The PACE4S Pilot Study Protocol

Protocol Version: 0.4, 26 April 2026

Full Title: **Power-assisted circuit exercise for stroke (PACE4S): a prospective, single-arm, pilot study with mixed methods approach**

Short Title: Power-assisted circuit exercise for stroke (PACE4S): a pilot study

Acronym: PACE4S

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VERSION CONTROL

Version	Issue date	Reasons for amendments; additional changes
0.1	01/12/2025	Preliminary version for advisory group
0.2	08/12/2025	Eligibility criteria revised, intervention developed, data analysis revised.
0.3	09/03/2026	Appendices and recruitment pathway revised
0.4	26/04/26	Amendments in line with REC approval conditions

SIGNATURES

I agree to conduct the trial in compliance with the approved protocol, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator: Rachel Young		
Signature:		**Date:** 09/03/2026

Co-Chief Investigator: George Peat		
Signature:		**Date:** Click or tap to enter a date.

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List of Abbreviations and Acronyms

ACSM	American College of Sports Medicine
AE	Adverse event
AWRC	Advanced Wellbeing Research Centre
BP	Blood pressure
BPM	Beats per minute
CONSORT	Consolidated Standards of Reporting Trials
EQ-5D-5L	EuroQoL 5-Dimensions-5-Likert
HR	Heart rate
HRA	Health Research Authority
ICJME	International Committee of Medical Journal Editors
IRAS	Integrated Research Application System
ISRAAC	Israac Somali Community Association
ISRCTN	International Standard Randomised Controlled Trial Number
Mod-RS	Modified Rankin Score
mmHg	Millimetres of mercury
NA	Not appropriate/assessed
NIHR	National Institute for Health and Care Research

PACE	Power-Assisted Circuit Exercise
PACE4S	Power-Assisted Exercise for Stroke
PHIND	Patient History Integrated Datastore
PLwS	People/person living with stroke
PPIE	Patient and Public Involvement and Engagement
PROM	Patient-Reported Outcome Measure
PROMIS	Patient-Reported Outcomes Measurement Information System
QOL	Quality of life
REC	Research Ethics Committee
RfPB	Research for Patient Benefit
SAE	Serious adverse event
$Sa0_2$	Oxygen saturation
SDC	Statistical disclosure control
SHU	Sheffield Hallam University
SPIRIT	Standard Protocol Items: Recommended for Interventional Trials
VAS	Visual Analogue Scale

Structured Summary

Short title:	Power Assisted Circuit Exercise for Stroke (PACE4S): A Pilot Study
ISRCTN Number:	XXXXX: TBC
Sponsor:	Sheffield Hallam University
Funding Source(s):	NIHR RfPB
Funder Reference:	NIHR208223
Contracting Organisation:	Sheffield Teaching Hospitals NHS Foundation Trust
IRAS Number:	368373

Trial Design	Interventional; single-arm; pilot study	
Trial Intervention	Power assisted circuit exercise	
Trial Participants	Community dwelling people living with stroke	
	Inclusion	**Exclusion**
Key Eligibility Criteria	• Community dwelling adult aged 18 or older • Adult-onset stroke • Modified Rankin Scale Score 3 or 4 • Able to comprehend purpose of study and give informed consent	• Medical clearance declined • Functional Ambulatory Category score <1 • Body weight >150KG • Unable to follow verbal or non-verbal instructions or prompts
Planned Sample Size	**Phase 1: n=15** **Phase 2: n=15** Unpowered, mixed-methods study with aim to purposively recruit a diverse sample of participants to enable intervention refinement and tailoring according to demographic characteristics.	
Treatment duration	8-weeks	
Follow-up duration	<7-days for quantitative data collection <14-days for qualitative data collection	
Date of First Enrolment (planned)	18/04/2026	
	Objectives	**Outcome Measures**
Primary	To assess the feasibility and preliminary efficacy of a tailored power-assisted circuit exercise intervention for PLwS	**Intervention feasibility:** • Participant recruitment • Decline and uptake • Programme attendance and completion/drop out • Reasons for discontinuation • Adverse events

		Preliminary efficacy: • Change in time to complete mobility assessments • Change in submaximal exercise test performance • Change in resting cardiovascular parameters
Key Secondary	To evaluate recruitment strategies, intervention adherence, and safety	• Demographic characteristics of recruited participants • Recruitment pathways • Exercise intensity, duration and frequency • Reported enjoyment, fatigue and side effects • Support required to access intervention

Names, affiliations, and role of protocol contributors

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Open Science

Trial registration

The trial will be registered on the Open Science Framework and ISRCTN (https://www.isrctn.com/) prior to participant recruitment and data collection.

Protocol and data analysis plan

The study protocol has been prepared with reference to the SPIRIT 2025 guidelines (https://www.consort-spirit.org/) and will be published on Open Science Framework before participant recruitment and data collection commence.

Data sharing

A data management plan has been submitted to NIHR and can be accessed here: Data Management and Access Plan

Funding and conflicts of interest

This study is funded by the NIHR Research for Patient Benefit NIHR208223. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Dissemination plan

Research outputs and findings will be disseminated to local, regional, and national audiences and 'interest-holders' by a variety of channels, including the National Centre for Exercise and Sports Medicine, South Yorkshire Integrated Care Board, South Yorkshire and East Midlands Integrated Stroke Delivery Networks, leisure operators and the Stroke Association.

The research team will target multiple sectors through the opportunity to disseminate findings at regional and national conferences. Three academic journal articles will be published in international peer reviewed journals. Accessible outputs will be co-created with the Patient and Public Involvement and Engagement group and circulated amongst service providers and service users.

Authorship

Authorship of outputs will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) criteria (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

1. INTRODUCTION

1.1. Background and Rationale

Exercise interventions aimed at improving cardiovascular fitness and strength are beneficial for people living with stroke (PLwS) [1]. However, people living with moderate to severe impairment following stroke are under-represented in research and it has been recommended that non-ambulatory participants are included in future trials [2]. A systematic review published by Lloyd et al. [3] focussed on the impact of exercise interventions for non-ambulatory PLwS; it was concluded that assistive technologies including exoskeletons and body-weight supported treadmills did improve physical performance. However, rehabilitation technologies are expensive and not typically available in community or leisure venues. Power-assisted circuit exercise (PACE) equipment has been installed across approximately 100 venues within the UK and is used by people with long term conditions including stroke. Qualitative research on the experience of using PACE amongst PLwS, including people with very limited mobility, has indicated that it is an acceptable and beneficial exercise solution [4].

This study aims to refine a PACE intervention for PLwS and to evaluate the feasibility within the stroke pathway. Quantitative data will report adverse effects and impact on physical performance. Qualitative data will inform refinement of the intervention, seeking to define how patients may be supported in engaging with a PACE intervention. The intervention will be delivered in two sequential phases to allow iterative refinement.

1.2. Objectives

The **primary objective** is to assess feasibility and preliminary efficacy of a tailored physical activity intervention for PLwS.

Secondary objectives are to evaluate recruitment strategies, intervention adherence, and safety.

2. METHODS: PATIENT AND PUBLIC INVOLVEMENT, TRIAL DESIGN

2.1. Patient and Public Involvement

A diverse Patient and Public Involvement and Engagement (PPIE) group (n=5) who have lived experience of stroke were appointed at the outset of the project. The schedule of PPIE activities is detailed in **Appendix 1**. To date, the group have shaped the intervention design, selection of tools to report quality of life and development of participant facing materials. They will remain involved throughout data collection, analysis and programme development.

2.2. Trial Design

Prospective, single-arm, pilot study with a mixed methods approach.

3. METHODS: PARTICIPANTS, INTERVENTIONS, AND OUTCOMES

3.1. Setting

Advanced Wellbeing Research Centre (AWRC) at Sheffield Hallam University. Single site.

3.2. Participants

The target population are community-dwelling people living with stroke. Potential participants will be made aware of the study through NHS and third sector networks. The Participant Approach Guide is available in **Appendix 2.** Recruitment materials are available in **Appendix 3.**

Eligibility Criteria

Eligibility criteria have been informed by two systematic reviews of exercise intervention for PLwS [2, 3] and the 2023 Clinical Guideline for Stroke [5].

Table 1. Eligibility criteria

Inclusion Criteria	***How assessed***
Community dwelling adult with stroke diagnosis aged 18 or older • Onset of most recent stroke >28 days • Stroke diagnosis confirmed during hospital admission • Ischaemic and haemorrhagic stroke eligible • Recurrent stroke eligible	Screening assessment + baseline assessment
Modified Rankin Scale Score of 3 or 4 • 3=moderate disability, requires some help but able to walk without assistance • 4=moderate severe disability, unable to walk without assistance and unable to attend to own bodily needs without assistance The criteria developed by London and Kamal [6] will be used to determine Modified Rankin Scale score for each participant.	Screening assessment + baseline assessment
Able to comprehend purpose of study and give informed consent	Screening assessment + initial visit
Exclusion criteria	
Medical clearance declined • Any contraindication to exercise as stated by the American College of Sports Medicine [7] • Abnormal response during baseline exercise test including: o Syncope o Abnormal heart rate response o Abnormal blood pressure response o Moderate or severe pain reported/observed	Screening assessment + baseline assessment [**Appendix 5]**
Functional Ambulation Category score <1: non-functional ambulator, unable to walk with assistance. (https://www.physio-pedia.com/Functional_Ambulation_Category)	Screening assessment + baseline assessment
Unable to follow verbal or non-verbal guidance	Screening assessment + baseline assessment

The eligibility screening tool is available in **Appendix 4.**

3.3. Intervention and comparator

Comparator

This is a single-arm study with no comparator. For an intended future hybrid effectiveness-implementation study, we anticipate using a 'standard care'/'treatment as usual' comparator. Qualitative data collection and stakeholder consultation in the current study may be used to inform this.

Intervention

The intervention protocol for each session, including pre-exercise checks, exercise, monitoring and post-exercise feedback is available in **Appendix 9.**

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, eg. 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 minimum of 48 hours between each session. This may be refined for Phase Two according to participant's 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 start. The target heart rate during the conditioning phase of each exercise session will be 40%-70% age predicted heart rate reserve. Heart rate will be continuously monitored with a Brachial Arm Monitor (Polar Verity Sense POLAR).

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.

Supervision

Chief Investigator/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 verbal screen prior to each exercise session:

- Has anything changed since your last session? (eg. 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) X2 repeated measurements
- Heart rate (Polar brachial monitor)
- Oxygen saturation (SaO2) (finger sensor)

Measurements will need to be within the following parameters detailed in Table Two to commence exercise.

Table 2. Parameters to commence exercise

Measurement	**Lower limit**	**Upper limit**
Blood pressure	90/60 mmHg	180/110 mmHg
Sa02	92%	NA
Heart rate	55 BPM*	100 BPM

*BPM (beats per minute)

If any measurements are recorded outside of the parameters detailed in Table 2, 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.

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 in Table 2.

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 care giver/family member present
- Option to gradually increase session intensity and duration
- Option to avoid specific machines

Training of study personnel

All research assistants will be required to complete the NIHR 'Good Clinical Practice' module. In addition, they will be issued with a training resource and attend a three-hour training session which will include:

- Nature of stroke related impairments including motor, sensory, communicative and cognitive
- Safe access to and dismounting of PACE machines including use of accessories
- Instruction and supervision of power assisted exercise
- Intervention monitoring and data inputting
- Indications for session termination

A plan of the training programme and resource content is available in **Appendix 8**.

3.4. Outcomes

Intervention feasibility and refinement

- Participant recruitment: total no. of potential participants screened; total no. of participants recruited; recruitment rate per month; diversity of recruited participants (age, sex, gender, ethnicity, marital status, deprivation, distance from treatment facility, severity of stroke); reasons for ineligibility and non-participation

- Intervention acceptability, completion and adherence: no.(%) completing each session and intervention as whole; exercise intensity, duration and frequency; reported enjoyment, fatigue and side effects; support required to access intervention; reasons for discontinuation/non-completion; participant and research assistant experiences of intervention

Preliminary efficacy

- Pre-post-intervention change in physical performance (Resting heart rate (beats per minute); SaO2 (%); Blood pressure (systolic/diastolic mm/Hg); Submaximal aerobic capacity – effort score/duration on PACE Cross Cycle at 85% age predicted max heart rate; 10M Timed Walk Test; Timed up and Go Test
- Pre-post-intervention change in patient-reported outcomes (PROMIS QoL questionnaire (total score); Stroke Impact Scale (total score plus subsection scores); EQ-5D-5L)

Harms

- Frequency and nature of adverse events

The protocol for the physical performance tests is available in **Appendix 5** and the risk assessment is in **Appendix 6.**

The demographic questionnaire and validated quality of life questionnaires are in **Appendix 7.**

Topic guides for the qualitative interviews and focus groups are available in **Appendix 13**.

3.5. Participant timeline

Table 3. Schedule of enrolment, interventions, and assessments

	Telephone eligibility screen	Baseline assessment	Intervention delivery	Follow-up assessment	Post-intervention qualitative
TIMEPOINT	***-2 weeks***	**-1 week**	***0***	***11***	***11-13 wks***
ENROLMENT:					
Eligibility assessment	●				
Informed consent to treatment		●			
INTERVENTIONS:					
Group-based, power-assisted circuit exercise (2/wk x 8 wk)			●		
ASSESSMENTS:					
Demographic characteristics†	●	●			
Medical screen‡	●				
Peri-exercise monitoring§:					
Heart rate			●		
Perceived exertion			●		
Performance output			●		
Fatigue VAS			●		
Patient-reported outcomes:					
EQ-5D-5L		●		●	
Stroke Impact Scale		●		●	
PROMIS		●		●	
Physical performance testing¶:					
Heart rate		●		●	
Oxygen saturation (SaO_2)		●		●	
Blood pressure		●		●	
Submaximal exercise test (cross-cycle)		●		●	
10m Walk Test		●		●	
Timed Up and Go Test		●		●	
Adverse events			●		
Focus groups / interviews					●

† age, sex, gender, ethnicity, marital status, postcode area, number of people in household, employment status
§ See for additional detail
¶ See for additional detail

3.6. Harms

Exercise therapy for patient populations is a relatively safe intervention that is not associated with serious adverse events. Types of PACE are available in some community settings for PLwS and other chronic health conditions. The intervention risk assessment is available in **Appendix 10.**

Monitoring of harms in this study will be non-systematic. Any adverse events occurring during the exercise sessions will be recorded by the research assistants and reported to the Chief Investigators (Young/Peat) and Co-Investigator (Ali) to review severity, seriousness and relatedness (see under Monitoring).

Adverse events will be defined in terms of seriousness, relatedness and severity:

- Serious: an event that leads to either death, hospitalisation or a serious risk of deterioration in health.
- Non-serious: for example, fatigue, pain or minor injury which does not require hospital care or impact long term health outcomes
- Relatedness will be classified as: unrelated, unlikely, possibly, probably, and definitely. Factors including temporal relationship between adverse event and intervention delivery, biological plausibility and nature of adverse event will be reviewed by Lead Investigators (Young/Peat) and Co-I (Ali).
- Severity will be defined in terms of the outcome of the adverse event.

The adverse event tracking record is available in **Appendix 11.**

3.7. Sample Size

Phase 1: n = 15. Phase 2: n= 15. [Total n=30].

No sample size calculation was performed for this single-arm pilot study. The sample size is intended to allow recruitment of a diverse sample of participants for iterative intervention refinement and tailoring over two phases.

3.8. Recruitment

Participants will be identified and approached via:

- Community Stroke Service, Sheffield Teaching Hospitals NHS Foundation Trust
- ISRAAC community
- Stroke Association
- Move Well Scheme
- PHIND software tool (as indicated)

A recruitment website will embed links to written and audio-visual recruitment materials which will be aphasia-friendly. The recruitment website and printed materials will be circulated by the Community Stroke Service clinical team (Co-I Skerratt), ISRAAC (Co-I Hersi) and Sheffield Stroke Association. The participant information sheets and proposed content of the recruitment website is available in **Appendix 3.**

Recruitment will be conducted in waves to ensure demographic diversity. An interim evaluation of recruited participants at n=10 will profile demographic status and stroke severity. If indicated, the PHIND database will be utilised to facilitate purposive recruitment of under-represented groups.

Recruitment process

Expression of interest

Potential participants may express interest through the following routes:

- submit email enquiry to dedicated project in-box (PACE4S@shu.ac.uk)
- text message or call Chief Investigator (Young)
- submit a response on Microsoft Form embedded on project website
- completion of consent to contact form supervised by clinician from Sheffield Community Stroke Service

Telephone eligibility screening

Eligibility screening by Chief Investigator (Young) will comprise initial telephone conversation to check eligibility according to inclusion/exclusion criteria. Time and date of telephone appointment will be confirmed by letter (postal or email depending on participant preference). The letter will include a summary of the screening process including questions which will be asked**.**

If not able to speak in English due to aphasia or international language, arrangements will be made to conduct eligibility screening face to face, either at the at the participant's residence with carer or translator present.

During the eligibility screening, potential participants will have the opportunity to ask questions about the study. If a potential medical contraindication [7] is identified, the participant will be referred to either their GP or Co-Investigator Dr Ali Ali for further assessment.

Any person deemed ineligible for the study will be signposted to other appropriate services (eg. GP, Move Well activity referral scheme, Stroke Association).

Familiarisation visit with baseline assessment

Potential participants meeting the eligibility criteria will be invited to the AWRC for a familiarisation visit combined with baseline assessment. An AWRC information pack will be provided and taxi transport offered.

Familiarisation will include:

- meet Chief Investigator (RY) and Co-Investigator (NK)
- view the Movement Analysis Lab and PACE equipment
- view the reception/waiting area and restroom facilities

Potential participants will have the option of consenting to take part in the study and proceeding straight to baseline assessment. Alternatively, they may take up to seven days to make a decision regarding consent to proceed with the baseline assessment and participation in the study.

Research Assistants responsible for intervention delivery will be invited to an interview which will explore their experiences for intervention delivery in alignment with the Sekhon Framework of acceptability. They

will be approached by Co-Investigator Dr Humphreys, and their participation will be anonymised from the Chief Investigator. The participant information sheet is available in **Appendix 12.**

4.0 METHODS: ASSIGNMENT OF INTERVENTIONS

This is a single-arm study. All eligible consenting participants will be allocated to the power-assisted circuit exercise (PACE) intervention.

5.0 METHODS: DATA COLLECTION, MANAGEMENT, AND ANALYSIS

Data collection

Data collection for this trial will comprise:

5.1 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, emergency contact) will be stored alongside an anonymised participant code on the secured SHU J-Drive. Medical history including date of stroke(s), other relevant medical history and current prescribed medication will be recorded on an Excel spreadsheet by research team and stored separately on the secured SHU Q-Drive.

5.2 Demographic characteristics (baseline visit)

- Collected at baseline visit by electronic questionnaire (Qualtrics) on a university-approved i-tablet.
- 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 online lookup tool, number of people in household, and employment status.
- The data will be exported into Excel and stored alongside anonymised participant code on the SHU Q-Drive.

5.3 Physical performance tests (baseline visit and post-intervention follow-up (~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 10M Walk Test.
- If an abnormal or adverse exercise response is detected during the aerobic exercise test, the test will be terminated.
- Measurements will be recorded on a SHU IPad or laptop by NK or RY into an encrypted Excel spreadsheet stored on SHU Q-Drive. The anonymised participant code will be used to avoid identifying data being stored alongside clinical/physical data.

5.4 Patient-reported outcome measures (PROM) at baseline visit and post-intervention follow-up (~9 weeks)

- PROMIS, EQ-5D-5L and Stroke Impact Scale questionnaires will be set up in electronic format (Qualtrics) on a university-approved i-tablet.
- 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 anonymised participant code on the secured SHU Q-drive.

5.5 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; post-session enjoyment and difficulty ratings. Detailed procedures are given in **Appendix 9.**
- The data will be inputted 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 inputted into an electronic, anonymised Xcel file and stored on the secured SHU Q-Drive.

5.6 Qualitative data from 1-2-1 interviews and focus groups (after the intervention and post-intervention follow-up measures)

- Conducted by a member of the research team (HH).
- Qualitative data will be collected with reference to topic guides (see **Appendix 13**).
- Focus groups and interviews will be 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 onto 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.

A summary of data collection and storage is available in **Table 4**.

Table 4. Data collection and storage			
Identifying participant data			
Data content	**Format**	**Collection point**	**Storage**
Identifying • Name • Address • Mobile • Email • DoB • Emergency contact	Verbally shared by participant/carer Inputted by Chief Investigator into Excel.	Eligibility screen and familiarisation/ baseline assessment	SHU J Drive
Anonymised participant data			
Data content	**Format**	**Collection point**	**Storage**
Clinical history	Verbally shared by participant/carer Inputted by Chief Investigator into Excel.	Eligibility screen and familiarisation/ baseline assessment	SHU Q Drive
Demographic data	Qualtrics questionnaire exported into Excel	Familiarisation/ baseline assessment	SHU Q Drive
Physical performance data	Observed and recorded into Excel by research team.	Familiarisation/ baseline assessment + post-intervention assessment	SHU Q Drive
Participant goals	Verbally shared by participant/carer Inputted by Chief Investigator onto electronic Excel.doc	Session #1 intervention	SHU Q Drive
Session data	Inputted by research team onto paper inputted into Excel	Session #1 to session #16	Paper docs stored in locked cabinet in AWRC SHU Q Drive
Interview/focus group data	SHU Dictaphone exported as MP4 file. Transcribed into word.doc Audio files deleted post transcription. OR Microsoft Teams, audio file saved as an MP4 file. Transcribed to word.doc. Audio files deleted post transcription.	Post intervention	Q Drive

5.7 Data management

Data management plan has been submitted to NIHR. Data Management and Access Plan

5.8 Data analysis

This pilot study is not intended to estimate effects of intervention. No inferential statistical tests are planned or indicated. Instead, analysis is aligned to the stated objectives of assessing feasibility, detecting a 'signal' of change in outcomes at post-intervention, and understanding recruitment and intervention fidelity using descriptive statistics.

The pilot study has been designed in two phases with a target sample of 15 participants each. This sample size was felt to be sufficient to gain useful information but achievable within a 24-week recruitment and intervention period. As the intention is to refine the intervention between phase 1 and 2, we will conduct analyses separately on each phase and for all participants combined.

- Participant flowchart (as per CONSORT)

- Descriptive characteristics of participants will be summarised using descriptive statistics (simple frequencies, measures of central tendency and dispersion) for age*, sex, gender, self-reported ethnicity, marital status, Indices of Multiple Deprivation decile*, distance from home address to AWRC*, stroke severity (modified Rankin Scale Score). Calculated for the following analysis samples in phase 1, phase 2, and combined phase 1 + phase 2:
    - all potential participants at eligibility screen (aggregated not individual data)
    - all consenting participants recruited
    - all consenting participants recruited and completing intervention

  * derived variables (e.g. from date of birth or postcode)

- Descriptive analysis of adverse events/harms

- Pre- and post-intervention group means/medians and SD/IQR will be reported for all repeated physical performance tests and PROMIS.

- Audio data collected during qualitative interviews and focus groups will be transcribed verbatim. The data will undergo framework analysis aligned with the Sekhon Acceptability Framework [8].

5.9 Handling of missing data

The frequency and pattern of missing data from self- and interviewer-administered questionnaires will be described and reported. No imputation will be attempted.

5.10 Statistical disclosure control (SDC)

To minimise the risk that the identity of a participant is revealed, we will check all statistical outputs for potentially disclosive issues, and apply SDC measures adapted from the Handbook on Statistical Disclosure Control for Outputs, e.g. minimum threshold of 5 for cell counts, averaging or rounding values.

6.0 METHODS: MONITORING

6.1 Safety Monitoring

The occurrence of adverse events considered to be related to the trial interventions will be monitored and assessed using case report forms. There will be a monthly review led by the Chief Investigator which will be documented. Decisions and actions will be communicated with the research team and Clinical Research and Innovation Office at Sheffield Teaching Hospitals NHS Foundation Trust.

6.2 Expected adverse events

Expected adverse events from PACE for PLwS include:

- musculoskeletal pain or ache lasting up to 48 hours
- increased fatigue/malaise lasting up to 48 hours;

6.3 Serious Adverse Events

A Serious Adverse Event (SAE) is an untoward event that: (a) results in death; (b) is life threatening; (c) requires hospitalisation or prolongation of existing hospitalisation; (d) results in persistent or significant disability/incapacity; (e) consists of a congenital anomaly/birth defect; or (f) is otherwise considered medically significant by the investigator.

In accordance with HRA guidance any SAE that is judged to be unrelated and unexpected will be reported to the Research Ethics Committee (REC) that issued the favourable ethical opinion within 15 days of the Chief Investigator becoming aware of the event. The current approved version of the HRA's *Report of Serious Adverse Event (non-CTIMP)* form will be used.

All SAEs considered to be potentially related to the trial procedures and occurring from the point when participants are registered on the study will be notified to the Sponsor and CI within 24 hours of the research staff at the site becoming aware of the event. The appropriate Case Report Form must be completed within one week of receipt, and ideally within 24 hours. The medically-qualified co-I (Ali) will be asked to assess whether they considered the SAE was due to the study procedures. Any follow-up information should be sent to CI and Sponsor as it is available. Events will be followed up until the event has been resolved or a final outcome has been reached.

All SAEs either confirmed or suspected to be related to the trial procedures will be reviewed by the Trial Steering Committee. There will be a monthly review of adverse events led by the Chief Investigator.

6.4 Urgent Safety Measures

Any Urgent Safety Measure taken to protect a research participant from an immediate hazard to their health and safety will be immediately notified to the Sponsor and by email within 3 days to relevant Research Ethics Committee, and HRA procedures for subsequent protocol amendments followed.

6.5 Responsibilities for safety reporting

Responsibility	Person
Using medical judgement in assigning seriousness, causality	Dr Ali Ali
Ensuring that SAEs are recorded and reported to Shefield Teaching Hospitals NHS Foundation Trust and Sheffield Hallam University in line with requirements of the protocol	Rachel Young
Clinical oversight of the safety of patients participating in the trial, including an ongoing review of the risk/benefit	Rachel Young
Assessing seriousness and causality where it has not been possible to obtain local clinical assessment	Dr Ali Ali
Review of all SAEs as described above	Dr Ali Ali
Central data collection and verification of SAEs	Sarah Wilkinson (CRIO@STH)
Ensuring SAEs are reported to the HRA	Rachel Young
Preparing annual reports to the REC in collaboration with appropriate members of the TMG, and reports required by the Sponsor	Rachel Young

6.6 Stopping criteria

Two serious adverse events with definite or probable relatedness to the intervention.

In the event of stopping criteria being triggered, intervention delivery and assessment will be ceased with immediate effect. The research team, recruiter and participants will be notified. The serious adverse events will be reviewed by the Clinical Research and Innovation Office at Sheffield Teaching Hospitals NHS Foundation Trust. The HRA will be notified by the Chief Investigator.

6.7 Project end date

The project end date will be defined on completion of the final focus group during following Phase Two of intervention delivery. This will be before 30/03 27.

7.0 ETHICS

Research ethics approval

IRAS and NHS Ethics approval will be obtained prior to patient recruitment.

Protocol amendments

To be added

Added consent to contact process

Defined project end date**Consent or assent**

Written informed consent to participate in the PACE4S study will be obtained by at the baseline assessment by Dr Rachel Young (Chief Investigator) and Dr Nik Kudiersky (Co-Investigator).

Confidentiality

Participant confidentiality will be maintained in accordance with the Research Ethics and Integrity Policy at Sheffield Hallam University: https://www.shu.ac.uk/research/excellence/ethics-and-integrity

REFERENCES

[1] Saunders, D. H., Sanderson, M., Hayes, S., Johnson, L., Kramer, S., Carter, D., Jarvis, H., Brazzelli, M., & Mead, G. E. (2020). Physical fitness training for stroke patients. *Cochrane Database of Systematic Reviews*, *2025*(12), CD003316. https://doi.org/10.1002/14651858.CD003316.pub7

[2] Saunders, D. H., Carstairs, S. A., Cheyne, J. D., Fileman, M., Morris, J., Morton, S., Wylie, G., & Mead, G. E. (2025). Combined cardiorespiratory and resistance training for people with stroke. *Cochrane Database of Systematic Reviews*, *2025*(9), CD016002. https://doi.org/10.1002/14651858.CD01600

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[4] Young, R., Broom, D., O'Brien, R., Sage, K., & Smith, C. (2021). Users' experience of community-based power assisted exercise: a transition from NHS to third sector services. *International Journal of Qualitative Studies on Health and Well-Being*, *16*(1), 1949899. https://doi.org/10.1080/17482631.2021.1949899

[5] Royal College of Physicians (2023) National Clinical Guideline for Stroke. https://www.strokeguideline.org/

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[8] Sekhon, M., Cartwright, M., & Francis, J. J. (2017). Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Services Research*, *17*(1), Article 88. https://doi.org/10.1186/s12913-017-2031-8

APPENDICES

Appendix 1: Schedule of PPIE Activities

Date (approx)	Activity	Location	Renumeration
July 25	Introduction	On-line	£25 + internet
August 25	Co-design materials	On-line	£25 + internet
October 25	Project plan	AWRC	£50 + travel
November 25	QOL questionnaires	On-line	£50 + internet
January 25	Study recruitment materials	AWRC	£50 + travel
March/April 26	View the PACE circuit	AWRC	£50 + travel
Summer 26	Review interviews with participants	AWRC	£50 + travel
Autumn 26	Workshop at ISRAAC	ISRAAC	£50 + travel
Winter 26	Workshop at ISRAAC	ISRAAC	£50 + travel
Winter/Spring 27	X2 on-line workshops	On-line	£25 + internet
Spring 27	Final project outputs	AWRC	£50 + internet

Appendix 2: Participant approach guide

The following professional groups will be briefed about the project and identified as recruiters who may approach potential participants about the project:

- NHS clinicians employed within the Stroke Service Pathway at Sheffield Teaching Hospitals NHS Foundation Trust
- ISRAAC leadership team
- Coordinators and support staff employed at Stroke Association, Sheffield branch
- Move Well exercise referral instructors

The recruiters will be given the following guidance:

- Please identify potential participants who appear to meet the eligibility criteria as detailed in Table 1 of the protocol (this will be pasted into briefing doc).
- Please note that communication impairment should not be a barrier to recruitment to the study.
- It is important that you maintain a neutral position about the study, avoid encouraging potential participants to take part or indicating that the intervention is likely to be effective.
- Please advise potential participants that they are not expected to share their decision about the study with you

The following is a guide to how you may approach the conversation:

There is an exercise study running at the research centre in Attercliffe for people living with stroke. Volunteers are invited to take part in an eight-week programme of exercise on adapted exercise equipment. The research project will pay for transport including taxis if needed. If you would like to read more about it then more information is available on this sheet/website. If you'd like to find out more about the study you need to email or text message the research team – their details can be found here. You don't need to tell me whether or not you've decided to get in touch with them. If you would rather the research team contacted you can complete the 'consent to contact' form.

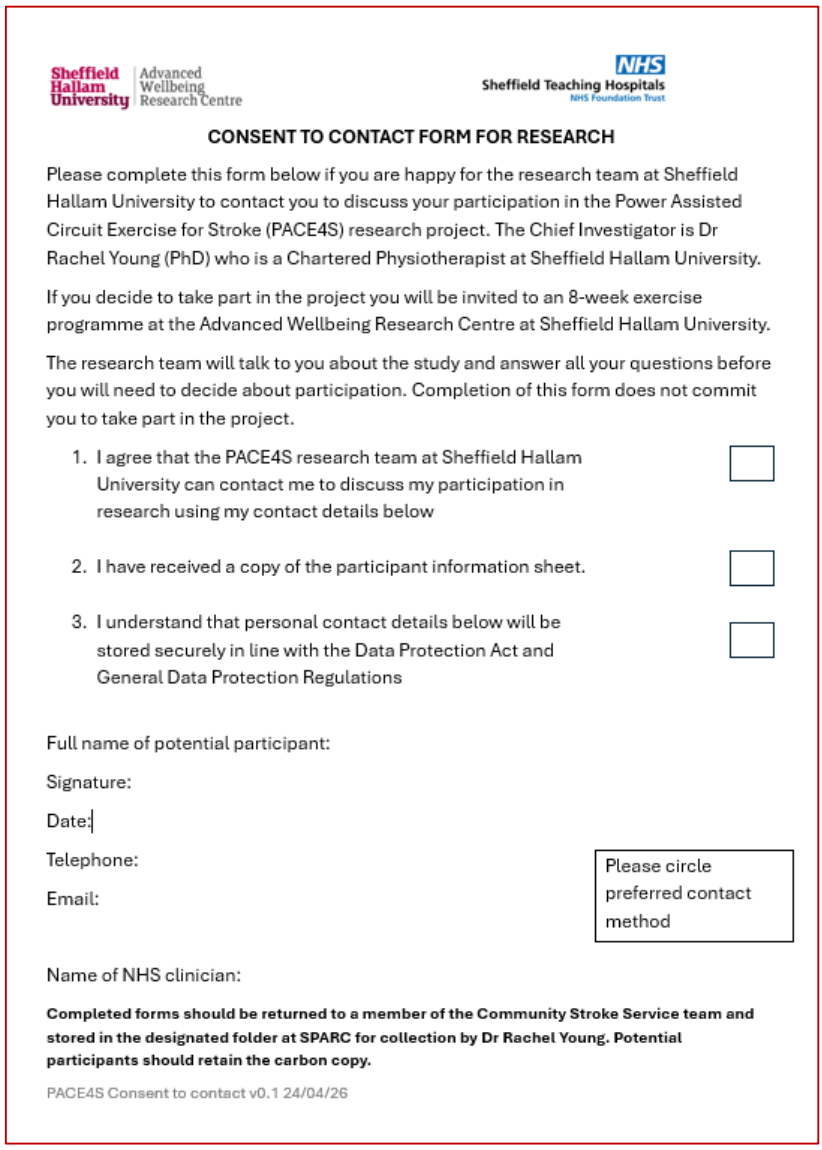
NHS clinicians will have carbonated copies of the consent to contact form. This can be completed in the presence of the clinician. Patient should retain carbon copy. Consent to contact forms should be stored at the SPARC Hospital site within STH NHS Foundation Trust and will be collected by a member of the research team.

The Stroke Association will circulate the following email through the consented mailing list:

There is an exercise study running at the research centre in Attercliffe for people living with stroke. Volunteers are invited to take part in an eight-week programme of exercise on adapted exercise equipment. To take part in the study you need to have a confirmed stroke diagnosis and be living with some changes to your movement and mobility. The research project will pay for transport including taxis if needed. If you would like to read more about it then information is available on the attached sheet/website.

If you'd like to find out more about the project you need to email or text message the research team – their details can be found here. [insert]

Copy of consent to contact form:



Sheffield Hallam University | Advanced Wellbeing Research Centre

Sheffield Teaching Hospitals NHS Foundation Trust

CONSENT TO CONTACT FORM FOR RESEARCH

Please complete this form below if you are happy for the research team at Sheffield Hallam University to contact you to discuss your participation in the Power Assisted Circuit Exercise for Stroke (PACE4S) research project. The Chief Investigator is Dr Rachel Young (PhD) who is a Chartered Physiotherapist at Sheffield Hallam University.

If you decide to take part in the project you will be invited to an 8-week exercise programme at the Advanced Wellbeing Research Centre at Sheffield Hallam University.

The research team will talk to you about the study and answer all your questions before you will need to decide about participation. Completion of this form does not commit you to take part in the project.

1. I agree that the PACE4S research team at Sheffield Hallam University can contact me to discuss my participation in research using my contact details below ☐
2. I have received a copy of the participant information sheet. ☐
3. I understand that personal contact details below will be stored securely in line with the Data Protection Act and General Data Protection Regulations ☐

Full name of potential participant:

Signature:

Date:

Telephone:

Email:

Please circle preferred contact method

Name of NHS clinician:

Completed forms should be returned to a member of the Community Stroke Service team and stored in the designated folder at SPARC for collection by Dr Rachel Young. Potential participants should retain the carbon copy.

PACE4S Consent to contact v0.1 24/04/26

Appendix 3: Participant recruitment materials (LOGOS WILL BE INSERTED)

Power Assisted Circuit Exercise for Stroke

Summary

You are invited to consider taking part in a research project which will help us to develop exercise pathways for people living with stroke. We are seeking volunteers to join an eight-week programme of exercise using seated equipment with a motor which helps users to move their arms and legs. The study will be at the Advanced Wellbeing Research Centre in Attercliffe, Sheffield. We will take some measurements at the start and end of the eight-week programme to see whether the exercise has changed your walking, fitness and quality of life. The adapted exercise machines are shown in the image below:

Power assisted equipment





Images accessed with permission from Clowne Leisure Centre and Innerva.com

What is the purpose of this project?

We know that physical activity or exercise helps people living with stroke to improve their mobility, fitness and quality of life.

However, some people living with stroke find it difficult to use normal exercise equipment due to muscle weakness and reduced balance. This project will help us to understand whether power assisted exercise might be a solution to this challenge.

What's already known?

Power assisted exercise machines are available in some gyms and leisure centres in the UK and are already used by some people living with stroke. However, no previous research study has measured whether power assisted exercise can help to improve mobility, fitness and wellbeing following stroke.

Why are we doing this research?

Most areas in the UK do not have access to power assisted exercise equipment. It is important that we measure the extent to which power assisted exercise can help people living with stroke so that we can improve rehabilitation opportunities.

How many participants will be involved in this study?

We have space for 30 people living with stroke in South Yorkshire to join the 8-week exercise programme between Spring 2026 and Winter 2027.

Who can take part in the study?

To be able to take part in the study you will need to have had a confirmed diagnosis of stroke and be living at home with some changes to your mobility. The list below provides more detail:

- History of one or more stroke(s)
- Aged 18 years or older
- Need some help with everyday activities and/or walking
- Able to stand and take a couple of steps (with assistance if needed)

If your doctor or a healthcare professional has advised you to avoid exercise or physical activity, then you may not be suitable for the study.

If you are unable to stand or transfer between seated surfaces without a hoist or transfer device, then you will not be able to take part in the study.

If you weigh more than 150 Kilograms/24 stone, then you will not be able to take part in the study.

If you are still in hospital, or your stroke was less than 28 days ago then you will need to wait until you have been discharged home and one month has passed since your most recent stroke.

The research team will check that all volunteers understand the purpose of the study and are able to give their informed consent to take part.

What if I would like to try a different type of exercise?

There are other services in the Sheffield area which help people living with stroke to take part in exercise. Local organisations including Sheffield Stroke Association and the Move Well Scheme can provide more information. Alternatively, you can talk to your GP about exercise options. Your decision about the project will not be shared with the person who gave you this information sheet.

What would taking part involve?

The information below describes how you can sign up to the study, the measurements which will be taken and details of the exercise programme itself.

Signing up

If you are interested in taking part in the project, you can send an email to **PACE4S@shu.ac.uk,** OR send a text or WhatsApp message to number **07811 XXX XXX**. Please include your preferred name and contact number and/or email.

A member of the research team will get in touch with you to schedule either a telephone call or home visit, depending on which you prefer. The date and time of the telephone call or home visit will be confirmed by letter or email.

If you find it difficult to communicate in English, we can arrange for a family member or translator to help with the conversation.

Measurement session

If you decide that you would like to take part in the study, you will be invited to the Advanced Wellbeing Research Centre in Attercliffe, Sheffield. We can arrange taxi transport if required and we will cover travel expenses.

We will measure your heart rate, blood pressure, oxygen levels, height and weight. You will complete a supervised 10-minute exercise session on one of the power assisted exercise machines whilst we measure your heart rate. If we notice anything unusual about the way in which your body responds to the exercise, we will contact your GP or a medical doctor for further guidance.

If you can walk 10 metres or more, we will measure how long it takes you to stand up, walk 3 metres and return to your seat. If you are able, we will measure how long it takes you to walk 10-metres in a straight line.

You will be asked to complete some questionnaires which will ask you about your quality of life and how your stroke has affected you. You can complete these with help from the research team or on your own.

At the end of the 8-week study the measurements described above will be repeated.

Exercise programme

The exercise programme will run for 8-weeks, with two sessions planned per week. At the start of each session, the research team will check how you are feeling and measure your heart rate and blood pressure. The aim will be to exercise on three power assisted machines, spending between 10 and 15 minutes on each machine. We expect that it may take several sessions to build up to this.

More information about power assisted equipment can be accessed at the manufacturer's website: https://www.innerva.com/

A Chartered Physiotherapist plus two trained research assistants will supervise your first two sessions. The research assistants will supervise the remaining exercise sessions. They will help you to get on and off the machines, monitor your heart rate and help you to progress towards your goals. Each exercise session will be a maximum of one hour long.

We know that living with stroke can be unpredictable. The research team will understand that you may need to occasionally miss sessions, or that you may feel tired and only be able to exercise at a low effort level during some visits.

All exercise sessions will be at the Advanced Wellbeing Research Centre in Attercliffe, Sheffield.

At the end of your exercise programme, you will have the option of taking part in an interview or focus group to talk about your experiences of taking part in the project.

Can I bring a family member of carer?

Yes, a family member or carer will be welcome to join you during your exercise sessions. Translators are also welcome.

Will I be exercising on my own or in a group?

The exercise sessions will be delivered to small groups of 2-3 people. If you would prefer single gender sessions, please tell the research team and this will be arranged for you.

Do I need any special clothing or equipment?

We will recommend that you wear loose, comfortable clothing and flat shoes for the exercise sessions. You will not need any specialist equipment and clothing. Headscarves may be worn on the motor-assisted machines.

Can I choose the time and day of my sessions?

We will ask you about your weekly routines to aim to plan your sessions at a time which is convenient for you. We will not be able to offer evening or weekend sessions.

How will travel to the research centre be supported?

The research project will cover all transport costs. If you can drive or arrange a lift with a carer or family member then we will reimburse travel at 45-pence per mile. There is free parking directly outside the entrance to the research centre which is reserved for research participants.

If you would prefer to travel by taxi, then the research team can book these for you and pay directly. This includes wheelchair taxis. If you prefer to book your own taxi service, then the cost of these will be reimbursed. You will be required to retain receipts.

Can I do other types of exercise or therapy during the study?

You can continue your existing therapies or exercise routines. We will request that you avoid taking up any other new types of physical activity during the 8-week study.

Disclosure

If you decide to take part in the study, we will send a letter to your GP which describes the purpose of the study and your involvement in it.

What if I want to drop out of the study?

You may opt out of the study at any time without giving any reason to the research team. If you indicate that you would be happy to talk to us about reasons for opting out, then we might invite you to a follow-up interview. Opting out of the study will **not** affect your access to future treatment, healthcare or other research opportunities.

What are the possible benefits of taking part?

We know that exercise can help stroke recovery and it is possible that the power-assisted exercise will improve your fitness, mobility and quality of life. You may also enjoy the social contact with the research team and other study volunteers. We will give you a £30 retail voucher as a 'thank you' for taking part. **What are the possible disadvantages and risks of taking part?**

There is a small risk of injury or health complication associated with any type of exercise for people living with stroke. You will be observed and assisted throughout your exercise sessions to minimise this risk. If an injury or health complication does occur, then medical advice will be arranged immediately. You may feel tired after the exercise sessions.

How will we use and store information about you?

Sheffield Hallam University is the sponsor of this research and holds indemnity insurance for the project.

We will need to use information from you for this research project.

This information will include your name and contact details. We will store data about your medical history and demographic status. During the project we will collect and store data about your exercise programme and how you responded to it. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Sheffield Hallam University is the sponsor of this research.

Sheffield Hallam University is responsible for looking after your information. We will not share your information related to this research project with any other organisations.

We will keep all information about you safe and secure by:

- Paper documents will be stored in a locked cabinet in a secured area of the Advanced Wellbeing Research Centre at Sheffield Hallam University.
- Electronic documents containing your name and contact details will be stored in a secured server at Sheffield Hallam University which can only be accessed by senior members of the research team.

- Electronic documents containing information about your medical history and research activity will be anonymised with a code number and stored on a separate secure server at Sheffield Hallam University.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 of years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to drop out of the study, you may request that we do not report any of the data collected during your time on the project. If you take part in an interview, then you can request that your data is withdrawn for up to seven days after the interview. We cannot withdraw data collected during focus groups.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- Patient data and research leaflet - Health Research Authority
- By asking one of the research team
- By sending an email to r.young@shu.ac.uk or DPO@shu.ac.uk

Risk of disclosure

Please note that whilst we will treat your data and the information about you with us securely, there may be exceptions if we identify any evidence or concerns about a potential risk, harm or wrongdoing for yourself or another person. Examples of this

could include concerns about your mental health, risk of suicide or driving without medical approval. If we are concerned about your physical or mental wellbeing, we may contact your GP. For other concerns we may be obliged to contact other relevant statutory bodies or agencies in line with Sheffield Hallam University safeguarding policy: https://www.shu.ac.uk/about-us/governance/governance-documents/safeguarding

You should contact the Data Protection Officer if: • you have a query about how your data is used by the University • you would like to report a data security breach (e.g. if you think your personal data has been lost or disclosed inappropriately) • you would like to complain about how the University has used your personal data DPO@shu.ac.uk	**You should contact the Head of Research Ethics (Dr Mayur Ranchordas) if:** • you have concerns with how the research was undertaken or how you were treated ethicssupport@shu.ac.uk

Postal address: Sheffield Hallam University, Howard Street, Sheffield S1 1WBT Telephone: 0114 225 5555

Sheffield Hallam University | Advanced Wellbeing Research Centre

Sheffield Hallam University Knowledge Applied | Centre for Applied Health and Social Care Research

University of Sheffield

NHS Sheffield Teaching Hospitals NHS Foundation Trust

ISRAAC Bringing Communities Together

Do you live with the effects of stroke?

Opportunity to join a research project using power-assisted exercise equipment

Who can join the project?

- Adults living with limited mobility or movement following stroke

What is power assisted exercise?

- Seated exercise machines with a motor which helps movement of the arms and legs (photographs opposite)



What would I need to do if I joined the project?

- Attend power assisted exercise sessions twice a week for 8 weeks
- Complete an exercise test at the start and end of the project
- Complete questionnaires about your quality of life
- Option to take part in an interview of focus group

Where is the study?

- Advanced Wellbeing Research Centre in Attercliffe

Contact: PACE4S@shu.ac.uk or Rachel Young (mobile)

FUNDED BY NIHR | National Institute for Health and Care Research

Appendix 4: Eligibility screening tool

PACE4S Eligibility Screen

Conversation and question guide

Chief Investigator (RY) makes introduction and briefly outlines the background to PACE4S, ie. a funded study to explore how a power assisted exercise programme might help people to engage in exercise as part of their stroke recovery. RY will check whether the potential participant has had access to the study recruitment materials/information and ask whether they have any questions at this stage.

RY will explain that the purpose of the call is to check whether the potential participant is suitable for the study and to give them the opportunity to consider whether they would like to take part.

RY will refer to the appointment letter and explain that the questions will be asked to help the research team to understand more about the potential participant and whether the study might be a positive option for them. RY will reassure that all information will be anonymised and stored confidentially at Sheffield Hallam University and not shared with any external organisations. RY will explain that the decision to take part (or not) in the study will not be shared with the recruiter who approached them about the study.

Questions

- How did you hear about the study?

Next, we need a bit of background information about you:

J-Drive data:

- *What is your given name?*
- *What is your preferred name?*
- *What is your family/surname?*
- *What is your year of birth?*
- *What is your residential postcode?*

Q-Drive data:

- *When did your stroke happen?*
- *What type of stroke was it? Ie. a clot or a bleed?*
- *For how long were you in hospital?*

If age at onset of stroke was younger than 18 years, then we need to explain that the study is intended for people with adult-onset stroke. If residential address outside S. Yorkshire we need to advise that travel expenses will not be covered. If stroke diagnosis not confirmed, we need to explain that this is a requirement of joining the study.

The next set of questions are intended to determine the modified Rankin Scale (mod-RS) score. The scoring system developed by London and Kamal [1] has been adapted.

We now need to understand a bit more about your stroke and how it has affected you:

Q-Drive data

Table One: Modified Rankin Scale		
Question	**Response**	**Action**
1. Can you walk on your own, either with or without a walking aid?	Yes/No	Yes: go to Q3 No: go to Q2
2. Can you walk with somebody helping you?	Yes/No	Yes: mod-RS = 4 No: mod-RS = 5
3. Do you need help with everyday activities such as washing, dressing, bathing, cooking and simple finances?	Yes/No	Yes: mod-RS = 3 No: = Q4
4. Can you do more complex activities such as driving, household bills, hobbies or work?	Yes/No	No: mod-RS = 2 Yes: = Q5
5. Do you have any symptoms from your stroke?	Yes/No	Yes: mod-RS = 1 No: mod-RS = 0

If modified Rankin Scale score is not 3 or 4, then we will explain that they are not eligible to join the study. If modified Rankin Scale <3 then recommend Move Well scheme for other physical activity options. If modified Rankin Scale >4 then recommend inclusive exercise options, eg. 'Cycling for All.'

I will next ask you about your general health and any other conditions which you live with:

- *Do you take prescribed medications? If so, what are they?*
- *Do you monitor your blood pressure? If so, what are your typical readings?*
- *Are you receiving treatment for, or having investigations for any health condition other than your stroke?*
- *Has your doctor advised against exercise or physical activity?*

If prescribed medication, reported medical history or current investigations indicate contra-indication to exercise [2] then the participant will be advised that we need to contact their GP or consult with Co-I Dr Ali Ali to check suitability for study participation.

If you do decide to take part in the study, then you will need to travel to the Advanced Wellbeing Research Centre (AWRC) in Attercliffe twice a week. We will provide taxis or cover your travel costs, depending on your preference. You will be welcome to bring along a carer or family member.

- *Do you have any questions about travel arrangements?*
- *Can you tell me, in your own words, what taking part involves and what choices you have?*
- *Do you think that you will be able to manage two exercise sessions per week at the research centre?*
- *What overall questions do you have about the project?*

If potential participant meets eligibility criteria we will explain that the next step is familiarisation/baseline assessment at the AWRC. Potential participant will have the option of taking up to 7-days to consider whether they would like to proceed. If interest is confirmed, visit to AWRC will be scheduled and travel arrangements confirmed.

If there is uncertainty about the potential participant's capacity to understand the purpose of the study and provide informed consent (as indicated by their responses to questions highlighted in yellow) then the Chief Investigator will suggest that they visit the AWRC for a familiarisation visit with a carer or support worker to meet the research team and have a look around the venue. This will give the potential participant more opportunity to comprehend the purpose of the study, and the Chief Investigator will be able to evaluate the potential participant's ability to provide informed consent and the extent to which a cognitive or communication impairment may be impacting capacity. If reasonable doubt about capacity to give informed consent remains at the familiarisation visit, then the Chief Investigator will explain to the potential participant and carer/support worker that there are concerns about their suitability for the study and signpost to alternative activities available in their locality. The Chief Investigator is a Chartered Physiotherapist with >30 years' experience in neurological rehabilitation and an extensive track record in assessing whether a patient/participant can comprehend the purpose of physical rehabilitation.

References

1. London, L., & Kamal, N. (2025). Designing a Patient Outcome Clinical Assessment Tool for Modified Rankin Scale: "You Feel the Same Way Too." *Informatics (Basel)*, *12*(3), 78. https://doi.org/10.3390/informatics12030078
2. American College of Sports Medicine, issuing body. (2025). *ACSM's guidelines for exercise testing and prescription*. (Twelfth edition / ACSM.). Wolters Kluwer

Appendix 5: Physical Assessment Protocol

The testing procedures described below will be conducted at the baseline visit and repeated one week following completion of the PACE intervention.

Prior to commencing the test, the research team will screen for any contraindications to exercise.

Contraindications for exercise testing and training

If participants have any of the following conditions or symptoms, exercise testing or training will not be completed, and appropriate actions will be taken to mitigate risk.

- Acute myocardial infarction (within 5 days)
- Unstable angina
- Active endocarditis
- Acute myocarditis or pericarditis
- Known obstructive left main coronary artery stenosis
- Suspected dissecting aortic aneurysm
- Uncontrolled arrhythmias causing symptoms or haemodynamic compromise
- Tachyarrhythmias with uncontrolled ventricular rates
- Acquired advanced or complete heart block
- Symptomatic severe aortic stenosis
- Moderate to severe aortic stenosis with uncertain relation to symptoms
- Hypertrophic obstructive cardiomyopathy with severe resting gradient
- Uncontrolled heart failure
- Pulmonary oedema
- Grade 3 hypertension or above (systolic or diastolic blood pressures >180/110 mmHg)
- Acute pulmonary embolus or pulmonary infarction
- Respiratory failure
- Ambient desaturation at rest <85%
- Oxygen supplementation
- Uncontrolled asthma
- Thrombosis of lower extremities
- Syncope
- Cognitive impairment leading to inability to cooperate
- Acute non-cardiopulmonary disorder that may affect exercise performance or be aggravated by exercise
  (e.g. sepsis, acute infection, acute renal failure, febrile illness)
- Uncorrected medical conditions, such as:
    - Significant anaemia
    - Significant electrolyte imbalance
    - Hyperthyroidism

Sub-maximal exercise test protocol

Prior to commencing the physical tests, the Chartered Physiotherapist will observe active range of movement in all four limbs from a seated position. Passive range of movement will be assessed following active. Patterns of motor weakness or stiffness will be recorded and assistance/supervision will be tailored accordingly.

The submaximal exercise test will be conducted on the Cross Cycle machine manufactured by Innerva. (Cross Cycle Specification). Unlike conventional exercise machines, which increase workload by adding more resistance, the proposed power-assisted exercise test requires participants to increase their effort by pushing harder against the pedals and handles. The target effort level will gradually increase, guided by a visual incremental target displayed on a screen. The exercise protocol will be individualised based on each participant's level of disability (modified Rankin Scale score) and upper-limb strength (measured via a handgrip dynamometer). This tailored approach will ensure that effort level increases at an appropriate pace, reducing the risk of premature or excessive fatigue. Heart rate will be continuously monitored with a Brachial Arm Monitor (Polar Verity Sense POLAR); reported and observed exertion will be monitored by the research team. The test will be located in the Movement Analysis Laboratory at the Advanced Wellbeing Research Centre.

The sub-maximal exercise test will be stopped either when the participant reaches 85% of their predicted maximum heart rate [2], or earlier if the participant asks to stop for any reason. Blood pressure (arm cuff) and blood oxygen saturation (fingertip pulse oximeter) levels will be measured before the test begins, immediately after the test finishes, and during the recovery period.

Indications for termination of exercise test or training

The exercise test will be stopped immediately if any of the following occur:

- Participant asks to stop for any reason
- Unexpected pain or discomfort
- Chest pain suggestive of ischaemia (angina)
- Breathing difficulties
- Signs of poor perfusion (cyanosis or pallor)
- New or worsening central nervous system symptoms (e.g., ataxia, dizziness, syncope)
- Loss of coordination
- Mental confusion

*Adapted from Fletcher et al., (2013) with oversight from Study Doctor.

Heart rate calculations

Age-predicted maximum heart rate will be estimated using population-specific equations that adjust for age and, where appropriate, the presence of heart failure or use of beta-blockers, in accordance with guidance from the Association of Chartered Physiotherapists in Cardiovascular Rehabilitation [3]. Heart rate reserve will be calculated by subtracting resting heart rate from age-predicted maximum heart rate.

For participants with atrial fibrillation or pacemakers, heart rate will be interpreted with caution. In these individuals, exercise intensity targets will be guided primarily by perceived exertion [4] and breathing responses (avoiding laboured hyperventilation)—heart rate responses will be used for dose monitoring purposes only.

Supervision

Chief Investigator/Chartered Physiotherapist (RY) and Co-Investigator/Clinical Exercise Physiologist (NK) will supervise the exercise test.

Signposting for medical support

If unusual resting values are identified (e.g. previously undiagnosed hypotension or hypertension), or if new or concerning symptoms are reported, the participant will be advised to contact their GP for further assessment with oversight from the Study Doctor.

Exercise training is recommended by clinical guidelines for people with chronic stroke [5]. In the unlikely event that a participant experiences unusual physiological responses or concerning symptoms during or following exercise, the following actions will be taken depending on the severity of the health concern:

- Exercise intolerance (e.g. feeling unwell during or after exercise): the exercise session will be modified, paused, or discontinued as appropriate.

- Acute or clinically concerning symptoms (e.g. angina, dizziness, disproportionate breathlessness, or acute neurological change): exercise will be stopped immediately and urgent assessment will be initiated in accordance with local first aid procedures.

Mobility assessment

Mobility assessment will be conducted after the exercise test. A 15-minute rest will be scheduled to allow recovery from the exercise test. The mobility assessments will be conducted in the movement analysis laboratory, instructed and supervised by Dr Rachel Young and Dr Nik Kudiersky.

Timed Up and Go Test

Equipment will be a 45cm high bariatric chair and cone positioned 3M distance from chair. Instruction: ‘stand up from the chair, walk around the cone towards your right-hand side and return to sit down on the chair.’ The test will be repeated turning towards the left. The time from leaving the seat to sitting down will be recorded.

10 Metre Walk Test

Participants will walk for 10 metres in a straight line along a distanced marked walkway in the movement analysis laboratory.

References

[1] Fletcher, G. F., Ades, P. A., Kligfield, P., Arena, R., Balady, G. J., Bittner, V. A., ... & Williams, M. A. (2013). Exercise standards for testing and training: a scientific statement from the American Heart Association. Circulation, 128(8), 873-934.https://doi.org/10.1161/CIR.0b013e31829b5b44

[2] Ozemek, C., Bonikowske, A., Christle, J., & Gallo, P. (2025). ACSM's guidelines for exercise testing and prescription. Lippincott Williams & Wilkins.

[3] Association of Chartered Physiotherapists in Cardiovascular Rehabilitation (ACPICR). Standards for Physical Activity and Exercise in the Cardiovascular Population (4th Edition). 2023.

[4] Borg G. Borg's perceived exertion and pain scales. Champaign, IL, US: Human Kinetics; 1998. viii, 104 p. (Borg's perceived exertion and pain scales).

[5] Royal College of Physicians. National Clinical Guideline for Stroke (5th edition) [Internet]. Intercollegiate Stroke Working Party; 2016. Available from: https://www.strokeguideline.org/app/uploads/2023/03/2016-National-Clinical-Guideline-for-Stroke-5th-edition.pdf?utm

Appendix 6: Physical assessment risk assessment

Description of the Process/Activity: PACE4S Project –Physical Assessment People with stroke who have been checked by a Chartered Physiotherapist and Clinical Exercise Physiologist for contraindications to exercise.	Location(s): AWRC – Motion Analysis Lab (MAL) RA Ref:

Hazard	Who could be harmed?	Existing safety precautions	Risk level	Additional safety precautions needed to reduce the risk level?	Revised risk level	Date completed
Assisting participants to access the Cross Cycle machine - Risk to posture and subsequent musculoskeletal injury	Research Physiotherapist/ Clinical Exercise Physiologist	1. Screening will identify and exclude people who cannot stand and transfer 2. Participants will be asked about any changes in health/condition since screening at start of physical assessment 3. Ability to move legs and trunk from a seated position will be assessed prior to transfer onto machine 4. Moving and handling training for assessors 5. Sara Steady transfer aid will be available in the event of an unexpected decline in mobility (eg. due to participant fatigue)	Medium S2xL2=4			06 02 26
Technical failure/fault with PACE machine	Participant/ Research team	1. Machine checked by manufacturer before first use.	Low S2XL1=3	Stop use and contact manufacturer	Low	06 02 26
Risk of falls when transferring on	Participants	1. Research Physiotherapist and Clinical Exercise Physiologist will both	Medium S3XL2=6			06 02 26

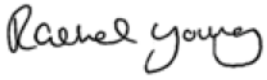
or off the Cross Cycle machine		supervise or assist the transfer as required. 2. Floor space and surrounding area will be free of trip hazards with good lighting. 3. Participants will use walking aids as used for their transfers at home				
Risk of musculoskeletal injury caused by Cross Cycle assessment	Participants	1. Screening assessment will identify any pre-existing MSK injuries 2. Range of active and passive limb movement will be assessed by research physiotherapist in seated position before transfer onto machine 3. First few minutes of submaximal exercise test will be conducted at low intensity, allowing time to warm up 4. Machine accessories will be used, ie. adapted glove and loops to decrease range of movement of exercise. 5. Continuous observation of participant by Research Physiotherapist and Clinical Exercise Physiologist	Medium S2xL2=4 This would normally be low, but due to the moderate to severe levels of disability in this group the likelihood has been increased	.		06 02 26
Cardiovascular complications -Extra strain is placed on the cardiovascular system when completing submaximal exercise test	Participants involved in the trial	1. Pre-screening for co-existing health conditions. 2. Resting heart rate, blood pressure and SaO2 will be recorded prior to starting exercise test- any atypical readings will trigger medical review and delayed/terminated recruitment to the project. 3. Heart rate will be measured continuously with a Polar Verity monitor on the upper	Medium S4xL1=4	1. Qualified first aider available within AWRC at all times 2. Defibrillator available in AWRC reception adjacent to movement analysis lab	Medium (S3xL1=4)	06 02 26

		arm; abnormal heart responses will lead to test termination and medical review. 4. Continuous observation of participant by Research Physiotherapist and Clinical Exercise Physiologist using reported and observed exertion to assess exercise intensity alongside heart rate data 5. Participant can request to terminate test at any time point. 6. Post session check for any adverse reactions. Adverse & serious adverse event protocols in place				
Fall during mobility assessment	Participants	1. 15-minute rest prior to mobility assessments 2. Screening assessment will establish walking ability and any person reporting that they do not normally walk more than 10M will be exempt from mobility assessments 3. Assessors will have evaluated the ability to transfer on and off the Cross Cycle machine prior to mobility assessment – where ability to complete mobility assessments is doubted they will not be conducted 4. Assessors will closely supervise participants throughout mobility assessments	Medium S2xL2=4			06 02 26

		5. Mobility assessments will be conducted on designated walkways in the movement analysis lab with clear flooring and good lighting 6. Participants will be permitted to use usual walking aids				
Fatigue following physical assessment	Participants	1. Exercise intensity will be gradually increased during submaximal test and terminated at 85% of age predicted max heart rate or at the request of participant 2. 15 minute rest between exercise test and mobility assessments 3. Participants with limited mobility <10M will not complete mobility assessments 4. Water and light snacks will be available 5. Transport arrangements will be supported	Low (S1xL3=3)			06 02 26
Hygiene and infection control	Participants	1. Contact points will be wiped between uses	Low S2xL1=2			06 02 26
Participant becoming anxious	Participants	1. Carer/family member/translator will be permitted to accompany sessions 2. Research team will demonstrate all activities prior to the testing 3. Participants will have the opportunity to ask questions and share their thoughts about their experiences 4. Assessors (RY/NK) have extensive experience in	Low S2XL1 = 3		Low	06 02 26

		communicating with people with stroke and adjusting conversation as required				

Communication of significant findings		
Method of communication (describe): **Emergency Procedures** If First Aid trained then perform emergency first aid if the subject faints or experiences cardiovascular complications. Otherwise, dial 888 (0114 225 2888) to request first aid support or to call an ambulance. **Monitoring Procedures** The application of the risk control measures specified above should be enforced through regular checks, and all staff taking part in the work should be fully conversant with the risk assessment and the required controls. Staff should be informed of any changes, particularly where risk control measures are modified in any way.	Person/people to communicate findings: Dr Rachel Young, Chief Investigator	Target date(s): As soon as it practically possible (aim for with 24-hrs)

Approval			
Carried out by: Rachel Young	Post: Principal Researcher/Physiotherapist	Signature: 	Date: 06 02 26
Approved by:	Post:	Signature:	Date:
Approved by:	Post:	Signature:	Date:

Appendix 7: Questionnaires

These will be collected using Qualtrics software. The questionnaire preamble will include information about why demographic/quality of life data is being collected and explain that the data will be anonymised. The information shared will not impact study eligibility or access to other services.

The following questions and response options will be included:

- What was your year of birth?
- What is your gender?
    - Male
    - Female
    - Other (please specify)
    - Prefer not to say
- Is your gender identity the same as you were assigned at birth?
    - Yes
    - No
    - Prefer not to say
- What is your marital status?
    - Married
    - Living with partner
    - Single
    - Prefer not to say
    - Other (please specify)
- How many people live in your household?
- Which of the following best describes how you see yourself?
    - Asian or Asian British/Bangladeshi
    - Asian or Asian British/Indian
    - Asian or Asian British/Pakistani
    - Any other Asian or Asian British background
    - Arab
    - Black or Black British African
    - Black or Black British Caribbean
    - Any other Black or Black British background
    - Mixed White and Asian
    - Mixed White and Black African
    - Mixed White and Black Caribbean
    - Other Mixed background
    - Chinese
    - White British
    - White Irish
    - Gypsy or Irish Traveller
    - Other White background
    - Any other ethnic group
    - Prefer not to say
- What is your postcode?

- Are you currently:
    - Retired
    - Student
    - Looking after home or family
    - Working
    - Unable to work
    - Unemployed
    - Other (please specify)
    - Prefer not to say

Validated Questionnaires:

Euro-Qol- 5L Questionnaire



EQ5D-5L.pdf

PROMIS – Global Health Questionnaire



PROMIS-Global-Health.pdf

Stroke Impact Scale



Stroke-Impact-Scale-SIS.pdf

Appendix 8: Training resource for Research Assistants

The Research Assistants will be responsible for intervention delivery. A condition of employment will be successful completion of the following training activities:

1. NIHR Good Clinical Practice (GCP) on-line module

2. Completion of an audio-visual teaching resource (30 minutes) and associated questions:
    a. What is a stroke?
    b. What are the risk factors for stroke?
    c. What impairments can occur after stroke?
    d. How can exercise help people to recover after stroke?
    e. What are the cautions associated with exercise after stroke?
    f. What are the barriers encountered by people living with stroke to exercise or physical activity?
    g. How do health inequalities affect people living with stroke?

3. Half day in-person training session:
    a. Introduction to power assisted exercise equipment
    b. Practical session on the equipment
    c. Practical session on taking and recording BP/HR/Sa02
    d. Project protocol and participant pathway
    e. Practical session mirroring the intervention protocol including observations and monitoring

Appendix 9: Intervention record

This data will be recorded onto an anonymised tabulated paper document during each session. It will be inputted into an Excel document stored on the secured Q-Drive within one-week of each session.

The paper file will be stored in a locked cabinet at the research centre.

Will include

Pre-session

- Cardio-respiratory obs (BP/Sa02/HR)
- Reported fatigue on VAS
- How did you feel after last session?
- Any updates/setbacks/improvements?
- Goals (session 1)

Peri-session

- Heart rate (5-min intervals)
- Rate of perceived exertion (5 min intervals)
- Duration on each named machine
- Machine effort score

Post-session

- Cardio-respiratory obs (BP/Sa02/HR)
- Reported fatigue on VAS
- Reported enjoyment (emoji Likert Scale)
- Safety incidents
- Adverse events

Session Data Procedures and Data Input

All research assistants will undergo training which will include data input instructions.

Session 1: participants will be facilitated by the Chief Investigator (RY) and a designated research assistant to discuss their expectations of the intervention and goals. Any concerns about the programme will be discussed. A summary of the conversation will be recorded into a word.doc.

Session data will be inputted onto paper documents. An anonymised paper file will be stored for each participant.

Five minutes pre-exercise:

Heart rate, blood pressure and SaO2 will be recorded on the formatted paper document. Participant will indicate reported fatigue symptoms on a Fatigue VAS.

During exercise (5-minute increments)

Heart rate and reported rate of perceived exertion will be recorded on the paper form by the research assistants.

Duration of time on each PACE machine and effort in watts detected will be recorded on the paper form by the research assistants.

Any safety concerns or adverse events will be recorded and reported to the Chief Investigator as per the SAE protocol.

Five minutes post-exercise:

Heart rate, blood pressure and SaO2 will be recorded on the formatted paper document. Participant will indicate reported fatigue symptoms on a Fatigue VAS. Likert Scales (1-4) using emojis (paper format) will be completed by participants to indicate; 1) session enjoyment 2) session difficulty.

The data from the paper records will be inputted into an Xcel document by a research assistant within 48 hours of each session.

The recorded intervention data will be reviewed by the Chief Investigator bi-monthly to check for intervention fidelity. This analysis will inform intervention refinement and guide continued support for the team of Research Assistants.

Appendix 10: Intervention risk assessment

Description of the Process/Activity: PACE4S Project – Power Assisted Circuit Exercise Sessions People with stroke who have completed baseline assessment will attend 2x sessions a week, for 8 weeks at SHU (AWRC). Exercise session will last a maximum of one hour and will be at a light to moderate intensity.	Location(s): AWRC – Motion Analysis Lab (MAL) RA Ref:

Hazard	Who could be harmed?	Existing safety precautions	Risk level	Additional safety precautions needed to reduce the risk level?	Revised risk level	Action by whom?	By when ?	Date completed
Assisting participants to access the PACE machines - Risk to posture and subsequent musculoskeletal injury	Research Assistants/ Research Physiotherapist	1. Screening and baseline assessment will identify and exclude people who cannot stand and transfer 2. Participants will be asked about any changes in health/condition at start of each session 3. Moving and handling training for all team members 4. Sara Steady transfer aid will be available in the event of an unexpected decline in mobility (eg. due to participant fatigue)	Medium (S2xL2= 4)					06 02 26

Technical failure/fault with PACE machine	Participant/Research team	1. Machine checked by manufacturer before first use.	Low (S2XL1=3)	Stop use and contact manufacturer	Low	Manufacturer will repair any reported faults		06 02 26
Risk of falls when transferring between PACE machines	Participants	1. Two research assistants will be present throughout all sessions to supervise/assist as required. 2. Floor space and surrounding area will be free of trip hazards with good lighting. 3. Participants will use walking aids as determined during baseline assessment	Medium (S3XL2=6)					06 02 26
Risk of musculoskeletal injury caused by PACE intervention	Participants involved in the trial	1. Screening and baseline assessment will identify any pre-existing MSK injuries and reduced range of movement. Intervention will be adjusted accordingly. 2. Initial two sessions will be supervised by a Chartered Physiotherapist with expertise in stroke 3. All sessions will be supervised by two trained	Medium (S2xL2=4) This would normally be low, but due to the moderate to severe levels of disability in this group the likelihood has been increased	.				06 02 26

		research assistants 4. Participants perform appropriate warm up during first 5-10 minutes 5. PACE accessories will be used, ie. adapted glove and loops to decrease range of movement of exercise. 6. Post session check by research assistants on participants to check for injuries.						
Cardiovascular complications -Extra strain is placed on the cardiovascular system when exercising	Participants involved in the trial	1. Pre-screening for co-existing health conditions. 2. Baseline assessment will detect any abnormal exercise responses (heart rate and BP). BP and heart rate will be checked prior to each session. 3. Allow the participant to become accustomed to PACE equipment	Medium (S4xL1= 4)	1. Qualified first aider available within AWRC at all times 2. Defibrillator available in AWRC reception adjacent to movement analysis lab	Medium (S3xL1= 4)	Chief Investigator		06 02 26

		4. Physiotherapist to recommend safe exercises prior to session design. 5. Participants response to PACE exercise monitored carefully during each session including heart rate monitoring and reported exertion. 6. Post session check carried out by research assistants on participants to check for any adverse reactions. Adverse & serious adverse event protocols in place						
Fatigue following exercise	Participants involved in the trial	1. Sessions will be tailored to the individual 2. Session will be progressed gradually 3. Participants will be asked for feedback on the session pre, post and during each session 4. Exercise intensity will be gradually increased. Vigorous intensity	Low (S1xL3= 3)					06 02 26

		exercise (>70% age predicted max heart rate) will be avoided.						
Hygiene and infection control	Participants involved in the trial	1. Contact points will be wiped between uses	Low (S2xL1= 2)					06 02 26
Participant becoming anxious	Participants involved in the trial	1.Continuity of research assistants between sessions to build trusted relationships 2. Carer/family member/translator will be permitted to accompany sessions 3. Session pre-screen will include opportunity to share any concerns	Low (S2XL1 = 3)		Low			06 02 26
Risk to research team conducting home screening visits for eligibility in the community.	Research team	1. Visits will be conducted in daylight hours 2. Researcher will plan route ahead and drive in serviced vehicle 3. Researcher will ensure a named colleague knows of whereabouts and report to them on safe	Low (S3XL1 = 3)					06 02 26

		completion of visit 3. Researcher will carry charged mobile device						

Communication of significant findings		
Method of communication (describe): **Emergency Procedures** If First Aid trained then perform emergency first aid if the subject faints or experiences cardiovascular complications. Otherwise, dial 888 (0114 225 2888) to request first aid support or to call an ambulance. **Monitoring Procedures** The application of the risk control measures specified above should be enforced through regular checks, and all staff taking part in the work should be fully conversant with the risk assessment and the required controls. Staff should be informed of any changes, particularly where risk control measures are modified in any way.	Person/people to communicate findings: Dr Rachel Young, Chief Investigator	Target date(s): As soon as it practically possible (aim for with 24-hrs)

Approval			
Carried out by: Rachel Young	Post: Principal Researcher/Physiotherapist	Signature: 	Date: 06 02 26
Approved by:	Post:	Signature:	Date:
Approved by:	Post:	Signature:	Date:

Review of risk assessment
The frequency of the review is (refer to guidance):

Review date :	Carried out by:	Signature:
Review date :	Carried out by:	Signature:
Review date :	Carried out by:	Signature:
Review date :	Carried out by:	Signature:
Review date :	Carried out by:	Signature:
Review date :	Carried out by:	Signature:

Appendix 11: Adverse event tracking record

Sheffield Hallam University | Advanced Wellbeing Research Centre

Adverse Events: PACE4S

Subject Initials _____ Subject Number _____

Event No	Event	Start date DD-MMM-YYYY	End date DD-MMM-YYYY	Or indicate here if ongoing at study end	Intensity (1)	Relation to study (2)	Action taken (3)	Outcome (4)	Serious? Y/N (if Y complete SAE page and report to HRA)
1									
2									
3									
4									
5									
6									
7									
8									
9									

1: 1-mild; 2-moderate; 3-severe
2: 1-definite; 2-probable; 3-possible; 4-unlikely; 5-unrelated; 6-not assessable
3: 1-none; 2-study dose reduced; 3-study withdrawn; 4-specific treatment; 5-other

Report of Serious Adverse Event (For all studies except Clinical Trials of Investigational Medicinal Products)

The Chief Investigator (CI) should report any SAE that is both related to the research procedures and is unexpected. The report should be emailed to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event

Details of the Chief Investigator

Question	***Answer***
Name:	Dr Rachel Young
Address:	Advanced Wellbeing Research Centre, Sheffield Hallam University, Olympic Legacy Park, Sheffield, S9 3TU
Telephone:	07811467134
Email:	r.young@shu.ac.uk

Details of the study

Question	***Answer***
Full title of study:	Power Assisted Circuit Exercise for Stroke
Name of REC:	Replace text here
REC reference number:	Replace text here
IRAS ID:	368373

Research sponsor:	Sheffield Hallam University
Sponsor's reference for this report: (if applicable)	

Type of event

Please categorise this event, ticking all appropriate options:

Death

Life threatening

Hospitalisation or prolongation of existing hospitalisation

Persistent or significant disability or incapacity

Congenital anomaly or birth defect

Other

Circumstances of event

Question	***Answer***
Date of SAE:	
Location:	
Describe the circumstances of the event: (Attach copy of detailed report if necessary)	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

Declaration

Signature of Chief Investigator:

Print name:

Date of submission:

Acknowledgement of receipt by REC (please insert name):

The [ ] Research Ethics Committee acknowledges receipt of the above.

Signed:

Name:

Position on REC:

Date:

Signed original to be sent back to Chief Investigator (or other person submitting report) Copy to be kept for information by REC.

Appendix 12: Participant information sheet for Research Assistants

Participant recruitment materials (LOGOS WILL BE INSERTED)

Power Assisted Circuit Exercise for Stroke

Study Information for Research Assistants

Summary

You are invited to consider taking part in an interview which will explore your experiences of supervising the Power Assisted Circuit Exercise (PACE) intervention. The interviews will take place either in-person or on-line using Microsoft Teams, depending on your preference. The interview will be facilitated by a researcher who has not been involved in the delivery of the intervention. It will take no longer than one hour.

What is the purpose of the interview?

One of the aims of the PACE project is to refine the intervention in preparation for scaling it across community settings. Your perspective of the intervention for people living with stroke will help the research team to understand more about the acceptability of the intervention and how the future workforce could be supported in supervising it.

Who can take part in the study?

The interview is open to all Research Assistants who have experience of supervising the PACE intervention for people living with stroke. Even if you are not currently working on the project we will still be interested in your perspective.

What if I don't want to be interviewed?

Taking part in the interview is entirely voluntary. If you decide not to take part, then you can continue to work as a Research Assistant on the PACE4S project.

What would taking part involve?

The interview will be conducted either in-person on Sheffield Hallam University premises or on-line using Microsoft Teams. The interviewer will ask you questions about your experiences of supervising the PACE intervention and cover topics including:

- Observed benefits and effectiveness of PACE
- Limitations and challenges associated with PACE
- How the intervention could be improved
- Your experiences as a Research Assistant on the project

You may decline to answer any questions or terminate the interview if you do not feel comfortable.

If you are interested in taking part in the project, you can send an email to XXXX@shu.ac.uk confirming interest. Please include your preferred name and contact number and/or email.

The researcher will get in touch with you to schedule your interview and confirm preference for on-line or in-person.

Will I be interviewed on my own or in a group?

The interviews will be conducted individually with a member of the qualitative research team.

Can I choose the time and day of my interview?

Interviews will be scheduled during office hours. We will schedule your interview at a time and date which is convenient for you.

What if I want to drop out of the interview?

You may opt out of the interview at any time up to the scheduled start time without giving any reason to the research team. You may request that the interview is terminated at any point during the interview.

Data collected during terminated interviews will be deleted immediately and not used within the analysis or reporting of the study.

If you complete the interview, you may request that your interview data is withdrawn from analysis for up to seven days following the interview. In this case, the anonymised data will be archived within the secured IT systems at Sheffield Hallam University and not included in any reports from the study. After seven days, your anonymised interview data will be included in the analysis and reporting of the study.

Opting out of the interview or requesting that your data is withheld from analysis afterwards will **not** affect your employment as a Research Assistant at Sheffield Hallam University.

What are the possible benefits of taking part?

The interview will be an opportunity to reflect on your experiences as a Research Assistant and contribute to the development of the PACE intervention.

What are the possible disadvantages and risks of taking part?

The interview will require up to one hour of your time. If you choose to be interviewed on University premises, then you will need to also account for travel time.

The focus of the interview will be on the PACE intervention and your experiences as a Research Assistant. Reflecting on your experience of supporting people living with stroke may trigger some emotional responses. The interviewer will aim to be sensitive to this and tailor the pace and focus of the interview accordingly.

How will we use and store information about you?

The data will be anonymised by the interviewer. Your data will be anonymised by the qualitative research team and will not be directly identifiable by the Chief Investigator.

Sheffield Hallam University is the sponsor of this research. The University undertakes research as part of its function for the community under its legal status. Data protection allows us to use personal data for research with appropriate safeguards in place under the legal basis of **public tasks that are in the public**

interest. A full statement of your rights can be found at: www.shu.ac.uk/about-this-website/privacy-policy/privacy-notices/privacy-notice-for-research. However, all University research is reviewed to ensure that participants are treated appropriately and their rights respected. This study was approved by the University's Research Ethics Committee and the Health Research Authority with reference number *xxxxxxx*. Further information at: www.shu.ac.uk/research/excellence/ethics-and-integrity

What will happen to the findings from this study?

We will not share your personal data, we will use the anonymised code to make sure that the information collected from you will not enable anyone to identify you. The anonymised data will be published in academic journals and shared at networking events. If the findings indicate benefit for people living with stroke, then the anonymised data will be shared to help to gain more funding to expand the research programme.

You should contact the Data Protection Officer if:	**You should contact the Head of Research Ethics (Dr Mayur Ranchordas) if:**
• you have a query about how your data is used by the University • you would like to report a data security breach (e.g. if you think your personal data has been lost or disclosed inappropriately) • you would like to complain about how the University has used your personal data DPO@shu.ac.uk	• you have concerns with how the research was undertaken or how you were treated ethicssupport@shu.ac.uk

Appendix 13: Focus group and interview topic guides

PACE4S Interview Guide (Research Assistant Participants)

- General introductions, aims, reiterate consent and freedom to withdraw
- Respect for others' opinions, confidentiality within the group, etc.

Affective Attitude

What was your overall experience of delivering the sessions?
Was there anything you particularly liked about delivering the exercise programme?
Was there anything you didn't like or that you think could be improved?

- How would you improve this?

Burden

Did you have any challenges or difficulties in delivering the group sessions?
Is there anything that could be done to make your job easier? *(within the session / outside of the session)*

Intervention coherence

How clear did you feel about the purpose and aims of the programme?
How clear did you feel about your role within the programme?

Ethicality

How well did the programme match your professional values and beliefs? Was there anything about it that challenged these values?
How reasonable did you feel that the exercise programme was for the people taking part? Did it feel right for you in terms of content, level of intensity, etc.? (If not, what was missing or not right?)

Perceived effectiveness

How effective did you think the programme was?
Were there participants for whom the intervention was more or less effective?'

In what ways, if any, do you think the programme influenced participants' recovery or wellbeing?

Opportunity cost

How did delivering the programme fit within your wider workload?

What did you have to prioritise or deprioritise in order to deliver it?

Self-efficacy

How confident were you about delivering the exercise programme?
How adequately did the training and supervision you received prepare you to deliver the programme?
Is there anything else you might want or need to feel more confident?

Scaling up the programme in future

What do you think needs to be considered when scaling up programmes like this and implementing them beyond a research trial?

- Who could deliver this sort of programme, what training would they need, where could it be delivered?

Affective Attitude revisited

Would you recommend the programme to people who had experienced a stroke? (*Why/why not?*)
Is there anything that you have not already mentioned that you think could be improved about the programme?

Thank and debrief

PACE4S Topic guide: Research Participants (Interview Phase One /Focus Group Phase Two)

Please note that the topic guide for the focus groups may be refined pending on findings from Phase One. Substantial changes to the topic guide will be referred for ethical review.

For interviews with non-completers, the questions will be adapted according to their context. They will not be directly asked about their reasons for discontinuation.

- General introductions, aims, reiterate consent and freedom to withdraw
- Reminder about the exercise programme we are discussing today

Recruitment and sign-up

Can you tell me how you came to know about the exercise programme?
What made you want to take part?
How did you find the process of signing up and getting enrolled? *(consent, information provided, etc.)*
Is there anything you think could be changed or improved to make it easier for people like you to join the programme in future?
What did you expect the programme to be like? *(how/from where was this expectation formed?)*
Did you have any worries or concerns before you started?

Affective Attitude

How did you find the exercise sessions?
Was there anything you particularly liked about the exercise programme?
Was there anything you didn't like or you think could be improved?

- *(location, timing, content, number of people in the group, exercise instructor, etc).*

Burden

How much effort did it take from you to take part in the exercise programme?
Is there anything that could be done to make it easier? *(within the session / outside of the session e.g. joining, attending)*
How many of the sessions did you complete?
Did you have any challenges or difficulties in attending the group sessions? (*what could be done to overcome these in future?) (transport, funding for travel costs, preferred/ideal venues)*

Intervention coherence

Did you have any trouble understanding what you were being asked to do during the sessions – for example following the trainer's instructions? *(how could this have been made clearer?)*

Ethicality

How well did the exercise programme fit with the point you are at in your stroke recovery?
How reasonable did you feel that the exercise programme was for you? Did it feel right for you in terms of content, level of intensity, etc.? (If not, what was missing or not right?)

Perceived effectiveness

What were your hopes or goals when you started the programme - what were you hoping to gain? How close did you get to achieving these goals?
Was there anything else you gained or that changed for the better, that you didn't expect when you started?
Is there anything you can do now that you couldn't do when you started? How much of that do you think is down to the exercise programme (vs. natural recovery or some other aspect of treatment/rehabilitation)
What impact do you think the programme is likely to have on your overall stroke recovery?

Opportunity cost

What were the costs to you of doing the programme (not just financial, but any type of cost)? Was there anything that you lost or had to give up so that you could take part?
Did taking part in the programme interfere with any of your other priorities or values?

Self-efficacy

How confident were you about taking part in the exercise programme?
How confident are you about continuing to exercise after the programme?
What (if any) type of support do you think you might want or need to continue exercising?
Would you recommend the programme to other people who had experienced a stroke? (*Why/why not?*)
Is there anything that you have not already mentioned that you really liked or that you think could be improved about the programme?

Thank and debrief

Appendix 14: Participant Flow Chart

