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Remote rehabilitation after intensive care

Submission date 04/07/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/07/2022	**Overall study status** Ongoing	
Last Edited 30/05/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Patients in intensive care units (ICU) need a great deal of special care and support as they are very ill. This can include time spent on a breathing machine. When patients leave hospital, their muscles are often still weak and their ability to do everyday things may still be affected. They also can feel very upset, with flashbacks to what happened, and confused memories of their time in the ICU. Patients need rehabilitation (support and exercises) when they are home but in most areas in the UK there is no organised rehabilitation for people after they get home. The aim of this study is to find out if a rehabilitation programme can help people after getting home from intensive care. This research will test a 6-week remote (online) rehabilitation programme.

Who can participate?
Patients who have gone home after critical illness and have been on a breathing machine in intensive care

What does the study involve?
Half of the participants will get standard NHS care and half will get the 6-week iRehab programme. The remote rehabilitation programme will be delivered by a trained healthcare team who understand the effects of critical illness. Patients have helped to identify what should be included so it is based on what patients' needs are. The programme will be online, using written and computer-based information, exercise and strategies to promote recovery. If a person does not have a computer the researchers will provide a tablet (portable device) or send information by post. The healthcare team will speak to every patient taking part in the programme (online or by phone) on a weekly basis, to give guidance about how to manage symptoms. The researchers will ask everyone in the study about their quality of life, physical strength, and emotional wellbeing. They will also ask everyone about their tiredness, views about illness, and anxiety levels. This will be collected at 8 weeks and at 6 months by researchers. The researchers will also measure the value for money for the NHS.

Where is the study run from?
Warwick Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2022 to January 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (UK)

Who is the main contact?
1. Dr Brenda O'Neill, b.oneill@ulster.ac.uk
2. Prof. Danny McAuley, d.f.mcauley@qub.ac.uk
3. Ms Kerry Raynes
4. Prof. Julie Bruce, irehab@warwick.ac.uk

Study website
https://www.warwick.ac.uk/irehab

Contact information

Type(s)
Principal Investigator

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Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310777

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 310777, NIHR HTA 132871, CPMS 53647

Study information

Scientific Title
Remote multicomponent rehabilitation compared to standard care for survivors of critical illness after hospital discharge: a randomised controlled assessor-blind clinical and cost-effectiveness trial with an internal pilot (iRehab)

Acronym
iRehab

Study objectives
Hypothesis: For people following a hospital admission that included ≥48 hours in an ICU for a critical illness, a 6-week remote multicomponent rehabilitation intervention improves health-related quality of life, physical function, fatigue, mood, and other health-related outcomes after 8 weeks, compared to best practice standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2022, London - Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK;+44 (0)207 104 8225; londoncentral.rec@hra.nhs.uk), ref: 22/LO/0314

Study design
Pragmatic randomized (allocation ratio 1: 1.17) controlled assessor-blind multi-centre trial with internal pilot and embedded process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact iRehab@warwick.ac.uk to request a participant information sheet

Health condition(s) or problem(s) studied
Any condition requiring admission to intensive care and 48 hours of invasive mechanical ventilation

Interventions
Six-week remote multi-component, individualised, rehabilitation intervention incorporating: weekly symptom management; targeted exercise; psychological support; and peer support and information compared to standard care

Half of the participants will be randomised to receive standard NHS care and half will receive the 6-week iRehab programme. The randomisation schedule with be generated using a computerised system. Randomisation will use a minimisation algorithm. The remote rehabilitation programme will be delivered by a trained healthcare team who understand the effects of critical illness. Patients have helped to identify what should be included so it is based on what patients' needs are. The programme will be online, using written and computer-based information, exercise and strategies to promote recovery. If a person does not have a computer the researchers will provide a tablet (portable device) or send information by post. The healthcare team will speak to every patient taking part in the programme (online or by phone) on a weekly basis, to give guidance about how to manage symptoms. The researchers will ask everyone in the study about their quality of life, physical strength, and emotional wellbeing. They will also ask everyone about their tiredness, views about illness, and anxiety levels. This will be collected at 8 weeks and at 6 months by researchers. The researchers will also measure value for money for the NHS.

Intervention Type
Mixed

Primary outcome measure
Health-related quality of life (HRQoL) measured using EQ-5D-5L at 8 weeks

Secondary outcome measures
1. Physical function measured using 30-sec Sit-To-Stand at 8 weeks and 6 months
2. Illness perceptions measured using Brief Illness Perceptions Questionnaire at 8 weeks and 6 months
3. Fatigue measured using Functional Assessment of Chronic Illness therapy at 8 weeks and 6 months
4. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS) at 8 weeks and 6 months
5. Health and social care use measured using the healthcare and social care utilisation questionnaire at 8 weeks and 6 months
6. Safety measured using data on serious adverse events collected at 8 weeks and 6 months

Added 10/10/2023:
7. Intervention acceptability measured using a Theoretical Framework Acceptability Questionnaire (TFAQ) at 8 weeks

Overall study start date
01/01/2022

Completion date
31/01/2026

Eligibility

Key inclusion criteria
Adults within 12 weeks of hospital discharge after treatment of a critical illness requiring ICU care and mechanical ventilation for ≥48 hours

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
428

Total final enrolment
429

Key exclusion criteria
1. Declined consent or unable to provide consent
2. Previous randomisation into the present trial
3. Participating in another rehabilitation or self-management support trial
4. Contra-indication to exercise
5. Severe mental health problems that preclude participation in a group intervention
6. Discharged to a rehabilitation unit, or care home with/without nursing care
7. Prisoners

Date of first enrolment
18/11/2022

Date of final enrolment
18/04/2025

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Study participating centre
James Paget University Hospital
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
Queen Elizabeth Hospital
Woolwich Stadium Road
Woolwich
London
United Kingdom
SE18 4QH

Study participating centre
Aintree University Hospital
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7AL

Study participating centre

Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

Study participating centre
Freeman hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre
The Royal Oldham Hospital
Rochdale Road

Oldham
United Kingdom
OL1 2JH

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
North Devon District Hospital
Raleigh Park
Barnstaple
United Kingdom
EX31 4JB

Study participating centre
Musgrove Park Hospital
Musgrove Park
Taunton
United Kingdom
TA1 5DA

Study participating centre
Ulster Hospital
Upper Newtownards Rd
Dundonald
Belfast
United Kingdom
BT16 1RH

Study participating centre
Craigavon Area Hospital
Lurgan Rd
Craigavon
United Kingdom
BT63 5QQ

Study participating centre
University Hospital (coventry)
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Altnagelvin Area Hospital
Glenshane Road
Londonderry
United Kingdom
BT47 6SB

Study participating centre
Hereford County Hospital
Stonebow Road
Hereford
United Kingdom
HR1 2BN

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Glangwili General Hospital
Dolgwili Road
Carmarthen
United Kingdom
SA31 2AF

Study participating centre
Derriford Hospital
Derriford Road
Plymouth

United Kingdom
PL6 8DH

Study participating centre
Manchester Royal Infirmary
Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Watford General Hospital
60 Vicarage Road
Watford
United Kingdom
WD18 0HB

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
North Manchester General Hospital
Delaunays Road
Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre
Queens Hospital
Queens Road
Croydon
United Kingdom
CR9 2PQ

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
The Royal Glamorgan Hospital
Ynysmaerdy
Pontyclun
United Kingdom
CF72 8XR

Study participating centre
Good Hope Hospital
Rectory Road
Sutton Coldfield
United Kingdom
B75 7RR

Study participating centre
Birmingham Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5SS

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre

Ysbyty Gwynedd Day Hospital
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham Technology Park
Wrexham
United Kingdom
LL13 7TD

Study participating centre
West Suffolk Hospital
Hardwick Ln
Bury Saint Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Kingston Hospital
Galsworthy Road
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Warrington Hospital (site)
Warrington Hospital
Lovely Lane
Warrington
United Kingdom
WA5 1QG

Study participating centre
The Whittington Hospital
Highgate Hill
London

United Kingdom
N19 5NF

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
King George Hospital
Barley Ln
Ilford
United Kingdom
IG3 8YB

Study participating centre
Whiston Hospital (site)
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Study participating centre
West Cumberland Hospital
Homewood
Hensingham
Whitehaven
United Kingdom
CA28 8JG

Study participating centre
Great Western Hospital
Great Western Hospital
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Princess Royal Hospital
Apley Castle,
Grainger Drive
Apley
Telford
United Kingdom
TF1 6TF

Study participating centre

Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Rotherham General Hospital
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
City Hospitals Sunderland
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Newham University Hospital
Glen Road
Plaistow
London
United Kingdom
E13 8SL

Study participating centre
Whipps Cross Hospital
Whipps Cross Road
London

United Kingdom
E11 1NR

Sponsor information

Organisation
University of Ulster

Sponsor details
Shore Road
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BT37 OQB
+44 (0)2895365123
N.Curry@ulster.ac.uk

Sponsor type
University/education

Website
http://www.ulster.ac.uk/

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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 a high-impact peer-reviewed journal.

Intention to publish date
28/02/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Brenda O'Neill (b.oneill@ulster.ac.uk).
Type of data: Individual participant data collected during the trial, after deidentification.
When the data will become available and for how long: 3 months following publication of the study manuscripts.
By what access criteria data will be shared including with whom: Requests for data sharing will be reviewed on an individual basis by the chief investigators.
What types of analyses: All purposes/research questions will be considered on a case-by-case basis.
What mechanism: Data requests should be directed to b.oneill@ulster.ac.uk. To gain access, data requestors will need to sign a data access agreement. Data sharing will be undertaken in accordance with the required regulatory requirements.
Consent from participants: Participants consent to information being collected potentially being used to support future research, and being shared anonymously with other researchers. Any proposed research should have ethics approval where necessary.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Protocol article		10/04/2025	30/05/2025	Yes	No