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Recovery following intensive care treatment

Submission date 20/06/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/06/2017	**Overall study status** Completed	
Last Edited 04/07/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Most patients discharged from an intensive care unit (ICU) are expected to go home. However, about 1 in 12 die unexpectedly on general wards before leaving hospital. The high death rate occurs despite hospitals using 'early warning' scoring systems and visits from ICU teams. A plan which reduces this death rate is urgently needed. This study uses several approaches to get a clear picture of how to improve care.

Who can participate?
Patients, relatives and staff aged 18 or over with experience of ward care after ICU

What does the study involve?
The researchers talk to patients, relatives and staff with experience of ward care after ICU,look at the notes of patients cared for in wards after discharge from ICU, and look at published research to find ways of improving care in this patient group. Patient representatives help the researchers to use this information to design a plan to deliver better care to patients who have been in ICU, whilst they remain in hospital. Information is combined from several sources with experts skilled at making plans work in order to make the best possible plan. After this study, the plan is tested to see whether it could be put in place in local hospitals and tested in a large study.

What are the possible benefits and risks of participating?
There would be no benefits to participants from taking part in this study. Sharing their experiences may help to raise awareness of common issues. It is hoped in the longer term that this study will contribute to improved standards of care in the future, and better working practices, based on the information collected. Over 2300 lives would be saved in the UK each year if this plan worked and stopped only a quarter of the unexpected deaths in patients discharged from ICU. There are no known risks to this study. However, discussing such a sensitive topic may be distressing to participants. The ICU follow-up team are available initially to answer any questions or concerns and signpost participants to other support if required. All information gathered within the interviews is anonymised at the point of collection, so no individuals are identifiable.

Where is the study run from?
Oxford University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2015 to January 2019 (as of 22/10/2018)

Who is funding the study?
National Institute for Health Research - Research for Patient Benefit (UK)

Who is the main contact?
Mrs Sarah Vollam
sarah.vollam@ndcn.ox.ac.uk

Study website
https://www.ndcn.ox.ac.uk/research/critical-care-research-group-kadoorie-centre/research-studies/recovery-following-intensive-care-treatment-reflect

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PID12321

Study information

Scientific Title
Designing an intervention to improve in-hospital outcome for patients who have been discharged from intensive care

Acronym
REFLECT

Study objectives
To develop a multifaceted human factors-based intervention to reduce in-hospital mortality rates in patients who have been discharged from intensive care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 4, 03/05/2017, ref: 17/WA/0139

Study design
Multisite multiphase convergent parallel mixed methods study

Primary study design
Observational

Secondary study design
Mixed methods study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Post-intensive care unit in-hospital ward stay

Interventions
Mixed methods exploratory study comprising four sub-studies:
A. Retrospective Case Record Review (deceased patients)
Human factors-focused review of medical notes of patients who were discharged from intensive care and did not survive to hospital discharge.
B. Patient and relative interviews
Interviews with patients and relatives of deceased patients about the delivery of care following intensive care discharge.
C. Staff focus groups/interviews
Interviews with staff involved in the delivery of ward care to patients following intensive care discharge.
D. Retrospective Case Record Review (survivors)

Human factors-focused review of medical notes of patients who were discharged from intensive care and survived to hospital discharge.

Intervention Type
Other

Primary outcome measure
As this is a mixed methods exploratory study, the outcomes are not as clearly defined as in an interventional study. The primary objective is to develop a multifaceted human factors based intervention to reduce in-hospital mortality rates in patients who have been discharged from intensive care. The primary outcome measure is the intervention plan which will be delivered at the end of the study.

Secondary outcome measures
A. Retrospective case record review (RCRR) (deceased patients): identify examples of high quality care and areas for improvement from medical records of deceased patients
Outcome measure: Aspects of care identified and the human factors-based factors which contributed
B. Interview study (patients and relatives): identify examples of high quality care and areas for improvement from patients' and relatives' perspective
Outcome measure: Aspects of care identified
C. Interview/focus groups study (staff): identify examples of high quality care and areas for improvement from staff perspective
Outcome measure: Aspects of care identified and potential approaches identified by patients
D. Retrospective case record review (survivors): identify examples of high quality care and areas for improvement from medical records of survivors
Outcome measure: Aspects of care identified and the human factors-based factors which contributed

All secondary outcome measures will be assessed at the end of primary data collection period, prior to intervention design (12 months into the study).

Overall study start date
23/09/2015

Completion date
31/01/2019

Eligibility

Key inclusion criteria
Participant group by sub-study:
A. RCRR (deceased patients):
Patients discharged from ICU to wards who subsequently died before hospital discharge.

B. Patient and relative interviews and focus groups:
1. Patients discharged from ICU to a ward and subsequently discharged out of hospital
2. Relatives of patients who survived their post-ICU ward stay
3. Relatives of patients who died following ICU discharge before hospital discharge
Participants will be sought with varying experiences, to facilitate maximum variation in the sample (76)

C. Staff interviews/focus groups:
Staff involved in the care of patients discharge from intensive care to wards (including nurses, doctors, physiotherapists, dieticians and other allied health professionals). As above, purposive sampling will be utilised to ensure a diverse range of exposure, experience and background training.

D. RCRR (survivors):
Patients discharged from ICU to a ward and subsequently discharged out of hospital. Ideally including some of those interviewed as above

Inclusion criteria by sub-study:
A. RCRR (deceased):
1. Male or female, aged 18 years or over
2. Patient discharged from ICU to a ward and died prior to hospital discharge

B. Patient/relative interviews:
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or over
3. Patient or relative of patient who was discharged from ICU to a ward and survived to hospital discharge, or relative of patient who was discharged from ICU and did not survive to hospital discharge

C. Staff interviews/focus groups:
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or over
3. A member of NHS staff involved in the care of patients discharged from ICU to wards

D. RCRR (survivors):
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or over
3. Discharged from ICU to a ward and subsequently discharged from hospital

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
380

Total final enrolment
355

Key exclusion criteria
The participant may not enter the study if ANY of the following apply:
A. RCRR (deceased):
1. Inaccessible medical notes (all efforts will be made to obtain access to medical notes, but these are occasionally misplaced within the hospital system, or are unavailable due to investigation of an ongoing complaint)

B. Patient/relatives interviews/focus groups:
1. Lack of capacity to consent
2. Poor spoken English (it will not be possible to conduct the interviews through an interpreter)

C. Staff focus groups:
1. Does not meet inclusion criteria

D. RCRR (survivors):
1. Does not meet inclusion criteria

Date of first enrolment
01/07/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Services
Clinical Trials and Research Governance

Joint Research Office
Block 60
Churchill Hospital
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Oxford
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research - Research for Patient Benefit

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer reviewed journals.

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mrs Sarah Vollam (sarah.vollam@ndcn.ox.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/06/2017	No	Yes
Participant information sheet			22/06/2017	No	Yes
Participant information sheet			22/06/2017	No	Yes
Protocol article	protocol	25/01/2019		Yes	No
Interim results article	case record review	06/01/2021	12/01/2021	Yes	No
Interim results article	Human factors analysis	24/03/2021	28/09/2021	Yes	No
Interim results article	Patient Harm and Institutional Avoidability of Out-of-Hours Discharge From Intensive Care: An Analysis Using Mixed Methods	01/07/2022	25/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Abstract results		26/07/2019	04/07/2024	No	No