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A Pragmatic Randomised, Controlled Trial of Intensive Care post-discharge review clinics in improving Longer-term outcomes from critical illness

Submission date
21/12/2006

Recruitment status
No longer recruiting

Registration date
21/02/2007

Overall study status
Completed

Last Edited
21/10/2009

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
https://www.charttrials.abdn.ac.uk/practical/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
PRaCTICaL

Study objectives
The hypothesis is that intensive care post-discharge review clinics are effective and cost-effective at improving physical and psychological quality of life in the year after intensive care discharge.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fife and Forth Valley Local Research Ethics Committee, approval was issued on 21st June 2006. An amendment was submitted and approved on 28 October 2006 (ref: 06/S0501/26).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Patient information can be found at: https://www.charttrials.abdn.ac.uk/practical/pis.php

Health condition(s) or problem(s) studied
Outcomes following critical illness and ICU discharge

Interventions

Eligible patients will be randomised to one of two intervention groups after ICU discharge but prior to hospital discharge:
1. ICU post-discharge review clinic group - these patients will be randomised to visit an ICU post-discharge review clinic at two to three months and nine months after hospital discharge.
2. Standard care group - in line with standard clinical practice in the UK patients allocated to the standard care group will have no intensive care post-discharge follow-up after hospital discharge. Patients will be followed-up for the trial outcome measures and end points only over the first year after ICU discharge. In line with good clinical practice, if there are concerns about the well being of these patients at trial follow-up, a General Practitioner (GP) letter will be generated.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Health Related Quality Of Life (HR-QOL) 12 months after ICU discharge as measured by the physical and mental component scores of the Short Form health survey (SF-36).

Secondary outcome measures
1. HR-QOL six months after ICU discharge assessed by SF-36
2. Quality-Adjusted Life Years (QALYs) at 12 months using Euro-Quality of Life (EQ-5D) questionnaire
3. Incidence and severity of PTSD measured by Davidson Trauma Score (DTS) at six and 12 months
4. Anxiety and depression using HADS at six and 12 months
5. Contacts with health services measured as part of the economic analysis
6. Patient satisfaction at 12 months using a patient satisfaction survey
7. Primary and secondary health care costs in the year after hospital discharge
8. Mortality in 12 months after ICU discharge

Overall study start date
01/09/2006

Completion date
30/11/2008

Eligibility

Key inclusion criteria
Patients receiving level three dependency care (Intensive Care Unit [ICU]) for more than one hour at any time during their hospital stay and who survive until the time of hospital discharge.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
270

Key exclusion criteria
1. Age less than 18 years
2. Not expected to survive to leave hospital
3. Unable to complete questionnaires
4. Unable to attend clinics
5. Patients who do not consent

Date of first enrolment
01/09/2006

Date of final enrolment
30/11/2008

Locations

Countries of recruitment
United Kingdom

Study participating centre
Health Services Research Unit
Aberdeen
United Kingdom
ABS5 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
King's College
Aberdeen
Scotland
United Kingdom
AB24 3FX

Sponsor type
University/education

Website
http://www.abdn.ac.uk/r&i/index.shtml

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (UK) (ref: CZH/4/2254)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/07/2007		Yes	No
Results article	results	16/10/2009		Yes	No