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Assessing the effects of online physical and mental health rehabilitation for people recovering from stroke

Submission date 06/01/2025	**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 23/01/2025	**Overall study status** Ongoing	
Last Edited 06/05/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
After a stroke, some people have long-term health problems that can greatly affect their quality of life. Some people can lead a relatively normal life after a stroke. Others struggle with daily activities and cannot enjoy life as much as they once could. Stroke survivors have told us that when their hospital or follow-up care finishes after about six months, the lack of treatment for their ongoing physical and mental health problems is very challenging and frustrating. People who have had a stroke and their families have told us that problems with feeling very tired (fatigue), feeling worried, poor fitness, and low confidence are common. The aim is to run a research study in the UK to test if an online rehabilitation programme, can improve the quality of life for people with long-term mild to moderate physical and/or mental health problems after stroke. This study plans to find out if this rehabilitation programme is better than usual care.

Who can participate?
Adult patients aged over 18 years old with long-term mild to moderate physical and/or mental health problems after a stroke who were discharged from hospital between six and 36 months ago

What does the study involve?
This study will test 2 treatments:
1) A single online session of advice and support;
2) A 10-week supervised, live online, home-based, group exercise and recovery support programme.
Participants will be randomly added to either the advice group or the supervised group and followed up for 12 months. Those taking part will then be asked to complete online quality of life and symptom questionnaires 4 times over 12 months. This will help to find out if the online programme can help people with long-term problems after a stroke. It will also tell the team if the programme is good value for the NHS.

What are the possible benefits and risks of participating?
Although this study may not offer any direct benefit, the findings may help people recovering

from stroke in the future. The researchers do not anticipate any serious risk to participants. There is always a very small chance that exercise can make people feel unwell. Exercise may cause tiredness, breathlessness and sore muscles, but this should get a bit easier over time. All exercises will be advised and monitored by specialist staff. Sometimes people can find the support sessions upsetting. Fully trained specialist staff will provide appropriate support and assistance if needed.

Where is the study run from?
The study will be managed by a team at Warwick Clinical Trials Unit (at the University of Warwick). This team includes patient partners and experts in stroke, exercise, clinical trials, statistics, and health economics.

The ReSTORe specialists who will talk to participants by phone or video call to check eligibility, complete questionnaires and deliver the online group sessions will be based at University Hospitals Coventry and Warwickshire (UHCW) NHS Trust.

When is the study starting and how long is it expected to run for?
March 2025 to April 2027

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

Who is the main contact?
The University of Warwick, Clinical Trials Unit. The Trial Manager is Mrs Lucy Eggleston and the Trial Coordinator is Ms Nicole De Valliere.

Contact information

Type(s)
Scientific, Principal investigator

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Type(s)
Public

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Integrated Research Application System (IRAS)
342547

Central Portfolio Management System (CPMS)
57126

National Institute for Health and Care Research (NIHR)
NIHR HTA 157510

Protocol serial number
GM641224

Study information

Scientific Title
Remote STrOke Rehabilitation (ReSTORe): a UK-wide randomised controlled trial

Acronym
ReSTORe

Study objectives
The ReSTORe intervention will be clinically and cost-effective compared to best practice usual care for adults with long-term mild to moderate physical and/or mental health disability 6 to 36 months post-hospital discharge after stroke.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/01/2025, East Midlands – Derby Research Ethics Committee (2 Redman Place, Stratford, London, EC20 1JQ, United Kingdom; +44 (0)207 1048 154; derby.rec@hra.nhs.uk), ref: 24/EM/0274

Primary study design
Interventional

Study design
Multi-centre randomized controlled trial with embedded process evaluation and health economic evaluation

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Adults with long-term mild to moderate physical and/or mental health disability after stroke (six to 36 months post-hospital discharge).

Interventions
ReSTORe programme: A 10-week rehabilitation intervention including: 1) a 1-hour, 1:1 online assessment; 2) supervised, live online, home-based, group exercise sessions; 3) live online facilitated group psychosocial and motivational support sessions; 4) signposting to a library of 'on-demand' exercise sessions; 5) a participant workbook.

Control: Best practice usual care: a single online 1:1 appointment with a ReSTORe specialist, including general advice on safe and effective physical activity guided by publicly available Stroke Association information leaflets.

Intervention Type
Other

Primary outcome(s)
Health-related quality of life (HRQoL) measured using the PROMIS® 29+2 Profile v2.1 (PROPr) at 6 months post-randomisation

Key secondary outcome(s)
1. Health-related quality of life (HRQoL) measured using the PROMIS® 29+2 Profile v2.1 (PROPr) at 3 and 12 months post-randomisation. Sub-scores: depression, fatigue, sleep disturbance, pain interference, physical function, social roles/activities and cognitive function. Sub-scales: anxiety and pain intensity.
2. Neurological HRQoL measured using the PROMIS Neuro-QoL short-form v2.0 - Cognitive Function at 3, 6 and 12 months
3. Health utility measured using the EQ-5D-5L at 3, 6 and 12 months
4. Physical Activity measured using the International Physical Activity Questionnaire Short-Form (IPAQ-SF) at 3, 6 and 12 months
5. General health measured by self-reporting of current overall health compared to baseline at 3, 6 and 12 months
6. Health and social care resource use measured using a participant self-report resource use questionnaire at 3, 6 and 12 months
7. Recurrent stroke measured using participant self-report and healthcare data at 3, 6 and 12 months
8. All-cause/cardiovascular mortality measured using healthcare data at 3, 6 and 12 months
9. Adverse events attributable to the trial measured using participant self-report and healthcare data at 3, 6 and 12 months

Completion date
20/04/2027

Eligibility

Key inclusion criteria

Current key inclusion criteria as of 24/03/2026:
1. UK resident
2. Aged ≥18
3. 6 to 36 months post-hospital discharge after admission for stroke
4. Participant self-report of ongoing post-stroke physical and/or mental health problem
5. Simplified Modified Rankin Scale questionnaire (smRSq) score ≤4
6. Language and cognitive ability sufficient to follow visual instruction and complete study activities, with support as required. The Consent Support Tool communication screening test will be used to assist as required *
7. Access to, and ability/support to use, a computer or device with internet audio and video
8. Able to understand spoken and written English themselves, or with support from family or friends

* As advised by a ReSTORe specialist.

Previous key inclusion criteria:
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6. Language and cognitive ability sufficient to follow visual instruction and complete study activities, with support as required. The Consent Support Tool communication screening test will be used to assist as required.
7. Access to, and ability/support to use, a computer or device with internet audio and video.
8. Able to understand spoken and written English themselves, or with support from family or friends

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

Current key exclusion criteria as of 24/03/2026:
1. Exercise is contraindicated. This is based on internationally accepted guidelines (American College of Sports Medicine), which identify those who are at considerable risk of exercise-induced complications. There are very few potential participants in whom exercise would be contraindicated, e.g., critical aortic stenosis. *
2. Severe physical disability (smRSq>4) or inability to sit or stand independently with or without aid. Previous work developing exercise interventions for people with stroke highlighted high dropout and session incompletion rates in people who needed support from another individual to stand or sit and transition from one exercise to the next.
3. Mental health or cognitive impairment sufficient to prevent engagement with the study or make participation unsafe. *
4. Living in an institution, e.g. prison, nursing home, or immediate care. +
5. Previous randomisation into the ReSTORe Trial.
6. Another individual from the same household taking part in the ReSTORe trial.

* As advised by a ReSTORe specialist.
+ This exclusion criterion is in place to minimise the risk of cross-contamination between trial arms. If two members of the same household were to be randomised, one allocated to the control group and the other to the ReSTORe intervention, there is a potential risk that the control participant could be inadvertently exposed to elements of the ReSTORe intervention. This could compromise the integrity of the control arm and affect the reliability and validity of the trial outcomes. To prevent this, the WCTU CDMS system will not permit a second individual from the same household to be randomised, and such cases will be excluded.

Previous key exclusion criteria:
1. Exercise contra-indicated based on internationally accepted guidelines (American College of Sports Medicine)
2. Severe physical disability (smRSq>4) or inability to sit or stand independently with or without aid
3. Mental health or cognitive impairment sufficient to prevent engagement with the study or make participation unsafe
4. Living in locations other than ‘home’ e.g. prison, nursing home, intermediate care

Date of first enrolment
31/03/2025

Date of final enrolment
22/04/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
West Midlands Research Delivery Network
Birmingham Research Park
97 Vincent Drive
Birmingham
England
B15 2SQ

Study participating centre
NHS Research Scotland Primary Care Network
School of Medicine, University of Dundee, Ninewells Hospital
Dundee
Scotland
DD1 9SY

Study participating centre
Health and Care Research Wales Support and Delivery Centre
25 Cowbridge Road East
Cardiff
Wales
CF11 9AB

Study participating centre
Yorkshire and Humber RRDN
21 Queen St
Leeds
England
LS1 2TW

Study participating centre
North West RRDN
Manchester University NHS Foundation Trust
Manchester
England
M13 9WL

Study participating centre
Kent Community Health NHS Foundation Trust
Trinity House
110-120 Eureka Park
Eureka Business Park

Ashford
England
TN25 4AZ

Study participating centre
North London RRDN & NOCLOR
Noclor NHS Research Office
Kentish Town
England
NW5 3EG

Study participating centre
Lincolnshire Community Health Services NHS Trust
Beech House
Witham Park
Waterside South
Lincoln
England
LN5 7JH

Study participating centre
North East & North Cumbria RRDN
Regent Point, Regent Farm Road, Gosforth
Newcastle
England
NE3 3HD

Study participating centre
East Midlands Regional Research Delivery Network
Paget House
2 West Street
Leicester
England
LE1 6XP

Study participating centre
Leicestershire Partnership NHS Trust Community Services
George Hine House
Gipsy Lane
Humberstone
Leicester

England
LE5 0TD

Study participating centre
Norfolk Community Health and Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
Norwich
England
NR2 3TU

Study participating centre
East Coast Community Healthcare - Norwich
15 Hooper Lane
Norwich
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NR3 4ED

Study participating centre
Locola Health and Wellbeing
Eddercliffe Centre, Bradford Road, Liversedge, West Yorkshire, WF15 6LP
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WF15 6LP

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
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Study participating centre
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14 Tewin Road
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Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
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Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

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 will be available upon reasonable request after publication of the main study results. Requests for data sharing will be managed in accordance with the University of Warwick policy on data sharing.

IPD sharing plan summary

Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet version 6.0	11/11/2025	11/11/2025	No	Yes
Participant information sheet			24/03/2026	No	Yes
Protocol file		02/03/2026	24/03/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes