ISRCTN09412438 https://doi.org/10.1186/ISRCTN09412438

The RECOVER Study: Rehabilitation after Intensive Care

Submission date	Recruitment status	[X] Prospectively registered
24/08/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/09/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/05/2019	Other	

Plain English summary of protocol

Background and study aims.
Recovery from serious illness can take a long time. Patients who have been treated in the intensive care unit (ICU) can become physically weak and often lose weight. Although you are now recovering you might still be quite weak and might have problems with things like walking, eating and getting dressed. We want to find out whether giving people more support with their rehabilitation after they leave intensive care will help them recover quicker. This additional support will be provided by a rehabilitation assistant. In order to measure how you are recovering we will perform a set of tests and questionnaires at 3, 6 and 12 months after you enter the study. We hope that the information this study provides will help us improve support to patients in the future.

Who can participate?
The RECOVER study plans to recruit 240 patients, either men or women, who have spent 2 or more days on a breathing machine (ventilator) while in intensive care. Most of the patients in this group would be suitable for the study but they must be 18 years or older.

What does the study involve?
The study randomly divides people into two groups. One group will receive the care which is currently routinely provided after intensive care discharge. You will work with the nurses, dieticians, physiotherapists and other staff who will help you with your recovery on the ward. The other group will also receive this care, but in addition will receive enhanced rehabilitation, for example extra exercises and help with eating. This would be carried out while you are in hospital after your discharge from the intensive care unit, and would involve being visited frequently by a rehabilitation assistant. At the end of the study we will compare how patients in the two groups are to see if the enhanced rehabilitation helps.
We will also take a blood sample at the start of the study and further samples will be taken every week that you are in hospital and at the 3-month visit. The blood samples will tell us if you have any inflammation in your body, which might affect how well you respond to the rehabilitation. This part of the study is optional and you can still take part in the study if you decide you do not want the extra blood samples taken. To compare the two groups we will use

some simple tests to find out how you are during the 12 months after being discharged from the intensive care unit. In particular, we will perform a set of tests and questionnaires at 3, 6 and 12 months after you enter the study.

What are the possible benefits and risks of participating?
If you are randomised to receive normal ward care, the level of rehabilitation you receive would be no different from what currently happens, except that we will perform some simple tests and ask you to fill in some questionnaires to find out how you are. If you are in the group that receives enhanced rehabilitation, you may or may not benefit from the extra treatment: this is what we are trying to find out. We are not aware of any risks from taking part. It is possible that the extra exercises might make you feel more tired, but we will tailor these exercises to the amount you can manage.

Where is the study run from?
NHS Lothian and the University of Edinburgh, in conjunction with the Edinburgh Clinical Trials Unit. Two hospitals in Edinburgh are involved; the Royal Infirmary and the Western General.

When is the study starting and how long is it expected to run for?
The study started in December 2010 and we expect to have recruited 240 patients by January 2013. All patients will be followed up for a further 12 months after joining the study.

Who is funding the study?
The Chief Scientist Office of the Scottish Executive Health Department.

Who is the main contact?
Professor T. Walsh
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Study website
http://www.clinicaltrials.ed.ac.uk/CurrentTrials/RecoverGeneralInformation.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UKCRN 8849; CZH/4/531

Study information

Scientific Title
Evaluation of a Rehabilitation Complex Intervention for patients following Intensive Care Discharge. The RECOVER Study

Acronym
RECOVER

Study objectives
Patients who survive intensive care (ICU) and their carers cope with severe disability during a protracted and often incomplete recovery. The problems suffered include physical, psychological, and social problems, which are prevalent and often severe. Health related quality of life (HRQoL) is reduced and recovers slowly, and the direct (health care) and indirect (carers /family) costs during this period are probably high but are not well studied. A recent report (Quality Critical Care) (DoH, 2005), and a NICE guideline (NICE, 2009) have highlighted the need to improve rehabilitation for this patient group.

The aim of this study is to evaluate the outcome of enhanced ward-based rehabilitation, compared to current standard care, on patient's physical function at 3, 6 and 12 months after intensive care discharge. The intervention utilises a generic rehabilitation assistant to deliver coordinated enhanced treatment to patients throughout the hospital and provide support after hospital discharge, under the supervision of existing multidisciplinary teams. A feasibility randomised controlled trial of enhanced physiotherapy and dietetic management using a generic rehabilitation assistant demonstrated markedly enhanced levels of treatments could be successfully delivered with this model.

Our focus is on assessing the clinical and cost effectiveness of service reorganisation that better achieves the recommendations in the NICE guideline, and delivers greater physical and dietetic rehabilitation treatments.

On 07/09/2012 the overall trial end date was changed from 01/02/2012 to 31/01/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Scotland Research Ethics Committee (REC) A, 08/06/2010, ref: 10/MRE00/18

Study design
Multicentre prospective randomised controlled parallel group trial with concealment of outcome assessment

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at http://www.clinicaltrials.ed.ac.uk/CurrentTrials/RecoverGeneralInformation.aspx

Health condition(s) or problem(s) studied
Rehabilitation; intensive care

Interventions
Participants will be randomised into one of two groups:

Intervention group
Standard ward-based care delivered by the NHS service with additional access to enhanced rehabilitation during ward stay and telephone contact after discharge, based around a generic rehabilitation assistant working with existing NHS clinical teams.

Control group
Standard ward-based care delivered by the current NHS service

Total duration of intervention is from randomisation to 3 months post-randomisation. The total duration of follow-up is 12 months from randomisation for both groups.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rivermead Mobility Index, assessed at 3 months

Secondary outcome measures
The impact of the complex intervention on physical, psychological and social functioning will be measured at 3 months using:
1. Total, Physical Component Score, and Mental Component Score SF12v2
2. Euroqol EQ-5D score
3. Hospital Anxiety and Depression (HAD) questionnaire
4. Davidson's Trauma Scale score (DTS)
5. Nutritional Status (subjective global assessment of nutrition; SGA nutrition)

6. MRC Muscle Strength
7. Hand grip strength strength (HG dynamometry)
8. 2m timed up and go time
9. Visual analogue score
10. Health economic questionnaire
11. Process measures
12. Research Log of Generic Rehabilitation Assistants

Assessments at 6 and 12 months - Rivermead Mobility Index, SF12v2, EQ-5D, HAD, DTS and health economic questionnaires, visual analogue score and overall patient satisfaction measure.

Additional outcomes:
13. To compare patient and carer experiences between usual care and the new strategy
14. To evaluate the cost-effectiveness of the novel approach

Overall study start date
01/10/2010

Completion date
31/01/2014

Eligibility

Key inclusion criteria
1. The patient has required 48 hours or more mechanical ventilation in the intensive care unit (ICU)
2. The consultant in charge of the patient considers them fit for discharge from the ICU

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
240 patients from 2 centres in Scotland

Key exclusion criteria
Current exclusion criteria as of 07/09/2012:
1. Primary neurological admission diagnosis (brain trauma; intracerebral bleed; stroke; Guillain-Barre syndrome)
2. The clinician in charge of care has agreed with the patient and/or family that only palliative care will be provided.
3. Patients currently receiving home ventilation or planning to commence a program of home ventilation
4. The patient is expected to be discharged from ICU to a non-study hospital where the intervention cannot be received

5. Gaining informed consent, following the intervention or follow-up is not feasible, despite resources available, due to communication difficulties
6. Patient currently enrolled in another RCT with similar endpoints
7. Patient aged <18 years at time of screening

Previous exclusion criteria until 07/09/2012:
1. Primary neurological admission diagnosis (brain trauma; intracerebral bleed; stroke; Guillain-Barre syndrome)
2. Patients for whom a dedicated rehabilitation programme already exists (transplantation, stroke)
3. Patient currently enrolled in another RCT with similar endpoints

Date of first enrolment
01/10/2010

Date of final enrolment
31/01/2013

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Edinburgh Royal Infirmary
Edinburgh
United Kingdom
EH16 2SA

Study participating centre
Western General Hospital
Edinburgh
United Kingdom
EH4 2XU

Sponsor information

Organisation
Lothian University Hospitals Division (UK)

Sponsor details

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Sponsor type
Hospital/treatment centre

Organisation
University of Edinburgh

Sponsor details
Old College
South Bridge
Edinburgh
Scotland
United Kingdom
EH8 9YL

Sponsor type
University/education

Organisation
NHS Lothian

Sponsor details

Sponsor type
Not defined

Website
http://www.nhslothian.scot.nhs.uk/Pages/default.aspx

ROR
https://ror.org/03q82t418

Funder(s)

Funder type

Government

Funder Name
Chief Scientist Office of the Scottish Executive Health Department (UK) (ref: CZH/4/531)

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	02/07/2012		Yes	No
Results article	results	01/06/2015		Yes	No
Other publications	secondary analysis	01/07/2018	02/05/2019	Yes	No