

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/10/2009	Condition category Signs and Symptoms	<input type="checkbox"/> 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

Contact name

Dr Brian Cuthbertson

Contact details

Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
United Kingdom
AB5 2ZD
+44 (0)1224 552730
b.h.cuthbertson@abdn.ac.uk

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