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A study to evaluate whether power assisted exercise can help people living with stroke to improve their mobility and fitness

Submission date 04/06/2026	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol
Registration date 03/07/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 03/07/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This project aims to develop a programme of power assisted group exercise for people living with stroke.
People living with stroke can find it hard to take part in exercise due to changes in movement. They report feeling intimidated in regular gyms where the equipment can be difficult to use. A growing number of leisure centres in the UK offer a circuit of seated exercise equipment which is motorised and gives users a 'helping hand' to perform repeated movements. This type of exercise is called 'power assisted exercise' and is popular amongst people living with health conditions including stroke. However, people living with stroke are not routinely supported to take part in power assisted exercise.

Who can participate?
Adults who live with disability caused by stroke will be invited to take part in the study. Participants need to be able to stand up and take a couple of steps. It is important that participants understand the purpose of the study and that there is no medical reason why they should not do physical exercise.

What does the study involve?
Participants will be invited to 16 sessions of supervised exercise on specialist power assisted equipment. The plan is to attend two sessions a week for eight weeks. At the start and end of the programme we will take measurements of fitness, mobility and quality of life. Travel arrangements and costs will be supported.

What are the possible benefits and risks of participation?
Participants may benefit from the exercise programme and notice improvements in their physical and mental wellbeing. It is possible that some participants may feel more tired than usual or find it difficult to find time to attend the sessions. There is a very small risk of more serious complications caused by the exercise, but participants will be continuously monitored to minimise this risk.

Where is the study run from?
The exercise programme will be at the Advanced Wellbeing Research Centre on the Olympic Legacy Park in Attercliffe, Sheffield.

When is the study starting and how long is it expected to run for?
The study is starting in June 2026 and is expected to run until February 2027.

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

Who is the main contact?
Dr Rachel Young, r.young@shu.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
368373

Central Portfolio Management System (CPMS)
64919

National Institute for Health and Care Research (NIHR)
208223

Study information

Scientific Title
Power Assisted Circuit Exercise for Stroke (PACE4S): A Refinement Study

Acronym
PACE4S

Study objectives
The aim of this study is to deliver, evaluate and refine a co-designed power assisted circuit exercise intervention for community dwelling people with stroke to take forward in a future effectiveness-implementation study.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/04/2026, West of Scotland REC 3 (Research Ethics – Room 29, 2nd Floor Administration Build, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 141 314 4485/0213; ggc.wosrec3@nhs.scot), ref: 26/WS/0049

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke

Interventions
Type of exercise
All exercise will be performed on three seated PACE machines manufactured by Innerva: Cross Cycle, Chest and Legs, and Tricep Dip Leg Press. Participants will be supervised whilst transferring on and off the machines by the research assistant(s). Where required, accessories to aid use of the equipment will be provided, e.g. bolster cushion, assistive glove. Participants will be encouraged to exercise on all three machines during each session, but this will be tailored according to participant ability and confidence.

Frequency
Two sessions per week with a minimum of 48 hours between each session. This may be refined for Phase Two according to participants' reported fatigue, observed tolerance of the intervention, and attendance/completion data.

Intensity
Exercise intensity will be monitored through heart rate, rate of perceived exertion (Borg Scale), and observed exertion (skin changes, perspiration, breathlessness). Each session will include a low-intensity 5-minute warm-up and a 5 to 10-minute cool-down aiming to return to a resting state. The target heart rate during the conditioning phase of each exercise session will be 40% to 70% age-predicted heart rate reserve.

Duration
Maximum session duration will be 60 minutes, including warm-up, cool-down, transfers between machines, and monitoring. The target duration for each session will be 40 minutes and will be tailored according to reported fatigue levels and observed exercise tolerance. The intervention will be scheduled over eight consecutive weeks, comprising a total of 16 sessions.

Supervision
The Chief Investigator and Chartered Physiotherapist (RY) will supervise the first two exercise sessions for each participant. Two trained research assistants will attend and assist each session. Students enrolled on pre-registration physiotherapy courses at Sheffield Hallam University will have the opportunity to observe and support intervention delivery through the schedule of professional placements in a supernumerary capacity.

Monitoring
Research assistants will conduct a verbal screen prior to each exercise session:
• Has anything changed since your last session? (e.g. pain, energy levels, setbacks, improvements)
• How did you feel after the last session?
• How tired or energised do you feel today? (Indicate fatigue levels on a Visual Analogue Scale)

Research assistants will record the following physical observations whilst the participant is seated at the start of each session:
• Blood pressure (non-invasive cuff around the upper arm), repeated twice
• Heart rate (Polar brachial monitor)
• Oxygen saturation (SaO_2) (finger sensor)

Measurements will need to be within the following parameters detailed below to commence exercise.

Measurement	Lower limit	Upper limit
Blood pressure	90/60 mmHg	180/110 mmHg
SaO_2	92%	N/A
Heart rate	55 BPM*	100 BPM
*BPM = beats per minute

If any measurements are recorded outside of the parameters detailed above, then the participant will continue to rest in sitting for 5 minutes and the measures will be repeated. If abnormal readings are repeated, the participant will be signposted to their GP for medical review, and the exercise session will not proceed on that date. In the event of a participant not being able to contact a GP, Co-Investigator Dr Ali Ali will initiate medical review.

Heart rate and rate of perceived exertion will be recorded at 5-minute intervals throughout the exercise session. Participants will be observed throughout each session for signs of over-exertion, including excess breathlessness, skin colour changes, and perspiration. Participants showing signs of over-exertion will be advised to rest until observations have returned to the parameters detailed above.

Fatigue will be monitored on a Visual Analogue Scale (VAS) at the start and end of each session. Session enjoyment will be recorded on a pictorial Likert chart at the end of each session.

Tailoring
Session one will include a participant-centred conversation to explore expectations, goals, concerns, and preferences. Co-design and PPIE activities have recommended the following adjustments according to participant preference:
• Option to have a caregiver/family member present
• Option to gradually increase session intensity and duration
• Option to avoid specific machines

Data collection

Data collection for this trial will comprise:

Eligibility screen (telephone eligibility screen and medical eligibility screen \[if indicated]):
Recording of participant details and eligibility checks from telephone eligibility screening and, if indicated, medical eligibility screening. Identifying data (name, date of birth/age, address, telephone number, emergency contact) will be stored alongside an anonymised participant code on the secured SHU J-Drive. Medical history, including date of stroke(s), modified Rankin Scale score at point of recruitment, other relevant medical history, and current prescribed medication, will be recorded on an Excel document by the research team and stored separately on the secured SHU Q-Drive.

Demographic characteristics (baseline visit):
Collected at the baseline visit by electronic questionnaire (Qualtrics) on a university-approved iPad. Participants will have the option of supported self-completion or interviewer-administered completion with a member of the research team. The questionnaire will include questions on age, sex, gender, ethnicity, marital status, postcode (for conversion to Index of Multiple

Deprivation 2025 using an online lookup tool), number of people in household, and employment status. The data will be exported into Excel and stored alongside the anonymised participant code on the SHU Q-Drive.

Physical performance tests (baseline visit and post-intervention follow-up \[approximately 9 weeks]):
These will be administered in person by a member of the research team (NK) with a second team member in support. Tests will include blood pressure, oxygen saturation (SaO_2), resting heart rate, a submaximal exercise test (heart rate responses, duration, rate of perceived exertion, maximum watts generated), Timed Up and Go Test, and 10-metre Walk Test. Measurements will be recorded on an SHU iPad or laptop by NK or RY into an encrypted Excel spreadsheet stored on the SHU Q-Drive. The anonymised participant code will be used to avoid identifying data being stored alongside clinical/physical data.

Patient-reported outcome measures (PROMs) at baseline visit and post-intervention follow-up (approximately 9 weeks):
PROMIS, EQ-5D-5L, and Stroke Impact Scale questionnaires will be set up in electronic format (Qualtrics) on a university-approved iPad. Participants will have the option of supported self-completion or interviewer-administered completion with a member of the research team. Data will be exported from Qualtrics into Excel and stored alongside the anonymised participant code on the secured SHU Q-Drive.

Peri-exercise session monitoring (immediately before, during, and after each exercise session):
Consisting of in-person measurements taken by the trained research assistants. This will include a summary of pre-intervention expectations, goals, concerns, and preferences; pre- and post-session heart rate, SaO_2, blood pressure, and fatigue (VAS); repeated measures of heart rate and perceived exertion; duration on each machine and watts; and post-session enjoyment and difficulty ratings. Detailed procedures are given in Appendix 3. The data will be input during each session into an anonymised paper-based file for each participant. The paper files will be stored in a locked cabinet in a secured area of the research centre. The data will be input into an electronic, anonymised Excel file and stored on the secured SHU Q-Drive.

Qualitative data from one-to-one interviews and focus groups (after the intervention and post-intervention follow-up measures)

• Qualitative data will be collected with reference to topic guides by Co-Investigator Dr Helen Humphries. In-person focus groups and interviews will be conducted at the AWRC and recorded on SHU encrypted dictaphones. A pictorial topic guide will be available in paper format and participants will have the opportunity to write on these. Field notes will be documented on paper documents by the researcher.

The audio file will be transcribed verbatim into an anonymised Word document and stored on the secured SHU Q-Drive. Images of the completed pictorial topic guides and field notes will be uploaded as JPEG files for analysis on the SHU Q-Drive. Once transcription is completed, the audio files will be permanently deleted.

Remote interviews or focus groups will be scheduled according to participants' preferences and will be conducted using Microsoft Teams. The audiovisual recording will be downloaded as an MP4 file and stored on the secured J-Drive. Anonymised transcription will be stored on the Q-Drive.

Project timetable
The intervention will be delivered across two phases to allow for refinement of the intervention between Phase One and Phase Two. Phase One will be delivered between May and August 2026. Phase Two will be delivered between October 2026 and January 2027. An interim analysis will be published in September 2026, which will inform refinement. Permission to implement changes to the protocol based on the findings from Phase One will be submitted as an amendment to the REC.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment measured using participant recruitment recorded according to referral source at baseline

2. Attendance measured using record of attendance, completion and drop out at continuous from baseline to follow-up assessment (0-10 weeks)

3. Adverse events measured using adverse events; severity and frequency at continuous from baseline to follow-up assessment (0-10 weeks)

Key secondary outcome(s)
1. Mobility measured using Timed Up and Go Test at baseline, 9 weeks

2. Mobility measured using 10 Metre Walk Test at baseline, 9 weeks

3. Cardiovascular fitness measured using resting heart rate and blood pressure at baseline, 9 weeks

4. Cardiovascular fitness measured using submaximal exercise test at baseline, 9 weeks

5. Quality of life measured using EQ-5D-L at baseline, 9 weeks

6. Quality of life measured using PROMIS Global Health Questionnaire at baseline, 9 weeks

7. Quality of life measured using Stroke Impact Scale at baseline, 9 weeks

Completion date
19/02/2027

Eligibility

Key inclusion criteria
1. Community dwelling adult aged 18 years or older (The study will not be delivered to people receiving in-patient rehabilitation)
2. Confirmed diagnosis of stroke; haemorrhagic or ischaemic (People with recurrent strokes will be eligible for recruitment)
3. Modified Rankin Scale score of 3 or 4 (We aim to target people living with some mobility impairment and/or dependence in activities of daily living. This will ensure that people typically excluded from previous exercise trials for stroke will have the opportunity to participate. The

criteria developed by [London and Karmal 2025] will be implemented during the screening process to determine Modified Rankin Scale score)
4. Able to comprehend purpose of the study and provide informed consent (During the screening telephone call or home visit the Chief Investigator who is a Chartered Physiotherapist with expertise in stroke rehabilitation, will consider whether the potential participant has comprehended the purpose of the study and the commitment associated with participation. We do not plan to conduct quantified tests of mental capacity (e.g. Mini Mental Test) as this would not represent real world practice)

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
1. Contraindication to exercise according to American College of Sport's Medicine (The screening telephone call or home visit will include questions about past medical history,current investigations,active treatments and prescribed medication. Wherever there is a concern about safety to engage in exercise due to a co-existing medical condition(s) recruitment to the study will be deferred and a medical review from either the GP or Co-Investigator,Dr Ali Ali (stroke consultant) will be requested)
2. The baseline assessment will include a submaximal exercise test with a target intensity of 85% age-predicted maximum heart rate (adjusted for beta-blockers). Heart rate,observed exertion and reported exertion will be monitored throughout the test. Blood pressure and oxygen saturation will be checked prior to and immediately after testing. Any abnormal responses to exercise will trigger medical review and deferred recruitment to the study.
3. Body weight greater than 150KG (The PACE equipment is CE Certified to support people weighing up to 150 KG. Weight will be checked during the baseline assessment. Any person weighing more than 150KG will be supported in accessing alternative physical activity options and nutritional advice)
4. Functional Ambulation Category less than 1 (People who are dependent on hoists or transfer aids to move between seated surfaces will not be eligible to join the study due to risk of injury to themselves or the research assistants)
5. Unable to follow verbal or non-verbal prompts or instructions (The ability to follow single-stage instructions which will be conveyed through a combination of verbal and non-verbal prompts with support from translators or carers as required will be assessed during the baseline assessment)

Date of first enrolment
01/06/2026

Date of final enrolment
31/01/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
Sheffield Hallam University
Advanced Wellbeing Research Centre
Sheffield
England
S9 3TU

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
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S5 7AU

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name

National Institute for Health and Care 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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Flyer version 0.3	24/04/2026	25/06/2026	No	No
Participant information sheet	version 0.5	29/05/2026	25/06/2026	No	Yes
Protocol file	version 0.4	26/04/2026	25/06/2026	No	No