
|  | 3 | 20 participants x 1.5 hours/participant - $1,896 | $63.20 | 30 | $1,896 |
| Outcome assessment (patient and family) post discharge – based on experience we anticipate follow up phone calls for data collection to take approximately 1 hour per participant | 1 | 20 participants x 1 hour/participant = $1,200 | $59.98 | 20 | $1,200 |
|  | 2 | 40 participants x 1 hour/participant = $2,500 | $62.48 | 40 | $2,500 |
|  | 3 | 40 participants x 1 hour/participant = $2,528 | $63.20 | 40 | $2,528 |

#Hourly rates inclusive of on-costs. Costing of this position has been based on the salary of a Clinical Nurse (Level 6, step 4) with incremental annual salary increases of 2.5%.

**Services – not applicable**

**Consumables and running – total amount requested $4500**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Item** | **Quantity** | **Year** | **Justification** | **Unit cost** | **Total cost** |
| Incidental printing | NA | 1 | Printing of educational materials and CRF | NA | $300 |
| Incidental printing | NA | 2 | Printing of educational materials and CRF | NA | $150 |
| Incidental printing | NA | 3 | Printing of educational materials and CRF | NA | $150 |
| Open access publication |  | 3 |  |  | $4,000 |
|  |  |  |  |  |  |

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