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Optimising decision-making and support for families of patients who have life-sustaining treatments withheld/withdrawn in adult intensive care units

Submission date
11/11/2024

Recruitment status
Recruiting

Registration date
06/12/2024

Overall study status
Ongoing

Last Edited
13/06/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Every year, many patients are admitted to ICUs. While many will get better, one out of five patients will die in ICU. When it becomes clear that a patient cannot get better, a decision may be made to stop treatments, like turning off life-support machines or discontinuing certain medications. Most ICU patients cannot make these decisions themselves, so healthcare staff will involve family members or surrogates in decision-making. Being part of end-of-life decisions and the process of stopping treatments can be very stressful for family members. They can feel anxious, and depressed, and have long-lasting feelings of guilt or loss. This study aims to explore these experiences, to develop ways (called a supportive care model) to improve decision-making and management of stopping life-sustaining treatments. The goal is to reduce the impact on family members and improve end-of-life care in ICUs.

Who can participate?
What does the study involve?
During this 18-month study, the research team will interview 40 family members of patients who died in the ICU after a decision to stop life-sustaining treatments. The family members' recollections of end-of-life decision-making and their experiences and involvement in withholding/withdrawal of life-sustaining treatments will be explored. The research team will ask about their memories of their relative dying in the ICU and how they managed afterwards. The relatives or next of kin drawn from across the West Midlands will be interviewed. The intention is to talk with a wide range of families, representing a diverse community. The study findings and draft of the supportive care model will be presented, discussed, and refined during a half-day stakeholder event where everyone will work together to design the next stage of research to test the model in practice.

Patient and public involvement (PPI)
Two people who have been involved in a decision to stop treatments for a relative in the ICU helped shape this proposal. The research team then presented it to a PPI group that included

members with experience of relatives dying in the ICU. All found the topic important to investigate and made suggestions that were incorporated into this proposal. A member of the public is a co-applicant, and a PPI advisory group of four public expert members, who have gone through similar experiences, will give us advice throughout our research.

What are the possible benefits and risks of participating?
While participants may not experience personal benefits from participating in this research, their views will help us to understand the challenges families face in making decisions regarding life-sustaining treatments in ICUs and how they experience the death of their loved ones. By sharing their experiences, they can help us identify effective coping strategies and suggest improvements in support services for those going through similar situations during the dying process, after death, and throughout bereavement. An anonymised acknowledgement of the contribution of study participants will be provided in all study outputs, such as publications. There are no obvious risks for the participants taking part in this study. However, is it appreciated that talking about complex life experiences is an emotive issue and that sharing experiences may be upsetting.

Where is the study run from?
The University of Birmingham, UK

When is the study starting and how long is it expected to run for?
June 2024 to January 2026

Who is funding the study?
NIHR, Research for Patient Benefit Programme

Who is the main contact?
Dr Sepideh Setayesh, s.setayesh@bham.ac.uk

Contact information

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334017

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR206331

Study information

Scientific Title
Optimising dEcision-making and support for famiLies of PatIentS who have life-sustaining treatments withheld/withdrawn in adult intensive care units

Acronym
ELPIS

Study objectives
The aim of this study is to develop a theoretically driven experience-based model of care to support family members' end-of-life decision-making and improve practices associated with withholding/withdrawing life-sustaining treatments in adult ICUs.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/09/2024, London - Dulwich Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JO, United Kingdom; +44 (0)20 7972 2582; dulwich.rec@hra.nhs.uk), ref: 24/PR/0871

Study design
Pragmatic grounded theory study

Primary study design
Observational

Secondary study design
Qualitative

Study setting(s)
Home, Internet/virtual, Telephone

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
End of life decision making in intensive care units.

Interventions
During this 18-month study, the research team will interview 40 family members of patients who died in the ICU after a decision to stop life-sustaining treatments. The family members' recollections of end-of-life decision-making and their experiences and involvement in withholding/withdrawal of life-sustaining treatments will be explored. The research team will ask about their memories of their relative dying in the ICU and how they managed afterwards. The relatives or next of kin drawn from across the West Midlands will be interviewed. The intention is to talk with a wide range of families, representing a diverse community. The study findings and draft of the supportive care model will be presented, discussed, and refined during a half-day stakeholder event where everyone will work together to design the next stage of research to test the model in practice.

A three-phase pragmatic grounded theory research design will be used to achieve the aim and objectives of this study.

Phase 1 and Phase 2
Phase 1: Using purposive sampling we will recruit 20-25 family members who have experienced the death of a relative in adult ICU to participate in semi-structured interviews. The interviews will explore family members' experiences of withholding/withdrawing life-sustaining treatment and involvement in end-of-life decision-making and what they found helpful/unhelpful in terms of the support provided at that time. Interviews will be recorded, transcribed
and then undergo constant comparison analysis. This iterative non-linear process moves from initial coding to category development to generate abstract concepts and tentative propositions.

Phase 2: The generated abstract concepts and tentative propositions from Phase 1 will be used to direct ongoing data collection (semi-structured interviews). It is envisaged a further 10-15 participants will be recruited using theoretical sampling to explore our tentative inferences, test the evolving theory and ensure any final model is grounded in the data and theoretically saturated. The study will use semi-structured interviews to collect data for Phase 1 and 2. The regional recruitment will allow for face-to-face in-person interviews to be undertaken if preferred by participants (either at the University of Birmingham or the participant's home). If not preferred, participants will be offered the choice of a remote interview via telephone or a

video call via Microsoft Teams. Interviews will be undertaken by experienced qualitative researchers and are anticipated to last between 60-90 minutes. Interview guides will be developed iteratively to ensure a range of views are captured and in Phase 2 emergent theory explored and importantly challenged.
All interview data, and associated field notes and memos from Phases 1 and 2 will be transcribed and imported into a qualitative data management software (NVivo©) to support the different levels of analyses. Data analysis in grounded theory involves a process of conceptualising data through various levels of coding, abstraction and development of themes and sub-themes often through diagrammatic schema. In this study, it is envisaged that the first conceptual map(s) will be developed from the Phase 1 constant comparative analysis of interviews (intermediate coding). This map will be superimposed on the Phase 1 interview guide and used to refine the Phase 2 interviews and direct theoretical sampling. This stage will explore the tentative inferences, test the evolving theory (advanced coding) and ensure any final model is grounded in the data and theoretically saturated. When the analysis is complete, a diagrammatic representation of findings will be developed and the underlying theory will be explained in reporting.

Phase 3
This phase will involve enriching the supportive care model at a co-production workshop with 30 key stakeholders including family members, PPI members, ICU survivors, and ICU clinicians. The workshop will be held online to reduce the inconvenience of having to travel to participate, widen participation, and reduce costs. Family members who participated in Phase 1 and 2 of the project (n=6) and PPI members (n=4) will be invited. ICU survivors (n=5) will be recruited via ICUSteps, an intensive care patient support charity. ICU clinicians (n=15) will be recruited from the Midlands Critical Care and Trauma Networks. The tentative theoretical model will be presented first during the virtual workshop and then participants will be divided into smaller discussion groups led by members of the research team. It is envisaged that this will encourage interaction and allow participants to feel they can fully contribute in a non-judgmental and empowering way. Discussions will focus on reflections on the model recommendations and guidance for model implementation to inform future testing. Co-facilitators will keep notes of the discussions taking place in the small discussion groups and this information will be analysed using manifest content analysis, where the analysis stays at the ‘surface’, describing what the participants actually said, and the visible and obvious in the data. The findings will be used to refine the model and facilitate co-production of future practice recommendations. During the workshop, the team plans to share and discuss the future research plans to gather stakeholders’ views on the proposed design and outcomes to be assessed, which will be incorporated into future grant applications.

Intervention Type
Other

Primary outcome measure
Experiences of decision-making during withdrawal of care by bereaved relatives of ICU patients measured using data collected during interviews

Secondary outcome measures
Experiences of care during withdrawal of care by bereaved relatives of ICU patients measured using data collected during interviews

Overall study start date
01/06/2024

Completion date
30/01/2026

Eligibility

Key inclusion criteria
1. Documented withholding/withdrawal of life-sustaining treatments in an adult patient's chart
2. At least 3 months have passed since the death of the patient in the ICU
3. The patients did not follow the process for organ donation
4. The next of kin has not expressed a wish not to be contacted following the death of the patient
5. Older than 18 years old

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Bereaved for less than 3 months
2. Lack of capacity to understand the information in the participant information sheet and inability to provide informed consent
3. Less than 18 years old

Date of first enrolment
15/11/2024

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Sandwell and West Birmingham Hospitals NHS Trust
City Hospital
Dudley Road
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B18 7QH

Sponsor information

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University of Birmingham

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Sponsor type
University/education

Website
https://www.birmingham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study team will create a website to share what is discovered and use images, summaries, and newsletters, give talks at conferences and write articles to let people know about the findings.

Intention to publish date
30/11/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sepideh Setayesh, s.setayesh@bham.ac.uk. The type of data that will be shared is anonymized interview data. The timing for availability is January 2026. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			13/11/2024	No	Yes