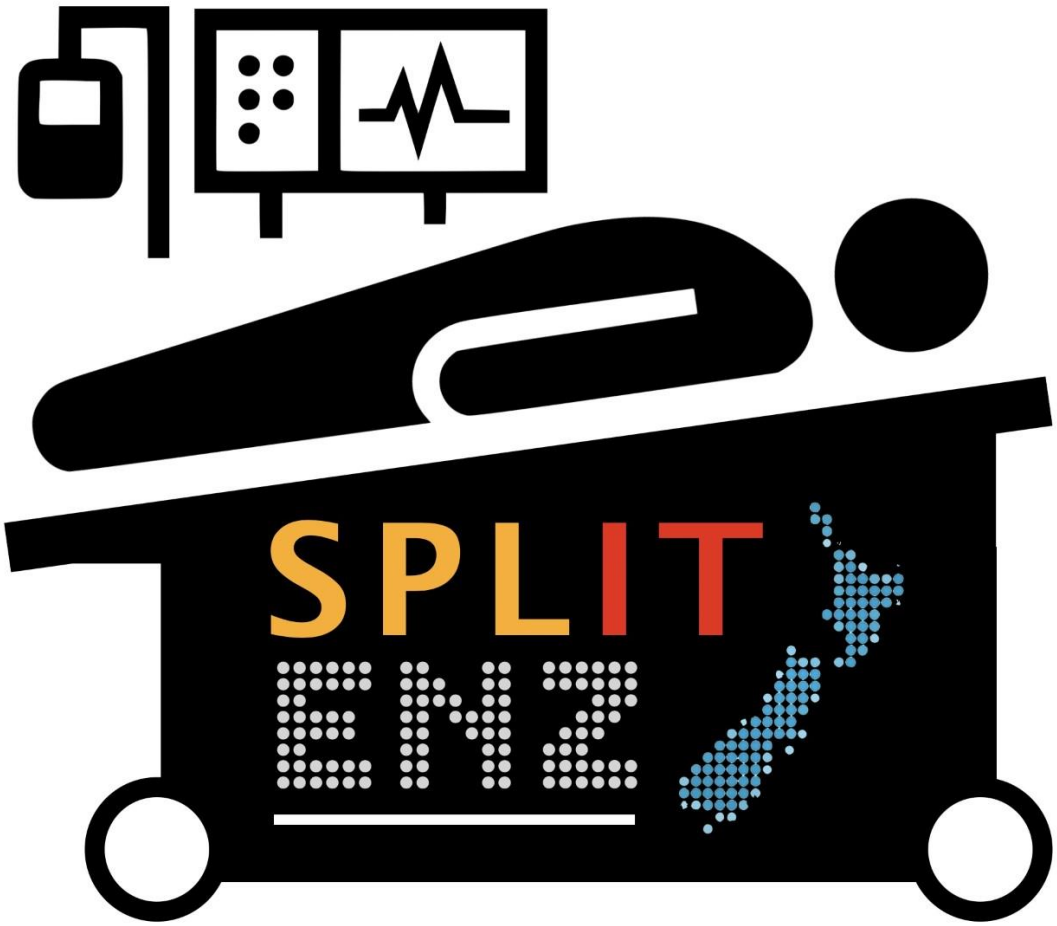
SPLIT ENZ: Survivorship of Patients post Long InTensive care stay, Exploration/Experience in a New Zealand cohort



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SPLIT ENZ*: Survivorship of Patients post Long Intensive care stay, Exploration/Experience in a New Zealand cohort

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CONTENTS

INTRODUCTION

In 2014, Intensive Care celebrated its 60th anniversary as a specialty health care service. The first Intensive Care Unit (ICU) in Australasia was founded in Auckland in 1958 but it wasn't until the 1970's that the service was recognized as a stand-alone specialty. Over the years the Intensive Care discipline has grown, with the establishment of the Australia and New Zealand Intensive Care Society (ANZICS) and College of Intensive Care Medicine (CICM) driving training, research and education. In the early years of Intensive Care, focus was very much around technology driven therapies providing organ support and mechanical ventilation to the Critically Ill.

Over the last decade the ICU mantra has moved away from highly technological "doing everything", to a less is more, approach, focusing on improving quality of care (Auriemma, Van den Berghe, & Halpern, 2019). The in-hospital mortality rate among Australasian ICU's is the lowest it has ever been (ANZICS, 2020). Whilst survival is clearly a primary aim of Intensive Care, there is a growing emphasis on the survivorship journey, morbidity, and poor quality of life for patients post Critical Illness (Hodgson et al. 2017). New or worsening of impairments in any of the physical, mental health or cognitive function is collectively known as the Post Intensive Care Syndrome (PICS) a common occurrence post critical illness (Needham et al. 2012). Presently there is no operational definition or diagnostic criteria applied to the syndrome and to date, there is no published research on the impact of these impairments in New Zealand.

Long term outcomes after Critical Illness

Much of the early understanding of PICS has come from patient follow up clinic settings in the United Kingdom and United States (Lasiter et al. 2016). Even before the term PICS was used to describe the myriad of post ICU impairments, Cuthbertson et al. (2010) showed quality of life was significantly impacted for patients up to five years after critical illness. Herridge et al. (2015), went on to show that patients with respiratory failure and the Acute Respiratory Distress Syndrome (ARDS) continued to have high morbidity and mortality, and poor functional, cognitive, and mental health outcomes for months to years after.

More recently, Haines et al. (2018) also provides an important observational study evaluating 5-year outcomes for 150 Australian patients recovering from critical illness. They found mortality was highest in the year following discharge home, with nearly half of all patients dying in this timeframe. In those that survived, most of the recovery occurred in the first-year, albeit with impairments in quality of life, mental health and function.

Who is most at risk for PICS?

There are numerous factors that have been found to contribute to the risk for PICS. Individual patient characteristics such as social demographics, personality type education level, and previous health (especially depression and anxiety) as well as a negative ICU experience (delirium, pain, and Insomnia) are major contributing factors to PICS (Girard et al. 2010; Lee, Kang and Jeong, 2020). The ICU-acquired weakness (ICU-AW) is an important contributor to the physical & functional deficits of PICS. Mechanical ventilation and the resultant delivery of sedation, Neuromuscular Blocking Agents (NMBA's), steroids and immobility contribute to this functional weakness (Lee, Kang & Jeong, 2020). Certainly, long periods of mechanical ventilation (>7-14 days) are correlated to prolonged impairments, but even relatively shorter periods of mechanical ventilation (>72 hours) and a moderate length of ICU stay (7 days) can impact on functional outcomes and return to work (Damuth et al. 2015; Herridge et al. 2016; Hodgson et al. 2017).

ICU length of stay is an important determinant of outcome post critical illness (Hermans et al. 2019). Patients defined as being "long term" or "chronically critically ill" are more likely to have had the highest acuity with importunate reliance on multi organ support and mechanical ventilation. Recently, the long-term patient has been re-defined to reflect the complex nature and impact of critical illness and the prolonged recovery required both in the ICU and once home. The term "persistently critically ill" is now used to characterise those who progress to continued reliance on life support that **is no longer related to their original illness**. Bagshaw et al. (2018), Darvall et al. (2019), and Iwashyna et al. (2015) suggest this occurs around day 10 ICU stay, but these patients may have ICU stays of anywhere between 7-21 days.

The Persistently Critically ill account for only 5.0% of all ICU patients in Australia and New Zealand—yet 32.8% of all ICU bed-days and 14.6% of all hospital-bed-days by ICU patients. There is approximately one in six persistently critically ill patients in Australasian ICU's (Bagshaw et al. 2018; Darvall et al. 2019). It is these patients that represent those with the greatest risk for PICS. With an ageing population who are increasing medically complex and frail, this figure is predicted to increase (Darvall et al. 2019).

Outcome Measures used in PICS research

There is currently no standardised, comprehensive tool to measure PICS, with over 250 separate tools in existence (Turnbull et al. 2016). Whilst research around validated tools such as PICS questionnaires are beginning to emerge, they are not without limitations and are currently not generalisable to a New Zealand population (Jeong & Kang, 2019; Wang et al. 2019). Currently, the emphasis is on identifying a set of tools/questionnaires that can best quantify impairments in each of the domains of PICS. This will ensure the same reproducible outcome measures, with comparability between studies and the generation of good quality meta-analyses (Hodgson et al. 2016). Several International expert Critical Care expert committees have published recommendations in the core outcome sets (COS) that should be used in research evaluating long term outcomes in ICU survivors (Denehy et al. 2014; Mikkelsen et al. 2020; Needham et al. 2017; Robinson et al. 2017; Spies et al. 2020). The recommended COS in these domains is summarised in Appendix One.

Core Outcomes must reflect the views of critical illness survivors and their families. Research on survivorship should focus on the preeminence of the patient's values and preferences of their own recovery. Dinglas, Faraone & Needham (2018) identified survival, physical function, cognition, mental health, health-related quality of life, pain, return to work and social health important areas of focus for future research as identified by survivors of critical illness.

Overview of relevant research

Since PICS was first conceptualised nearly a decade ago by the Society of Critical Care Medicine (SCCM) an ever-growing body of knowledge is developing. Despite

the emerging awareness of the importance of PICS in survivors of critical illness, there remains only a paucity of high-quality research focussed on patient centred outcomes and the PICS journey.

Jackson et al. (2014) in their American prospective cohort study, followed up over 400 patients treated in the ICU from respiratory failure and shock at 3- and 12-months post CI. The primary outcome was to assess the association between age and duration of delirium with mental health outcomes and functional disability. They used Beck Depression Inventory-II, Post Traumatic Stress Disorder (PTSD) Checklist and the Activity of Daily Living Scales, Pfeffer Functional Activities Questionnaire and Katz activities of Daily Living Scales as outcome measures. They found Depression was common, with 37% reporting mild depression at 3 months and 33% at 12 months. Only 7% had symptoms consistent with PTSD. Disabilities were also common, with 26% reporting functional deficits at 3 months and 23% at 12 months. Interestingly Delirium was not found to be associated with mental health issues or functional deficits, however, the researchers did not assess patient's cognitive function, despite delirium being a known risk factor (Girard et al. 2010). Even a relatively short duration of mechanical ventilation (2 days) and ICU length of stay (mean 5 days) was linked to important negative sequelae for patients.

Marra et al. (2018) published their seminal research, exploring the co-occurrence of PICS in 406 survivors of CI in their multi-centre cohort study. The researchers actively excluded patients with known impairments in baseline activities of daily living (ADL) and cognitive dysfunction (including post cardiac surgical patients who had undergone cardiopulmonary bypass in the previous 3 months) to understand the effect of critical illness in the development of new impairments. They followed up patients at 3 and 12 months and assessed impairments in function, depression and cognition using the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), Katz Activities of Daily Living Index, and Beck Depression Inventory-II. They found 128 (38%) & 97 patients (33%) had cognitive impairment at 3 and 12 months, 100 (26%) and 69 patients (21%) had functional disabilities at 3 and 12 months and 121 (33%) and 97 patients (31%) had depression at 3 and 12 months. A single PICS problem

occurred in 130 (39%) and 101 patients (35%) at 3 and 12 months, double PICS problem with 62 (19%) and 47 patients (16%) at 3 and 12 months. Only 19 (6%) and 12 patients (4%) had a combination of 3 PICS problems at 3 and 12 months. Overall, approximately 4 in 10 patients were PICS free at 3 months. Of those with one PICS problem at 3 months (211 patients), 21% were PICS free at 12 months, 55% still had PICS problems at 12 months, 9% died and 16% were lost to follow up. Of those who were PICS free at 3 months (119 patients), 64% remained PICS free at 12 months and 16% developed a PICS problem at 12 months. Significant factors leading to the development of PICS were advancing age and higher clinical frailty scores. Survivors who were PICS free tended to have less duration of mechanical ventilation, less delirium, were younger, and had fewer co-morbidities. This novel piece of work has been instrumental in highlighting the extent and impact of the effects of a critical illness on newly acquired impairments leading to cognitive dysfunction, functional disability, and depression.

Hodgson et al. (2017) uses a lens on disability by mapping PICS impairments to the World Health Organization (WHO) International Classification of Functioning Disability and Health (ICF). Hodgson et al. (2017) studied the prevalence of disability among 262 Australian Survivors of CI at 6 months using the World Health Organisation's Disability Assessment Schedule 2.0 (WHODAS) as the primary outcome measure. The World Health Organisation's Disability Assessment Schedule 2.0 (WHODAS) was developed to measure disability across six major life domains: cognition, mobility, self-care, interpersonal relationships, work and household roles, and participation in society. As well as WHODAS 2.0, they also used the Hospital Anxiety and Depression Score (HADS), and Impact of events Scale Revised (IESr) to assess mental health outcomes, the EQ-5D-5L to measure quality of life, and the telephone Interview for Cognitive Status (TICS) to assess cognitive function. They found the moderate to severe disability was highly prevalent in survivors at 6 months, with 50% had mild disability and 25% had moderate to severe disability. Those with moderate to severe disability were more likely to have a history of depression and anxiety and have a longer duration of mechanical ventilation, have a worse health related quality of life, significant reduction in mobility, personal care and activities, have depression, anxiety and PTSD. Furthermore, only 40% had returned to work or study because of these

disabilities. This finding is certainly echoed in other work by Hodgson et al. (2018) where only 31/107 (29%) of patients had returned to work at 6 months. In summary, cognition, mental health, and physical function are affected impacting on all areas of function; physical, mental, social, financial and relationships, and overall quality of life. (Hodgson et al. 2017; Ohtake et al. 2018).

Heydon et al. (2020) provides another insightful Australian based study exploring the needs of 50 survivors and their families. They assessed patients for PICS using the Eq-5D-5L, the Functional Activities Questionnaire (FAQ), and a novel "needs" questionnaire regarding healthcare service usage and socioeconomic status. Study participants demonstrated a statistically significant decline in their health outcomes at baseline with a modest improvement at 3 months. Unsurprisingly, they found an increase in healthcare service usage during the 3 months post CI and the biggest self-reported need unmet among these patients was mental health support. They also report concerns around socioeconomic factors that continued for patients at the 3 month follow up timeframe.

Long term outcomes post COVID-19

Unfortunately, New Zealand is no longer a haven from COVID-19, with a re-emergence of the Delta variant transmission in the community. We anticipate that this will impact on the overall patient cohort in the ICU for the near future and will be a significant population relevant to this study.

The long-term effects and outcomes post COVID-19 are clearly documented. A recent meta-analysis showed that 80% of the infected patients with SARS-CoV-2 developed one or more long-term symptoms. The five most common symptoms were fatigue (58%), headache (44%), attention disorder (27%), hair loss (25%), and dyspnea (24%) (Lopez-Leon, 2021). However, more than 55 prolonged symptoms were identified in patients infected with Coronavirus in that meta-analysis. There are wide variations in the definition and timing of these problematic outcomes post COVID-19, but most clinicians would recognise the term "Long-Covid". Whilst long COVID is different to PICS there are many similarities. What is clear from the evidence is that a large proportion of patients who were in the ICU with COVID-19, have significantly prolonged recovery, where

disability is a key feature (Rousseau et al. 2021). A study by Rousseau (2021) assessed 92 Belgian patients at 3 months post discharge using a standardized assessment, exploring health-related quality of life (EQ-5D-3L), sleep disorders (PSQI), and the three principal components of PICS: physical status (Barthel index, handgrip and quadriceps strength), mental health disorders (HADS and IES-R), and cognitive impairment (MoCA). Over 85% of participants had not returned to baseline function with notable sequalae resulting in sleep disorders, cognitive, mental health and physical dysfunction, a spectrum of recovery issues that are also key features of PICS.

Summary:

It is clear the profound effect and impact, critical illness has on the individual and family. Not only do impairments relating to cognition, mental health, and physical function create new and lasting disability, but quality of life, return to work and social aspects, are also affected. In Australasia, research is only just emerging with some important seminal studies conducted, enabling a greater understanding of the recovery journey and extent of disability in survivors. However, there is a distinct lack of research conducted in New Zealand with almost no understanding of the needs of patients and Whānau in the year during recovery or level of disability and dysfunction. To understand the extent of disability and the survival journey in New Zealanders with and without COVID-19 would be of huge benefit. It could contribute to and stimulate further research into specific resources and strategies that will improve health outcomes in the future for critical ill patients.

Aim(s) and objectives of Study

The aims of this study are:

I. To estimate the proportion of intensive care survivors with moderate or severe disability at different time-points after discharge.

II. To describe the data distributions of a variety of relevant clinical variables in intensive care survivors and estimate associations between baseline characteristics of intensive care survivors and disability and its change with time.

III. To describe unmet health needs in ICU survivors.

STUDY DESIGN

This study will be a mixed methods design. The first component is a prospective cohort study using validated tools (questionnaires) to assess and quantify the level of disability in the 12 months following critical illness. Functional disability will be assessed using WHODAS 2.0. Other important variables related to disability are Health-related quality of life, mental health, and cognition; and these will be assessed post-discharge, and after six months and 12 months. This will address Aims I and II of the study.

The second component is a qualitative study that will explore the process of recovery for participants. The major impetus will be to identify the ongoing needs (met and unmet) in the year following critical illness, (aim III of the study). This design will use a nested convenience sample conducting semi-structured Interviews at around 6-8 months post discharge home. This study design has been chosen to measure and quantify the impairments and symptoms related to PICS alongside qualitative interviews to allow the participant to tell their story of recovery. This method will provide context and meaning to the quantitative findings and highlight what the ongoing needs are for participants who are recovering from critical illness. This will hopefully stimulate further interest or research into strategies to better meet these needs for participants recovering from critical illness in the future. The qualitative study protocol is described on pages 26-29.

Study Setting/ Location

This will be single centre study with participants recruited at Wellington Hospital Intensive Care Unit (ICU). Considering, Wellington ICU retrieves a third of all patents from the lower North Island and upper South Island, a large number of recruited participants will likely be spread across the lower North Island and upper South Island at follow up.

Study Sample

The study sample will be all adult patients (> 18 years old) admitted to Wellington ICU who meet the inclusion criteria within the recruitment period. This is likely to comprise a mix of patients with and without COVID-19 who meet the inclusion criteria.

ELIGIBILITY CRITERIA

Inclusion criteria

All patient participants will be adult ICU patients admitted to Wellington ICU who are > 18 years old, been in an ICU for seven or more consecutive days, or patients who were mechanical ventilated for >72 hours. Patients who have been in another New Zealand ICU/Critical Care Unit prior to retrieval to Wellington ICU will be included once both admissions = >7 days.

Mechanical Ventilation is defined as a positive pressure ventilation (PPV) mode via an Endotracheal, Nasotracheal or Tracheostomy tube. Patients who have been extubated from PPV for a period and then reintubated are also included if both periods of PPV exceed 72 hours. Patients with COVID-19 will be included.

Exclusion criteria

- Patients who are < 18 years old
- Non-English speakers
- Patients not expected to survive their hospital stay (deemed by ICU Senior Medical Officer (SMO) once inclusion criteria met).
- Patients in whom follow up would be challenging/impossible (e.g., prisoners, people who are homeless).

- Patients with pre-existing neuromuscular disorder (e.g., Muscular Dystrophy, Multiple Sclerosis, Myasthenia Gravis, Guillain Barre).
- Neurovascular/neurotrauma/status epilepticus.
- Patients who have or suspected to have hypoxic/ischemic brain injury/encephalopathy.
- Significant pre-existing psychiatric disease or intellectual disability such that the patient was mentally, cognitively, or functionally impaired prior to ICU admission.
- Patients with diagnosed neurodegenerative disease
- Patients with prior moderate to severe cognitive impairment (as recorded in the patient health records/medical notes).
- Any other significant disease or disorder which, in the opinion of the Investigator, may influence the result of the trial.

Patients who have a past medical history/diagnosis of depression or PTSD will be included but analysed separately as a subpopulation as these patients have a high likelihood of additional mental health issues post critical illness (Hodgson et al. 2020). This information will be obtained through the patient's electronic health records. Prior mental health issues that have not been formally diagnosed, or where the participant may not have sought help (and thus not recorded as part of the patients Past Medical History) will be ascertained at the first follow up and the patient directly asked the following question(s) (see appendix 2).

- Have you ever been diagnosed with a mental health problem by a Doctor or Psychologist?
- If so, what was the diagnosis they made?

Patients who are post cardiac surgery and have undergone cardiopulmonary bypass (CPB) will also be included but analysed separately as a sub-group. These patients are high risk for post-operative cognitive dysfunction because of CPB, and this may skew the results overall (especially for the cognitive outcome) (Relander et al. 2020). However, we feel it is still important to measure and highlight the outcomes and recovery journey for this group of patients, because they represent a considerable patient group admitted to the ICU.

STUDY OUTCOMES

Primary Outcomes

The primary outcome for the prospective cohort study is the prevalence of moderate or severe disability, as defined by the **World Health Organization Disability Assessment Schedule 2.0** (WHODAS-12) 6 months after discharge.

The Hypothesis is "in adult ICU patients who have had a prolonged stay in the ICU, > 20% will experience moderate to severe disability in the year following critical illness"

Secondary Outcomes

Health-related Quality of Life: EQ-5D-5L derived health utilities

Mental health– Impact of events Scale Revised (IES-R), Hospital Anxiety and Depression scale (HADS),

Cognitive function - The Montreal Cognitive Assessment – Blind (MOCA-Blind)

- Mortality/survival
- Return to work/study (WHODAS 2.0)
- Self-reported needs met/unmet (Qualitative Interview)

(Appendix three)

Other Data Measures (collected retrospectively once patient consent given)

Pre-illness state/Pre ICU function:

- Clinical frailty score
- Functional Comorbidity Index and types of co-morbidities
- Charlson Comorbidity Index

Length of stay & Funding:

- ACC funding (yes/no)
- Hospital length of stay
  ICU length of stay

Measures of clinical status/acuity:

- Primary reason for ICU admission/diagnosis
- Apache II and Apache III score

- Sequential organ failure score(s) (SOFA score) daily
- Number and type of clinical complications in the ICU (described/listed)
- Pa02/Fio2 ratio per day whilst mechanically ventilated
- Number of reintubations/failed extubations during ICU stay

Duration (hours/days) of interventions:

- Renal Replacement Therapy (continuous/intermittent dialysis), Extra-corporeal membrane oxygenation (ECMO), vasopressors, invasive hemodynamic monitoring, antibiotic therapy duration.
- Time to negative PCR and if isolated for COVID-19
- Daily oxygen therapy: specifying High Flow Nasal Prongs (HFNP), Low flow oxygen (i.e. via nasal prongs) Non-Invasive ventilation (e.g.: BIPAP or CPAP), Direct Tracheostomy Interface (DTI).
- Oxygen free days
- Mechanical Ventilation duration hours/days and mode
- Time to extubation and Tracheostomy decannulation
- Tracheostomy weaning duration
- Sedation types and doses per day
- Mean Richmond Agitation Sedation scores per day
- Paralysis agents (NMBA's) doses and type per day
- Delirium duration hours/days as evidenced by CAM-ICU scores

Other:

- Best daily ICU mobility score (if recorded)
- Chelsea Physical Assessment Score on discharge (CPAx)
- If a patient diary was assigned to the patient in the ICU

STUDY PROCEDURES

Recruitment of participants

The ICU database will be screened daily by the Coordinating Investigator (CI) within the recruitment period for those who meet the inclusion criteria. Once the inclusion criteria are met, patients will be screened to ensure they do not meet any of the exclusion criteria. If they meet all the inclusion criteria and none of the

exclusions apply, the patient and whanau will be approached. It is highly likely that patients will be unable to provide consent at that time, so whanau will be given information around the study and informed that once the patient is able to give consent, they will be approached. This is likely to be just prior to hospital discharge.

Consent

All information around the study will be presented in written format using plain English, non-jargon and clear formatting (Appendix four). The CI will also go through the written information in a face-to-face meeting or via phone call with the patient and whanau along with the written material in preparation for consent.

An approach consistent with section 7.4 of the Health and Disability Code, will be used to gain consent. However, it is acknowledged that the consent process may be required to change if there is COVID-19 in the community and/or if the National Alert levels escalate to a local lockdown. There are two proposed processes for gaining consent for this research. One for the optimal scenario where there is no community transmission of COVID-19; and a second where a patient has COVID-19 or there is community transmission. It is likely some of the participants in this study will themselves be patients with COVID-19. The following outlines the different scenarios and their contingencies:

When consent can be gained in hospital:

Consent will be gained from prospective participants prior to discharge home from hospital (whilst recovering on a ward), but only when they are able to give informed consent (i.e. when awake and not delirious). The patient and whānau/family will be given all the necessary information about the study by the CI in a face-to-face meeting, and consent forms will be given to the patient. The patient will be given sufficient time to think about participation and if they are happy to take part, signed consent forms will be collected.

Where consent cannot be gained in hospital:

Consent is unlikely to be gained before hospital discharge for a number of reasons; Firstly, it is unlikely that the CI will have freedom to move around the hospital with local inter-hospital lockdowns and in COVID hot zones. Secondly if the patient remains infectious with COVID-19, obtaining signed paper consent forms will be impossible. Face to face meetings may also be logistically challenging. Thirdly, the patient may be transferred to another facility/domicile within or outside of the DHB, and the opportunity to gain written consent may be easily missed.

In these scenario's the patient will be followed up by phone call(s) once home and two options to gain that consent will be used. The patient will be asked at the phone call by the CI which method they would prefer and this will be documented.

1. Consent forms can be mailed to patient's current/home address with a prepaid envelope provided for mail back to the centre. Completed consent forms can either be e-mailed or mailed back to the CI. Prepaid envelopes will be provided for mail back to the centre. If the patient finds it easier to take a photo of the signed page and send it this way, that can be done via email or text back to the CI.
2. An online consent via the REDCAP (Research Electronic Data Capture) system has been set up to enable online consents and signatures for patients who prefer to consent via an electronic platform. Exactly the same wording and elements are used in the electronic version as are used in the paper copy (which has already undergone ETHICS review), with minor formatting alterations. A link to the consent form can be texted and emailed, and the participant has the option to sign the form either using a PC, an IPad, or a smart phone. There is no need for the patient to log in or create a user account, they simply access the link, and it takes them straight to the consent form pages and are able to sign using a mouse or stylet in the signature field. If participants are unable to use a mouse to sign (if using a smart phone for example), then a free text box has also been added to provide their full name and date of birth as consent. A pdf copy of this consent form is provided on page 38, appendix six.

At each follow up, participants will be asked verbally if they still wish to continue in the study. If they identify they want to withdraw, they will be withdrawn from the study. Data up until that point will continue to be used. Participants will also be informed they do not need to provide a reason and their continued care and treatments will not be affected by their decision to withdraw. This is clearly outlined in the participant information sheet.

There are a number of other, non-COVID scenarios for consent that may arise. They are summarised in the following table with the relevant contingency plan to manage each:

Scenario	Approach
Patient declines to participate in the study or withdraws consent but is happy to consent to the use of some or all study data.	The participant (or family's) specific wishes will be documented in a note to file and we will use whichever approach the patient wants us to.
Patient does not recover sufficiently from their illness to provide informed consent prior to hospital discharge	We will continue to follow-up the patient by phone and obtain written informed consent as soon as possible. Where a patient agrees to participate in the study but does not return a written informed consent form (for example due to illiteracy or other factors), we will document all conversations with the participant in a note to file and will only include the participant's data where a clear wish to participate is expressed
Patient does not recover sufficiently from their illness to provide informed consent by the start of the study follow up (2-4 weeks after hospital discharge) or dies before informed consent can be obtained.	We will include some of the data already collected such as date of death, ethnicity and cause of death (for the final data reporting purposes).
Patient is physically incapacitated as a result of their illness (e.g. severe limb weakness) and are competent but cannot sign a consent form	In this situation we will document the patient's wishes in a note to file and include the patient in the study if they indicate that they are willing to participate. At a time in the follow up when the patient becomes able to sign the consent form, this will be completed by the Coordinating Investigator.
Patient has no next of kin or other identifiable person to ask about their wishes	The patient will be enrolled and at the earliest available opportunity the patient can consent, they will be approached, and all information given thoroughly.

Randomisation

There is open recruitment of patients into the study, no blinding or randomisation process.

Initial data collection

Once recruited into the study at the point they become eligible, data will be collected around admission details, demographics and ethnicity, baseline function (Functional Comorbidity Index, clinical frailty score) from the ICU database, Medical Applications portal (MAP) and the patient's clinical notes. Data will be documented on screening and data collection templates and inputted into an excel spreadsheet.

Once consent has been gained, the patient's clinical data will be recorded on data collection templates. This will include type and number of clinical complications (i.e Sepsis, Ventilator Associated Pneumonia, duration of renal dialysis), diagnoses during ICU stay, duration of mechanical ventilation, sedation Analgesia & muscle relaxant daily doses, delirium duration, patient diary use, presence of ICU acquired weakness, ICU mobility scores, and ICU length of stay. All data measures that will be recorded are listed on pages 14 & 15.

Participant Timeline: Screening, Consent & Follow up (Summary)

Time point	**Day 7 ICU or mechanically ventilated for 72 hours or more**	**ICU discharge**	**Wellington Hospital discharge (home or DHB of domicile)**	**2-4 weeks post discharge**	**6 months**	**12 months**
Patient Informed Consent						
Data Collection	• Ethnicity and Iwi/Hapu • Dates and times of admission to Hospital, ward, ICU • Clinical frailty score • Apache II score • Functional Comorbidity Index • Daily SOFA scores • Daily Fio2/pao2 ratio (during mechanical ventilation) • Primary reason for ICU admission/diagnosis	• Number and type of clinical complications in the ICU (described/listed) • Pa02/Fio2 ratio per day whilst mechanically ventilated • Number of reintubations/failed extubations during ICU stay **Duration (hours/days) of interventions:** • Renal Replacement Therapy (continuous/intermittent dialysis), Extra-corporeal membrane oxygenation (ECMO), vasopressors, invasive hemodynamic monitoring, antibiotic therapy. • Time to negative PCR & time in isolation room for COVID-19. • Daily oxygen therapy: specifying High Flow Nasal Prongs (HFNP), Low flow oxygen (i.e. via nasal prongs) Non-Invasive ventilation (e.g.:		**Follow up** • Hospital Anxiety and Depression Scale (HADS) • Impact of Events Scale revised (IES-R) • Montreal Cognitive Assessment (MOCA-Blind) • World Health Organisation Disability Assessment Schedule 2.0 (WHODAS) • EQ-5D-5L •		

		BIPAP or CPAP), Direct Tracheostomy Interface (DTI) or room air only. • Mechanical Ventilation duration hours/days and mode • Time to extubation and Tracheostomy decannulation • Tracheostomy weaning duration • Sedation types and doses per day • Mean Richmond Agitation Sedation scores per day • Paralysis agents (NMBA's) doses and type per day • Delirium duration hours/days as evidenced by CAM-ICU scores • Best daily ICU mobility score (if recorded) • Evidence of ICU Acquired neuromuscular weakness (mild, mod or severe on day of ICU discharge) • If a patient diary was assigned to the patient in the ICU		

Follow up timeframe

The Clinical Applications Portal and medical Applications portal will be accessed to provide the patients final discharge home date. This will be recorded in the patient data logs and on the excel spreadsheet and key dates for follow up will be logged.

Just prior to each follow up period, a call will be made to participants to ascertain the preference for time, date & mode of follow up. These follow up time frames will be:

2-4 weeks post discharge home

6 months post discharge home

12 months post discharge home.

Prior to each follow up (1-2 weeks before), the questionnaires and a templated letter will be emailed and mailed to participants with an information cover sheet outlining the process for follow up, what to expect and what is expected of them. The purpose of this is to enable participants to have a visual reference at the same time of the telephone assessments, so that it is easier for them to follow, less time consuming, improve efficiency, and enhance the quality of the information reported (see appendix five). The templated letter emphasises if the participant wishes to complete them "on paper" prior to the follow up, this is allowed (but not necessary).

Outcome Measures

At these follow up periods, the following tools/outcome measures will be completed by telephone/video conferencing in this order

- World Health Organisation Disability Assessment Schedule 2.0 (WHODAS) (primary)
- Montreal Cognitive Assessment (MOCA-blind)
- Hospital Anxiety and Depression Scale (HADS)
- Impact of Events Scale revised (IES-R)
- EQ-5D-5L

These tools have been chosen based on applicability to a New Zealand population, recommendations from expert committees and international research(ers). However, they have also been chosen considering resource constraints, feasibility, and ease of use. Combined, all these questionnaires take around 25 minutes to complete (WHODAS 5 mins, Moca blind 5-10 mins, EQ-5D – 5 mins, HADS 2-5 mins, IES-r – 5 mins). This core outcome set has been used in many post ICU follow up studies without any problems (Needham et al. 2017).

Withdrawal of Participants:

Participants will be given 3 attempts to be contacted by phone to complete follow up. If the first phone call is unsuccessful in contacting participant (and they are given other means to return contact), a further two calls will be made. They will also be sent reminder texts, emails, or mail, prior to follow up to ensure continued engagement with the study. However, those who do not respond after 3 phone calls (plus text, mail) over a 4-week period will be considered lost to follow up and withdrawn. Data up until that point will continue to be used.

Participants who are readmitted back to the hospital at the time of follow up will continue to be followed up, with assessments delayed until discharge home again. If the participant becomes deceased, date and reasons for death will be recorded to enable close reporting of loss to follow up as possible (and the participant will obviously be withdrawn).

Participants who communicate their wish to withdraw either verbally or in writing at any time, will be withdrawn immediately. Participants will be informed (and it is stated in the participant information) they can withdraw at any point for any reason, and they do not have to state why. Data up until that point will be continued to be used in the study. This aspect will be clearly communicated in the participant information/consent form.

STATISTICAL CONSIDERATIONS AND DATA ANALYSIS

Sample size and statistical power

In this study in a single center there are going to be an estimated 100 potential participants at 6 months. Based on this, the 95% confidence interval for a

proportion is going to be plus or minus 10%; and this gives scope, based on a likely proportion of participants with moderate/severe disability using WHODAS 5% to have 3 predictor variables in a multivariate logistic regression. We will endeavor to oversample (to 125 participants), extending the recruitment period if needed, while keeping the overall project within the timelines required for PhD completion. This should ensure that data from 100 participants are available for analysis at 6 months. We will continue to follow up at 12 months the patients recruited as planned, but, will ensure at least 100 participants data is available at 6 months.

Estimated Loss to Follow up

It is estimated that a significant proportion of patients will be lost to follow up, either as a result of death or attrition. Studies oversees report highly variable mortality rates in the year post ICU, around 20%-50% (Detsky et al. 2017; Garland et al. 2014, Haines et al. 2018). For COVID-19 patients, mortality is also high at around 30% 6 months post discharge, and with an in-hospital mortality rate reported to be anywhere between 50-97% (Oliveira et al. 2021). However, as the pandemic has progressed, and knowledge and care has improved, their 30-day survival is much improved, with a mortality rate around 20% (Bateson and Peake, 2021).

Other factors such as consent withdrawal and inability to contact the patient reported in Australian studies to result in 10-20% attrition (Heydon et al. 2020, Hodgson et al. 2017, Skinner et al. 2015). Wilcox and Ely (2019) highlight that larger studies with bigger research teams may result in approx. 70-80% completion rate, however those smaller studies with single/limited research teams may experience logistical and feasibility issues that compound loss to follow up.

Strategies to reduce loss to follow up:

Best practice research recommendations stipulate the importance of thorough reporting of the rate of loss to follow up, alongside demographic and baseline patient information of those unable to complete (Needham et al. 2005). Loss to

follow up will be collated and reported, while strategies will be used to maximise continued recruitment throughout the study. Some of these strategies are outlined in literature published by Madden et al. (2017) and Kaur et al. (2014) and include asking patient/family preference for interview (paper questionnaire, email or technology based etc.), regular contact to ensure engagement through the year (text, mail reminders), ensuring up to date multiple contact methods is obtained at consent and clear written information delivered prior to follow up (See Appendix seven).

Statistical methods

Continuous variables will be described by mean and standard deviation (SD); median and inter-quartile range, and minimum to maximum. Where appropriate frequency histograms and boxplots will also be used to summarise data distributions. Categorical variables will be described by numerators and denominators and proportions expressed as percentages.

Proportions will be estimated together with confidence intervals by standard binomial methods. It is anticipated that asymptotic methods for the confidence intervals will be satisfactory but should there be many small frequency counts exact binomial methods will also be used (Aim I).

Associations between disability measured by the WHODAS and potential univariate predictors will be by logistic regression with disability categorized and moderate/severe versus lesser degrees of disability. As a sensitivity analysis WHODAS will be treated on a continuous scale and ordinary regression used. For the latter normality assumptions will be assessed by residual analyses to determine if a data transformation will be needed or if another form of regression such as ordinal regression might be more suitable. With the anticipated 25-30 participants with moderate/severe disability this gives limited scope for multivariate analysis but as discussed below a more limited number of potential predictors will be used in a multivariate model to determine if associations remain after adjusting for confounding.

We selected *a priori* the following covariates as potential predictors of disability after intensive care admission:

Age, Gender, Ethnicity, APACHE II score, SOFA score, duration of sepsis (days), frailty score, Functional Comorbidity Index, length of ICU stay reported in days, presence of ICU-AW (reported as a dichotomous outcome), duration of mechanical ventilation (in hours), duration of delirium (reported as days the patient was CAM-ICU positive), total doses of sedation, benzodiazepines, and neuromuscular blockade drugs (NMBA's), prior history of depression, anxiety or PTSD (obtained from medical records, ICU database admission and MAP) and whether the ICU admission was for Cardiothoracic surgery and/or cardiopulmonary bypass. Drug doses (sedation, benzodiazepines, MNBA's) will be transformed into mean doses per day and analysed over number of days received.

Each of those potential predictors will be examined by univariate predictors with accompanying illustrative plots. In general, the analysis strategy will treat disability as a dichotomous variable and use logistic regression to estimate odds ratios for association and as discussed to explore linear regression and ordinal regression treating the WHODAS as a continuous response variable and possibly as an ordinal response variable. Although the primary interest is in disability after 12 months the associations at earlier points; one month and six months, will also be estimated. At least one author has categorized disability based on the WHODAS-12 as: none, mild, and moderate to severe disability (Karnatovskaia et al. (2017); however, it is likely to be more useful to explore if the instrument can be used on its native scale or use ordinal regression based on the full range of scores rather than other cut-off values.

Although not directly related to the study aims, mortality will also be assessed using Kaplan-Meier curves and associated estimates of median, or where relevant other percentiles, survival.

SPLIT ENZ QUALITATIVE STUDY PROTOCOL

Qualitative data collection/patient interviews

A qualitative investigation into the recovery journey of ICU survivors will be conducted. Participants will be approached at their 6 month follow up from a nested sample of the main study. Sequential sampling will be used initially, moving to theoretical sampling approach thereafter. The **first** ten-twenty participants will be approached at the 6 month follow up (after the assessment questionnaires are completed) and verbal consent will be sought. Information will be mailed or emailed to the potential participants together with a consent form (see appendix six) to ensure the participant is given all the available information prior to the interview. The interview will be scheduled after the 6 month follow up at a time convenient for the participant and consent collected just prior to the interview. All interviews will be undertaken by the coordinating investigator to ensure consistency after the CI has undertaken relevant Qualitative interview workshops and training via the Higher Education Development Centre (HEDC) through the University of Otago at any time before the Qualitative part of the study begins to recruit. Depending thematic saturation as part of Grounded theory, will dictate the number of participants required for the qualitative study. However, ten participants have been chosen as a rough guide. It may be more or less than this depending on what material is gained at the time of interview.

Participants will be interviewed once using their preferred method either face to face taped interview, ZOOM or telephone (whatever method is feasible/preferential for the participant and in line with National COVID alert levels. However in person interviews would be the preferred first option). Whānau/family will be wholly encouraged to support the participant in these interviews, but any information or data given to the CI by them will not be used or transcribed for the final analysis.

The following key themes will be explored based on prior research highlighting themes common to the recovery experience (Keen et al. 2016; Keong and Jang, 2018): (Appendix seven)

- Experience of recovery overall

- Coping strategies and a focus on things that helped i.e spiritual, Whānau & social connectivity.
- Needs met or unmet.

Overview

Grounded theory qualitative methods will be undertaken to explore in-depth participant experience of recovery. Semi-structured recorded interviews will occur with an initial ten participants selected sequentially (i.e first ten participants who consent). The CI will use a semi-structured interview schedule, which includes a mix of open and closed questions. As with the grounded theory process, the data will be analysed immediately thereafter to determine the themes and subthemes that emerge out of these interviews. Interviews will be audio-recorded transcribed verbatim, coded and checked for accuracy with another researcher. From the data obtained the process of sampling will move to theoretical sampling process whereby participants will be chosen who will best answer questions and themes that were captured during the initial interviews. At this stage it is not known what these may be but will be identified during the first 10 interviews.

Qualitative data coding and analysis:

Several strategies will be used during the process, simultaneous collection, and analysis of data, open and axial coding with comparative analysis (within cases and across cases), refining theoretical ideas and memo writing (Glaser 1978, Charmaz 2001). Thematic analysis will be undertaken using N vivo software. The PI will independently read and code the transcripts, the codes will be examined and by an iterative process will be condensed into similar themes. A second researcher will check the transcripts for truth and completeness. To achieve saturation of the themes the researchers will move back and forth between data collection and analysis, re-identifying themes and sub themes. Work completed early in the study will inform subsequent recruitment using theoretical sampling data collection, and analysis.

Data Protection

All data will be collected on appropriate study templates by the PI. It will be stored in a locked research office in the ICU. It will be archived for 10 years in accordance with the University of Otago guidelines.

Feedback of results:

At the consent process, participants will have indicated if they would like to have the results fed back to them directly. A copy of the report will be sent to each of the participants on completion of the study once the sponsor deems it appropriate to do so.

ETHICAL CONSIDERATIONS

Research ethics approval will be obtained prior to the start of the study from the responsible local and national human research ethics committee. The study will be conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP) and within the laws and regulations of New Zealand. The Consent process is described on page 14.

Confidentiality and Data Protection

Patients will be allocated a unique study number once entered to the study by the CI. Study data will be obtained from the patients' written medical records, ICU database and the electronic health record/concerto (Medical Applications Portal & Clinical app). The study data and the study enrolment logs will be kept separately in a locked room in the ICU, Wellington Hospital. Once the unique participant number is allocated, documentation will be de-identified from there on in and referred to using that number.

Patient Safety

It is anticipated that a proportion of patients may have persistent issues around mental health, physical function, and cognition. Whilst this study should not cause additional distress, there will be some patients who experience moderate to severe symptoms related to their PICS. At patient follow up if the patient is found to be in distress with unmanageable symptoms, consent will be sought to contact the patients GP will be asked to provide help and treatment where possible. A safety escalation plan will be put in place that ensures participants

who identify are assessed as having mental health issues, anxiety or depression can be instituted (see appendix eight). If there is an immediate physical issue that is also a cause for concern, this will be assessed at the time and consent from the participant to contact their GP will be sought. The PI will be responsible for ensuring the GP is contacted and made aware and a note to file will be created in the Medical Applications Portal.

Significance to Māori

Approximately 10-20 % of patients admitted to Wellington ICU each year are of Māori descent. It is important that this study sample is reflective of and inclusive to Māori patients to ensure that the voice of Māori participants is heard. The qualitative aspect of this study will be an important method by which we will hear and understand the recovery journey and identify what needs unmet remain. Boosted sampling may be employed to ensure a sufficient number of Māori patients are included in the qualitative part of the study sample.

Critical to this research there will be consultation throughout the study to ensure it is culturally appropriate, and responsive to the needs of all included patients. Consultation with several groups, the University of Otago Te Hononga Pukenga, the DHB's Māori health unit and the Research advisory group for Māori (RAGM) will be contacted. The ICU Te Kete group will also be contacted for advice around correct Tikanga around follow up for Māori participants. The PI will also attend adequate Tikinga research workshops (already completed).

OUTCOMES AND SIGNIFICANCE

There is little published research on PICS in Australasia, all of which comes from Australia (Haines et al. 2018; Heydon et al. 2020; Hodgson et al. 2017; Skinner et al. 2011). Clearly, there is a need for research in almost every conceptual area of PICS within Aotearoa. By completing this research several objectives will be achieved; firstly, it will be the only research to date conducted in New Zealand identifying the impact and extent of disability related to PICS for survivors of critical illness. Second, it will validate the WHODAS tool within this population, providing a useful outcome measure and practical screening tool for primary care clinicians caring for patients during recovery and rehabilitation. WHODAS would

also be beneficial to future researchers as outcome measures to report disability and function. Third, the qualitative research will highlight the patient's story of recovery, to provide context to the quantitative findings and crucially, to identify what the needs (met or unmet) are of these patients in the year post CI.

It is hoped, exploring these areas, will contribute to and stimulate further research into specific resources and strategies that will improve health outcomes for New Zealanders in the future. Once completed, we may be able to identify specific resources, funding or services needed to meet the needs of these patients. However, first we must acknowledge and highlight the problem.

Appendix One–Recommended Core outcome sets by committee

REFERENCE	EXPERT GROUP	Core Outcome Measures Across the Domains of PICS					
		Mental Health	**Physical/function**	**Cognitive**	**Health related Quality of life (HQOL)**	**Pain**	**Timeframe for Follow up**
Mikkelsen et al. (2020). Society of Critical Care Medicine's International Consensus Conference on Prediction and Identification of Long-Term Impairments After Critical Illness	Society of Critical Care Medicine (SCCM) United States	1. Hospital Anxiety & Depression Scale (HADS) 2. Impact of Event Scale-Revised (IES-r)	1. 6 Minute walk test (6-MWT) 2. EQ-5D-5L	Montreal Cognitive Assessment (MOCA)	EQ-5D-5L and/or Short form-36 (SF-36)	None specified	2-4 weeks post hospital discharge, then at clinically relevant timeframes
Needham et al. (2017). Core Outcome Measures for Clinical Research in Acute Respiratory Failure Survivors	Society of Critical Care Medicine (SCCM) United States	1. HADS 2. IES-r	50% of the committee deemed the 6 MWT, muscle testing and hand grip strength critical for inclusion.	Montreal Cognitive Assessment-BLIND (50% agreement)	EQ-5D-5L Or SF-36	EQ-5D-5L pain question	Not assessed or specified
Spies et al. (2020). Instruments to measure outcomes of post-intensive care syndrome in outpatient care settings – Results of an expert consensus and feasibility field test	Members of the Enhanced Recovery after Intensive Care' (ERIC) research trial **Europe (Germany)**	Patient Health Questionnaire-4 (PHQ-4).	• Timed Up-and-Go (TUG) • Bilateral handgrip strength	MiniCog or Animal Naming	EQ-5D-5L	None specified	At initial screening ⇩
		1. Generalized Anxiety Disorder Scale-7 (GAD-7) 2. Impact of Event Scale – revised (IES-R)	1. 2-Minute Walk Test (2-MWT) 2. handgrip strength 3. Short Physical Performance Battery (SPPB)	1. Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) 2. Trail Making Test (TMT) A and B	WHODAS	**None specified**	If screening shows impairments in one of the assessments

Appendix Two

Additional Questions to ask at follow up

- Have you ever been diagnosed with a Mental health problem by a Doctor or Psychologist?
- If so, what was the diagnosis they made?

Appendix Three – Overview of Outcome Measures used for SPLIT ENZ

Tool	Area Measured	Validation	Use and Scoring
World Health Organisation's Disability Assessment Schedule 2.0 (WHODAS)	Function and disability	It has been tested for validity against the Functional Independence Measure (FIM), Short Form36 (SF-36) and the WHOQoL and in several patient populations, including Critical Care Surgical and trauma (Haylett & Gustafson, 2018; Hodgson et al. 2017).	The 12-item WHODAS covers six domains of functioning with scores from 0 (no difficulty) to 4 (extreme difficulty). The total score between 0 and 48, is then divided by 48 and multiplied by 100 to convert it to a percentage of maximum disability. • No disability 0–4% • Mild disability 5–24% • Moderate disability 25–49% • Severe disability 50–95% • Complete disability 96–100%
EQ-5D-5L **(Euroqol Group, 1990)**	Health Related Quality of Life (HRQOL)	The EQ-5D-5L is a standardised instrument to measure HRQOL.	Measured in five domains: mobility, personal care, usual activities, pain, anxiety, and depression. Each dimension has five levels ('no problems' = 1 to 'extreme problems' = 5). The EQ-5D-5L consists of 2 pages: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS™). The descriptive system codes each response from 1-5, to achieve a 5-digit code, called an index value. This index value can be transformed into a health profile. By using the crosswalk link function and the individual responses to the EQ-5D-5L descriptive system, index values for the EQ-5D-5L can also be calculated. The EQ VAS is used as a measure of overall self-rated health status as a numerical score.
Hospital Anxiety and Depression Scale (HADS) **(Snaith, 2003)**	Anxiety and depression	Widely used and validated across multiple cohorts including Critical Care (Sukantarat, Williamson & Brett, 2007). Recommended in 2/3 COS (Mikkelsen et al. 2020 & Needham et al. 2017).	The HADS contains 14 questions: seven to assess anxiety and seven for depression. For the 14 questions, a four-point Likert scale (range 0–3) gives a possible score of 0 (none) to 21 (severe) for each of the two subscales. • 0-7 indicate normal/no anxiety or depression • ≥8 to 10 indicate clinically significant anxiety or depression symptoms (borderline cases) • ≥11 indicate severe psychological distress
Impact of Events Scale Revised (IES-r) **(Weiss & Marmar, 1997)**	PTSS/PTSD	Widely used and validated across multiple cohorts including Critical Care (Jackson et al. 2007; Hosey et al. 2020). Recommended in all 3 COS (Mikkelsen et al. 2020 & Needham et al. 2017).	There are 22 questions that cover the three diagnostic clusters: intrusion; avoidance (eight questions each); and hyperarousal (six questions). Respondents report on a five-point Likert scale: 'not at all' (item score 0) to 'extremely' (4) how distressed they have been in the past 7 days in relation to a specific event. The IES-R yields a total score (ranging from 0 to 88) and subscale scores can also be calculated for the Intrusion, Avoidance, and Hyperarousal subscales. The total mean IES-R score = The sum of the means of the three subscale scores. The maximum mean score on each of the three

			subscales is '4', therefore the maximum 'total mean' IES- R score is 12. A total IES-R score of 33 or over from a theoretical maximum of 88 signifies the likely presence of PTSD.
Montreal Cognitive Assessment (MOCA-blind)	Cognitive Function	Recommended in the COS from Needham et al. 2017 & Mikkelsen et al. 2020. The MOCA Blind has had the visual exercises removed to enable telephone/remote assessment.	The total possible score is 22 points; a score of 18 or above is considered normal. Cut offs have not been validated in the critically ill.

Appendix Four Participant Information and Consent

V4_TC_Qual Interview_Patient Cc

Appendix Five

PARTICIPANT INFORMATION PACK

Tēnā koe
Thank you for agreeing to participate in this study. Sharing your time during this follow up interview is of huge benefit to the ICU community to help us understand what we can do for patients and whānau who are recovering from Critical Illness. We really appreciate your time.

Here are the key dates for your follow up:

Final discharge home date:

1. FOLLOW UP – (2-4 weeks post hospital discharge)

Date/week scheduled: _____

2. FOLLOW UP – (6 months post hospital discharge)

Date/week scheduled: _____

3. FOLLOW UP – (12 months post hospital discharge)

Date/week scheduled: _____

The following questionnaires will be completed at follow up and are attached. This is to help you visualise the questions as the researcher reads them out over the phone. **You do not need to complete them prior to follow up, just use them as a visual guide during the follow up** (If you do wish to complete them on paper beforehand, that is fine, just let the researcher know when they call).

1. WHODAS 2.0
2. Montreal Cognitive Assessment (MOCA-blind)
3. Hospital anxiety and depression scale (HADS)
4. Impact of Events Scale Revised (IES-r)
5. EQ-5D

Do not worry if you lose these documents prior to the follow up. Replacements can be sent out at any time and everything can still be completed as planned.

Researcher contact details:
Lynsey.sutton-smith@ccdhb.org.nz or sutly853@student.otago.ac.nz
0211211385

Appendix Six Participant Information and Consent – Qualitative study

V4_TCOFF_Qual Interview_Patient Cc

REDCAP consent pdf:

REDCAP consent_SPLIT ENZ.p

Appendix Seven

Interview Instructions and Probes

This is a DRAFT interview schedule. It is likely to be adjusted based on feedback and issues that arise during the trial.

Thank you once again for agreeing to participate in this interview. We are very appreciative of your time. We are interested in the experiences of people who are recovering after an illness in the ICU. We want to understand what the recovery journey is like for you and your Whānau and what your needs are during this time.

Theme 1: The recovery journey (open ended)

Tell me about your experience of recovery so far.

- Possible prompts:

1. What kind of problems have you been experiencing?
2. How has recovery been for you and your Whānau?

Theme 2: Coping and Adaptation

What things have you done to help you cope/what things make it better for you?

- Possible prompts:

1. Who has been your support system? (socially, culturally, health needs)
2. What spiritual or cultural aspects made recovery easier for you?
3. What would you like to do that you currently cannot (hobbies, socialising, connectivity with nature etc)

Theme 3: Needs met or unmet.

What aspects of recovery have you most needed help with?

Have you been able to access enough help, support, or services to get you through recovery?

- Possible prompts:

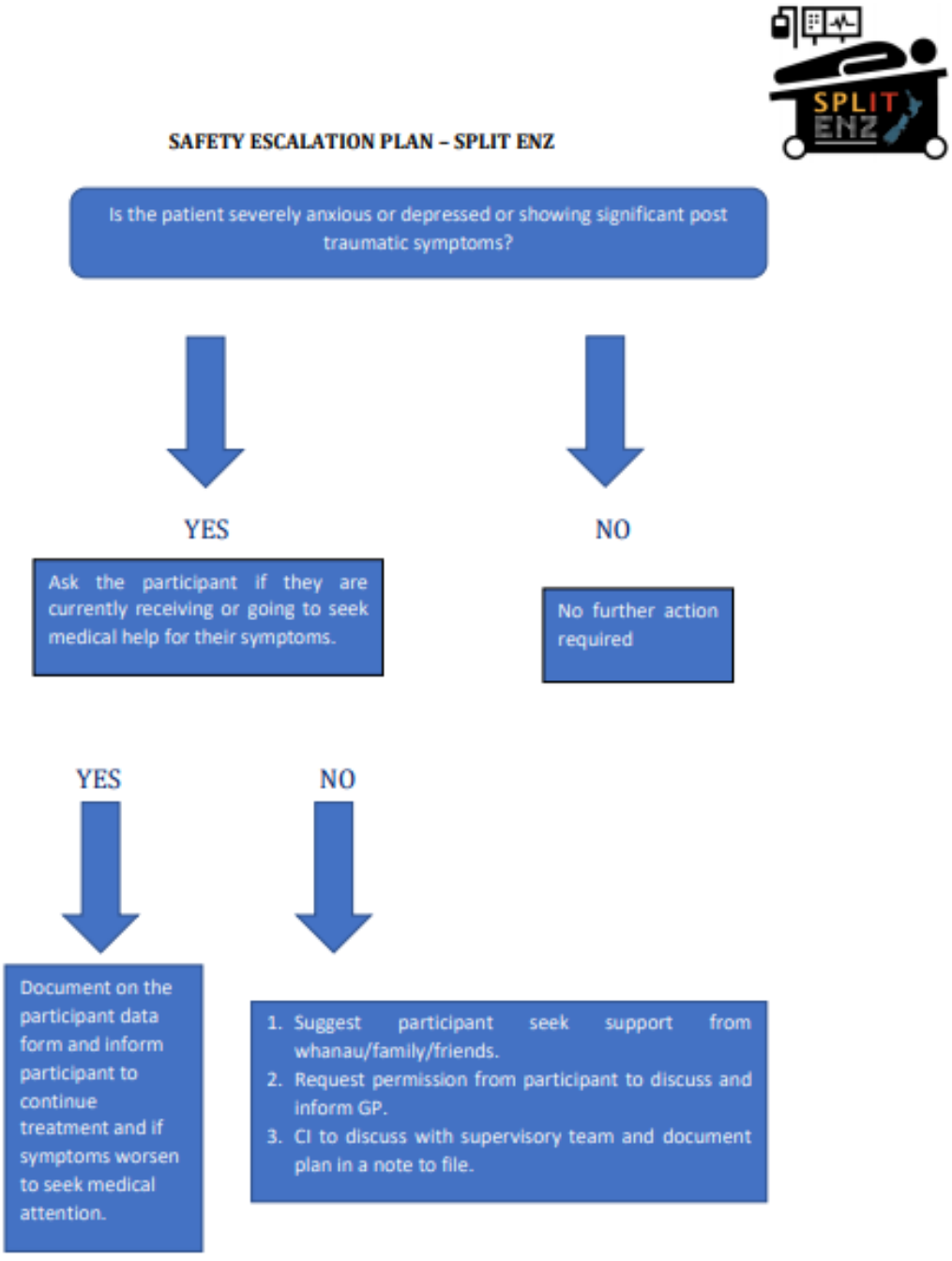
1. What about your recovery concerns you most?

2. What aspects have you been able to get help with?

3. What things have you not got help with?

4. How many times since discharge have you seen your GP or been hospitalised?

Appendix Eight



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