

Remote rehabilitation after intensive care

Submission date 04/07/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/07/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/09/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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

Contact information

Type(s)

Principal investigator

Contact name

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ORCID ID

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Type(s)

Principal investigator

Contact name

Prof Danny McAuley

ORCID ID

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

310777

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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 will 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Northern Ireland

Scotland

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, Huntsman 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

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

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**

Protocol
article

HRA
research

	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol</u> <u>article</u>	10/04 /2025	30/05 /2025	Yes	No
<u>HRA</u> <u>research</u>		20/09	No	No

<u>summary</u>								/2023
<u>Other publications</u>	Development of a patient centred, structured, individually tailored, multi-component intervention to promote rehabilitation and recovery after critical illness: content, theory, and construction		04/08 /2025	23/09 /2025	Yes			No
<u>Participant information sheet</u>	Participant information sheet		11/11 /2025	11/11 /2025	No			Yes
<u>Study website</u>	Study website		11/11 /2025	11/11 /2025	No			Yes