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

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| **Submission date**<br>06/01/2025 | **Recruitment status**<br>Recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>23/01/2025 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>23/01/2025 | **Condition category**<br>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?
July 2024 to March 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.

### Study website
https://warwick.ac.uk/restorestudy

# Contact information

### Type(s)
Scientific, Principal Investigator


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Public

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
342547

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 57126, GM641224, NIHR HTA 157510

## 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

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

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Home, Internet/virtual, Medical and other records, Telephone

## Study type(s)
Quality of life, Treatment

## Participant information sheet
Participant information can be found at: https://warwick.ac.uk/fac/sci/med/research/ctu/trials/restore/public /restore_patient_information_sheet.pdf

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

## Secondary outcome measures
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

### Overall study start date
01/07/2024

### Completion date
01/03/2027

## Eligibility

### Key inclusion criteria
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

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
600

### 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
13/01/2025

### Date of final enrolment
31/12/2025

## Locations

### Countries of recruitment
England

Scotland

United Kingdom

Wales

### Study participating centre
**West Midlands Research Delivery Network**
Birmingham Research Park
97 Vincent Drive
Birmingham
United Kingdom
B15 2SQ

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

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

# Sponsor information

### Organisation
University Hospitals Coventry and Warwickshire NHS Trust

### Sponsor details
Research Sponsorship, Research and Development Department, 4th Floor Rotunda,
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Coventry
England
United Kingdom
CV2 2DX
+44 (0)2476 966195
researchsponsorship@uhcw.nhs.uk

### Sponsor type
Hospital/treatment centre

### Website
https://www.uhcw.nhs.uk/

### ROR
https://ror.org/025n38288

# Funder(s)

### Funder type
Government

### Funder Name
Health Technology Assessment Programme

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

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

## Publication and dissemination plan

Full results of the study will be prepared by the research team and lay partners and submitted to funders as a final report. Findings will be submitted to peer-reviewed journals and disseminated to the medical and exercise rehabilitation communities. We will publish papers in open-access journals describing the development and refinement of the ReSTORe intervention, and the study protocol, as per recommended guidance for transparent reporting, the Consolidated Standards of Reporting Trials (CONSORT) guidelines (www.consort-statement.org).

The ReSTORe intervention will be manualised and available for public access once the study has been completed. If appropriate, we will develop a practitioner training programme to support the implementation of ReSTORe. Our lay partners will help prepare the final report and assist with the dissemination of study results. We will produce a lay summary for participants and the hospitals/centres involved. Results will be publicised via the study website. HRA guidance on information for participants at the end of a study will be followed: https://www.hra.nhs.uk /about-us/consultations/closed-consultations/guidance-participant- information-end-study-consultation/.

## Intention to publish date

01/03/2028

## 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

Stored in non-publicly available repository, Available on request