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Rehabilitation following critical illness

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 09/11/2022	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jane Eddleston

Contact details
Central Manchester Healthcare NHS Trust
Critical Care Unit
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL.
+44 (0)161 276 4551/2
Jeddleston@fs3.cmht.nwest.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RHC18082

Study information

Scientific Title
Rehabilitation following critical illness

Study objectives
To test whether the provision of a self-help rehabilitation package to patients recovering from a critical illness will: help to alleviate the stress many patients feel during their convalescence; improve their physical and psychological recovery; reduce costs to the NHS in terms of fewer readmissions to hospital, reduction in GP visits and fewer specialist referrals

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Critical illness rehabilitation

Interventions
1. Self-help rehabilitation package
2. Standard post-ICU care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Added 12/01/10:
1. Levels of depression and anxiety (Hospital Anxiety and Depression Scale)

2. Phobic symptoms (Fear Index)
3. Posttraumatic stress disorder (PTSD)-related symptoms (Impact of Events Scale)
4. Scores on the Short-Form Health Survey physical dimension
Measured at 8 wks and 6 months after intensive care unit (ICU) treatment
5. Memory for ICU was assessed at 2 wks post-ICU discharge using the ICU Memory Tool

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1998

Completion date
01/01/2000

Eligibility

Key inclusion criteria
Patients in rehabilitation from intensive care units (ICUs)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
126 (added 12/01/10; see publication)

Total final enrolment
126

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/1998

Date of final enrolment
01/01/2000

Locations

Countries of recruitment
United Kingdom

Study participating centre
Central Manchester Healthcare NHS Trust
Manchester
United Kingdom
M13 9WL.

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive North West (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	resuts	01/10/2003		Yes	No