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# Remote rehabilitation after intensive care

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| **Submission date**<br>04/07/2022 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>26/07/2022 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>30/05/2025 | **Condition category**<br>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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# 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
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Oxford Road
Manchester
United Kingdom
M13 9WL

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

**Study participating centre**
**Wythenshawe Hospital**
Southmoor Road
Wythenshawe
Manchester
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M23 9LT

**Study participating centre**
**North Manchester General Hospital**
Delaunays Road
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M8 5RB

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

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

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

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

**Study participating centre**
**Birmingham Heartlands Hospital**
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Birmingham
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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
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Bangor
United Kingdom
LL57 2PW

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

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**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
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WA5 1QG

**Study participating centre**
**The Whittington Hospital**
Highgate Hill
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N19 5NF

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Pond Street
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NW3 2QG

**Study participating centre**
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IG3 8YB

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L35 5DR

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**Study participating centre**
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TS4 3BW

**Study participating centre**
**Cumberland Infirmary**
Newtown Road
Carlisle
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CA2 7HY

**Study participating centre**
**West Cumberland Hospital**
Homewood
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Whitehaven
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CA28 8JG

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

**Study participating centre**
**Doncaster Royal Infirmary**
Armthorpe Road
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DN2 5LT

**Study participating centre**
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TF1 6TF

**Study participating centre**

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Brighton
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BN2 5BE

**Study participating centre**
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Herries Road
Sheffield
United Kingdom
S5 7AU

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

**Study participating centre**
**City Hospitals Sunderland**
Kayll Road
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SR4 7TP

**Study participating centre**
**Newham University Hospital**
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E13 8SL

**Study participating centre**
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# Sponsor information

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Shore Road
Newtownabbey
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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 |