# THE PSYCHOLOGICAL IMPACT OF SURVIVING AN INTENSIVE CARE ADMISSION DUE TO CORONAVIRUS DISEASE 2019 (COVID-19) ON PATIENTS IN THE UNITED KINGDOM

**SHORT STUDY TITLE / ACRONYM**

**P**sychological **Im**pact of **COVID**-19 on Intensive Care Survivors / PIM-COVID

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The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

**For and on behalf of the Study Sponsor:**

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**List of Abbreviations**

| | |
|---|---|
| ARDS | Acute Respiratory Distress Syndrome |
| APACHE II | Acute Physiologic Assessment and Chronic Health Evaluation II |
| ASR | Annual Safety Report |
| CA | Competent Authority |
| CAS-1R | Cognitive Attentional Syndrome Scale-1 (Revised) |
| CI | Chief Investigator |
| COVID-19 | Coronavirus Disease 2019 |
| CRF | Case Report Form |
| HADS | Hospital Anxiety and Depression Scale |
| HRQoL | Health-Related Quality of Life |
| ICU | Intensive Care Unit |
| ICM | Intensive Care Medicine |
| IES-6 | Impact of Event Scale-6 |
| IES-R | Impact of Events Scale-Revised |
| Main REC | Main Research Ethics Committee |
| NHS | National Health Service |
| NIHR | National Institute for Health Research |
| PI | Principle Investigator |
| PICS | Post-Intensive Care Syndrome |
| PTSD | Post Traumatic Stress Disorder |
| R&D | Research & Development |
| RD&I | Research, Development and Innovation |
| REC | Research Ethics Committee |
| REDCap | Research Electronic Data Capture |
| SAE | Serious Adverse Event |
| SARS | Severe Acute Respiratory Syndrome |
| SARS-CoV-2 | Severe Acute Respiratory Syndrome Coronavirus 2 |
| SOFA | Sequential Organ Failure Assessment |
| SOP | Standard Operating Procedure |
| TRIC | Trainee Research in Intensive Care |

## 1. Study Summary

| | |
|---|---|
| **Title** | The psychological impact of surviving an intensive care admission due to coronavirus disease 2019 (COVID-19) on patients in the United Kingdom |
| **Protocol short title / Acronym** | **P**sychological **Im**pact of **COVID**-19 on Intensive Care Survivors / PIM-COVID |
| **Protocol Version number and Date** | Version: 1.6<br>8 April 2022 |
| **IRAS** | 282400 |
| **Is the study a Pilot?** | No |
| **Study Duration** | 24 months |
| **Methodology / Study Design** | Mixed methods: multicentre longitudinal observational study, longitudinal semi-structured interviews and observational structured survey. |
| **Sponsor** | Liverpool University Hospitals NHS Foundation Trust |
| **Co-Chief Investigators** | Dr Alicia Waite<br>Professor Ingeborg Welters |
| **Medical conditions under investigation** | 1) Anxiety, 2) depression and 3) trauma symptoms |
| **Purpose of study** | To assess the short- and long-term psychological impact on patients who have survived an admission to intensive care due to COVID-19, and identify possible predictors of anxiety, depression and trauma symptoms in this patient group. |
| **Primary objective** | To identify the proportion of patients surviving an admission to intensive care due to COVID-19 who experience anxiety, depression and/or trauma symptoms in the 6 months post-discharge, assessed using the Hospital Anxiety and Depression Scale (HADS) and the Impact of Event Scale-6 (IES-6), respectively. |
| **Secondary objectives** | 1. Identify demographic, clinical, physical and/or psychosocial predictors of depression, anxiety and/or trauma symptoms at 3-, 6- and 12-months post discharge from ICU. |

| | |
|---|---|
| | 2. Assess the feasibility of using a self-reported online questionnaire to assess anxiety, depression and/or trauma symptoms in patients following ICU admission.<br>3. Explore the experiences of critical care survivors following COVID-19 infection during their recovery phase, including perceptions about the care received and support available to them, using semi-structured interviews<br>4. Assess geographical differences in the availability and structure of follow-up services offered to patients with critical COVID-19 after hospital discharge.<br>5. Gain feedback from the study team members on their involvement in the study. |
| **Main Inclusion and Exclusion Criteria** | **Inclusion criteria:**<br>1. Adult patients ≥18 years<br>2. Survived to intensive care / high dependency unit discharge following an admission of ≥24 hours<br>3. Diagnosed positive for COVID-19<br><br>**Exclusion criteria:**<br>1. Unable to complete questionnaires<br>2. Unable or unwilling to consent<br>3. Unable to speak, understand or communicate in English<br>4. Patients with diagnosed pre-existing cognitive impairment (at the time of ICU admission)<br>5. Patients with no fixed abode, at which postal questionnaire might be not received, and who have no access to a personal email address. |
| **Randomisation** | Not applicable |
| **Statistical Methodology and Analysis** | Trajectories of anxiety, depression, and trauma symptoms will be estimated using growth curve analysis. We will estimate and predict individual survivors' slope and intercept scores. We will then regress predictor variables onto intercept and slope scores for all outcomes to identify variables likely to determine trajectories of anxiety, depression and trauma symptoms. Feasibility will be assessed using descriptive analyses. |

## 2. Introduction

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) was first reported in Wuhan, China in December 2019 (1). SARS-CoV-2 was later termed coronavirus disease 2019 (COVID-19) by the World Health Organisation (WHO). On March 12, 2020 a pandemic was declared, which continues to emerge globally (2). At the time of writing, COVID-19 infections number over one million and have been responsible for over 123,000 deaths worldwide (3).

COVID-19 is responsible for a spectrum of clinical presentations, ranging from asymptomatic or mild disease in the majority of patients, to pneumonia and acute respiratory distress syndrome (ARDS) in those more severely affected (1). Initial reports suggested 5% of 1099 patients in China with confirmed COVID-19 were admitted to an intensive care unit (ICU) (4). Meanwhile, 12% of positive cases required ICU admission in Lombardy, Italy, accounting for 16% of all hospitalised patients (5). Based on recent UK-wide data from 258 ICUs where at least one patient has had COVID-19, the ICU mortality rate amongst patients with confirmed COVID-19 is 41.1% (6).

In a 5 year longitudinal study of patients who developed ARDS not caused by COVID-19, prolonged symptoms of anxiety, depression and post-traumatic stress disorder (PTSD) were found to affect 23-38% of patients, with a median duration of symptoms of between 33 and 39 months (7). Not all patients admitted to ICU with COVID-19 will have ARDS, but admission to ICU is itself associated with a significant burden of post-ICU psychological sequelae. Symptoms of anxiety, depression and PTSD have been reported to affect up to 73% of survivors (8-10). Furthermore, symptoms of anxiety, depression and PTSD persist in 34% (8), 29% (9) and 34% (10) of ICU survivors respectively at 12-14 months following ICU admission.

The severe acute respiratory syndrome (SARS) pandemic in 2002-2003 was also caused by a coronavirus, but affected significantly fewer individuals despite having a higher case fatality rate (10.9% (11) vs 3.2% (4)). At the peak of the SARS outbreak, patients reported significantly higher stress levels than healthy controls (12), with similar symptoms reported up to 1 year later, with 64% of patients reporting symptoms suggesting psychiatric morbidity (13). Furthermore, amongst SARS survivors, females were more likely to have symptoms of anxiety, depression, stress and trauma, and were three times more likely than males to have psychiatric morbidity (13). Female gender was also found to be an independent risk factor for chronic PTSD up to 30 months after the SARS outbreak (14). These results contrast with pre-existing data for ICU survivors, in whom gender is not a significant risk factor for anxiety, depression or PTSD (8-10). Instead, recognised risk factors for emotional distress following ICU

admission include previous psychiatric morbidity, receipt of benzodiazepines in ICU and psychiatric symptoms during admission (8-10). Furthermore, psychological symptoms may be part of Post Intensive Care Syndrome, which also includes cognitive and physical impairments that are new or have worsened following ICU admission and persist on discharge from hospital (15, 16).

Whilst data emerges about the short-term impact of COVID-19 (17), the long-term implications to patients and healthcare systems remain unclear. With population-wide social distancing and societal lockdown enacted in many countries, the mental health of the general public is under strain(18). Data from previous pandemics suggests that pandemic-related factors such as quarantine may also have an impact on the psychological wellbeing of ICU survivors (19). It is plausible that this heightened anxiety primes patients, who subsequently require treatment in ICU for COVID-19, to develop psychological distress (17).

We anticipate that there will be a significant burden to healthcare systems as a result of psychological distress. Current national guidelines state that at-risk ICU survivors who have had an admission of more than 4 days should be invited to a follow up clinic 2-3 months after discharge from ICU (20). However, hospital and community based services to support ICU survivors in their recovery were limited before COVID-19, with some hospitals not even offering an ICU follow up clinic (21). The number of patients expected to require admission to ICU during COVID-19 is far beyond existing UK critical care capacity, and in the context of enhanced baseline societal anxiety, the potential volume of patients with post-ICU psychological distress could far exceed existing healthcare capacity overwhelming current services. In order to be able to expand services as necessary and support ICU survivors properly to help them regain their quality of life, and return to working and contributing to society, we must first identify how many, and to what extent patients are affected.

In this study, we aim to: 1. identify the proportion of COVID-19-positive critical care survivors who experience anxiety, depression and/or trauma symptoms up to 12 months after discharge from ICU, using validated tools; 2. identify predictors of post-ICU anxiety, depression and/or trauma in COVID-19 ICU survivors; 3. explore the experiences of critical care survivors following COVID-19 infection during their recovery phase, including perceptions about the care received and support available to them and 4. assess geographical differences in the availability and structure of follow-up services offered to critical COVID-19 survivors. This information may be used to inform healthcare systems about the psychological support required for survivors of this pandemic, and may inform healthcare planning for future pandemics.

## 3. Study Objectives, Design and Statistics

### *3.1 Study Aim*

To assess the short- and long-term psychological impact on patients who have survived an admission to intensive care due to COVID-19 in the United Kingdom, and identify possible predictors of anxiety, depression and trauma symptoms in this patient group.

### *3.2 Study Objectives*

**Primary objective:**

To identify the proportion of patients who survive ICU admission following treatment for COVID-19 that experience anxiety, depression and/or trauma symptoms at 6 months, assessed using the Hospital Anxiety and Depression Scale (HADS) and the Impact of Event Scale-6 (IES-6), respectively.

**Exploratory objectives:**

1. Identify demographic, clinical, physical and/or psychosocial predictors of depression, anxiety and/or trauma symptoms at 3-, 6- and 12-months after ICU discharge in patients being treated for COVID-19 within the ICU.
2. Assess the feasibility of using a self-reported questionnaire to assess anxiety, depression and/or trauma symptoms in patients following ICU admission with COVID-19.
3. Explore the experiences of critical care survivors following COVID-19 infection during their recovery phase, including perceptions about the care received and support available to them, using semi-structured interviews.
4. Assess geographical differences in the availability and structure of follow-up services offered to patients with critical COVID-19 after hospital discharge.
5. Gain feedback from the study team members on their involvement in this trainee-led study.

### *3.3 Study Outcomes*

**Primary outcome:**

Prevalence and incidence of:

1. Anxiety
2. Depression
3. Trauma

Anxiety and depression will be assessed using the HADS. The HADS is a 14-item self-report measure in which participants rate the presence of symptoms of anxiety (7 items) and depression (7 items) over the

preceding week using a 4-point Likert scale, with options from 0 (absence) to 3 (extreme presence). Responses are summed to produce two subscale scores, ranging from 0-21, with higher scores indicative of higher anxiety and depression levels, respectively. The HADS is widely used to assess anxiety and depression in people with physical health difficulties and demonstrates good psychometric properties when used in an intensive care setting. Cut-off scores of ≥8 on anxiety and depression subscales of the HADS were used to define caseness (22, 23). A recent meta-analysis (24) showed the anxiety cut-off to predict structured interview diagnoses of either anxiety or depression with a sensitivity of 73% and specificity of 65%, and the depression cut-off to predict diagnosed depression with a sensitivity of 86% and specificity of 81%.

Trauma will be assessed using the IES-6. The IES-6 is a validated tool in survivors of ARDS for screening for post-traumatic stress disorder. It is an abbreviated version of the IES-R test and contains six questions (25). We have chosen the IES-6 over the IES-R because it is shorter, is validated in a very similar patient population, will provide similar information, and is likely to have a higher completion rate by patients because it is shorter. Furthermore, in collaboration with ICU steps it was felt that this was the best approach for this cohort of ICU survivors.

**Exploratory outcomes***:*

1. Identify demographic, clinical, physical and/or psychosocial predictors of depression, anxiety and/or trauma symptoms at 3-, 6- and 12-months post discharge from ICU.

    a. Demographic and clinical predictors.

(*See* Schedule of Study Procedure *for specific data that will be collected.*)

    b. Physical predictors.

The EuroQol 5-dimension, 5-level questionnaire (EQ-5D-5L) is a five-domain, self-report measure assessing mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants are asked to rate each question, indicating no problems, slight problems, moderate problems, severe problems or extreme problems. In addition, participants are invited to rate their health on a visual analogue scale from 0-100, where zero represent the worst health imaginable and 100 represents the best health imaginable. EQ-5D-5L is the recommended questionnaire to assess the HRQoL of critically ill patients (26). In this study, EQ-5D-5L will be used as a subjective assessment of the physical function of participants.

c. Psychosocial predictors (metacognitive beliefs and processes).

Metacognitive beliefs and processes will be assessed using the Cognitive Attentional Syndrome Scale-1 (Revised; CAS-1R (27)). The CAS-1R is a 10-item self-report measure assessing positive and negative metacognitive beliefs, frequency of worry/rumination and the use of a range of counterproductive coping strategies used in response to negative thoughts and feelings. Participants are asked to rate the degree to which they have engaged in a particular coping strategy or thought process during the previous week. Responses are scaled from 0%-100% and are summed to produce a total score. Higher scores indicate greater conviction in metacognitive beliefs and greater use of maladaptive coping strategies to manage distress. The CAS-1R has demonstrated good psychometric properties in physical health populations.

2. Assess the feasibility of using a self-reported online questionnaire to assess anxiety, depression and/or trauma symptoms in patients following ICU admission.

Outcomes:

- Recruitment number (total number of patients recruited per month)
- Recruitment rate (proportion of those deemed eligible recruited)
- Retention rate (proportion of participants who provide data at subsequent data capture points)
- Rate of missing key data
- Estimation of quantities needed for an accurate sample size calculation (e.g. HADS standard deviation)

3. Explore the experiences of critical care survivors following COVID-19 infection during their recovery phase, including perceptions about the care received and support available to them, using semi-structured interviews. The central study team will conduct semi-structured interviews in a representative sample of 40 patients. (*See* Schedule of Events *for additional information.)*

4. Assess geographical differences in the availability and structure of follow-up services offered to patients with critical COVID-19 after hospital discharge.

5. Explore the factors influencing the involvement of study team members in the study.

### *3.4 Study Design*

This is a multicentre longitudinal study. Exploratory outcomes will be address through mixed methods, including longitudinal, semi-structured interviews and observational structured surveys.

### *3.5 Study Statistics*

This study is planned as a descriptive study in an effort to quantify the psychological impact on ICU survivors of COVID-19. It is anticipated that the study will report its findings using descriptive methods in the absence of a comparator group.

Trajectories of anxiety, depression, and trauma symptoms will be estimated using growth curve analysis. To improve power, we will use the full range of anxiety, depression and trauma symptom scores (not cut-off scores). Growth modelling is latent variable covariance modelling to estimate the intercept (value of the initial observation) and slope (the rate of change from this observation over time) of a time series of mean scores. We will estimate full sample single class models (eg, assuming homogeneity across the sample) for each outcome. Initial fixed parameters will be; error variance constrained to equality across observations, mean intercept and slope constrained to zero, intercept and slope constrained to equality, and intercept and slope covariance constrained to zero. Parameters will be systematically relaxed in that order until good fitting models (CFI > .95, RMSEA .05) are identified with maximum fixed parameters. Linear and quadratic slope models will be tested; linear models being defined as slope parameters 0, 1, 4, and 12 and quadratic slopes as 0, 1, 8 and 24.

We will estimate and predict individual survivors' slope and intercept scores. Scores will be calculated using the regression method, setting intercepts for observed variables to 0 and imposing equality of variance. We will then regress predictor variables onto intercept and slope scores for all outcomes to identify variables likely to determine trajectories of anxiety, depression and trauma symptoms.

*Semi-structured interviews*

Analysis will use the principles of the constant comparative method and interpretive thematic analysis. One member of the research team will lead a process of iterating between the developing analysis and new data, and other members of the research team will develop and test the analysis by periodic discussion. The analysis will be interpretive and consider both latent and manifest aspects of the data, thereby acknowledging both the manner that participants talk as well as the explicit content. Analysis will progress in parallel with recruitment and will end when theoretical saturation is reached. Systematic data coding will be performed; exceptional case analysis will be discussed within the research team; and data

will be triangulated with quantitative data from the PIM-COVID study to enriching findings and interpretation. Analysis will be assisted by qualitative analysis software.

### *3.6 Sample size*

There is no formal sample size required. Overall we aim to recruit until September 2022 or when 1000 patients have answered the questionnaire at all three time points, whichever occurs first. We will initially approach 20 intensive care units for participation. If necessary we will extend the number of recruiting units to facilitate reaching this recruitment target. We have factored in a 40% return rate, so we will have to send out 2500 questionnaires in order to achieve our target.

With the semi-structured interviews, based on previous experience of qualitative evaluation of psychological effects on patients, we anticipate theoretical saturation with about 40 participants.

## 4. Recruitment and Withdrawal of Participants

### *4.1 Recruitment*

Recruitment will take place at hospitals across the UK, and be conducted by junior doctors who are either training, or have a specialist interest, in intensive care medicine; and/or allied health professionals working in intensive care (including Advanced Critical Care Practitioners). Therefore, recruitment will be balanced within the demands of the clinical workload. It is intended that all patients discharged from a recruiting ICU, that were admitted and treated for COVID-19, will be given an information sheet explaining the study to them and explaining the possibility of receiving three questionnaires during the year following discharge. Where this is not feasible, every reasonable effort will be made to contact these patients prior to hospital discharge. All ICUs with members in the Trainee Research in Intensive Care (TRIC) will be invited to participate.

For the semi-structured interviews, identification of participants will be performed by the central research team by accessing the PIM-COVID REDCap database. Where patients have agreed to be contacted by phone or email, these contact details will be available within the REDCap database. Patients who have provided consent to be contacted will be approached by telephone or email to discuss their potential participation in the study. A written information sheet will be sent via email or post as per participants' preferences. Participants have been asked whether or not they are happy to be contacted as part of the 3, 6 and 12 month questionnaires; participants who have indicated they would not like to be contacted will not be approached.

### *4.2 Inclusion criteria*

1. Adult patients ≥18 years
2. Survival to intensive care / high dependency unit discharge following an admission of ≥24 hours
3. Treated for COVID-19

### *4.3 Exclusion criteria*

1. Unable to complete questionnaires
2. Unable or unwilling to consent
3. Unable to speak, understand or communicate in English
4. Patients with diagnosed, pre-existing cognitive impairment (at the time of ICU admission)
5. Patients without a fixed abode, at which postal questionnaires might be received, and who have no access to a personal email address.

### *4.4 Criteria for Premature Withdrawal*

A patient may request to be withdrawn from the study at any time, for any reason, without prejudice and without an impact on their clinical care. A patient may also be withdrawn from the study at the request of his/her legal representative or clinical team, for any reason.

## 5. Study Procedures

### *5.1 Screening Procedures*

All patients discharged from the ICU will be screened against inclusion and exclusion criteria prior to enrolment. A screening and enrolment log will be kept with site files and will be archived following the end of the study (see section 7.3).

For the semi-structured interviews, a purposive sample of about 40 participants will be selected aiming for a sample that is diverse, representative of the cohort (in terms of ethnicity, sex, geographical location, degree of deprivation based on postcode, length of stay in ICU, etc), and inclusive of participants with and without evidence of psychological distress, based on answers to the 3 and 6 month questionnaires.

### *5.2 Consent, Enrolment and Participant Follow-up Procedures*

On ICU discharge, where possible, patients will be provided with an information sheet outlining the study. A member of the research team with a valid GCP certificate will provide verbal information about the

study and answer any questions. Patients will be given the option to opt out of the study at this point, and thenceforth. Patients will also be given the option to opt in and be contacted by phone, email and/or post. Even if a patient opts in, and provides their contact details, they can choose to not participate in the study, and when they receive the invitation to participate in the first survey they can actively decline to participate or just not respond to the invitation. If the patient indicates that they do not wish to participate, they will be withdrawn from the study. If they do not indicate that they do not want to be contacted, and do not reply to the first survey, they will still be sent subsequent surveys and invited to participate in those. Critically ill patients often have impaired capacity as a result of their underlying illness and/or sedating medications, but usually regain capacity prior to being discharged home. It is important that only patients with capacity participate in the study. A patient will only be provided with an information leaflet in hospital once they have regained capacity. If a patient has not been given an information leaflet prior to being discharged home, they will be sent an information sheet by post along with an invitation to participate. If after receiving the information sheet and unique login details, the patient has not yet indicated via the REDCap database that they either consent to participating in the study or decline to participate, they will be contacted by telephone by the study team (unless they have previously opted out of being contacted by phone). There are three possible outcomes of this telephone contact: i) the patient consents to participating in the study; ii) the patient asks to be contacted again for re-discussion of consent; iii) the patient declines to participate in the study. There are three methods for patients to provide their consent, via i) an online consent form in the REDCap database; ii) witnessed telephone consent; iii) a written consent form, which the patient can request. Verbal agreement to participate in the study will be obtained by a member of the study team and will be recorded in the patient notes. Verbal agreement must be witnessed by another member of the site study team or site medical staff. The patient may withdraw consent at any stage. Upon withdrawing their consent, a study participant will be given the option for i) any previously collected data to still be included in the data analysis; or ii) all of their data to be removed from the REDCap database, and as such none of their data to be included in the analysis.

Where patients consent to taking part in the study using the online consent form, they will be asked to enter their name and email address, and whether they are happy to be contacted by email, post and/or phone. If patients decide not to provide an email address or their name, the study team will still be able to identify which patient has responded as the link to that consent form is unique to the patient and the REDCap record identifier can be cross referenced with the screening log. Where patients do not consent to taking part in the study, no personal information will be requested.

Eligible patients, who have not already opted out, will be invited to participate in an online questionnaire at 3, 6 and 12 months following discharge from ICU, or alternatively a paper copy of the questionnaire can be sent to them at the relevant time points or they may choose to answer the questionnaire over the phone with a member of the study team documenting their responses on REDCap. Prior to patient contact, electronic healthcare records will be accessed, and/or contact made with the patient's registered general practitioner, to confirm the patient's survival status. This is intended as a pre-contact check to minimise distress caused to families/relatives by making contact in the event a patient has died following discharge from the ICU.

For patients who have provided their email address, an email will be sent at 3, 6 and 12 months with a unique link to their survey. The link to their survey at each timepoint will expire after 1 month. At the beginning of the questionnaire, the study information will be repeated. Patients will be able to leave the study by contacting their local study team at any point during the study. If patients indicate they would prefer to complete a paper version, they will be provided with a pre-paid envelope to return their completed questionnaire. If patients indicate they would like to complete their questionnaire over the phone, this can be arranged with a study team member.

No patient identifiable information will be entered into REDCap prior to gaining patient consent. Patient information that is analysed will be pseudo-anonymised and each patient will have a unique study identifier assigned for use in REDCap. When the patient consents to be part of the study, their name and email address where provided will be stored in the REDCap database. Only the local study team will have access to this. The REDCap database will be used for the study duration and closed when all data has been acquired. Patient contact details will be kept during the study period only and will not be stored on the REDCap database without the patient's consent. In the event that the patient dies after having consented to participating in the study, then they will remain in the study and their data will be included in the final analysis.

*Semi-structured interviews*

At the end of the 3, 6 and 12 month questionnaires there is a question asking if we can contact participants for feedback about the questionnaires. For the semi-structured interviews, we will approach patients (by phone or email) who have indicated that they agree to being contacted, and invite them to participate in interviews to provide further information about their experiences after ICU discharge. Participants will be invited to take part in an interview, at around 12 months after discharge from intensive care. A written

patient information sheet will be provided by email or post, and consent to participate can be provided verbally or in writing.

Using open-ended questions we will explore physical and psychological consequences patients may face during their recovery phase; including physical sequelae such as loss of smell, breathlessness, fatigue, and psychological issues such as isolation, anxiety, flashbacks, or sleeping problems. We would like to learn about the follow-up services offered to participants by their GPs, the hospital and patient support groups, whether they chose to engage with services offered and how the support available influenced their way of coping. We also plan to explore what aspects of their recovery and any support they received they considered beneficial, and what aspects they felt could have been improved. The patient will be invited to share their experience without interruption, and only where topics of interest have not been covered, the Interview Guide (Appendix 7) will be used to provide prompts.

The interviews will be conducted by a medically qualified research fellow trained in conducting qualitative interviews, over the telephone, online (via a secure platform such as MS Teams or Zoom) or in person, to ensure equitable access for prospective study participants. Interviews will be audio recorded, anonymised and transcribed. Recordings will be held in accordance with GDP regulations. Should patients become distressed during the interview, the one-on-one nature of the interviews should provide the opportunity for the interview to be postponed and to advise on additional support offered by locally available follow-up services, ICUsteps or other local support groups or their GP. Where patients describe psychological distress, a letter will be written to their GP and a copy sent to the patient, outlining what the patient has reported in the interview. We also have psychological support available within our study team to support patients who experience distress whilst recalling their experiences.

*Survey of Follow-up Services*

All intensive care units within the UK will be approached via email and invited to complete an online survey about follow-up services available for patients having been discharged from hospital after critical illness (See Appendix 7). ICUs will be contacted via the clinical ICU directors and through study teams, where sites are already involved in the PIM-COVID study. Invitations and information about the survey will be distributed through research network mailing lists and cascaded via social media.

*Survey of Study Team Members*

Study team members at all PIM-COVID sites will be invited to complete an online survey, which will explore the following:

- Socio-demographic characteristics of study team members
- Previous academic experience
- Feedback on involvement in the PIM-COVID study
- Attitudes towards health research
- Barriers and motivators to contributing to health research
- Future research plans

Questions evaluating participants attitudes, opinions and subjective feedback will be answered using a 5-point Likert scale. (See Appendix 8)

### *5.3 Schedule of study procedure*

Following screening and enrolment after ICU discharge, the following will be collected:

**Patient data from medical records:**

1. Age
2. Gender
3. Laboratory diagnosis of COVID-19
4. Physical health co-morbidities
5. Mental health comorbidities
6. Socioeconomic status (deprivation index calculated from postcode)

**Patient data from self-reported questionnaire:**

1. Highest educational level obtained (first questionnaire only)
2. Prior and current experience of, and treatment for, mental health difficulties
3. Current employment status

**ICU-acquired data:**

1. ICU date of discharge
2. ICU length of stay *
3. APACHE II score
4. Mechanical ventilation received **
5. Delirium during ICU admission ***
6. Benzodiazepine requirement during ICU admission

* Defined as the length of stay recorded on the ICNARC database

** Defined as invasive mechanical ventilation via an endotracheal tube or tracheostomy using PEEP ≥ 5cmH2O

*** Defined as present if recorded in the medical notes during ICU admission or discharge

**Psychological assessment via self-reported questionnaire:**

The following four self-report questionnaires will be administered at 3, 6 and 12 months following ICU discharge:

1. HADS
2. IES-6
3. CAS-1R
4. EQ-5D-5L

**Semi-structured interviews:**

The interview guide that will be used to help conduct the interviews is outlined in Appendix 7.

**Survey of Follow-up Services:**

The survey questions are outlined in Appendix 8.

**Survey of study team members:**

The survey questions are outlined in Appendix 9.

### *5.4 Accessing locally held data*

Where possible, locally collected data that contributes to the ICNARC database will be used rather than directly accessing patient notes. Accessing this data minimises error and bias in this study. Prior to study commencement, an agreement will be sought to access ICNARC data. Where additional information may be made available through large existing databases, including but not limited to ISARIC-CCP and GenOMICC, application will be made for data linkage and the necessary permissions sought.

### *5.5 Missing observations*

Every effort will be made to minimise missing baseline and outcome data in this study. Reasonable efforts will be made to obtain complete datasets. Where this is not possible, data will be reported as missing in the presentation of the results. In the event that participants are non-responders to the 3- and 6-month questionnaires, the 12-month questionnaire will still be sent to participants (unless consent has previously

been withdrawn). This will be accompanied by a telephone call to confirm the patient's willingness to continue as a study participant.

### *5.6 End of Study Definition*

The study end date is deemed to be the date of the last data capture. Reasonable attempts will be made to contact non-responders. The CI has the right at any time to terminate the study for clinical or administrative reasons. The end of the study will be reported to the Sponsor and REC within the required timeframe if the study is terminated prematurely. Investigators will inform patients of any premature termination of the study. Following the end of the study a summary report of the study will be provided to the REC within the required timeframe.

## 6. Assessment of Safety

### *6.1 Safety outcomes*

Whilst we do not anticipate any adverse events or safety risks for patients or members of the research team from participation in this study, it is possible that patients engaging with this study may be experiencing psychological distress. With each online or paper questionnaire, information will be provided about ICUsteps, a national support group network who are aware of and support this study. Participants will also be encouraged to engage with their local ICU follow up clinic if available locally (e.g. at 3 months) or contact their GP if they feel they need additional support.

### *6.2 Ethics Reporting*

Approval from a Research & Ethics Committee (REC) will be sought. The REC will be informed about any changes according to the official National Research Ethics System regulations. Local site investigators will be responsible for ensuring appropriate approvals from local research committees, audit committees or R&D centres are obtained as required to ensure compliance with local policies.

### *6.3 Data Safety and Monitoring Board*

This is a longitudinal study with no change in clinical practice. A data safety and monitoring board will not be established.

### *6.4 Ethics & Regulatory Approvals*

The study will be submitted centrally for consideration by a NRES approved Research Ethics Committee and by the HRA, as well as local RD&I approvals.

## 7. Data Handling

### *7.1 Confidentiality*

- All local sites will maintain an enrolment and recruitment log, which will include patient hospital identification number, name and contact details and will be held in a locked office at the local site. Only members of the local study team will have access to this list.
- Patient confidentiality will only be breached if a participant discloses information which may indicate harm to themselves or others. We will take every opportunity to discuss any possible breaches of confidentiality with patients before informing any appropriate agencies (e.g. patient's registered general practitioner).
- All enrolled patients will be allocated a unique study number which will be used for referencing data recorded and entered into the REDCap database. This study number will be used as the patient identifier to link to clinical variables.
- To avoid the possibility of identifying patients via their postcode, study members will be looking up the deprivation index using government data specific to England, Northern Ireland, Scotland and Wales. This deprivation index will then be entered into the REDCap database. The patient's postcode will be found in the patient's records and not be recorded in the REDCap database.
- All online questionnaires, and online generated data, will be held in a secure server. If necessary, paper copies of questionnaire results will be printed and stored at local sites. Printed questionnaires will be entered into the REDCap database by local study team members, so as to merge all data together for analysis.
- All paper documents (including participants' written consent forms and returned paper questionnaires) will be held securely at the study site in a restricted access area, in line with data protection regulations.
- The Chief Investigator will act as 'Custodian' for all data collected.
- No patient identifiable details will be included in the published study reports.
- No information regarding the study will be released to or by a third party without the prior written consent of the sponsoring institution.
- Representatives of the sponsoring institute may inspect all documents and records required to be maintained by the investigators.

### *7.2 Case Report Form*

Data will be recorded via individual electronic case report forms (eCRF) through the REDCap (https://www.project-redcap.org/) online database tool. Local investigators will be responsible for

individual hospital data input into REDCap. Local investigators are responsible for data collection, input and accuracy.

### *7.3 Record Retention and Archiving*

All research and relevant documents will be stored confidentially and securely for 10 years following the end of the study as per the Sponsor's standard operating procedure on research archiving. The members of the study management team will have access to stored data. Upon request, investigators can get access to data from their own site.

### *7.4 Compliance*

The study will be conducted in compliance with the principles of the Declaration of Helsinki (1996), and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework, Trust and Research Office policies and procedures and any subsequent amendments. Personal patient data will be pseudo-anonymised and will be held in compliance with EU General Data Protection Regulations (GDPR) and the UK Data Protection Act (2018).

### *7.5 Clinical Governance*

The study may be selected for audit by any method listed below:

- The project may be identified via the risk assessment process.
- An individual investigator or department may request an audit.
- A project may be identified via an allegation of research misconduct or fraud or a suspected breach of regulations.
- Projects may be selected at random. The Department of Health states that Trusts should be auditing a minimum of 10% of all research projects.
- Projects may be randomly selected for audit by an external organisation.
- Internal audits will be conducted by a sponsor's representative

### *7.6 Non-Compliance*

Non-compliances may be captured from a variety of different sources including eCRFs, communications and updates. The sponsor will maintain a log of the non-compliances to ascertain if there are any trends developing which require to be escalated. The sponsor will assess the non-compliances and action a timeframe in which they need to be dealt with. Each action will be given a different timeframe dependent on the severity. If the actions are not dealt with accordingly, the R&D team will agree to an appropriate action, including an on-site audit. All protocol and GCP deviations will be reported to the Sponsor and

serious non-compliance will be reported to REC, in line with the SAE/protocol deviation SOPs of the Sponsor.

### *7.7 Protocol Amendments*

Any changes in research activity will be reviewed and approved by the Chief Investigator and submitted in writing to the appropriate REC and local research site for approval prior to being included in an amended protocol.

### *7.8 Study Management*

The Co-Chief Investigators, Dr Alicia Waite and Professor Ingeborg Welters, will have managerial oversight of the project. The day-to-day management and data collection will be coordinated by the TRIC network, with junior doctors at each site performing patient identification, data collection and appropriate participant contact, in conjunction with allied health professionals working with the TRIC network. The analysis will be led by Dr Steve Brown, with clinical input provided by the TRIC network.

## 8. Finance and Publication Policy

### *8.1 Finance*

Funding is provided by the Intensive Care Society and the Mersey School of Anaesthesia.

### *8.2 Publication Policy*

It is planned to publish the study results, in mutual agreement with the investigator team, in a scientific journal and present the findings at international congresses. Publication of the results of the study as a whole is intended. Requirements for authorship will follow American Medical Association (AMA) guidance. Any publication will take account of the International Committee of Medical Journal Editors (ICMJE) relevant policies and guidelines. The study will also be registered in a public register in accordance with the recommendations of the ICMJE. Any published data will observe data protection legislation covering the study subject and investigators. Individual findings at individual study sites are known only to the responsible institution. A lay summary of the results will be made available to participants upon their request.

Publications or lectures presenting findings of the study (either as a whole or at individual investigation sites) must be approved by the chief investigator in advance, and the responsible institution reserves the

right to review and comment on such documentation before publication. Publication should include details of the sponsor and other major study contributors, but with no patient identifiable details.

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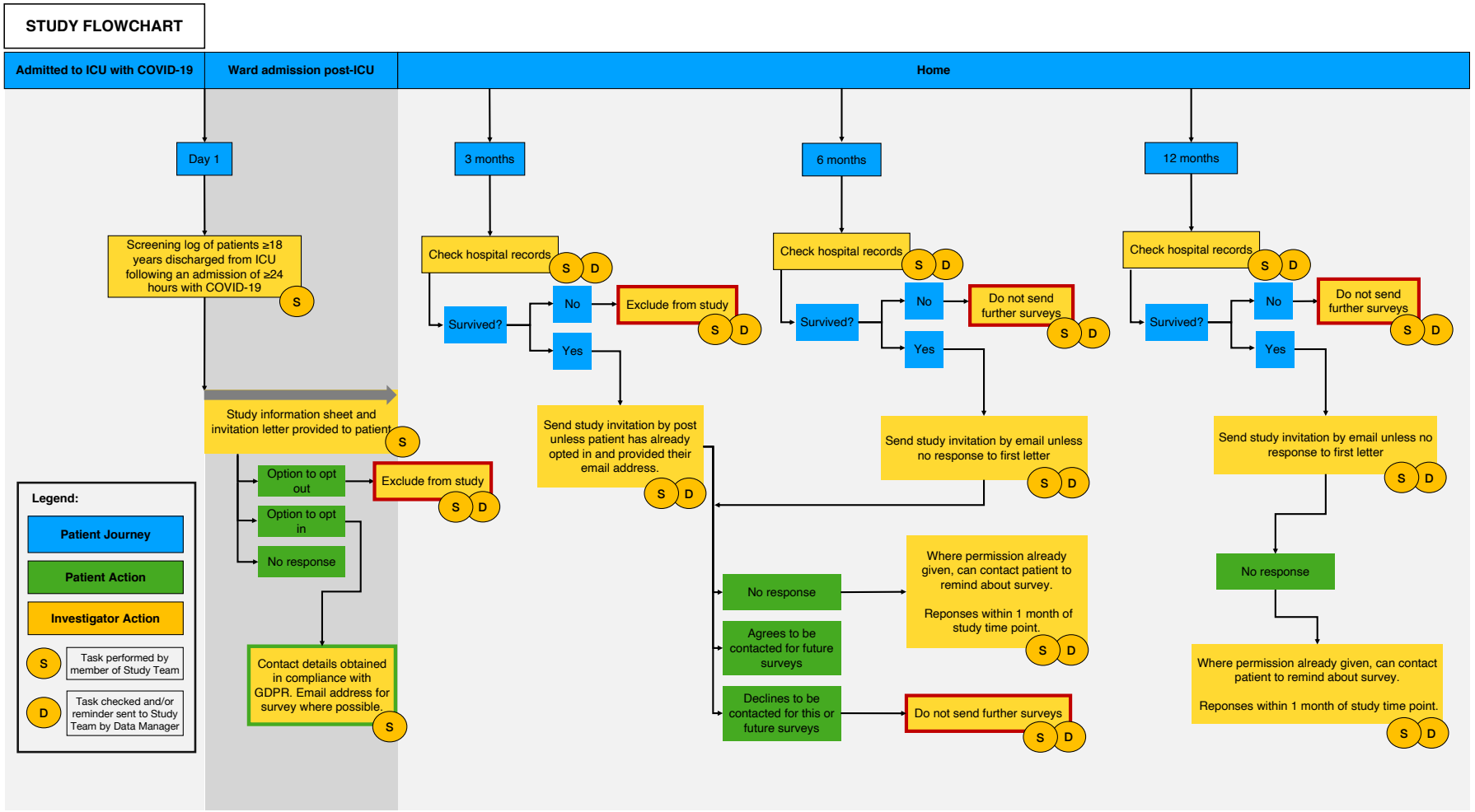
## 10. Appendices

### Appendix 1: Information with regards to Safety Reporting in Non-CTIMP Research

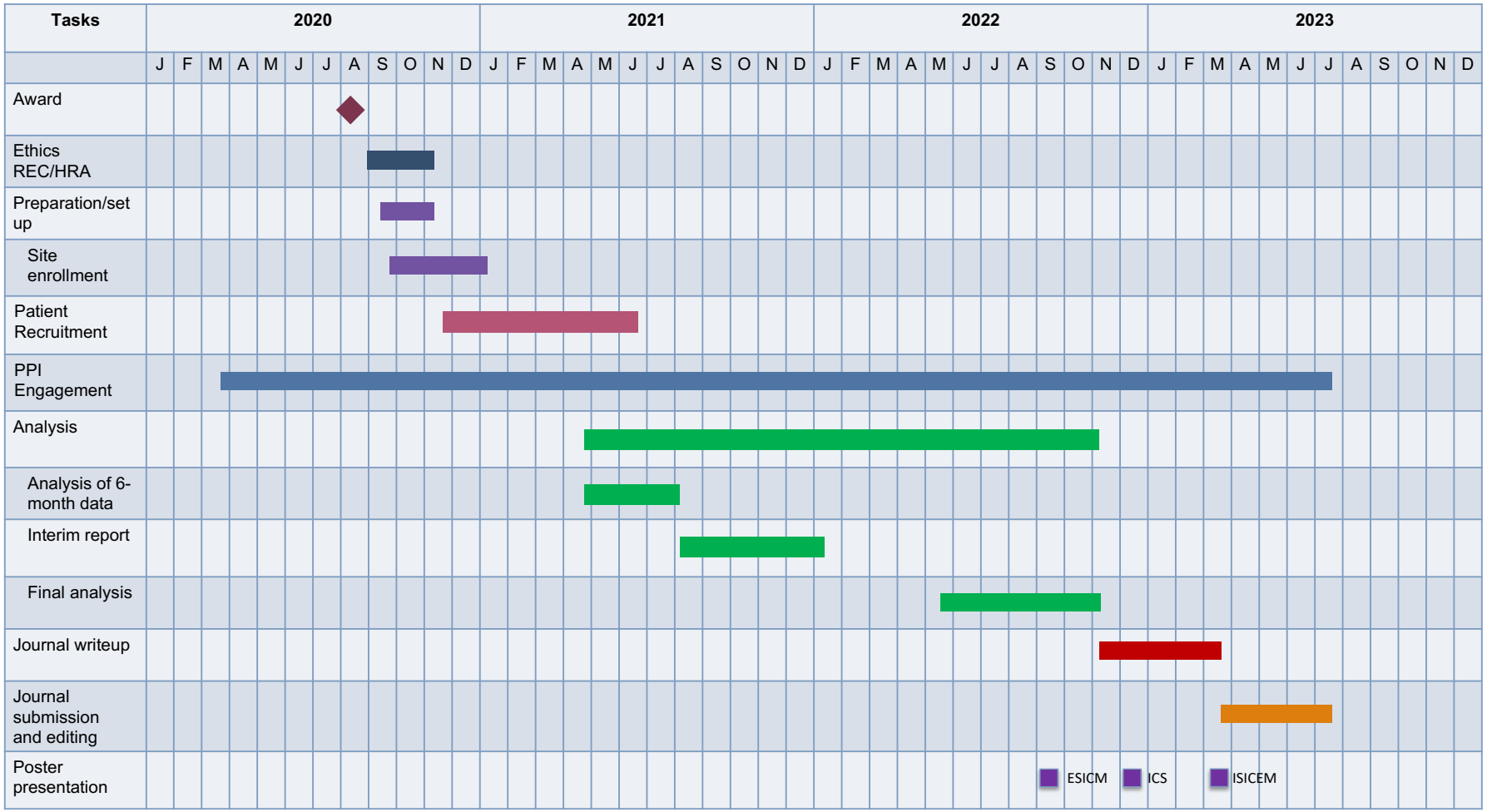
| | Who | When | How | To Whom |
|---|---|---|---|---|
| **SAE** | Chief Investigator | Report to sponsor within 24 hours of learning of the event<br><br>Report to the MREC within 15 days of learning of the event | SAE report form for non-CTIMPs, available from NRES website. | Sponsor and MREC |
| **Urgent Safety Measures** | Chief Investigator | Contact the sponsor and MREC immediately<br><br>Within 3 days | By phone<br><br>Substantial amendment form giving notice in writing setting out the reasons for the urgent safety measures and the plan for future action. | Main REC and sponsor<br><br>Main REC with a copy also sent to the sponsor. The MREC will acknowledge this within 30 days of receipt. |
| **Progress Reports** | Chief Investigator | Annually (starting 12 months after the date of favourable opinion) | Annual progress report form (non-CTIMPs) available from the NRES website | Main REC |
| **Declaration of the conclusion or early termination of the study** | Chief Investigator | Within 90 days (conclusion)<br><br>Within 15 days (early termination)<br><br>*The end of study should be defined in the protocol* | End of study declaration form available from the NRES website | Main REC with a copy to be sent to the sponsor |

| | | | | |
|---|---|---|---|---|
| **Summary of final Report** | Chief Investigator | Within one year of conclusion of the research | No standard format However, the following Information should be included:<br>Where the study has met its objectives, the main findings and arrangements for publication or dissemination including feedback to participants | Main REC with a copy to be sent to the sponsor |

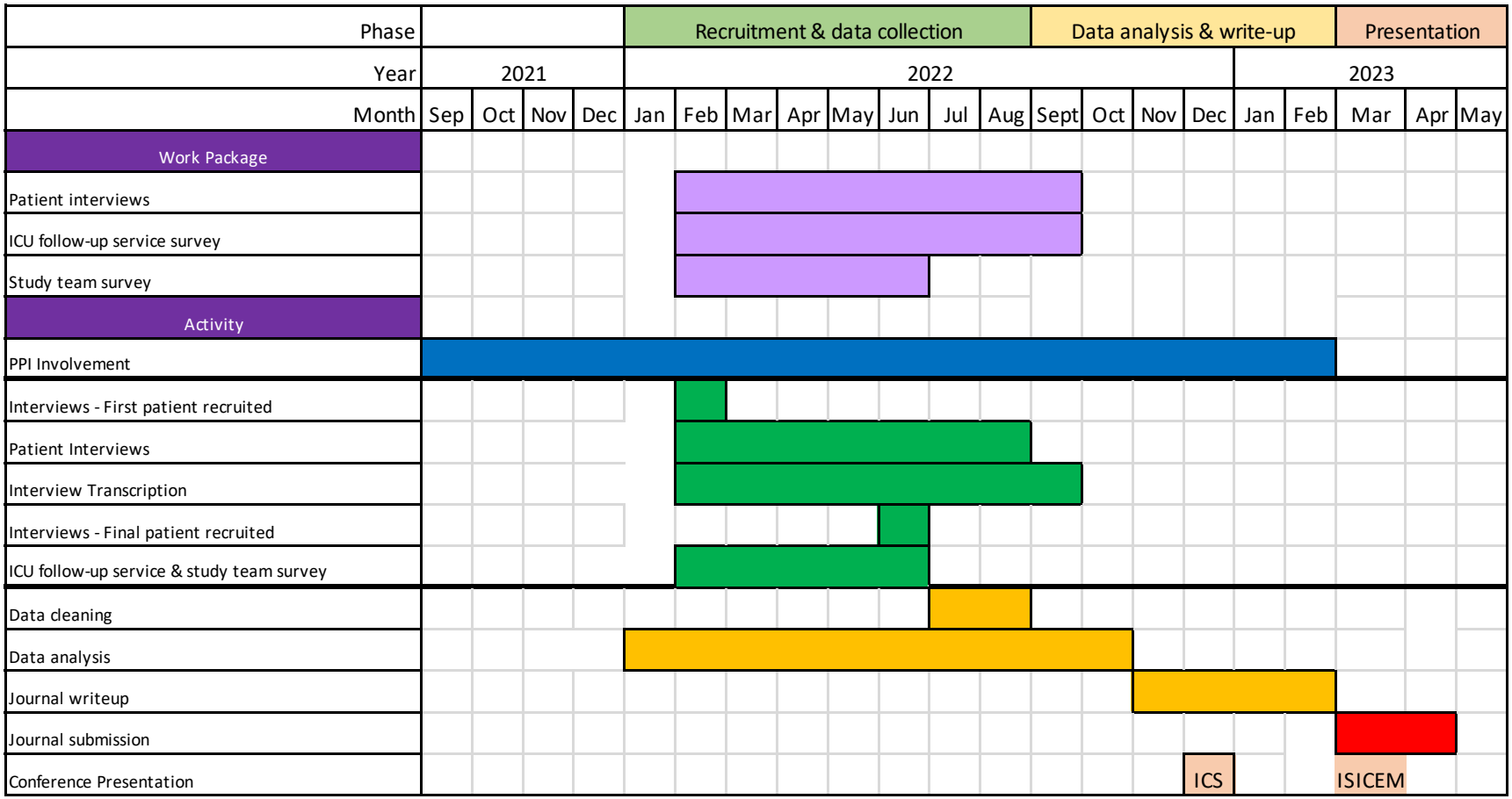
## Appendix 2: Study Flowchart



## Appendix 3a: Study Gantt Chart



## Appendix 3b: Interviews & Survey Gantt Chart



**Appendix 4: Invitation Letter, Patient Information Sheet and Consent Form**

< ENTER PATIENT ADDRESS>

<ENTER DATE>

Dear <ENTER PATIENT NAME>

**Psychological Impact of COVID-19 on Intensive Care Survivors Study**
**AN INVITATION TO PARTICIPATE**

We are conducting a research study investigating the psychological impact of surviving an intensive care admission due to COVID-19 on patients in the UK. You have been sent this invitation to participate because you were a patient in the <ENTER HOSPITAL NAME> intensive care unit where you were treated for COVID-19 infection.

Please read the patient information sheet provided carefully. If you have any questions or concerns in relation to the study, the local research team or the chief investigators will be happy to discuss these with you.

If the study team do not hear from you through the online survey system (a link and password is provided for you on a separate page), they will contact you by telephone to see whether or not you would like to take part in the study. There is no obligation for you to participate.

By following the link provided, you can let us know whether or not you would like to participate. If you indicate that you would like to take part, you will be asked to provide some basic information about yourself. Once you have answered these questions, you will be contacted via email or telephone to participate in the survey 3, 6, and 12 months after you were discharged from intensive care.

Thank you for your time in considering this request.

Yours sincerely,

<ENTER TRAINEE/CONSULTANT PI NAME>

# Psychological Impact of COVID-19 on Intensive Care Survivors

## PATIENT INFORMATION SHEET

**What is the purpose of the study?**

We are investigating the psychological impact of having been treated for Coronavirus disease 2019 (COVID-19). The purpose of this study is to improve our understanding of the psychological impact on patients of being diagnosed with COVID-19 and receiving treatment in intensive care. We are planning to ask you questions to assess symptoms of anxiety, depression and trauma that you may be experiencing. We will also ask you some questions which will enable us to identify potential risk factors for anxiety, depression and trauma following an intensive care admission due to COVID-19. We hope that by learning more about the psychological impact on people who have survived intensive care, we can improve our understanding and use the information to help inform healthcare planners about the number of intensive care survivors who might need psychological support once they go home.

**Why have you been chosen?**

You have been chosen because you had COVID-19 and were treated in intensive care.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. You are still free at any time to withdraw your consent without giving a reason. If you decide not to take part the standard of care you will receive will not be affected.

**What happens if I agree to take part?**

If you do decide to participate you will be given this information sheet to keep and will be asked to sign a consent form. The consent form can be completed online, over the telephone or on a paper form that we can post to you. If we have sent you this Invitation to Participate in the post and we do not hear back from you, a member of the local hospital team will contact you by telephone to see whether or not you are willing to participate in the study.

We will then ask you to complete questionnaires that ask you about symptoms relating to anxiety, depression and trauma. These questionnaires will be sent to you by the study team at the intensive care unit where you were a patient, at 3, 6 and 12 months after your ICU stay, where applicable.

You will be invited to complete these questionnaires online, but if you would prefer to complete a paper version of the questionnaire, or give your answers over the telephone to one of the study team members you can contact your local study team and they will organise this <ENTER LOCAL STUDY TEAM CONTACT DETAILS>.

We may contact your general practitioner to check your condition before sending out questionnaires. In addition to the questionnaires we send you, your local study team will collect information from hospital records about your past medical history and the support you received during your intensive care admission (e.g. whether you were on a ventilator).

**What are the possible advantages and disadvantages of taking part?**

Taking part in this study may contribute to improved treatment of patients with COVID-19 who are discharged from intensive care. The potential complications that may arise from this study are rare. We will be asking you questions about anxiety, depression and trauma symptoms. Sometimes, when people are asked to complete questionnaires about these topics, they can find this distressing. You may find that completing the questionnaire increases your level of anxiety, depression and trauma related to COVID-19, but this is uncommon. Should you be interested in support from others who have experience of what it is like to being a patient in intensive care, you can find a local support group and access other resources at the ICUsteps website: www.icusteps.org.

**What if something goes wrong?**

It is unlikely that anything will go wrong as a result of taking part in this study. If you have any concerns about this study you should contact the Chief Investigators (contact details below) who will do their best to answer your questions.

**Would my taking part in this study be kept confidential?**

Any information collected about you during the study will be kept strictly confidential and only be seen by staff involved in the study from the hospital trust where you were a patient in intensive care, the University of Liverpool, and people from regulatory authorities who ensure that studies such as this are carried out correctly. All of them will have a duty of confidentiality to you as a research participant.

Your contact details will only be held at the hospital where you were a patient in intensive care. We will keep your contact details for the duration of the study (2 years) in case we need to contact you.

Patient confidentiality will only be breached if you disclose information that may indicate harm to yourself or to others. We will try to contact you first and discuss this with you prior to contacting relevant agencies (e.g. your registered general practitioner) to inform them of concerns raised through this study.

**What happens to the questionnaires completed during this survey?**

Questionnaires will be completed online, via a system called REDCap; or by telephone with one of the study team members at the site where you were a patient recording your responses; or we can send you a paper version of the questionnaire.

REDCap is a secure online platform that is commonly used for surveys and study databases. The online questionnaires will be accessed via a link and password that is specific to you. Your responses will be stored using a unique participant number. Only the local study team will be able to tell that your participant number is linked to you, and when the study is finished and the data is analysed your responses will be anonymous. If you choose to complete the questionnaire online, we will ask you to enter your name and email address. These personal details will only be visible to the local study team, and will be deleted at the end of the study or if you decide to withdraw from the study.

If you request a paper version of the questionnaire, when you return the questionnaire one of the study team members will enter your responses into the online REDCap database, so that the information can be stored in the same format as questionnaires completed online.

All relevant documents related to the study will be stored confidentially and securely for 10 years following the end of the study. Members of the study management team will have access to stored data, and members of the study team at each site will be granted access to the data collected at their own site.

**What will happen to the results of the study?**

This study will take 2 years to complete. Publication of the results will follow shortly after this, through medical publications, websites and press releases. Results of the study will be made available to study participants. Anonymised results and updates on the study will be published regularly on the study website.

The data collected in this study may be used to support future research, but any data shared with third parties will be fully anonymised and cannot be traced back to the participant.

**Who is organising and funding the study?**

This study is being organised by a group of doctors and scientists led by Dr Alicia Waite who is a trainee and researcher in intensive care medicine at the University of Liverpool, and Professor Ingeborg Welters, who is an intensive care consultant, Research Lead at the Royal Liverpool University Hospital and a researcher at the University of Liverpool. The funding for this study comes from the Intensive Care Society and the Mersey School of Anaesthesia. The Sponsor of the study is the Liverpool University Hospitals NHS Foundation Trust.

**Who has reviewed the study?**

This research study has been reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been given a favourable opinion by the East Midlands – Derby Research and Ethics Committee.

**What happens if I have any questions, concerns or complaints about the study?**

If you have any questions about your participation in this study you should contact your hospital's Principal Investigator or a member of the research team. If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer. If you wish to complain formally, you can contact the Patient Advice and Liaison Service at your hospital: <INSERT TELEPHONE NUMBER FOR LOCAL PALS>.

We may ask you for feedback on the questionnaire itself, but this will be voluntary and will not be part of the study data.

**What happens if I don't want to carry on with the study?**

You are free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care you receive. If you decide you don't want to continue in the study you will be given two options regarding any data already collected about you: 1) you can decide that any data already collected can be included in the study, or 2) you can decide that all data about you should be removed from the study. Removing your data from the study will only be possible before the data is analysed.

There are two timepoints at which the data will be analysed: the first analysis will be 6 months into the study, and the second will be at 18 months.

**Any other questions?**

If you have any questions that remain unanswered, the local study team member will be happy to answer these for you. If you require any further information you may contact the Chief Investigators (details below).

**Chief Investigators:**

Name: Dr Alicia Waite
Address: Intensive Care Unit, Royal Liverpool University Hospital, L7 8XP
Phone: 0151 706 2410
Email: alicia.waite@liverpool.ac.uk

Name: Professor Ingeborg Welters
Address: Institute of Life Course and Medical Sciences, University of Liverpool, L7 8TX
Phone: 0151 706 2410
Email: i.welters@liverpool.ac.uk

To find your nearest ICUsteps support group for intensive care survivors visit **www.icusteps.org.**

**Thank you for taking the time to read this Patient Information Sheet.**

## CONSENT FORM

**Title of Project:** Psychological Impact of COVID-19 on Intensive Care Survivors

**Chief Investigators:** Dr Alicia Waite, Professor Ingeborg Welters

**Centre Number:** **Participant ID:**

1. I confirm that I have read the Patient Information Sheet dated 08/04/2022 (version 1.3) for the above study (or have had it read to me). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities and from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.

5. I agree to my General Practitioner being contacted, including any necessary exchange of information about me between my GP and the research team.

6. I agree to my contact details being held by the study team in order for the results of the study to be shared with me.

7. I agree to participate in the above study.

| Name of participant | Signature of Participant | Date |
|---|---|---|
| Name of person taking consent | Signature of person taking consent | Date |

**Appendix 5: Welsh Invitation Letter, Patient Information Sheet and Consent Form**

<Welsh translation available. English language only permitted by Clinicaltrials.gov

**Appendix 6a: Follow-up Interviews - Participant Information Sheet**

# Psychological Impact of COVID-19 on Intensive Care Survivors – Follow-up Interviews

## PARTICIPANT INFORMATION SHEET

**What is the purpose of the study?**

We are investigating the psychological impact of having been treated for Coronavirus disease 2019 (COVID-19). The purpose of this study is to improve our understanding of the psychological impact on patients of being diagnosed with COVID-19 and receiving treatment in intensive care. In addition to the questionnaires that you have completed, we would like to learn more about your experience since leaving intensive care, particularly about your recovery and factors that may influence this. We hope that by learning more about your experience after leaving intensive care we can make recommendations to improve services for other patients in their recovery phase.

**Why have you been chosen?**

You have been chosen because you had COVID-19 and were treated in intensive care. You have been taking part in the PIM-COVID study and indicated that you would be happy to be contacted for more feedback.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. You are free at any time to withdraw your consent without giving a reason. If you decide not to take part, the standard of care you will receive will not be affected.

**What happens if I agree to take part?**

If you do decide to participate you will be given this information sheet to keep and will be asked to sign a consent form. We will arrange an interview with you, 12 months after your ICU stay. In this interview we will ask you about your experience since leaving intensive care. The interview will be arranged at a time convenient for you and will be conducted by one of the central study team members. You can choose whether you would like to conduct the interview via telephone, online via video chat (e.g. MS Teams or Zoom), in person at the Royal Liverpool University Hospital, or at your home (government

restrictions permitting). The interview will be audio recorded and anonymised to maintain your confidentiality.

**What are the possible advantages and disadvantages of taking part?**

Taking part in this study may contribute to improved treatment of patients with COVID-19 who are discharged from intensive care. We will be asking you questions about your mental and physical health after leaving intensive care. Sometimes, when people are asked about these topics, they can find it distressing. You will be able to pause or stop the interview if this happens or rearrange the interview for another day. Should you feel that you require further support during or after the study, we can direct you to other resources and support options.

**What if something goes wrong?**

It is unlikely that anything will go wrong as a result of taking part in this study. If you have any concerns about this study you should contact the Chief Investigators (contact details below) who will do their best to answer your questions.

**Would my taking part in this study be kept confidential?**

Any personal information you provide us will be kept confidential and only seen by staff involved in the study. The only other group who will have access to your details are people from regulatory authorities who ensure that studies such as this are carried out correctly. All of them will have a duty of confidentiality to you as a research participant. Your contact details will be held on a secure computer, in a password protected file at the Royal Liverpool University Hospital, where the central study team are based. We will keep your details for the duration of the study in case we need to contact you.

Patient confidentiality will only be breached if you disclose information that may indicate harm to yourself or to others. We will try to contact you first and discuss this with you prior to contacting relevant agencies (e.g. your registered general practitioner) to inform them of concerns raised through this study.

**What happens to my answers given in the interview?**

The interviews will be conducted by a medically qualified researcher, trained in undertaking interviews. The audio recording of your interview will be anonymised and then transcribed for analysis by a third party (www.uktranspcription.com). Your recording will be stored using a unique participant number that is linked to you, but when the study is published your responses will be anonymous. Only the central

study team will be able to link your answers to you. Your personal details will only be visible to the study team and will be deleted at the end of the study or if you decide to withdraw from the study.

All relevant documents related to the study will be stored confidentially and securely for 10 years following the end of the study. Members of the study management team will have access to stored data, and members of the study team at each site will be granted access to the data collected at their own site.

**What will happen to the results of the study?**

This study will take approximately one year to complete. Publication of the results will follow shortly after this, through medical publications, websites and press releases. Results of the study will be made available to study participants. Anonymised results and updates on the study will be published on the study website www.pim-covid.com.

The data collected in this study may be used to support future research, but any data shared with third parties will be fully anonymised and cannot be traced back to the participant.

**Who is organising and funding the study?**

This study is being organised by a group of doctors and scientists led by Dr Alicia Waite who is a trainee and researcher in intensive care medicine at the University of Liverpool, and Professor Ingeborg Welters, who is an intensive care consultant, Research Lead at the Royal Liverpool University Hospital and a researcher at the University of Liverpool. The funding for this study comes from the Intensive Care Society and the Mersey School of Anaesthesia. The Sponsor of the study is the Liverpool University Hospitals NHS Foundation Trust.

**Who has reviewed the study?**

This research study has been reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been given a favourable opinion by the East Midlands – Derby Research and Ethics Committee.

**What happens if I have any questions, concerns or complaints about the study?**

If you have any questions about your participation in this study you should contact a member of the research team. If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection

Officer. The research team can give you details of the right Data Protection Officer. If you wish to complain formally, you can contact the Patient Advice and Liaison Service on 0151 706 4903.

We may ask you for feedback on the questionnaire itself, but this will be voluntary and will not be part of the study data.

**What happens if I don't want to carry on with the study?**

You are free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care you receive. If you decide you don't want to continue in the study you will be given two options regarding any data already collected about you: 1) you can decide that any data already collected can be included in the study, or 2) you can decide that all data about you should be removed from the study.

**Any other questions?**

If you have any questions that remain unanswered, the Chief Investigators (details below) will be happy to answer these for you.

**Chief Investigators:**

Name: Dr Alicia Waite
Address: Intensive Care Unit, Royal Liverpool University Hospital, L7 8XP
Phone: 0151 706 2410
Email: alicia.waite@liverpool.ac.uk

Name: Professor Ingeborg Welters
Address: Institute of Life Course and Medical Sciences, University of Liverpool, L7 8TX
Phone: 0151 706 2410
Email: i.welters@liverpool.ac.uk

To find your nearest ICUsteps support group for intensive care survivors visit **www.icusteps.org.**

**Thank you for taking the time to read this Patient Information Sheet.**

## Appendix 6b: Follow-up Interviews – Consent Form

### CONSENT FORM

**Title of Project:** Psychological Impact of COVID-19 on Intensive Care Survivors – Follow-up Interview

**Chief Investigators:** Dr Alicia Waite, Professor Ingeborg Welters

**Participant ID:**

1. I confirm that I have read the Participant Information Sheet dated 08/04/2022 (version 1.2) for the above study (or have had it read to me). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that the interview will be audio recorded and although the recording will be anonymised, it will be shared with a third party company in order to be transcribed.

4. I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.

5. I agree to my General Practitioner being contacted if there are concerns about my well-being, including any necessary exchange of information about me between my GP and the research team.

6. I agree to my contact details being held by the study team in order for the results of the study to be shared with me.

7. I agree to participate in the above study.

| Name of participant | Signature of Participant | Date |
|---|---|---|
| Name of person taking consent | Signature of person taking consent | Date |

## Appendix 7: Interview Guide

Interviews will be arranged at a time convenient for the participant and will be conducted via telephone, an online secure platform (e.g. MS Teams or Zoom), or in person at the Royal Liverpool University Hospital, James Cook University Hospital or the participant's home, as per the participant's preference and current government guidance regarding lockdowns.

Closed questions are to be avoided as much as possible. To ensure that the research questions are addressed, a semi-structured approach should be used. Interruptions from the interview should be kept to a minimum, with the interviewer reflecting, prompting and summarising, with open or closed questions and probing where appropriate. Participants should be encouraged to speak about their specific experience.

Before the interview commences, ensure that the participant has read the information sheet. Questions and prompts below are resources on which the interviewer can draw and only relevant questions should be asked.

**1. Introduction**

**2. Reassurance of confidentiality**

Ensure the participant that their answers will be treated confidentially, and their interview will be anonymised before being analysed. Confidentiality will only be broken if they say something that indicates risk to themselves or others.

**3. Clarification of research aims and the interview purpose**

**4. Time for questions from the participant about the interview and/or information sheet**

Remind participants that the interview will be recorded.

**5. Interview questions**

The format and sequencing will be guided by the patient's responses.

- What has your experience been since leaving intensive care?

- What psychological and/or physical symptoms have you experienced, including:
  - Difficulty concentrating
  - Breathlessness
  - Coughing
  - Difficulties sleeping
  - Nightmares
  - Pain
  - Weakness
  - Fatigue
  - Intrusive thoughts
  - Seeing insects

- Have your psychological and/or physical symptoms changed over the course of your recovery?
- If so, how?

- Do you think your physical symptoms (e.g. breathlessness, pain, weakness) have affected your mental well-being?

- How do you think that COVID-19 has affected your recovery, if at all?

- How have any of the following COVID-19 related factors influenced your recovery:
  - Restricted family/friend visiting whilst in hospital
  - Staff wearing PPE
  - Difficulty getting face to face appointments with your GP
  - Reminders about COVID-19 in the media.
  - Family support. Limits on family/friends visiting when at home because of lockdown. Or more family support because of furlough.

- What follow-up services have you been offered?

- Have you attended ICU follow-up clinic?
  - If no, why not?

  - If yes, did you find it helpful and what services were offered as part of that (ICU doctor, physio, dietician, respiratory physician)

- Were you given a phone number to contact for advice?
- Did you use it?
  - If no, why not?

- Is there any other support that you would have liked to have been offered?

- Were you contacted to attend a follow-up clinic? Would you have preferred to have been contacted once you got home (at an earlier time point that being invited for follow-up clinic)?
- At what time frame would you have found that helpful?

- What support do you think you would have benefitted from?

- Did you feel you knew what to expect during your recovery?
- Were you given any information regarding what experiences to expect during your recovery e.g. timespan / symptoms?
  - If so what information was given?
  - Where you satisfied with the information given?
- Specifically - were you given information about ICU recovery / ICUsteps / locally available support services?

**6. Close**

- Is there anything else you would like to share?

Thanks for taking part.

## Appendix 8: Survey of Intensive Care Follow-Up Services

Thank you very much for agreeing to provide the information included in this survey. We appreciate your contribution.

The COVID-19 pandemic has put significant strain on the NHS, not only in direct provision of acute care, but also on follow-up services. At the same time, patients who survive critical COVID-19 often suffer from long-term psychological sequelae, including anxiety, post traumatic distress syndrome and prolonged functional recovery ('long COVID'). In this survey we wish to evaluate the existing follow-up care provided by intensive care units within the UK to address the needs of patients after discharge from hospital.

**Instructions:**

Please complete the questions in the survey below.

- The survey software will enable or disable some questions depending on your responses.
- Based on validation testing we estimate it will take no more than 10 minutes to complete the survey.
- Please answer all questions as accurately as possible.
- Although for brevity we use the terms 'ICU', 'intensive care' and 'critical care' interchangeably, please also consider in your responses all high-dependency beds for which your service is responsible.
- Patients with COVID-19 are defined as patients with a positive PCR test and organ failure requiring treatment.

| **BACKGROUND INFORMATION** | | |
|---|---|---|
| 1 | Which of the following answers most accurately describes your hospital? | • District General Hospital<br>• Teaching Hospital<br>• Tertiary referral centre or University Hospital |
| 2 | What's the name of your trust and hospital? | • Trust name:<br>• Hospital name: |
| 3 | How many staffed Intensive Care beds (level 2 and level 3) does your Department have (excluding any surge areas)? | |
| 4 | Was your capacity increased during COVID-19? | • Yes (If yes, go to Q5)<br>• No |
| 5 | By what number of beds was your unit's capacity increased during COVID-19? | |
| 6 | Can you estimate the number of patients with COVID-19 admitted to your unit during the pandemic? | |

| FOLLOW-UP SERVICES | | |
|---|---|---|
| 7 | Do you currently run an ICU follow-up clinic for patients with COVID-19? | • Yes (If yes, go to Q2)<br>• No (If no, go to Q13) |
| 8 | Was the ICU follow-up clinic running prior to COVID-19? | • Yes (If yes, go to Q3)<br>• No (If no, go to Q4) |
| 9 | Have any changes been made to the way your ICU clinic is run for COVID-19 patients? | • Yes (Please specify)<br>• No |
| 10 | Have any changes been made to the way you run ICU clinics for non-COVID-19 patients? | • Yes (Please specify)<br>• No |
| 11 | If you had surge areas within your hospitals, where high flow oxygen/CPAP was provided but patients were cared for by medical teams, were these patients also invited to ICU follow-up clinic? | • Yes<br>• No<br>• Followed up by other specialties (Respiratory/ID) |
| 12 | How soon after hospital discharge do you contact patients? | • Within a week<br>• Within 2 weeks<br>• Within a month<br>• Within 2 months<br>• Within 3 months<br>• Other (please specify) |
| 13 | In addition to the ICU follow-up service, are there any alternative arrangements for follow-up for COVID-19 patients? | • Yes:<br>• Respiratory team led<br>• GP led<br>• ID led<br>• Other (please specify)<br>• No |
| 14 | Which MDT professionals are part of your ICU follow-up clinic? (Please select all that apply) | • ICU consultant<br>• Critical Care Nurse / Specialist Nurse<br>• Physiotherapist<br>• Psychologist<br>• Dietician<br>• Respiratory physician<br>• Infectious Diseases physician<br>• Other (Please specify) |
| 15 | Which patients do you invite to attend the ICU follow-up clinic? | • All patients admitted to the ICU<br>• All patients treated on the ICU for 24hrs or longer<br>• All patients treated on the ICU for 3 or 4 days or longer<br>• Other (Please specify) |
| 16 | At what time points do you invite patients to the clinic for their first visit? | • 3 months post ICU or hospital discharge<br>• 6 months post ICU or hospital discharge<br>• Other (please specify) |
| 17 | If patients are invited to attend more than one follow-up clinic, please indicate all relevant times: | • 3 months post ICU or hospital discharge<br>• 6 months post ICU or hospital discharge<br>• 12 months post ICU or hospital discharge<br>• Other (please specify) |
| 18 | What tools are used to determine a patients' functional recovery? (Please select all that apply) | • SF-36 (any version)<br>• HADS<br>• Locally derived questionnaire<br>• EQ-5D |

| | | |
|---|---|---|
| | | • PTSD screening tool (please specify)<br>• Others (please specify) |
| 19 | Does the clinic have pre-negotiated access to any of the following services (not simply referral letters), if they are not already integral to the ICU follow-up clinic? (Please select all that apply) | • Clinical psychologist<br>• Occupational therapist<br>• ENT<br>• Physiotherapy<br>• Urology/Sexual Health Medicine<br>• Other (Please specify) |
| 20 | How is the follow-up clinic funded? | • Not funded<br>• ICU budget<br>• Primary Care Trust<br>• Other (please specify)<br>• Don't know |
| 21 | In your opinion, is there a reason for your ICU having no follow-up clinic? (Please select all that apply) | • Financial constraints<br>• Lack of clinical need<br>• Lack of current evidence of benefit<br>• Other (please specify)<br>• No |
| 22 | Please feel free to add any additional comments here: | |

## Appendix 9: Study Team Survey

The PIM-COVID study is the first trainee-led study facilitated by the Trainee Research in Intensive Care (TRIC) Network. We are interested in your feedback on the study and finding out about your views on research. The results will be analysed and interpreted for future presentation and publication and will inform future activities of the TRIC network.

You have been asked to participate as you were a contributor to the PIM-COVID study. The survey will take you about five minutes to complete. Your responses will be stored confidentially and securely for 10 years.

For further information please contact PIM-COVID@liverpoolft.nhs.uk.

**DEMOGRAPHICS**
**We would like to know a little bit more about the demographics and previous research experiences of those involved in the PIM-COVID study teams.**

**Question 1**
**What is your role?**
*(Please select one option from the list below)*

- Foundation trainee ☐
- Core trainee ☐
- Specialist Registrar ☐
- Junior doctor not in training ☐
- Consultant ☐
- Research nurse ☐
- Advanced critical care practitioner ☐
- Psychologist ☐
- Allied healthcare professional *(please specify)* ☐

_____

- Other *(please specify)* ☐

_____

**Question 2**

**What is your gender?**

| | |
|---|---|
| Female | ☐ |
| Male | ☐ |
| Non-binary | ☐ |
| Prefer not to say | ☐ |

**Question 3**

**What is your ethnicity?**

| | |
|---|---|
| Asian or Asian British | ☐ |
| Black, African, Caribbean or Black British | ☐ |
| White | ☐ |
| Mixed or multiple ethnicities | ☐ |
| Other *(please specify)* | ☐ |
| _____ | |
| Prefer not to say | ☐ |

**Question 4**

**Are you currently employed in, or have previously been employed in, a position with protected research time as part of your job plan?**

*(Please select all that apply)*

| *If yes:* | Current role | Previous role |
|---|---|---|
| Academic Foundation Programme | ☐ | ☐ |
| Academic Clinical Fellow | ☐ | ☐ |
| Academic Clinical Lecturer | ☐ | ☐ |
| Research Fellow | ☐ | ☐ |
| Associate Principal Investigator (of another study) | ☐ | ☐ |
| Principal Investigator (of another study) | ☐ | ☐ |

| *If no:* | |
|---|---|
| No previous research experience | ☐ |
| Previous research experience but in my own time whist not employed in a research role (i.e. recruiting patients, data collection, research publication, research presentation) | ☐ |
| Other (please specify) | ☐ ☐ |
| _____ | |

**SITE TEAM**

**The following questions are about your experience of joining the study and the day-to-day running at your site.**

**Question 5**

**How did you hear about the PIM-COVID study?**

*(Please select all that apply)*

| | |
|---|---|
| From the Senior PI | ☐ |
| From the Trainee PI | ☐ |
| From an ICU consultant (not the Senior PI) | ☐ |
| TRIC network mailing list | ☐ |
| Twitter | ☐ |
| Other *(please specify)* | ☐ |

_____

**Question 6**

**What role did you have on the PIM-COVID delegation log?**

*(Please select one)*

| | |
|---|---|
| Trainee PI | ☐ |
| Senior PI | ☐ |
| Sub-investigator / co-investigator | ☐ |
| Not sure | ☐ |

**Question 7**

**Were you involved with the study set up at your hospital?**

| | |
|---|---|
| Yes | ☐ |
| No | ☐ |

*If you answered Yes to Question 7, please proceed to Question 8.*
*If you answered No to Question 7, please proceed to Question 9.*

**Question 8**

**To what extent do you agree with the following?**

| | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree |
|---|---|---|---|---|---|
| Setting up the study at my site was easy | ☐ | ☐ | ☐ | ☐ | ☐ |
| It was clear what was expected of the site team | ☐ | ☐ | ☐ | ☐ | ☐ |
| The site team were well supported by the central study team | ☐ | ☐ | ☐ | ☐ | ☐ |
| I knew who to contact if advice was needed | ☐ | ☐ | ☐ | ☐ | ☐ |

**Question 9**

**What duties did you undertake during the study?**

*(Please select all that apply)*

Identifying patients ☐
Recruiting participants ☐
Data collection and/or participant follow up ☐
Supporting other staff on the delegation log ☐
Managing site paperwork / screening log ☐

**Question 10**

**Who was involved in the day-to-day running of the study at your site?**

*(Please select all that apply)*

Trainee PI ☐
Research nurse ☐
Junior doctor ☐
Allied health professional (please specify) ☐

_____

Senior PI ☐
Don't know ☐

**Question 11**

**On average how much time did you dedicate to the PIM-COVID study per week?**
*(Please select one)*

- Up to 1 hour ☐
- 1-2 hours ☐
- 2-4 hours ☐
- 4+ hours ☐

**Question 12**

**How long were you actively involved in the PIM-COVID project?**
*(Please select one)*

- Up to 3 months ☐
- 3-6 months ☐
- 6-12 months ☐
- Participation still ongoing ☐

*If* 'Participation still ongoing' *selected, proceed to Question 14.*

**Question 13**

**If you stopped your involvement in the PIM-COVID study what was the reason?**
*(Please select all that apply)*

- Moved to a different job or department ☐
- Demands on time or other commitments ☐
- Did not want to continue ☐
- Site stopped collecting data ☐
- Other *(please specify)* ☐

_____

*Questions 14-24 are for junior doctors and allied health professionals only (not research nurses or Consultants), as indicated in Question 1.*

**MOTIVATION AND BARRIERS TO PARTICIPATING**

**We are looking to identify factors that influence trainee and allied health participation in clinical research. Please consider the following questions:**

**Question 14**

**How important were the following aspects in your decision to participate in PIM-COVID?**

| | Not at all important | Unimportant | Neither important nor unimportant | Important | Very important |
|---|---|---|---|---|---|
| Interest in the subject matter | ☐ | ☐ | ☐ | ☐ | ☐ |
| Desire to enhance patient care | ☐ | ☐ | ☐ | ☐ | ☐ |
| Career progression (i.e. to enhance CV or publication record) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Desire to pursue a career in academic medicine | ☐ | ☐ | ☐ | ☐ | ☐ |
| Gain experience in research | ☐ | ☐ | ☐ | ☐ | ☐ |
| Develop new or transferable skills | ☐ | ☐ | ☐ | ☐ | ☐ |
| Job variety | ☐ | ☐ | ☐ | ☐ | ☐ |

**Question 15**

**Please specify anything you were hoping to achieve being involved in PIM-COVID, if not mentioned above.**

_____

**Question 16**

**Did any of the following concerns or barriers impact your ability to undertake work on PIM-COVID?**

| | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree |
|---|---|---|---|---|---|
| Lack of protected research time | ☐ | ☐ | ☐ | ☐ | ☐ |
| Already involved in other research projects | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other non-clinical commitments (i.e. exams, quality improvement, teaching) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other clinical commitments | ☐ | ☐ | ☐ | ☐ | ☐ |
| No previous research experience | ☐ | ☐ | ☐ | ☐ | ☐ |
| Only based in department for a limited amount of time (e.g. trainee rotation) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lack of academic culture at my local site | ☐ | ☐ | ☐ | ☐ | ☐ |

**Question 17**

**Did you have any other concerns about participating in PIM-COVID that are not listed above?**

_____

**FEEDBACK ON THE PIM-COVID STUDY**

**PIM-COVID is the first UK-wide intensive care trainee-led study. We are interested in feedback on the study design, support provided for local site teams and the individual experiences of those involved.**

**Question 18**

**Regarding time commitments, to what extent do you agree with the following statements:**

| | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree |
|---|---|---|---|---|---|
| PIM-COVID work was flexible and could be done around my clinical commitments | ☐ | ☐ | ☐ | ☐ | ☐ |
| I was able to carry out PIM-COVID work during my work hours | ☐ | ☐ | ☐ | ☐ | ☐ |
| I needed to do work for PIM-COVID in my own time | ☐ | ☐ | ☐ | ☐ | ☐ |

**Question 19**

**Were you involved in conducting questionnaires with participants over the telephone?**

Yes ☐

No ☐

*If you answered Yes to Question 19 please answer the following question.*
*If you answered No to Question 19 please proceed to Question 21.*

**Question 20**

**To what extent do you agree with the following statements?**

| | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree |
|---|---|---|---|---|---|
| The number of questions made it difficult to complete questionnaires over the phone | ☐ | ☐ | ☐ | ☐ | ☐ |
| I found the personal and emotive questions unpleasant to ask over the phone | ☐ | ☐ | ☐ | ☐ | ☐ |
| Emotional support for staff carrying out questionnaires over the phone is important due to the nature of the study questionnaire. | ☐ | ☐ | ☐ | ☐ | ☐ |

**Question 21**

**Regarding your experience in PIM-COVID to what extent do you agree with the following statements?**

| | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree | Not applicable |
|---|---|---|---|---|---|---|
| I learnt about the study design process and seeking research approval | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| I learnt about study set up at my site | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| I learnt about data management at a study site | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

| | | | | | | |
|---|---|---|---|---|---|---|
| I learnt about the role of other members of a site team (including research nurses) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| I learnt about difficulties in recruitment to studies | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| I was involved in communication with the Research Development and Innovation team at my site | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**FUTURE PARTICIPATION IN RESEARCH**

**We would like to understand trainee's plans regarding research and academic opportunities they would like to be involved in.**

**Question 22**

**Do you intend to pursue a career in clinical academia?**

| | |
|---|---|
| Yes | ☐ |
| No | ☐ |
| Undecided | ☐ |

**Question 23**

**Regarding future research involvement to what extent do you agree with the following statements?**

| | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree |
|---|---|---|---|---|---|
| Research opportunities that are flexible around my clinical commitments are important to me | ☐ | ☐ | ☐ | ☐ | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| Leadership opportunities within research are important to me | ☐ | ☐ | ☐ | ☐ | ☐ |
| I would like to learn more about study set up and management | ☐ | ☐ | ☐ | ☐ | ☐ |
| I feel confident using research in my clinical practice | ☐ | ☐ | ☐ | ☐ | ☐ |
| I would be involved in research like PIM-COVID again | ☐ | ☐ | ☐ | ☐ | ☐ |

**Question 24**

**Regarding current expectations of healthcare professionals in UK training schemes to what extent do you agree with the following statements?**

| | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree |
|---|---|---|---|---|---|
| It is important for trainees to gain research experience | ☐ | ☐ | ☐ | ☐ | ☐ |
| I am aware of what research studies are happening in my local hospital | ☐ | ☐ | ☐ | ☐ | ☐ |
| I would use protected development time to contribute to further research | ☐ | ☐ | ☐ | ☐ | ☐ |
| I prefer quality improvement projects / audit to research | ☐ | ☐ | ☐ | ☐ | ☐ |

**Thank you for completing this survey.**