|  |
| --- |
| protocol |
| icuRESOLVE  Co-designing Peer Support With ICU Survivors: Phase 2 |
| Protocol Number (if applicable):  Version: #2  Date: 08/01/2018 |
|  |
| **Author/s:**  Kimberley Haines  Clare Holdsworth  Grey Searle  Jacki Carmody  Samantha Bates  Sarah Booth  Kathryn Cranwell  Belinda McLeod Smith |
| **CONFIDENTIAL**  This document is confidential and the property of Western Health. No part of it may be transmitted, reproduced, published, or used without prior written authorization from the institution.  **Statement of Compliance**  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). |

# Table of Contents

Contents

Table of Contents 2

Study Synopsis………………………………………………………………………………………………………………………3

1. Glossary of Abbreviations & Terms 6

**2.** **Study Sites** 7

2.1 Study Location/s 7

**3. Introduction/Background Information** 7

3.1 Lay Summary 7

3.2 Introduction 8

3.3 Background information 8

**4.** **Study Objectives** 9

4.1 Hypothesis 9

4.2 Study Aims 9

4.3 Outcome Measures 9

**5.** **Study Design** 11

5.1 Study Type & Design & Schedule 11

5.2 Standard Care and Additional to Standard Care Procedures 15

5.3 Randomization 15

**6. Study methodology** 15

**7.** **Study Population** 21

7.1 Recruitment Procedure 21

7.2 Inclusion Criteria 21

7.3 Exclusion Criteria 21

7.4 Consent 22

**8.** **Participant Safety and Withdrawal** 22

8.1 Risk Management and Safety 22

8.2 Handling of Withdrawals 22

**9.** **Statistical Methods** 23

9.1 Sample Size Estimation & Justification 23

9.2 Power Calculations 23

9.3 Statistical Methods To Be Undertaken 23

**10.** **Data Security & Handling** 24

10.1 Details of where records will be kept & How long will they be stored 24

10.2 Confidentiality and Security 24

**11.** **Appendices** 24

**12.** **References** 25

|  |  |
| --- | --- |
| **STUDY SYNOPSIS** |  |

|  |  |
| --- | --- |
| Title: | icuRESOLVE (Intensive Care Unit **RE**covery **S**olutions c**O**-**L**ed through sur**V**ivor **E**ngagement): Phase 2  Co-designing Peer Support With ICU Survivors |
| Short Title: | icuRESOLVE |
| Design: | Pilot feasibility randomized controlled trial |
| Study Centres: | Western Health (WH) |
| Hospital: | WH - Sunshine |
| Study Question: | Will a co-designed peer support model be feasible to deliver?  Will there be a signal favoring improved positive psychology (post-traumatic growth, resilience and social support) and reduced symptoms of psychological distress (depression, anxiety and post traumatic stress disorder (PTSD)) in ICU survivors who attend co-designed peer support model? |
| Study Objectives: | To evaluate the feasibility of implementing the peer support model developed in Phase 1 with regard to ICU survivors’ rate of recruitment, attendance and reported satisfaction.  To explore any treatment effects on psychological and social outcomes variances to inform the design (outcome measurement selection, sample size calculations and power) for a larger, multi-site randomized controlled trial to test efficacy. |
| Primary Objectives: | To evaluate the feasibility of implementing the peer support model developed in Phase 1 with regard to ICU survivors’ rate of recruitment, attendance and reported satisfaction. |
| Secondary Objectives | To explore any treatment effects on psychological and social outcomes variances to inform the design (outcome measurement selection, sample size calculations and power) for a larger, multi-site randomized controlled trial to test efficacy. |
| Inclusion Criteria: | Patients and their families will be eligible based on the term ‘ICU survivor’ (incorporating both) and if they meet the following inclusion criteria (as relevant to patient or family member):   * ICU admission at Sunshine hospital * Age >18 years * Able to speak and understand English * Able to receive and participate in phone surveys * Living in the community |
| Exclusion Criteria: | * Imminent death * Bereaved family members * Pre-existing or new cognitive conditions * Pre-existing or new psychiatric conditions * Severe neurological conditions * Not expected to return home following discharge |
| Number of Planned Subjects: | 60 participants.  Intervention group: 30  Control group: 30 |
| Safety considerations: | For intervention group participants, ensuring the psychological safety of the ICU survivors will be important as they may become upset or distressed when attending the peer support groups when and if they recall their ICU experiences or hear of others experiences.  For both groups, there is a low risk that there may experience a small degree of discomfort when answering questions for outcome measurement.  Appropriate and immediate supports will be in place whereby If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge and will be organised through your General Practitioner (GP) and you will be encouraged to contact your GP to discuss your specific requirements further. |
| Statistical Methods: | As this is a pilot trial, the sample size will be one of convenience determined in the absence of previous research on which to base a sample size and with no specific sample size required for pilot studies ([1](#_ENREF_1), [2](#_ENREF_2)).  The data obtained will be used to power for subsequent large randomised controlled trials. Data analysis will be as randomized. |
| Subgroups: | Planned sub-group analyses will be conducted based on the whether they are a patient or family member. Intervention effect sizes will be calculated to inform the power calculation of subsequent adequately powered trials. |

## **Glossary of Abbreviations & Terms**

|  |  |
| --- | --- |
| **Abbreviation** | **Description (using lay language)** |
| WH | Western Health |
| ICU | Intensive care unit |
| EBCD | Experience based co-design |
| icuRESOLVE | Intensive Care Unit **RE**covery **S**olutions c**O**-**L**ed through sur**V**ivor **E**ngagement |
| ICU Survivors | Refers to both patients and families |

## **Study Sites**

### Study Location/s

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Site** | **Address** | **Contact Person** | **Phone** | **Email** |
| Western Health Sunshie Hospital | Furlong Road, St.Albans VIC 3021 | Kimberley Haines | 0401 288 292 | Kimberley.haines@wh.org.au |

## **Introduction/Background Information**

### Lay Summary

International and local research indicates that ICU survivors (patients and families) experience adverse outcomes. In Australia, ICU survivors return home with little or no follow-up. Peer support holds potential to improve post-ICU outcomes although this warrants explorations. Typically new models of care are designed only from the perspective of the health professionals without any patient or family input. We have recently conducted Phase 1 of the icuRESOLVE Project, where we engaged both ICU survivors and staff using a new and innovative method called experience-based co-design (EBCD). Through EBCD a Peer Support model for ICU survivors was developed.

This study (phase 2 of the icuRESOLVE Project) aims to test the developed Peer Support Model to see if it is feasible to deliver (attendance rates, participant satisfaction, participant recruitment) as well as the impact of attending peer support on psychological and social outcomes. This is a small pilot study and the results of this study will inform a larger, multi-site randomized study.

The time commitment required by participants in the intervention group (peer support) is estimated at 13 hours over approximately 14 weeks. For participants in the control group (no peer support), time commitment is estimated at 1 hour (to complete health related questionnaires).

Anticipated ethical issues for the intervention group relate to a small risk of psychological distress by participating in the group sessions as they will be discussing their ICU experiences and recovery. For participants in both groups their may be a small degree that some of the questionnaires may be stressful or upsetting.

Survivors are able to access any help needed. We do not anticipate any risk to staff.

### Introduction

Physical, cognitive, emotional, financial and social problems are quite common among survivors (patients and families). This is recognised as Post Intensive Care Syndrome ([3](#_ENREF_3)). When survivors leave ICU, they are required to navigate increasingly complex health systems and reintegrate with their communities, while trying to make sense of their experiences and possible new impairments. This occurs at a time when they may be most vulnerable with potentially little support from the health system. Currently in Australia, ICU survivors receive little to no follow-up. Peer support has potential to address some of these challenges and system deficiencies and is relatively unexplored in critical care.

Typically new models of care are designed solely from the perspective of the health professionals. As such the model may not function to meet the end user (patients and families) needs. EBCD offers a methodology that creates an authentic partnership between professionals, patients and families with an emerging body of evidence for the effectiveness of this method ([4](#_ENREF_4)). It is relatively under-utilized in critical care research where few examples of co-design are described ([5](#_ENREF_5)).

An EBCD model of peer support was developed as part of Phase 1 of the icuRESOLVE project. This study now aims to implement the EBCD model of Peer Support through a pilot feasibility randomized controlled trial with the following objectives:

1. Evaluate the feasibility of implementing the peer support model developed in Phase 1 with regard to ICU survivors’ rate of recruitment, attendance and reported satisfaction.
2. To explore any treatment effects on psychological and social outcomes variances to inform the design (outcome measurement selection, sample size calculations and power) for a larger, multi-site randomized controlled trial to test efficacy.

### Background information

Peer support groups, based on shared experiential empathy, have existed in patient populations such as cancer for decades ([6](#_ENREF_6)) and more recently explored in cohorts including heart failure ([7](#_ENREF_7)), diabetes ([8](#_ENREF_8)), and traumatic brain injury ([9](#_ENREF_9)). Within critical care, peer support remains an emerging but important concept and not yet embedded into standard practice. Peer support for survivors of the intensive care unit (ICU) has significant potential to ameliorate the burden of Post Intensive Care Syndrome (PICS) ([10](#_ENREF_10)). Within the existing literature there are reports of effectiveness as summarized by Mikkelsen and colleagues ([10](#_ENREF_10)), but scant data on the process of developing and implementing peer support programs.

One limitation of many existing programs is adopting a traditional health care approach to design and implementation. In such a traditional model, design occurs solely from the perspective of health care professionals. However, this depends on providers’ ability to assume the needs and preferences of survivors and fails to recognize the role of the end-users (patients and families). Experience-based co-design (EBCD) offers a methodology that creates an authentic partnership between professionals, patients and families with an emerging body of evidence for the effectiveness of this method ([4](#_ENREF_4)). We recently undertook a systematic review for *Critical Care Medicine* regarding patient and family engagement in critical care and found there is a clear gap, where few examples of co-design are described ([5](#_ENREF_5)). On a spectrum of partnership, co-design is the most advanced form of partnership where decision-making is shared and co-ownership occurs ([5](#_ENREF_5)). Partnering with survivors to co-design their care may be the missing piece in our current approach to implementing ICU services such as follow-up clinics, where success has been limited ([11](#_ENREF_11)).

The evidence base for EBCD is rapidly growing. It has previously been used in intensive care and lung cancer services ([12](#_ENREF_12)), outpatient chemotherapy ([13](#_ENREF_13), [14](#_ENREF_14)), breast and lung cancer services ([15](#_ENREF_15)), amongst others, although evaluation data is limited. There is however a significant and comprehensive planned project using EBCD in mental health ([16](#_ENREF_16)) with a nested process evaluation ([17](#_ENREF_17)). Due to the paucity of evidence to evaluate the use of EBCD we therefore draw on aspects of this published protocol to inform the design of our study.

In Phase 1 of this study, we have used EBCD to design the peer support group. In early 2018, we plan to implement this peer support group and evaluate patient and family reported outcomes via a pilot randomized controlled trial (RCT). This will inform the design of a future larger, multi-site RCT.

**Significance**

Survivors of ICU are required to navigate increasingly complex health systems and reintegrate with their communities, while trying to make sense of their experiences and possible new impairments. This occurs at a time when they may be most vulnerable with potentially little support from the health system. Peer support has potential to address some of these challenges and system deficiencies.

We are not aware of any formal ICU survivor peer support group in existence within our local organization or even within Australia. This offers tremendous opportunity to develop a well-designed, co-led model using EBCD methodology in a template that could be replicated elsewhere, to ensure the model functions to meet end-user needs. Such an approach recognizes that patients and their families are resourceful and may identify needs and solutions that professionals may not ([4](#_ENREF_4)). EBCD offers a way to improve healthcare services ***with*** patients and their families rather than ***for***them. This methodology involves a ‘radical reconceptualization’ of the role of patients/families and a systematic process through which to engage them ([4](#_ENREF_4)). While EBCD is generally employed in quality improvement initiatives, it may transform attitudes and behaviors in the long term through co-ownership of solutions ([4](#_ENREF_4)).

Given the ideal peer support group model for critical care survivors has not been established ([10](#_ENREF_10)), we believe an EBCD approach is innovative, addresses issues of sustainability and pioneers the way for others. Moreover, survivors retain centrality in the process. This project takes a novel approach to exploring a plausible solution for enhanced recovery following critical illness. In Phase 1, this project evaluated the process of EBCD using qualitative inquiry. In Phase 2, this project will test the feasibility and evaluate the co-designed peer support model via a pilot RCT.

## **Study Objectives**

### Hypothesis

A co-designed peer support model will be feasible to deliver with approximately half of those approached recruited and a signal favoring improved positive psychology (post-traumatic growth, resilience and social support) and reduced symptoms of psychological distress (depression, anxiety and post traumatic stress disorder (PTSD)) will be observed in ICU survivors.

### Study Aims

This pilot randomized controlled trial aims to:

1. Evaluate the feasibility of implementing the peer support model developed in Phase 1 with regard to ICU survivors’ rate of recruitment, attendance and reported satisfaction.
2. To explore any treatment effects on psychological and social outcomes variances to inform the design (outcome measurement selection, sample size calculations and power) for a larger, multi-site randomized controlled trial to test efficacy.

### Outcome Measures

It is currently unknown which outcome measure/s are likely to be responsive to a peer support intervention.

**The primary outcome** is feasibility of implementing the peer support model, as measured bythe following uptake, participant satisfaction and process measures:

* Percentage of participants who agreed to participate of those who were approached for recruitment
* Percentage of participants who agreed to participate when approached by a) in-person approach vs. b) phone approach only (if unable to recruit in-person).
* Attendance rate of participants in the intervention group (e.g. percentage who attended more than half of the six sessions, percentage who attended less than half of the session and reasons unable to attend).
* ICU survivors satisfaction survey of the intervention (intervention group only)
* Percentage of participants who completed pre and post outcome measures (both groups)
* Length of time to complete outcome measures

**The secondary outcomes** will be used to calculate effect sizes and have been selected based on prior literature and the project team’s knowledge of the contemporary field of ICU recovery. These include:

* Post-traumatic growth - Post-Traumatic Growth Inventory
* Resilience - Connor Davidson Resilience Scale (CD-RISC) ([18](#_ENREF_18))
* Social support - PROMIS Inventory respectively (Social Isolation, Informational Support and Emotional Support from the PROMIS inventory)
* Anxiety and Depression - HADS
* Post-traumatic stress disorder - IES-R
* Quality of Life – EQ-5D-5L

All outcome measures are provided in Appendix A and further details provided following:

*Measurement of Post-Traumatic Growth, Resilience and Social Support*

**Post-traumatic growth** will be measured using the Post-Traumatic Growth Inventory (PTGI). This tool is a 21-item survey, with likert responses from 0-5 and is scored by adding all the responses. Individual Factors (Relating to Others, New Possibilities, Personal Strength, Spiritual Change, Appreciation of Life) can be measured by adding the scores of specific questions. Within the critical care literature, the PTGI has been used to evaluate:

* Parent distress following serious injury/illness to their child
* Parents after their children have had an ICU admission
* Psychological adjustment in patients following burns

**Resilience** will be measured using the ConnorDavidson Resilience Scale (CD-RISC) ([18](#_ENREF_18)). This scale is a 25-item survey, scored from 0-100 where a score >82 identifies individuals who are resilient ([18](#_ENREF_18)). While the CD-RISC does not have established psychometric properties in an ICU population, it has previously been validated in varied settings including the community. The CD-RISC measures factors of personal competency, tenacity, tolerance of negative effect, positive acceptance of change, secure relationships and spiritual influences and others ([18](#_ENREF_18)). As investigation of resilience in ICU survivors has been limited, this measure has been selected for use in this study due to its recent adoption in contemporary ICU research ([19](#_ENREF_19), [20](#_ENREF_20)).

**Social support** will be measured using a short-form measure of Social Isolation and Informational Support from the PROMIS inventory ([21](#_ENREF_21)). Social Isolation assesses perceptions of being avoided, excluded, detached, disconnected from or unknown by others ([21](#_ENREF_21)). Informational Support assesses perceived availability of helpful information or advice ([21](#_ENREF_21)). Similarly, while these scales do not have established psychometric in ICU survivors, they have been selected based on use by others investigators in critical care populations ([22](#_ENREF_22)).

*Measurement of Depression, Anxiety and PTSD*

Symptoms of **Anxiety and Depression** will be measured using the Hospital Anxiety and Depression Scale (HADS). It consists of 14 statements relevant to the sub-scores of generalised ‘anxiety’ (7 statements) or 'depression' (7 statements). Each statement has four possible responses, which are scored on a scale of 0-3, with a maximum score of 21 for both depression and anxiety ([23](#_ENREF_23)). A sub-score greater than 8 or a total score greater than 16 identifies individuals with symptoms of either anxiety or depression ([23](#_ENREF_23)). Whilst the psychometric properties of the HADs has not been widely investigated in the critical care population, one study has demonstrated content validity, internal consistency and criterion validity ([24](#_ENREF_24)). Due to its common use in ICU populations ([25](#_ENREF_25)) the HADS will be selected for use in this study.

Symptoms of **PTSD** will be measured using the Impact of Events Scale Revised (IES-R). This is a 22-item self-report questionnaire has three subscales – intrusion, avoidance and hyper arousal ([26](#_ENREF_26)). Each item has four responses levels that are summed to produce the total score (range 0-88) ([26](#_ENREF_26)). A cut-off score of 33 represents a probable diagnosis of PTSD ([27](#_ENREF_27)). Although the IES has limited psychometric properties in ICU survivors, it is the most frequently used self-report measure of PTSD in the critical care literature ([28](#_ENREF_28)).

*Measurement of Quality of Life*

The **EQ-5D-5L** is a standardized instrument developed by the EuroQol Group as a measure of health-related quality of life that can be used in a wide range of health conditions and treatments. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ VAS records the patient’s self-rated health on a vertical visual analogue scale. This can be used as a quantitative measure of health outcome that reflects the patient’s own judgment. The scores on these five dimensions can be presented as a health profile or can be converted to a single summary index number (utility) reflecting preferability compared to other health profiles. The EQ-5D has been used in previous ICU studies measuring quality of life in ICU survivors.

*Participant satisfaction* with the intervention will be measured by a **Satisfaction Survey** – see Appendix A.

# **Study Design**

### Study Type & Design & Schedule

1. Phase 2 is a pilot feasibility randomized controlled trial of the co-designed peer support model (developed in Phase 1) to 1) test the feasibility of the intervention and 2) explore any treatment effects on psychosocial outcomes to inform the design of a subsequent randomized controlled trial that will test for efficacy.
2. Participants will be adult ICU survivors recruited prior to hospital discharge following their ICU admission at Sunshine Hospital. For each patient, one family member/carer will be approached for recruitment. See Appendix I – Patient Information & Consent Form (PICF) & Appendix B – Telephone Script for Consent.
3. This study is single-centre design and will be conducted at Western Health, a tertiary health service in the Western region of Melbourne. The study will run only at Sunshine Hospital, as this is where the development of Phase 1 has occurred.
4. The study design will enable assessment of feasibility of the intervention (co-designed peer support model developed in Phase 1) including testing of recruitment procedures, intervention delivery/uptake and outcome measurement. Participants will be randomized to receive the intervention (peer support model) or standard care (no peer support). Outcome measures at baseline and follow up will be used to determine power for a subsequent larger, multi-site randomized controlled trial to test efficacy.
5. Participant data will be collected in the form of demographics and the previously listed outcome measures (questionnaires on page 2). At baseline, patient demographics will be collected, including age, gender, comorbid disease, and history of prior psychological conditions, educational level, employment, ICU admission diagnosis, mechanical ventilation hours, severity of illness, ICU and hospital length of stay. Baseline family demographics will also be collected including age, gender, and relationship to patient, history of prior psychological conditions, educational level, and employment. Demographic details will be recorded as detailed in Appendix C & D: Case Report Form Patient & Case Report Form Relative/Carer respectively.

The previously listed psychosocial questionnaires will be administered at baseline and follow up time points as outlined in the Study Table No. 1 below. It is anticipated that the questionnaires will take approximately half an hour to complete at each time point.

1. Blinded outcome assessors will collect baseline and follow-up outcome assessments. Initial baseline outcome measures will be conducted over the phone at one week following discharge home. Follow up outcome assessments will be conducted over the phone at close to 4 months post discharge home.

Data entry and coding will be undertaking by research assistants or project personnel. Paper forms will be stored in a locked cabinet in a locked office, and electronic data will be stored in a password-protected file, accessible only to investigators. Only investigators will be able to access data.

A blinded statistician will conduct data analysis. It is not possible to blind staff and participants involved in the peer support group.

1. The study will recruit a total of 60 participants. It is anticipated that a recruitment window of one week either side of hospital discharge will be required to complete recruitment. Once recruited, participants will be involved in the study until approximately 15 to 17 weeks post hospital discharge. See Study Flowchart below.

Participants will be randomized to receive intervention or control. See Table 1 & 2 (below) for Flow charts of Study Procedures.**Table 1 Study Procedures**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study Procedures** | **Assessment/Procedure** | **Screening** | **Baseline**  **(2 weeks post hospital discharge)** | **Follow-up**  **(15-17 weeks post hospital discharge)** |
| Informed Consent | **X** |  |  |
| Demographic Information |  | **X** |  |
| ***Psychosocial Outcome Measures*** | | | |
| Post Traumatic Growth Inventory |  | **X** | **X** |
| Connor Davidson Resilience Scale (CD-RISC) |  | **X** | **X** |
| PROMIS Inventory |  | **X** | **X** |
| Hospital Anxiety and Depression Scale (HADS) |  | **X** | **X** |
| Impact of Events Scale - Revised (IES-R) |  | **X** | **X** |
| ***Acceptability of Intervention*** | | | |
| Participant Satisfaction Survey (Intervention Group Only) |  |  | **X**  **(Intervention group only)** |

**Table 2 Study Flowcharts – Time Points and Study Activity**

|  |  |
| --- | --- |
| **Time Point** | **Study Activity** |
| ICU Discharge | Screening ICU database/hospital records for eligibility |
| Week of hospital discharge (while in patient) and up to two weeks post-hospital discharge | Recruitment (in person if in hospital or via phone if discharged) & Randomization |
| 2 weeks post discharge | * Baseline outcome measures completed via blinded assessor * Patient and family demographics collected via hospital records |

|  |  |
| --- | --- |
| ***Intervention Group*** | ***Control Group*** |
| *Two to three weeks post hospital discharge – intervention commences*  *Participants attend six Peer Support Group Sessions over 12 weeks, fortnightly for two hours*  *Participants will be notified of the Peer Support Groups by:*   * *At time of in person recruitment and randomization in hospital (where possible)* * *Letter of invitation* * *Follow up phone call* * *Follow up text message on the week of group* | *Standard Care (no peer support)* |

|  |  |
| --- | --- |
| ***Time-point*** | ***Study Activity*** |
| At 15 – 17 weeks post hospital discharge. | *Follow-up outcome measurement assessments conducted via blinded assessor via telephone* |

### Standard Care and Additional to Standard Care Procedures

Standard care: Patients and their families currently do not receive any formal post-hospital aftercare in the form of a peer support group. Standard care does involve referral to various community service providers.

Additional to standard care (Intervention) summarized here (detailed description Table 3):

|  |  |
| --- | --- |
| What? | In person, facilitated peer support group. Two components:  1) Educational/informational exchange delivered by staff on common problems faced after ICU  2) Group/peer to peer discussion of shared experiences and pragmatic solutions |
| When? | 1x fortnight, starting at 2 to 4 weeks post-hospital discharge |
| Where? | Sunshine Hospital, in separate room/building to the ICU |
| For how long? | 2 hours for total of 6 session across 12 weeks |

The peer support program will be an ongoing ‘rolling’ program, with sessions held every 2 weeks so participants can attend as close to hospital discharge as possible.

Outcome measurement: All outcome measures (questionnaire-based) that will be collected are not part of standard care. It is anticipated that the questionnaires will take approximately half an hour and will be conducted twice. Patient demographics (ICU admission diagnosis, length stay etc.) are routinely collected in medical records and ICU admission databases.

### Randomization

Participants will be randomized to Intervention (Peer Support Group) or Control (Standard Care – no Peer Support Group) using a 1:1 allocation method and using computer-generated random numbers from [www.randomization.com](http://www.randomization.com).

## **Study methodology**

*Allocation:* Eligible participants will be allocated to intervention or control as per randomization.

*Intervention:* The description of study intervention has been described using the TIDieR checklist for ease of reporting complex interventions (Table 3 below).

**Table 3 Description of intervention according to TIDieR checklist**

|  |  |
| --- | --- |
| **TIDieR criteria** | **Study Intervention** |
| **Item 1. Brief name:** Provide the name or a phrase that describes the intervention. | In-person, facilitated peer support group |
| **Item 2. Why:** Describe any rationale, theory, or goal of the elements essential to the intervention. | Physical, cognitive, emotional, financial and social problems are quite common among survivors (patients and families). This is recognised as Post Intensive Care Syndrome (1). When survivors leave ICU, they are required to navigate increasingly complex health systems and reintegrate with their communities, while trying to make sense of their experiences and possible new impairments. This occurs at a time when they may be most vulnerable with potentially little support from the health system. Currently in Australia, ICU survivors receive little to no follow-up. Peer support has potential to address some of these challenges and system deficiencies and is relatively unexplored in critical care. |
| **Item 3**. **What (materials):** Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. | **Participants randomised to the intervention group will receive the following informational materials:**  Upon recruitment, participants will receive an information letter outlining details of the icuRESOLVE Peer Support Program, including: What is Post Intensive Care Syndrome (PICS), How does it effect me and my family/carer, What is Peer Support, When are the Peer Support Sessions and what does attendance involve (**Appendix G**).  Reminder letter posted to their postal address with dates/times of the Peer Support Sessions prior to each session **(Appendix H)** Reminder text message within the week preceding each Peer Support Session  **Intervention Delivery** - Each Peer Support Session will be delivered by a clinician/s with ICU and group facilitation experience (e.g. Social Worker, Psychologist). Sessions will incorporate a short talk/presentation on a relevant topic to ICU survival. E.g. What is PICS, Clinician Stories...  **Facilitators:** Facilitators will all be registered clinicians in their speciality field of practice (Social Work and/or Psychology) and group facilitation is part of their scope of practice. These staff members are co-investigators of the project. The Project Manager is senior intensive care physiotherapist with expertise in follow-up of intensive care survivors and is highly skilled in debriefing (a method used in simulation training which has transferrable skills to group facilitation). |
| **Item 4. What (procedures):** Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. | **The icuRESOLVE Peer Support Program (developed in Phase 1) that will form the intervention:**  **Format:** Face to face, group based  **Duration of Program:** 6 sessions, fortnightly over 12 weeks. The program will run as a rolling/continuous program so that participants can commence the program upon recruitment in to the study  **Location:** A non clinical room at the hospital site with space for 20 participants including chairs, tables and access to bathrooms, tea/coffee, accessible for people with disability  **Time:** Alternating mornings & afternoons e.g. 10am-12pm; 12-2pm  **Session Length:** 2 hours  **Facilitator:** A clinician with ICU and group facilitation experience. E.g. Social worker, psychologist.  **Example** **Format:**  - 1st hour: Formal: a short talk on a relevant topic followed by facilitated group discussion with survivors sharing their stories. The group may also work on tasks (e.g. developing information sheets for the ICU waiting room). The group takes ownership of the content of future meetings.  - Tea/Coffee break including a light snack (e.g. biscuits)  - 2nd hour: Informal, non-facilitated conversation / discussion amongst group members  **Guest Speakers:** Examples include: What is PICS, Physiotherapist, Psychologist, Clinician Stories, Occupational Therapist, HARP, Social Worker. The group will identify the topics for future sessions and the icuRESOLVE Project Officer will identify Professionals to deliver the content at subsequent sessions.  **Infrastructure: -** icuRESOLVE Session Invite Letter **(Appendix G)** Reminder letters **(Appendix H)** and text messages for upcoming sessions, attendance: RSVP via phone/text. The group may setup a Facebook page/group.  **Enabling Activities:** Prior to each icuRESOLVE Peer Support Program Session, a session plan and overview will be developed by the icuRESOLVE Project Lead and circulated amongst the icuRESOLVE facilitators.  **Attendance:** Attendance and adherence to the protocol will be documented in **Appendix F**: **ICU RESOLVE Peer Support Group Membership & Attendance sheet.** |
| **Item 5. Who provided:** For each category of intervention provider (for example, psychologist, nursing assistant), describe their expertise, background and any specific training given. | **icuRESOLVE Project Lead:** An experienced ICU Clinician with expertise in project management, debriefing and consumer engagement  **icuRESOLVE Session Facilitator**: An experienced ICU Clinician with expertise in group facilitation. Facilitators will all be registered clinicians in their speciality field of practice (Social Work and/or Psychology) and group facilitation is part of their scope of practice. These staff members are co-investigators of the project. The Project Manager is senior intensive care physiotherapist with expertise in follow-up of intensive care survivors and is highly skilled in debriefing (a method used in simulation training which has transferrable skills to group facilitation).  **icuRESOLVE Guest Speakers:** To be determined by the participants. Speakers will be experts in their field - for example, Social Workers with experience working with ICU Survivors and their carers, ICU Consultants with expertise in management of ICU patients. |
| **Item 6. How:** Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. | The icuRESOLVE Peer Support Program will be delivered face-to-face in a group setting. |
| **Item 7. Where:** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. | The icuRESOLVE Peer Support Program will be delivered in a non-clinical room within the hospital setting. The room will have tables and chairs for 20 people. Additional rooms will be booked if the group size is anticipated to be greater than 20 to break the group in to smaller sizes if required to enable participants to more easily hear each other and interact. |
| **Item 8.** **When and how much:** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose. | The icuRESOLVE Peer Support Program will be run fortnightly over a 12-week period. A total of 6 sessions will be offered to each participant. Sessions will be 2 hours in duration. The Program is a rolling program so participants can commence attending following their discharge home. |
| **Item 9.** Tailoring: If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. | The icuRESOLVE Peer Support Program was developed using EBCD. To enable on-going consumer involvement in the peer support program, session content will in part be determined by the participants. Phase 1 identified the importance of ownership of the program by participants to enable to sessions to be tailored to their needs to improve engagement and attendance. |
| **Item 10**. **Modifications:** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). | N/A |
| **Item 11**. **How well (planned):** If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. | N/A |
| **Item 12:** **How well (actual):** If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned. | N/A |

## **Study Population**

### Recruitment Procedure

Screening – all patients discharged from Sunshine ICU will be screened at time of discharge to the ward, to identify eligibility for inclusion in the study. For eligible participants, their families/carer will also be identified through the patient or via the routinely documented next of kin information in their medical record.

Recruitment – Eligible patient participants will be approached in the week prior to their hospital discharge and invited to participate in the study by a research assistant who will explain and provide them with the PICF (see Appendix I). Eligible participants will be approached for recruitment up to two-weeks post-hospital discharge via phone, if they are unavailable prior to hospital discharge or discharged home unexpectedly or over the weekend. If patients are contacted post-discharge, a letter will be sent outlining the project with the PICF prior to the phone call (Appendix J).

If patients require time to consider their participation in the study, the research assistant will be able to contact them at a later date, up to two weeks post hospital discharge.

If the patient participant consents to participation in the study, their family member / carer will be approached and invited to participate in the study also – either at the same time as recruiting the patient or shortly afterward. Families/carers may be contacted via phone to recruit if they are unable to be approached while the patient is in hospital (for example due to working during the day).

A Telephone Script for phone recruitment is provided in Appendix B.

A research assistant (yet to be recruited) not involved in delivery of intervention or data analysis will complete screening and recruitment.

### Inclusion Criteria

Patients and their families will be eligible based on the term ‘ICU survivor’ as previously defined ([10](#_ENREF_10)) (incorporating both) and if they meet the following inclusion criteria (as relevant to patient or family member):

* ICU admission at Sunshine hospital
* Age >18 years
* Able to speak and understand English
* Able to receive and participate in phone surveys
* Living in the community

### Exclusion Criteria

* Imminent death
* Bereaved family members
* Pre-existing or new cognitive conditions
* Pre-existing or new psychiatric conditions
* Severe neurological conditions
* Not expected to return home following discharge

Bereaved families are excluded as the focus of this project is on issues of survivorship and peer support related to this. Bereaved families have distinct needs that are beyond the scope of this project.

People with pre-existing or new cognitive/psychiatric conditions who will be unable to engage with the protocol (for example completing the outcome measures) will be excluded.

Participants who are not expected to return home will be excluded as we anticipate they would not be able to feasibly attend an in-person support group.

Screening will occur as detailed in Appendix E – Phase 2 Participant Screening Log.

* 1. Consent

Individual consent to participate will be obtained from the ICU survivors and their family members. Patients and carers will be invited to participate in-person, during the week prior to discharge, or via telephone in the week after their hospital discharge by a research assistant who will explain and provide them with the PICF (Appendix I). Participants who consent to participate will be informed of which group they were randomized to by a research assistant.

# **Participant Safety and Withdrawal**

### Risk Management and Safety

For both groups, there is a low risk that there may experience a small degree of discomfort when answering questions for outcome measurement.

For participants in the intervention group, it is anticipated that discussing ICU and subsequent experiences may cause some participants psychological distress. This is identified as a low to medium risk.

If participants experience any distress, they will be offered an opportunity to debrief with a psychologist or social worker (a psychologist and social worker are available as part of their role within the project team) as soon as possible and advised to contact their GP for ongoing management. Written information will be available for participants at each Peer Support Session regarding how to access psychological support in the community. Participants will be reassured that they can withdraw from the study at any point.

Stopping guidelines: We anticipate we will recruit 60 participants within a year and will stop once we recruit this final number.

### Handling of Withdrawals

Participants may withdraw from the study at any time if they chose to do so. They will be asked in the PICF if the data already collected from them may be used ongoing. Due to the nature of this study it is not anticipated that further procedures will need to be instituted if a participant withdraws from the study.

# **Statistical Methods**

### Sample Size Estimation & Justification

As this is a pilot trial, the sample size will be one of convenience determined in the absence of previous research on which to base a sample size and with no specific sample size required for pilot studies ([1](#_ENREF_1), [2](#_ENREF_2)).

The data obtained will be used to power for subsequent large randomised controlled trials.

We aim to recruit a total of 30 participants to the intervention group (peer support) and a total of 30 participants to the control group (standard care), resulting in a total sample size of 60. From Phase 1 participant recruitment data, it is anticipated that approximately 50% of recruited patients will have a family member / carer who will also consent to participate. As such, it is anticipated that of total sample size of 60, 40 will be patients and 20 will be carer/family participants.

A total 20 carer/family participants should result in 10 per group (intervention and control), which is a generally accepted minimum to calculate variance.

Data analysis will be as randomized. Planned sub-group analyses will be conducted based on the whether they are a patient or family member. Intervention effect sizes will be calculated to inform the power calculation of subsequent adequately powered trials.

### Power Calculations

No formal power calculation is required as this is a pilot study aiming to calculate power to determine effect in a future larger, multi-site RCT.

### Statistical Methods To Be Undertaken

Feasibility will be described in numbers and percentages. Continuous variables will be reported as mean and standard deviation (SD), or median and interquartile range [IQR] depending on data distribution.

Effect sizes for all secondary outcomes will be calculated and interpreted within-group (from baseline to follow-up) and between-group (follow-up) according to Cohen, where applicable (0.4 or less = small; 0.5 = moderate and 0.8 = large) ([29](#_ENREF_29)). Sample sizes for a future trial will be estimated using G\*Power (Version 3.1.9.2, Universitat Dusseldorf, Dusseldorf, Germany).

1. **Data Security & Handling**

### Details of where records will be kept & How long they will be stored

Electronic data will be stored as explained below and will be kept on the Western Health Physiotherapy Department’s computer drive (as this is the PI’s department). Electronic data will only be accessible by the investigators. Following completion of the study, the data will be kept for 7 years and then destroyed/deleted. Hard copy (manual data) will be destroyed via confidential waste.

### Confidentiality and Security

Electronic data will be re-identifiable and entered into a password protected electronic database or restricted access folder during the study. This will only be accessible by the investigators. Hard copy (manual data) will be kept in a locked cupboard accessible only by the researchers.

### **Appendices**

Appendix A – Outcome measures

Appendix B – Telephone Script for Consent

Appendix C – CRF Patient

Appendix D – CRF Carer/Relative

Appendix E – Screening Log

Appendix F – Attendance/Adherence Log

Appendix G – Letter of invite for Peer Support Sessions

Appendix H – Reminder letter for subsequent Peer Support session

Appendix I – PICF

Appendix J – Letter to participate

# **References**

1. Shanyinde M, Pickering RM, Weatherall M. Questions asked and answered in pilot and feasibility randomized controlled trials. BMC medical research methodology. 2011;11:117.

2. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. BMC medical research methodology. 2010;10:1.

3. Needham DM, Davidson J, Cohen H, Hopkins RO, Weinert C, Wunsch H, et al. Improving long-term outcomes after discharge from intensive care unit: report from a stakeholders' conference. Critical care medicine. 2012;40(2):502-9.

4. Robert G, Cornwell J, Locock L, Purushotham A, Sturmey G, Gager M. Patients and staff as codesigners of healthcare services. Bmj. 2015;350:g7714.

5. Haines K, Kelly, P., Fitzgerald, P., Skinner, E., Iwashyna, T. Particeps Non Nocere: Patient and family engagement in critical care. Critical care medicine. 2016;Invited Concise Defintive Review - under review.

6. Hoey LM, Ieropoli SC, White VM, Jefford M. Systematic review of peer-support programs for people with cancer. Patient education and counseling. 2008;70(3):315-37.

7. Heisler M, Halasyamani L, Resnicow K, Neaton M, Shanahan J, Brown S, et al. "I am not alone": the feasibility and acceptability of interactive voice response-facilitated telephone peer support among older adults with heart failure. Congestive heart failure. 2007;13(3):149-57.

8. Heisler M. Overview of peer support models to improve diabetes self-management and clinical outcomes. Diabetes Spectrum. 2016;20(4):214.

9. Hibbard MR, Cantor J, Charatz H, Rosenthal R, Ashman T, Gundersen N, et al. Peer support in the community: initial findings of a mentoring program for individuals with traumatic brain injury and their families. The Journal of head trauma rehabilitation. 2002;17(2):112-31.

10. Mikkelsen ME, Jackson JC, Hopkins RO, Thompson C, Andrews A, Netzer G, et al. Peer Support as a Novel Strategy to Mitigate Post-Intensive Care Syndrome. AACN advanced critical care. 2016;27(2):221-9.

11. Cuthbertson BH, Rattray J, Campbell MK, Gager M, Roughton S, Smith A, et al. The PRaCTICaL study of nurse led, intensive care follow-up programmes for improving long term outcomes from critical illness: a pragmatic randomised controlled trial. Bmj. 2009;339:b3723.

12. Locock L, Robert G, Boaz A, Vougioukalou S, Shuldham C, Fielden J, et al. Testing accelerated experience-based co-design: a qualitative study of using a national archive of patient experience narrative interviews to promote rapid patient-centred service improvement. Health Services and Delivery Research. Southampton (UK)2014.

13. Tsianakas V, Robert G, Richardson A, Verity R, Oakley C, Murrells T, et al. Enhancing the experience of carers in the chemotherapy outpatient setting: an exploratory randomised controlled trial to test impact, acceptability and feasibility of a complex intervention co-designed by carers and staff. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2015;23(10):3069-80.

14. Ream E, Tsianakas, V., Verity, R., Oakley, C., Murrells, T., Robert G. Enhancing the role of carers in the outpatient chemotherapy setting: a particpatory action research project. United Kingdom: 2013.

15. Tsianakas V, Maben J, Wiseman T, Robert G, Richardson A, Madden P, et al. Using patients' experiences to identify priorities for quality improvement in breast cancer care: patient narratives, surveys or both? BMC health services research. 2012;12:271.

16. Palmer VJ, Chondros P, Piper D, Callander R, Weavell W, Godbee K, et al. The CORE study protocol: a stepped wedge cluster randomised controlled trial to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness in the community mental health setting. BMJ open. 2015;5(3):e006688.

17. Palmer JB, Piper, D., Richard, L., Furler, J., Herrman, H., Cameron, J., Godbee, K., Pierce D., Callander, R., Weavell, W., Gunn, J., Iedema, R. Balancing Opposing Forces - A Nested Process Evaluation Study Protocol for a Stepped Wedge Designed Cluster Randomized Controlled Trial of an Experience Based Codesign Intervention: The CORE Study. International Journal of Qualitative Methods. 2016;15(1):1-10.

18. Connor KM, Davidson JR. Development of a new resilience scale: the Connor-Davidson Resilience Scale (CD-RISC). Depression and anxiety. 2003;18(2):76-82.

19. Sottile PD, Lynch Y, Mealer M, Moss M. Association Between Resilience and Family Member Psychologic Symptoms in Critical Illness. Critical care medicine. 2016;44(8):e721-7.

20. Maley JH, Brewster I, Mayoral I, Siruckova R, Adams S, McGraw KA, et al. Resilience in Survivors of Critical Illness in the Context of the Survivors' Experience and Recovery. Annals of the American Thoracic Society. 2016.

21. Measures H. Health Measures - PROMIS 2016 [cited 2016 3 August].

22. Nadig N, Huff NG, Cox CE, Ford DW. Coping as a Multifaceted Construct: Associations With Psychological Outcomes Among Family Members of Mechanical Ventilation Survivors. Critical care medicine. 2016.

23. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta psychiatrica Scandinavica. 1983;67(6):361-70.

24. Sukantarat KT, Williamson RC, Brett SJ. Psychological assessment of ICU survivors: a comparison between the Hospital Anxiety and Depression scale and the Depression, Anxiety and Stress scale. Anaesthesia. 2007;62(3):239-43.

25. Davydow DS, Gifford JM, Desai SV, Bienvenu OJ, Needham DM. Depression in general intensive care unit survivors: a systematic review. Intensive care medicine. 2009;35(5):796-809.

26. Weiss D. The Impact of Event Scale-Revised. In: Wilson JK, T., editor. Assessing psychological trauma and PTSD: a practitioner's handbook. New York, United States: Guilford Press; 2007.

27. Creamer M, Bell, R., and Falilla, S. Psychometric properties of the Impact of Event ScaleRevised. Behaviour Research and Therapy. 2002;41:1489-96.

28. Needham DM. Improving Long-Term Outcomes Research for Acute Respiratory Failure United States2017 [cited 2017 26 October]. Available from: <http://www.improvelto.com/>.

29. Cohen J. Statistical power analysis for the behavioural sciences. New Jersey, United States: Lawrence Erlbaum Associates; 1988.