Study Title: Understanding how post-ICU follow-up is delivered within the role of Critical Care Outreach Teams (ERACC)

Internal Reference Number / Short title: ERACC: Qualitative follow-up study

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	Professor Stephen Morris, RAND Professor of Health Services Research, University of Cambridge Dr Stephen Gerry, Senior Medical Statistician, University of Oxford PPI members Miss Alison Phillips, Alison has lived experience of recovery from critical illness and has been key in developing this project. She will support stakeholder involvement throughout the work packages, advise us on patient recruitment, ensure there is a strong patient voice on the steering committee, and support dissemination, including presenting our findings at conferences. Ms Corina Cheeks, Corina is a member of the NIHR Oxford Biomedical Research Centre Diversity in Research Group. She has extensive experience as a co-applicant on research grants, supporting researchers to ensure equality of access for both patient and public contributors and research participants. Mr Richard Mandunya, PPI contributor and Oxford NIHR Diversity in Research Group member. Richard will advise on ensuring diversity and inclusion in our PPI, participant recruitment and dissemination.
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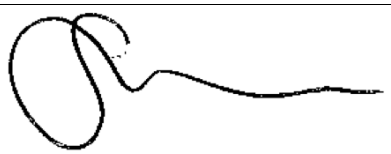
Funder:	This work is part of a wider programme of research, funded by an NIIHR Programme Grant for Applied Research (NIHR206266).
Chief Investigator Signature:	

Conflicts of interest:

There are no known conflicts of Interest.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, HRA (where required) unless authorised to do so.

TABLE OF CONTENTS

1. KEY STUDY CONTACTS 6
2. LAY SUMMARY 6
3. SYNOPSIS 7
4. ABBREVIATIONS 9
5. BACKGROUND AND RATIONALE 10
6. AIM / RESEARCH QUESTIONS / OBJECTIVES 11
7. STUDY DESIGN 11
   - 7.1 Methodology 12
   - 7.2 Sampling Strategy 13
   - 7.3 Methods of Data Collection 13
   - 7.4 Study Sequence and Duration 15
8. PARTICIPANT IDENTIFICATION 15
   - 8.1 Study Participants 15
   - 8.2 Inclusion Criteria 16
   - 8.3 Exclusion Criteria 16
9. STUDY ACTIVITIES 16
   - 9.1 Recruitment 16
   - 9.2 Informed Consent 17
   - 9.3 Subsequent Visits 19
   - 9.4 Discontinuation/Withdrawal of Participants from Study 21
   - 9.5 Definition of End of Study 22
10. ANALYSIS 22
    - 10.1 Description of Analytical Methods 22
11. DATA MANAGEMENT 23
    - 11.1 Access to Data 23
    - 11.2 Data Recording and Record Keeping 23
12. QUALITY ASSURANCE PROCEDURES 24
13. ETHICAL AND REGULATORY CONSIDERATIONS 24
    - 13.1 Declaration of Helsinki 24
    - 13.2 Approvals 24
    - 13.3 Other Ethical Considerations 25
    - 13.4 Reporting 25

13.5 Participant Confidentiality 25
13.6 Expenses and Benefits 25
14. FINANCE AND INSURANCE 25
14.1 Funding 26
14.2 Insurance 26
14.3 Contractual arrangements 26
15. PUBLICATION POLICY 26
16. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY 26
17. ARCHIVING 26
18. REFERENCES 27
APPENDIX A: PROGRAMME FLOWCHART 30
APPENDIX B: Protocol for managing potential distress during interviews with patients and relatives 30
During follow-up, discuss avenues of support again if needed, particularly follow-up clinic and post-ICU psychiatrist if available. 31
APPENDIX C: AMENDMENT HISTORY 31

1. KEY STUDY CONTACTS

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Funder(s)	National Institute for Health and Care Research (NIHR) Coordinating Centre, Grange House, 15 Church Street, Twickenham TW1 3NL Tel: 020 8843 8000 Fax: 020 8843 8001 Email: pgfar@nihr.ac.uk

2. LAY SUMMARY

This qualitative study is part of the first stage of the Enhanced Recovery following Critical Care (ERACC) programme. The main aim of the programme is to develop and implement an evidence based enhanced care pathway for patients discharged from ICU. Understanding how current UK critical care outreach team practice is delivered is essential to inform design of a future pathway. This qualitative study will include observations of staff as well as interviews with staff, patients who have been in ICU and their families*. The study will be conducted in 3-5 sites chosen to represent different models of post ICU care provision.

*When referring to family members within this protocol this encompasses, spouses, children, siblings, close friends etc.

3. SYNOPSIS

Study Title	Understanding how post-ICU follow-up is delivered within the role of Critical Care Outreach Teams
Internal ref. no. / short title	ERACC: Qualitative follow-up study
Sponsor	University of Oxford Research Governance, Ethics and Assurance (RGEA), Boundary Brook House, Oxford, OX3 7GB, United Kingdom Telephone: +44 1865 616480 Email: rgea.sponsor@admin.ox.ac.uk The Critical Care Research Group at the University of Oxford are coordinating and managing the study on behalf of the Sponsor.
Funder	National Institute for Health and Care Research (NIHR) Coordinating Centre, Grange House, 15 Church Street, Twickenham TW1 3NL Tel: 020 8843 8000 Fax: 020 8843 8001 Email: pgfar@nihr.ac.uk
Study Design, including methodology	A qualitative study using semi-structured interviews and ethnography **Interviews** CCOT (Critical Care Outreach Team) members, multi-disciplinary staff working with CCOTs (e.g. ward-based physiotherapists and nurses), and patients discharged from ICU and their family members. Participants will take part in one semi-structured interview, exploring their perception of how follow-up care is delivered within the workload of CCOTs. Interviews will be conducted face to face or via telephone or Video call with audio recording. **Focussed Ethnography** Observed participants will be members of the CCOTs. We will observe participants within their role, collecting data on the tasks they perform, people they interact with, and proportion of time spent on each activity they undertake. Direct patient care will not be observed.As part of the ethnography, in-situ informal interviews may be conducted to understand what was observed and to seek

	clarity on any phenomena observed (using techniques such as Think-aloud: 'talk me through what you did there'). CCOT members will provide informed consent to be observed. Other staff members and patients with whom CCOT members interact with will not be approached for consent, as they are not the direct focus of data collection, but will be given the opportunity to opt out of data collection.
Study Participants, including sampling strategy	CCOT members, multi-disciplinary staff working with CCOTs (e.g. ward-based physiotherapists and nurses), and patients discharged from ICU and their family members. Ethnography will be conducted at five NHS hospital sites with Critical Care Outreach Teams. Interview participants will be purposively sampled at the sites to provide a broad range of perspectives. Participants will also be sought through a national survey of CCOT practices, where there will be an option to express interest in participating in this study.
Sample Size	Ethnography: up to 200 hours Semi-structured interviews: Up to 30 (12 will be CCOT, up to 18 will be patients and family members) Sampling is based on the concept of Information Power (Malterud et al 2015) and the pragmatic aim of accessing a broad range of participants and CCOT interactions.
Planned Study Period	12 months 01/07/2025-30/06/2026 Duration of participation for interviews: less than one day Duration of participation for ethnography: up to six months for individual team members who may participate in observations on more than one occasion.
Planned Recruitment period	Jul 2025- Jun 2026
Aim/Research Questions/Objectives	
Primary	To understand how post-ICU follow-up care is delivered within the wider remit of CCOT workloads.
Secondary	To understand different models of post-ICU care delivery
	To understand what proportion of CCOT time is spent on ICU follow-up care and how this is prioritised (e.g. internal/external drivers)
	To understand the competing demands on CCOT time
	To understand the experience of CCOT staff of providing ICU follow-up care within their role

	To understand the wider staff perception of current ICU follow-up care provision and perception of what follow-up care should look like
	To understand patient and family member perceptions of ICU follow-up care provision

4. ABBREVIATIONS

CI	Chief Investigator
CCOT	Critical care Outreach team
CRF	Case Report Form
ERACC	Enhanced Recovery After Critical Care
HRA	Health Research Authority
ICF	Informed Consent Form
ICU	Intensive Care Unit
NHS	National Health Service
RES	Research Ethics Service
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
RGEA	Research Governance, Ethics and Assurance
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure

5. BACKGROUND AND RATIONALE

This work is part of a wider programme of research, funded by an NIHR Programme Grant for Applied Research (NIHR206266). This programme aims to design and test an enhanced care pathway for patients recovering from critical illness.

Over 14,000 patients discharged from an Intensive Care Unit (ICU) in England Wales or Northern Ireland each year (around 10% of the ICU discharged population) either die unexpectedly on the ward or are readmitted to an ICU following deterioration[1]. Nearly a third of those who survive to leave hospital are readmitted as an emergency within three months[2]. By one year, half of all the patients discharged have been readmitted to hospital as an emergency[3,4]. Patients and family members report finding discharge from intensive care frightening and felt unsupported[5]. These unacceptable outcomes occur despite three quarters of ICUs providing an in-hospital follow-up/recovery service to support care after ICU discharge[6,7] and the National Institute for Health and Care Excellence providing guidance for rehabilitation after ICU[7]. There is no evidence-based care pathway for these patients, unlike in other conditions such as stroke or following major surgery[8,9]. We plan to develop an enhanced care pathway for patients discharged from ICU.

A key difference between common enhanced recovery pathways and an Enhanced Recovery After Critical Care (ERACC) pathway is that patients following ICU are not cohorted to particular wards, but spread throughout the wards in a hospital depending on the original speciality underlying admission[6]. This results in a wide geographical spread and differing underlying skills in the receiving wards. Over three-quarters of UK ICUs provide follow-up/recovery teams intended to optimise the care of patients in hospital following an ICU stay[10]. However, the national Critical Care GIRFT report and a recent systematic review showed wide variation in provision[6,11]. Although they aim to support the ward team, help identify clinical deteriorations, and facilitate communication between settings[6,12,13], Critical Care Outreach Teams (CCOTs) currently follow local protocols based on very limited evidence[11,14]. Our previous work demonstrates follow-up visits do not ensure key aspects of care are delivered. Follow-up visits usually ceased 24-48 hours after transfer to the ward, despite ongoing clinical problems[15], limiting the possible impact on post-ICU recovery. Our work shows that post-ICU patients commonly have unmet clinical needs that can be delivered in an ERACC pathway after this point. In part, early discharge from CCOT care may reflect the wide remit of these teams[14], emphasising the importance of understanding current practice to allow comprehensive ERACC implementation. Evidence-based practice has neither been assimilated nor systematically implemented. A recent systematic review found no impact on ICU readmission or death[11].

Understanding how current UK ICU CCOT practice is delivered, and how it sits within the local, regional and national health requirements is essential in designing the future ERACC pathway, in which CCOTs are key stakeholders. In-depth understanding of provision breadth, CCOT and hospital cultures and their interactions is required. This study will inform later work to develop and test the pathway.

This qualitative study is part of the first stage of the Enhanced Recovery following Critical Care (ERACC) programme. In this study we aim to understand how post-ICU follow-up care is delivered within the wider remit of CCOT workloads. This study follows a national survey of critical care outreach practice conducted by the ERACC research team, and will lead into future work packages. The national survey aims to understand the current support of patients following discharge from ICU to the ward, and thoughts on how this could be improved. The survey includes questions on an individual staff members role as a Critical

Care Outreach practitioner, and includes details about the wider team and how post-ICU follow up care is currently provided and any suggested improvements. The survey, the results of literature reviews alongside the interviews as well as the observations of clinical care detailed within this protocol will help to inform the development of an enhanced care pathway for patients discharged from ICU.

Patient and Public (PPIE) collaborators have helped develop the research topic and the research questions that should be asked. PPIE have also been involved in developing the patient facing documents including the Patient information sheet and consent forms and the interview topic guides.

They will continue to be involved for the duration of the project. For more information on PPIE please see: https://www.nihr.ac.uk/patients-carers-and-the-public/

Appendix A includes a flow chart of the whole programme, this protocol is for work package 1 only. Subsequent work packages will be submitted in separate protocols.

This qualitative study will take place at five NHS sites, chosen to represent different models of post-ICU care provision, we will conduct a focused ethnography of CCOT workloads, focusing on how post-ICU follow-up care is integrated into this workflow. We will also conduct semi-structured interviews with CCOT staff, multiprofessional staff who work alongside these teams, and patients and their family members, to understand their perceptions of how post-ICU follow-up care is currently provided.

The risks to participants are minimal. There is a small chance that ethnographic observations may identify professional accountability issues which need to be escalated, and interviews may cause distress, although this is unlikely. Clear protocols will be in place to support researchers in dealing with these potential risks and protect participants.

6. AIM / RESEARCH QUESTIONS / OBJECTIVES

Aim / Research Questions / Objectives
Aim: To understand how post-ICU follow-up care is delivered within the wider remit of CCOT workloads.
Objectives: • To understand different models of post-ICU care delivery • To understand what proportion of CCOT time is spent on ICU follow-up care and how this is prioritised (e.g. internal/external drivers • To understand the competing demands on CCOT time • To understand the experiences of CCOT staff of providing ICU follow-up care within their role • To understand the wider staff perceptions of current ICU follow-up care provision and perception of what follow-up care should look like • To understand patient and family member perceptions of ICU follow-up care provision

7. STUDY DESIGN

7.1 Methodology

This is a pragmatic qualitative study aiming to understand how post-ICU follow-up visits are provided by critical care outreach teams, and how outreach team workloads may be adjusted to better support those discharged from ICU.

a.) To achieve this, we will collect data in two ways: interviewing staff, patients and family members about their experiences of post-ICU support provided by critical care outreach teams (up to 30 interviews);
b.) observing critical care outreach teams at five NHS sites whilst undertaking their day-to-day work (up to 200 hours).

The sample size (up to 30 semi-structured interviews and 200 hours of observation) is based on our pragmatic aims and the concept of information power[16].Our objective, to understand how post-ICU ward care is delivered in practice is relatively narrow, but involves a broad range of professionals and sits within the broad remit of critical care outreach services. Therefore, 30 interviews are deemed sufficient to allow us to access a broad range of perspectives (from both staff and patients and their families), and 200 hours of observations across five sites should afford us insight into how post-ICU care is delivered within the broad role of CCOTs across different clinical settings[17].

Sub-study A: semi-structured interviews

Up to 30 semi-structured interviews will be held with multi-professional staff involved in the care of patients discharged from ICU to the ward, patients discharged from ICU and their family members to understand their experiences of ongoing support from critical care outreach teams. Participants will be sought from three to five NHS trusts, selected to represent differing hospital sizes, critical care provision and post-ICU support services. Some participants may also be identified as part of a national survey of CCOT practice previously undertaken.

Sub-study B: Ethnographic Observations

Selected CCOT members at each site will be observed undertaking their usual role. Non-participant observations will be undertaken (observer plays no part in escalation processes), aiming to minimise the impact of the observer being present. Observations will focus on both the support offered to patients discharged from ICU to the ward (including type of support offered, duration of time spent, how these patients are identified and decision-making around prioritisation of visits), and the broader workload of these teams and how post-ICU support fits with this. The workflow of the CCOT members will be the main focus of these observations, but interactions with other healthcare professionals as part of their role will be included. No direct patient care will be observed.

Field notes of observations will be supplemented with informal discussions with clinical staff encountered during the observation period, exploring factors such as post-ICU support, specific events or behaviours, as well as discussing tasks undertaken during un-observed direct patient care episodes. These will be short discussions with staff lasting no longer than 10 minutes, aiming to develop understanding of situations which were observed and the underlying decision-making[17].

Data from the two approaches (semi-structured interviews and ethnographic observations) will be analysed separately and then together, to gain a full understanding of stakeholder perceptions of supporting post-ICU patients within critical care outreach teams, and how this is and can be delivered in practice.

7.2 Sampling Strategy

Sub-study A: Semi-structured Interviews

We will purposively select participants to achieve maximum variation in the sample, aiming to access participants with a broad range of experiences. This will include patients who have had varying durations of critical illness and ongoing care needs, various family members (i.e. spouses, children, siblings, close friends etc.) and clinical staff from a broad range of professions and clinical bandings.

Participants will be identified in two ways.

- Firstly, respondents to a national survey of critical care outreach nurses, conducted previously as part of the wider ERACC programme, will be given the option to express interest in being interviewed for this study. Those interested will be given the opportunity to provide contact details to the team within the electronic questionnaire responses. These will be used to select participants from a variety of geographical areas.
- Secondly, participants will be sought from five NHS trusts in the UK, selected to represent varying post-ICU service provision and clinical settings.

Sub-study B: Ethnographic Observations

Staff working in Critical Care Outreach Teams (CCOT) at the five sites will be purposively sampled to be observed during their role. Selection will be based on maximum variation from within the team to include a range of clinical experience, banding and roles. Members of the CCOT are predominantly nurses but may also include physiotherapists, occupational therapists and dietitians, so a range of professions will be sought.

7.3 Methods of Data Collection

Sub-study A: Semi-structured Interviews

Semi-structed interviews will be conducted by a member of the research team with experience of qualitative interviewing. Interviews will last around 30-60 minutes, and be recorded using QSR NVIVO transcription function or using a separate audio recording device (OLYMPUS Digital Voice Recorder VN-541PC) and transcribed after the interview. At the start of the interview the interviewer will confirm consent to participate, explain that the session will be audio recorded and that they may stop the interview at any time. Audio recordings will be transferred to an University of Oxford Computer and will be stored within the university system on a secure database with restricted access from the secure research facility and password protected. and transcribed verbatim at a later date by a member of the research team. All

transcriptions will be completed and audio files deleted within 6 months of the interview taking place. Participants will have the aims of the interview explained to them. Interviews will follow a topic guide including questions and prompts focused around support provided by CCOTs to patients discharged from ICU. It is not anticipated that any questions will be distressing or upsetting, and breaks will be offered if required by participants.

Patients and family members may be interviewed together (as dyadic interviews), or separately, depending on participant preference. Interviews will be conducted on the ward in a private room or at the patient bedside if sufficiently private, or by telephone or video call (MS record) within three months of discharge from hospital, to allow time to recover from their critical illness but sufficient proximity to the event to allow recall.. If the interview is taking place after the family member has been discharged from hospital a member of the research team will take contact details (phone number, email address) in order to make arrangements once the interview has taken place the researcher will destroy the contact details.

Staff interviews will be held in person in a private room in the hospital away from the clinical area, or by video calling (using MS Teams) or telephone, depending on participant preference.

Interviews conducted via video call will only have the audio transcribed/ recorded.

Sub-study B: Ethnographic Observations

Members of the CCOTs will be observed undertaking their role, including but not limited to visiting patients discharged from ICU. Shadowing clinical staff and observing interactions with other staff members ensures that the researcher is able to get a complete understanding of the CCOT role and how post-ICU support fits within this. Non-participant observations will be undertaken (with the observer playing no part in interactions) in the hope of minimising the Observer Effect, where participants change behaviour because of researcher presence[17,18]. By the fluid nature of the observations, and the researcher shadowing the clinical team to the patient location, interactions with other staff members will be observed, but direct care delivery will not be observed, to protect patient privacy. Instead, informal discussions (detailed below) will be undertaken with CCOT following visits to patients to capture brief details about the types of interventions provided during patient contact (e.g. advice provided, vital signs measured, mouth care provided, etc.) and to understand clinical prioritisation[17].

Informal Discussions

Ad-hoc informal discussions may be conducted with any staff interacting with the observed CCOT member, to give context to the interaction and develop further understanding of the CCOT role and decision-making processes[17]. Ad-hoc informal discussions may also be conducted with the CCOT member being observed in relation to unobserved direct patient care interactions. These will be short discussions lasting no longer than 10 minutes and responses will recorded as field notes.

No identifiable patient or staff data will be collected, and all data will be anonymised at the point of capture. Data (field notes and interview notes) will be collected with an electronic or handwritten case report form, which will be piloted prior to first use. Observation sessions will last no longer than 4 hours in duration, but staff may be observed on multiple occasions. Staff will also be observed at different shift

time-points (early, late, night and day) and different month clusters to ensure any temporal or seasonal variability to observations or escalation is captured. Staff from this phase may also be recruited for the staff interviews in sub-study A.

7.4 Study Sequence and Duration

Sub-study A: Semi-structured interviews

The study duration for patient and family member interview participants will be up to a week if interviews are conducted in hospital, but may be up 3 months if participants opt to be interviewed after hospital discharge. In this case, initial contact and translation for participation will be undertaken during their in-hospital stay, with contact made around two weeks after hospital discharge to confirm willingness to participate and arrange a time for interview, followed by the interview within three months of discharge from hospital. Translation of information sheets into common local languages at each site will be undertaken and interpretation services used during the informed consent process where needed. Two-way interpretation of qualitative interviews will be offered. Translation and interpretation is fully costed within the research grant

Sub-study B: ethnographic observations

For CCOT members who are observed during practice, participation may last up to four months, with up to six periods (maximum 200 hours across 5 sites) of observation during this time.

8. PARTICIPANT IDENTIFICATION

8.1 Study Participants

Sub-study A: Semi-structured Interviews

For the patient, family member and staff interviews, up to 30 participants are anticipated to be sufficient to provide a detailed account of post-ICU support from multiple perspectives, based on our previous work and guidance on information power[16,19,20]. Given the wide range of participant experiences and professions sought, data saturation will not be sought, but recruitment will cease when a broad range of participants have been accessedA screening log will be used to capture details on all of the individuals approached to take part in an interview and if applicable the reason they did not want to take part.

Sub-study B: Ethnographic Observations

Up to 10 periods of observation, lasting up to 4 hours each, at each of the participating sites (up to 200 hours in total). It is anticipated that between 9 and 12 CCOT members will provide consent to facilitate these observations. This is a focused ethnography considering a relatively narrow research question therefore up to 200 hours of observations is deemed sufficient to meet the objectives of the study, and to

ensure sufficient opportunities are available to observe the provision of post-ICU support as well as a range of other CCOT activities.

8.2 Inclusion Criteria

Sub-study A: Semi-structured Interview

- Patient/family member/staff member aged 18 or over
- Is willing and able to give informed consent for participation in the study
- Is a patient discharged from ICU to the ward, or a family member of a patient discharged from ICU to the ward, or a staff member who supports patients discharged from ICU to the ward
- Is willing and able to participate in an interview about their experiences

Sub-study B: Ethnographic Observations

- A member of the CCOT at participating sites
- Is willing and able to give informed consent for participation in the study
- Is willing and able to be observed during their clinical practice

8.3 Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- Not consenting to participate
- Patient not wishing for family member to take part

9. STUDY ACTIVITIES

9.1 Recruitment

Sub-study A: Semi-structured Interviews

Clinical Staff

Clinical staff who are involved in the care of patients discharged from ICU will be recruited at all five participating sites. Staff will be informed of the study through several methods, including e-mails from clinical managers, adverts on the local trust intranet and snowballing from other participants. Members of the CCOT will also be asked, as part of their participation in the **Ethnographic Observations.**

CCOT members from across the UK may also express interest in this study during participation in the national survey (outside of this study but conducted prior to this by the research team as part of the ERACC programme). At the end of the survey they will be given the option to provide their contact details to the study team within the survey software (RedCAP). These details will be used to select and contact participants.

Patients and family members

Patients discharged from ICU at the three sites and their family members will be given information about the study by the CCOT or ICU follow-up team at each site, during their routine visits. ICU discharge lists may also be screened by local research delivery teams who may approach patients about the study as well. Potential family members will be identified by patients during patient approach, and either approached along with patient (if they are present), or patients may take a PIS to be given to them to consider and contact the study team if they are interested in participating. All initial approaches will be made by a member of the direct care team, not the researchers. Translation services are available if English is not the patient or family members spoken language.

Sub-study B: Ethnographic Observations

Members of the CCOT will be the main focus of ethnographic observations, and will provide consent to participate in observations. Interactions with other clinicians will also be observed, but as the direct focus of observations is not the roles of those external to the CCOT but how these interactions influence CCOT workflow, consent to observe these interactions will not be sought from other parties, although the option to opt-out will be given, as detailed in the next section.

With the support of managers, CCOT members at each site will be approached to consider participating in ethnographic observations. Those who are interested in participating will be given the contact details of the research team.

9.2 Informed Consent

Sub-study A: Semi-structured Interviews

Staff who contact the research team to express interest in participating (either through the survey or advertisements described above) will be informed of the aims of the study and given a participant information sheet. The participant information leaflet will outline the exact nature of the study, what it will involve for the participant, the implications and constraints of the protocol, and any risks involved in

taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason, without affecting their legal rights and with no obligation to give the reason for withdrawal.

If after considering the information provided the staff member is willing to participate, they will contact the research team to arrange a suitable date and venue for the interview. A member of the research team or local research delivery team may visit the staff member in their clinical area to assess the potential participant against inclusion and exclusion, and obtain written informed consent prior to the interview, or this will be obtained at the start of the arranged interview.

Written informed consent will be obtained by means of participant dated signature and dated signature of the person who presented and obtained the informed consent..

The person who obtained the consent must be suitably qualified, experienced and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant.The original signed form will be retained at the study site. Another copy of the consent should also be retained by the ERACC research team. All those obtaining consent will have received informed consent training as well as Good Clinical Practice training.

If a participant has been identified from the national survey, consent will be taken remotely using the remote staff participant consent form and then a copy of the consent form will be sent to them prior to the interview for retention.

Patients and family members

Patients who have contacted the research team (either directly or through the CCOT) will be visited on the ward by a member of the research team or the local research delivery team. If appropriate, research staff will also ask participants if they have a family member who may be willing to participate. If so, the family member will either be approached at the same time as the patient participant or separately, following the same procedure below.

Potential participants will be informed of the aims of the study and given a Participant Information Sheet. The participant information sheet will outline the exact nature of the study, what it will involve for the participant, the implications and constraints of the protocol, and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason, without affecting their legal rights and with no obligation to give the reason for withdrawal.

If after considering the information provided the patient and/or family member is willing to participate, they will contact the research team to assess the potential participant against inclusion and exclusion criteria, and arrange a suitable date and venue for the interview, either in hospital or at home after hospital discharge. A member of the research team or local research delivery team may visit the patient/family member on the hospital ward to obtain written informed consent prior to the interview, or this will be obtained at the start of the arranged interview. A scanned copy will be made and returned to the participant for their records.

Written Informed Consent will be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified, experienced and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed

form will be retained at the study site and another copy will be retained by the ERACC research team. All those obtaining consent will have received informed consent training as well as Good Clinical Practice training.

Sub-study B: Ethnographic Observations

Consent will be managed using both 'opt-in' and 'opt-out' approaches.

Opt-in

For CCOT members at each site who contact the research team to express interest in participating, the approach outlined above for seeking informed consent for staff interviews will be followed. These individuals will consent to being directly observed in practice[21].

Opt-out

An opt-out option will be available to all professionals whose interactions with the CCOT members are observed as follows:

Information about the study will be disseminated by managers to all staff in the CCOT and ICUs where observations will take place. This information will also be sent to managers on all wards (given that CCOTs work across the hospital). An opt-out form will be available (via e-mail, as paper copies in each clinical area and from the researcher). These can be completed by anyone wishing to opt out of observations, and send either via internal post to each ICU where observations are taking place, or electronically to the research team. A list of those who have opted out, and their place of work will be kept and cross-checked prior to and during each observation. Posters will be displayed in clinical areas, outlining the study and informing staff of their opt-out options. Opt out forms will be stored securely as outlined in section 11.2 and destroyed as soon as the observations have been completed at each site.

9.3 Subsequent Visits

Sub-study A: Semi-structured interviews

Staff

The interview may immediately follow the informed consent conversation or may be arranged at a mutually convenient later date.

Interviews will be conducted by a member of the research team with experience of qualitative interviewing, and will last around 30-60 minutes. Interviews will be recorded using a separate recording device and transcribed after the interview. At the start of the telephone call, video call or face to face interview, the interviewer will confirm consent to participate, explain that the session will be audio recorded only and that they may stop the interview at any time. Participants will have the aims of the interview explained to them. Interviews will follow a topic guide including questions and prompts focused around their experiences of supporting patients in hospital after discharge from ICU.

It is not anticipated that any questions will be distressing, but there is the potential that some reflections on the challenges of providing good care in a high-pressure environment may be upsetting. Researchers will be experienced in conducting interviews with ICU staff, and will offer breaks, to resume the interview at another time, or end the discussion altogether. NHS Trust Occupational Health will be made aware that we are conducting this study and any staff member who causes concern to the researchers will be signposted to occupational health in the first instance. We have undertaken preliminary interviews with staff which have shown that staff are happy to discuss the care of this patient group.

Although the care of individual patients will not be discussed, there is a very small chance of eliciting answers which cause concern in terms of professional conduct. Although this is highly unlikely, in this instance the researchers would be accountable to act upon this and would seek advice from clinicians within their management structure in the first instance, with a view to raising this with the line manager of the subject.

Patients/family members

The interview may immediately follow the informed consent conversation, or may be arranged at a mutually convenient later date.

Patients and family members may be interviewed together (as dyadic interviews), or separately, depending on participant preference. Interviews will be conducted either in person on the ward, or by telephone within three months of the patient being discharged from hospital. Preference for this will be established during the consent conversation. If the interview is planned for after hospital discharge, the researcher will call the patient around two weeks after hospital discharge to arrange a mutually convenient time for the interview.

Interviews will be conducted by a member of the research team with experience of qualitative interviewing, and will last around 30-60 minutes. Interviews will be recorded using a separate recording device and transcribed after the interview. At the start of the telephone/video call (MS teams) or face to face interview, the interviewer will confirm consent to participate, explain that the session will be audio recorded and that they may stop the interview at any time. Participants will have the aims of the interview explained to them. Interviews will follow a topic guide including questions and prompts focused around their experiences of support in hospital after discharge from ICU.

It is not anticipated that any questions will be distressing, but there is the potential that some recollections of care may be upsetting if the care was perceived to be poor or the patient's health deteriorated on the ward. Researchers will be experienced in conducting interviews with patients and their families and will offer breaks, resume the interview at another time, or end the discussion altogether. **Appendix B** outlines the process for supporting and signposting the participant to additional help.

Sub-study B: Ethnographic Observations

Direct participant observations will be undertaken with consented CCOT members. Each observation period will last for up to 4 hours, with the period of observation varying throughout the day (and potentially overnight), to capture variations in workflow across shifts. Up to ten periods of observation will be undertaken at each site. A member of the research team will shadow the consented CCOT member(s)

– this may include more than one team member - during the observation period. Observation will focus on workflow of CCOT, including but not restricted to supporting patients discharged from ICU.

Although observations will be focused on the workflow of the consented CCOT member(s), we will observe CCOT members interacting with other staff members, including other members of the CCOT and wider multiprofessional team members (such as ward nurses, doctors or allied health professionals, ICU doctors and nurses, and operations managers). Arrangements for opting out of these observations is detailed section 9.2.

During observations, field notes will be documented in an ethnographic encounter record form. This will include brief notes about the types and content of work undertaken. These will include periods of direct patient care (which will not be directly observed) such responding to deteriorations, routine visits to patients and incidental interactions, telephone advice, ICU discharge planning and clinically based education and advice.

As CCOT members may be called to respond to emergency situations and will visit busy clinical environments, the researchers will take care to remain as unobtrusive as possible, adopt a sensitive approach to observations, and will, if necessary, withdraw from observations of emergency situations.

No direct care provision will be observed. Instead, focused brief interviews may be held with CCOT members or other staff to gather brief details about the types of patient interactions undertaken. These will not be recorded verbatim but recorded in note form.

9.4 Discontinuation/Withdrawal of Participants from Study

During the course of the study a participant may choose to withdraw early at any time. This may happen for several reasons, including but not limited to:

- The occurrence of significant distress during study interviews or observations
- Inability to comply with study procedures
- Participant decision

In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including, but not limited to:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with study requirements

Participants will be given the following withdrawal options:

1) Participants may withdraw from the interview and further communication but allow the research team to use the collected qualitative data.
2) Participants may withdraw from the interview/observations and further communication and not allow for their data to be used. In this case:
    a. Qualitative interviews: Staff, Patient and family members will be free to stop a scheduled interview or the interview itself at any point. Once the interview has taken place, they

have two weeks to withdraw from the study should they wish to. In this case their data can be securely destroyed if they wish. After two weeks, data will be included in results, but they will not be identifiable and no quotes from the interviews will be used in any outputs.

b. Observations: Field notes will be deleted and data from the withdrawn participant will not be transcribed or will be deleted from transcript where it is possible to identify their data, up until the point of de-identification.

Data collected to this point will be assessed and participants will be replaced if deemed necessary by the study team.

The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

9.5 Definition of End of Study

The end of study is the point at which all the study data has been collected and transcribed, and queries resolved.

10. ANALYSIS

10.1 Description of Analytical Methods

Interviews and field notes will be transcribed verbatim into a specialist software package for coding qualitative data (QSR NVIVO). An overarching thematic analysis approach will be taken to analyse these qualitative data[22]. This will ensure clear identification of the barriers and facilitators to providing post-ICU support within the CCOT role, and suits the pragmatic aims of this study. This approach has previously been used to identify areas of care which patients and staff believed could be improved[19,23].

Data from each sub-study will initially be analysed separately. Qualitative data from ethnographic participant observation field notes and informal discussions will be analysed using an inductive–iterative approach, aided by reflexive notes. To support reflexivity, reflexive diaries and regular supervision with an experienced ethnographer will aid data collection and analysis [17]

Preliminary coding will take place soon after the interviews/observations are conducted. This will allow any emerging themes to be explored in subsequent data collection. Preliminary coding will be refined using the steps outlined by Braun and Clark, and using the method of constant comparison (until no new themes emerge) to identify preliminary themes[22]. Analysis will continue until preliminary themes are refined into the final theme structure. Throughout preliminary coding, codes and developing themes will be discussed

with the research team. Once initial analysis of each data set is complete, data will be further analysed using cross-case comparison, across each case and type of data, using inductive analysis techniques based on thematic analysis[17,24]. Themes will be compared across data sets to identify commonalities, differences, and where the two approaches can contribute to build a more comprehensive picture of post-ICU support.

Once finalised, a report will be produced, reflecting the most important themes across the two data sets, represent the full range of experiences included in the interviews and observations. For the final output, these themes will be further categorised by aspects of the system which could be improved, and suggestions for improvement.

Credibility will be achieved through triangulation of data from the two methods (interviews and ethnography), including identification of similarities and differences from the two approaches. Confirmability will be ensured through careful field notes and reflexive accounts during data collection (collected as part of the case report form), regular meetings of the research group throughout analysis, to discuss codes and developing themes, and research diaries of decisions made in data collection and analysis to provide an audit trail. Transferability will be maximised by seeking three sites with differing post-ICU service provision, patient populations, and hospital size and setting, as well as including participants from outside these sites identified through the external UK survey.

11. DATA MANAGEMENT

11.1 Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

11.2 Data Recording and Record Keeping

A trial master file will be created for this study. Clean copies of all CRFs, key documents (e.g. study protocol) and relevant administration documentswill be maintained in this file. This file will be held digitally in the first instance on secured University of Oxford servers. The participants will be identified by a unique trial specific number and/or code in any database.

All study data will be entered on case report form. The participants will be identified by a unique study specific number and/or code in any database. The name and any other identifying detail will NOT be included in any study data electronic file.

Observations notes will be directly entered onto a case report form either electronically or on paper. In the case of paper case report forms, these will be transcribed into a word document uploaded into NVIVO at the earliest opportunity and the paper version scanned into the TMF and then disposed of in confidential waste.

If a patient or family member is taking part in an interview following patient discharge from hospital personal telephone numbers or other contact details will be collected by a member of the ERACC research team to allow recruitment after the patient has left hospital. These contact details will not be linked to any hospital data. All personal information will be stored on password protected computer servers and

accessed only by the research team member responsible for recruitment at that site. Any personal details will be destroyed at the end of the study.

There is potential for incidental inclusion of potentially identifiable information within participant responses. The transcripts and analysis data will be stored by study number within the NVIVO database. The name and any other identifying detail will NOT be included in any study data electronic file. The audio files of interviews will be destroyed once transcription is completed and checked.

The transcripts and analysis data will be held securely at the University of Oxford for 5 years after the end of the study.

All paper documentation (consent forms and opt out forms) will be stored in a secure research facility, behind two locked doors in a locked filing cabinet. Electronic records will be stored within the university system on a secure database with restricted access from the secure research facility and password protected. All data collected will be pseudonymised: all names removed and individuals will not be recognisable. Data will only be accessible to authorised research staff.

Authorised members of the University of Oxford and NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

There are situations in which we cannot guarantee confidentiality. This is for example, if we think there is a risk of harm to you or other people, an immediate risk to your safety or safety of other people. In the event the study team has to break confidentiality, you will be informed and provided with support.

12. QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice and the applicable requirements as stated in the Research Governance Framework. Local investigators must ensure that the research is conducted in accordance with relevant regulations and with Good Clinical Practice. A Programme Steering Committee has been established (with an independent chair). The committee will monitor progress of the trial and will have responsibility for deciding whether the trial should be stopped. The trial may be monitored or audited by responsible individuals from the Sponsor and NHS Trust.

13. ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

13.2 Approvals

Following Sponsor approval, the protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), HRA (where required), and host institution(s) for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

13.3 Other Ethical Considerations

Interviews have the potential to cover some distressing topics (such as the pressure of responding to emergencies and providing good care in a pressurised environment for staff, and the potential to recall poor care delivery for patients). This will be managed as outlined in section 9.3.

Ethnographic observations have the potential to be stressful or intrusive for staff, particularly when responding to emergency situations. The steps to be taken to manage this are outlined in section 9.3.

We will only seek consent from the CCOT members being directly observed as it is not possible to seek consent from every professional they may interact with. However, observations are focused on CCOT workload and interactions will only be observed in the context of how they influence CCOT workflow, therefore minimal data will be collected related to other staff. No direct patient care interactions will be observed. The option to opt out of observations is outlined in section 9.2.

13.4 Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the host organisation and Sponsor. An End of Study notification and final report should be submitted to the sponsor, host organisation the REC Committee, HRA (where required),

13.5 Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

13.6 Expenses and Benefits

We will give staff, patient and family members a £20 gift card for taking part in a 30-60 minute interview to thank them for their time. Enclosed will be a card including the public-facing study website details to increase opportunities for participants to hear about the final project results. The contribution of participants will be recognised in all publications, presentations and publicity associated with the study.

14. FINANCE AND INSURANCE

14.1 Funding

This study is funded by an NIHR Programme Grant for Applied Research (NIHR206266).

14.2 Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London).

14.3 Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

15. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

16. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

Yes. This work is part of a wider programme of research, funded by an NIHR Programme Grant for Applied Research (NIHR206266). This initial qualitative study will help to develop an understanding of how current UK critical care outreach team practice is delivered to inform design of a future pathway.

17. ARCHIVING

This study will be archived following completion of data collection, data analysis and publication. Study data and study documentation, including the trial master file will be archived according to university and departmental policy, for 5 years.

The transcripts and analysis data will be held securely at the University of Oxford for 5 years after the end of the study.

All paper documentation (consent forms) will be stored in a secure research facility, behind two locked doors in a locked filing cabinet. Electronic records will be stored within the university system on a secure database with restricted access from the secure research facility and password protected.

18. REFERENCES

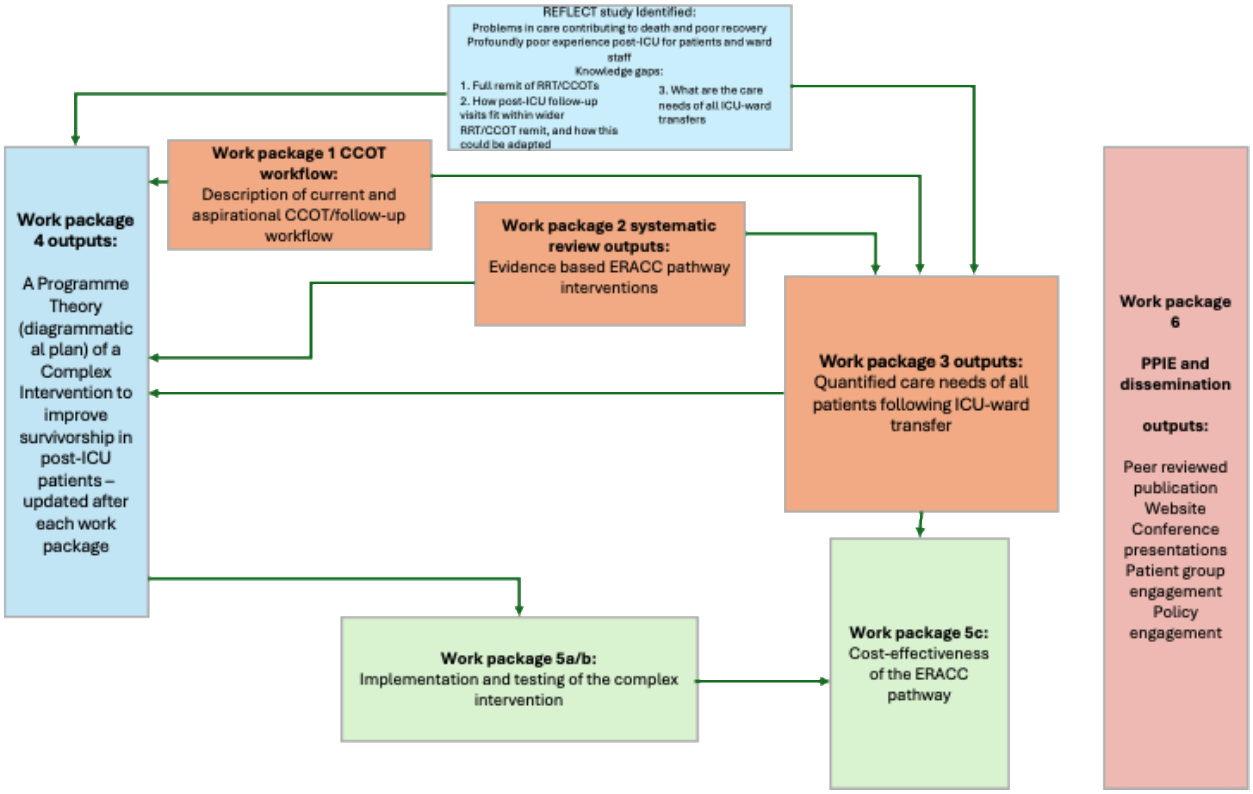
1. ICNARC. Key statistics from the Case Mix Programme — adult , general critical care units Critical care units in the Case Mix Programme. *Case Mix Programme Summ. Stat. 2018 -19* 1–11 (2019).
2. McPeake, J. *et al.* Hospital re-admission after critical care survival: a systematic review and meta-analysis. *Anaesthesia* **77**, (2022).
3. Hodgson, C. L. *et al.* The impact of disability in survivors of critical illness. *Intensive Care Med.* **43**, 992–1001 (2017).
4. Lone, N. *et al.* Five-Year Mortality and Hospital Costs Associated with Surviving Intensive Care. *Am. J. Respir. Crit. Care Med.* **194**, 198–208 (2016).
5. Field, K., Prinjha, S. & Rowan, K. 'One patient amongst many': a qualitative analysis of intensive care unit patients' experiences of transferring to the general ward. *Crit. Care Lond. Engl.* **12**, R21 (2008).
6. Batchelor, A. *Adult Critical Care GIRFT Programme National Specialty Report*. 1–89 (2021).
7. National Institute for Health and Care Excellence. *Clinical Guideline 83: Rehabilitation after Critical Illness*. 1–91 www.nice.org.uk (2009).
8. Aggarwal, G. *et al.* Evaluation of the Collaborative Use of an Evidence-Based Care Bundle in Emergency Laparotomy. *JAMA Surg.* **154**, e190145–e190145 (2019).
9. Ljungqvist, O. Enhanced Recovery after Surgery - Knowing, Not Guessing. *JAMA Surg.* **154**, (2019).
10. Connolly, B. *et al.* A UK survey of rehabilitation following critical illness: Implementation of NICE Clinical Guidance 83 (CG83) following hospital discharge. *BMJ Open* **4**, e004963 (2014).

11. Österlind, J., Gerhardsson, J. & Myrberg, T. Critical care transition programs on readmission or death: A systematic review and meta-analysis. *Acta Anaesthesiol. Scand.* **64**, 870–883 (2020).
12. FICM. *Guidelines for the Provision of Intensive Care Services*. *Faculty of Intensive Care Medicine* (2019).
13. Jónasdóttir, R. j., Jones, C., Sigurdsson, G. H., Jónsdóttir, H. & Jonsdottir, H. Structured nurse-led follow-up for patients after discharge from the intensive care unit: Prospective quasi-experimental study. *J. Adv. Nurs.* **74**, 709–723 (2018).
14. National Outreach Forum. Operational Standards and Competencies for Critical Care Outreach Services. 20 (2012).
15. Vollam, S. *et al.* Problems in care and avoidability of death after discharge from intensive care: a multi-centre retrospective case record review study. *Crit. Care* **25**, 10 (2021).
16. Malterud, K., Siersma, V. D. & Guassora, A. D. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qual. Health Res.* **26**, 1753–1760 (2016).
17. Hammersley, M. & Atkinson, P. *Ethnography. Principles and Practice*. (Taylor & Francis, London, 2019).
18. DeWalt, K. M. & DeWalt, B. R. *Participant Observation: A Guide for Fieldworkers*. (Rowman Altamira, 2002).
19. Buss, A. *et al.* Using a novel ambulatory monitoring system to support patient safety on an acute infectious disease ward during an unfolding pandemic. *J. Adv. Nurs.* **80**, 2452–2461 (2024).
20. Ede, J., Jeffs, E., Vollam, S. & Watkinson, P. A qualitative exploration of escalation of care in the acute ward setting. *Nurs. Crit. Care* **25**, (2020).
21. Participant Observation and Informed Consent: Relationships and Tactical Decision-Making in Nursing Research. https://journals.sagepub.com/doi/epdf/10.1177/096973309400100305 doi:10.1177/096973309400100305.
22. Braun, V. & Clarke, V. Using thematic analysis in psychology. *Qual. Res. Psychol.* **3**, 77–101 (2006).

23. Vollam, S. *et al.* Patient Harm and Institutional Avoidability of Out-of-Hours Discharge From Intensive Care: An Analysis Using Mixed Methods. *Crit. Care Med.* **50**, 1083–1092 (2022).
24. On the Analysis of Observational Data: A Discussion of the Worth and Uses of Inductive Techniques and Respondent Validation - M. Bloor, 1978. https://journals.sagepub.com/doi/abs/10.1177/003803857801200307.

APPENDIX A: PROGRAMME FLOWCHART

Enhanced Recovery After Critical Care (ERACC): Developing and Testing a Care Pathway for Patients Discharged From ICU.



APPENDIX B: Protocol for managing potential distress during interviews with patients and relatives

Pre-interview:

- Encourage participant to bring someone to support them to the interview.
- Ensure the participant understands the purpose of the interview, and what to expect.

During the interview:

- Before starting the interview, reinforce the purpose of the study and the interview. Explain what will happen and that the participant is free to ask to pause or stop at any time.
- Observe the usual practices in responding to the needs of the participant during the interview, offering to pause or stop the interview if necessary

After the interview:

- Offer advice on avenues of support if wanted, such as bereavement charities, participant's GP

- Offer attendance at the ICU follow-up clinic, including a post-ICU psychiatrist who specialises in supporting patients and relatives following ICU experience, where available
- Signpost to PALS if any concerns about care arose which the participant feels they would like to follow up
- A printed sheet of all contacts above will be offered
- Agree a timeframe to follow up with the participant to discuss any concerns which may have arisen since the interview and ensure they have not been adversely affected in any way

During follow-up, discuss avenues of support again if needed, particularly follow-up clinic and post-ICU psychiatrist if available.

APPENDIX C: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee, and HRA (where required).