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PeRsonAlised Community based TelerehabIlitation post StrokE to increase rehabilitation time and improve motor recovery: a feasibility study (PRACTISE)

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Study Title

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Sponsor

Glasgow Caledonian University.

Introduction

Stroke affects around 100,000 people in the UK each year, is the leading cause of disability and the fourth leading cause of death in the UK (SSNAP, 2022). The first six months after stroke is the optimum time for neuroplasticity and recovery and therefore a critical period for rehabilitation (Lee et al., 2015). Exercise post-stroke needs to be repetitive, task-specific and high-dose to optimise motor and functional recovery (Veerbeet et al., 2014, Klassen et al., 2020). The recent National Clinical Guideline for Stroke recommends patients should receive at least three hours a day of multidisciplinary therapy at least five days week (NICE, 2023, Stroke Guidelines, 2023). Delivering this dose of therapy in community settings is challenging (e.g., waiting lists, therapist availability) and around 40% of stroke survivors are discharged home without any further rehabilitation (Stroke Association, 2023) and thus receive sub-optimal levels of therapeutic rehabilitation. Therefore, alternative models of rehabilitation are required.

Telerehabilitation, recommended by the new Stroke Guidelines, has the potential to address the issues of sub-optimal levels of therapeutic care by offering access to specialist services, reducing transport requirements/costs (therapist and patient), whilst allowing for personalisation services, increased dose of therapy and enhanced monitoring (English et al., 2022). The Telerehabilitation platform, Giraffe allows therapists to provide personalised, video-based exercise programmes and with an inbuilt exercise diary. Previous research has shown the feasibility of the Giraffe platform to augment upper-limb physiotherapy at the in-patient stage of stroke rehabilitation (30mins of additional therapy, up to five times/week) and found the intervention to be feasible, safe and acceptable to patients, carers and Physiotherapists (Paul et al., 2019, Alhusayni et a., 2023). Goal setting is a central and recommended component stroke rehabilitation practice. The Goal setting and Action Planning (G-AP) framework is a theory- and evidence-based method, developed by one of our team, to support stroke survivors to consider, plan, and work towards their goals collaboratively with rehabilitation staff (Scobbie et al., 2011, Scobbie et al., 2013). Evaluations of G-AP in community stroke rehabilitation settings found it was acceptable to staff and people in their care, feasible to implement in practice and helpful in the setting and pursuit of person-centred goals (Scobbie et al., 2020, Brown et al., 2013). Supported self-management is advocated for within national clinical guidelines and current stroke policies (NICE, 2023, Stroke Guidelines, 2023). It's an approach designed to help stroke survivors to regain their confidence to manage the impact of their stroke and live their lives well after a stroke. The IMPETUS study showed that supported self-management helps to improve stroke survivor's quality of life, confidence, independence and helps people to adopt lifestyle changes that reduce their risk of secondary stroke (Kidd et al., 2022, Duncan Millar et al., 2022).

The PRACTISE intervention is based upon the use of telerehabilitation (Giraffe platform) incorporating evidence-based behavioural change techniques, with the addition of an evidence-based approach to support patients to set and pursue their personal goals (the Goal setting and Action Planning framework) and support for therapists to build trusted and supportive relationships for self-management (IMPETUS study). Therefore, the aim of the PRACTISE physiotherapy programme is to empower participants start to take control of their own personal rehabilitation needs outside of appointments. Progressing individuals towards the volume of therapy recommended by National Clinical Guideline for Stroke for optimal recovery benefits.

Introduction study aims and objectives

The aim of our research is to test a 16-week community, home-based physiotherapy programme (PRACTISE) to improve the amount of therapy exercise a stroke survivor does, therefore improving the outcome and reducing the level of disability. Prior to undertaking a definitive randomised controlled trial (RCT) to determine clinical and cost effective compared to usual care, this feasibility study will explore uncertainties about the intervention and trial processes.

The objectives of this feasibility study are to:

- Gather data on the number of participants screened, consented, retained, withdrawn (and reasons why) to determine eligibility and recruitment strategy for a future RCT.
- Explore factors related to Equality, Diversity and Inclusion (EDI) (i.e. disability, age, sex, socioeconomics, ethnicity, cognition, IT access/skills) in relation to study recruitment and retention.
- Evaluate the delivery of the PRACTISE intervention to allow refinement as necessary.
- Assess intervention fidelity, adherence and acceptability for people with stroke, carers and physiotherapists.
- Determine suitability of the primary and secondary outcomes for a future RCT.
- Gather outcome data to inform the sample size calculation required for a future RCT.
- Develop and test instruments to collect data on resource use and costs for a future economic evaluation.

Study Design

This is a pragmatic feasibility RCT with blinded outcome assessment and embedded process evaluation. It will involve TWO / THREE clinical sites: NHS Greater Glasgow and Clyde and Forth Valley (other could be, Lothian, Tayside) all of which have urban and rural communities and socioeconomic diversity.

Study overview

Study procedure – Intervention

The PRACTISE intervention is a 16-week personalised physiotherapy programme, delivered via in person and telerehabilitation appointments. Participants randomised to the intervention group will receive the PRACTISE intervention which in addition to usual physiotherapy assessment and exercise prescription incorporates: 1) Personalised online exercise programme delivered through the Giraffe platform; 2) Goal setting and Action Planning (G-AP); and 3) Supported self-management approaches. All of which are described in detail below (intervention content).

The PRACTISE intervention consists of nine appointments with the treating physiotherapist. The first five of these appointments are delivered face-to-face in the participant's home (Figure 1). These are delivered in Week-1 (2 x appointments), and Week's-2, -3, and -4. The remaining four appointments (Weeks-6, -8, -12, and -16) are delivered remotely via either telephone or the virtual conferencing system, Near Me. Approved for use by NHS Scotland, Near Me is a video consulting service that enables people to have health and social care appointments from home or wherever is convenient. If there is a clinical need, the 6th appointment (delivered in Week-6) can be delivered in person rather than online.

In Weeks-5, -7, -9, -10, -11, -13, -14, -15 participants will not receive any direct care from the physiotherapist. However, the physiotherapist will have prescribed rehabilitation exercises to the participant in conjunction with their own self-management plans and will remotely review the participants exercise diary each week, amending the programme remotely as indicated.

Those in the intervention group will receive usual care from their other rehabilitation professionals such as Occupational Therapists and Speech and Language Therapists and in addition any other physiotherapy which is not exercise related e.g. injection for shoulder joint pain.

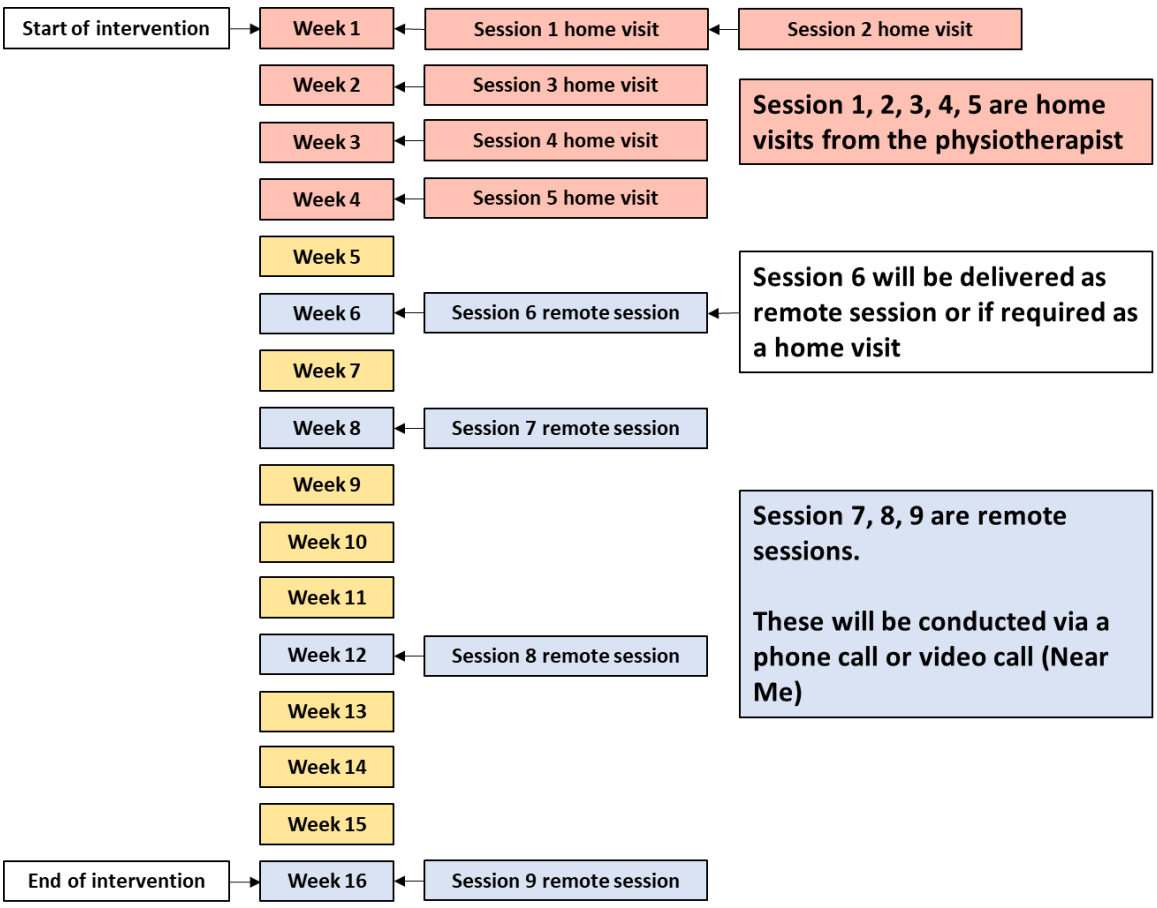


Figure 1. visual representation of the structure of the PRACTISE intervention showing the physiotherapy sessions

<u>Intervention content and delivery</u>

PRACTISE will be delivered by trained Physiotherapists. It is important to note that the PRACTISE intervention is not asking physiotherapist to deliver a new treatment or medication. It is more a restructuring of a delivery approach. A PRACTISE appointment will consist of usual physiotherapy assessment and exercise prescription, further incorporating: 1) Personalised online exercise programme delivered through the Giraffe platform; 2) G-AP; and 3) Supported self-management approaches. Participant will receive a PRACTISE workbook which will guide them through the intervention. This comprises a background to the study, weekly contacts points, goal setting and self-management reading and reflection activities. This workbook has been co-produced with people with lived experience of stroke.

In the first appointment, the treating physiotherapist will complete their assessment and provide relevant treatment based on their clinical judgment (inclusive of the Canadian Occupational Performance Measure), and patient notes. The participant and physiotherapist will agree goals and action plans (G-AP) that are important to the individual. The participants subsequent physiotherapy programme will be based on these goals, and may include e.g., facilitated movement, balance work, functional activity etc. The participant will have a personalised exercise programme set up on the online exercise platform (Giraffe) where they will be asked to complete their exercises as prescribed and to record the exercises completed in the online diary. The participant may be asked to consider some self-management self-learning before the next session. Subsequent appointments will follow a similar pattern of; 1) Physiotherapist visits the participant at home or conducts a remote appointment; 2) clinical review is conducted, and any relevant physiotherapy treatment is undertaken; 3) exercise diary, goals and action plans and supported self-management activities are collaboratively reviewed, discussed and adjusted, as indicated, to optimise motivation and ongoing practise. Between sessions with the physiotherapist, participants will be asked to conduct self-practice of their personalised exercise programme on the Giraffe platform, up to five days/week.

The Giraffe platform has been co-developed with patients and is an innovative, evidence-based, not-for-profit telerehabilitation platform (www.giraffehealth.com). The platform allows therapists to provide personalised, video-based exercise programmes and with an inbuilt exercise diary to allow recording of exercise progression. Therefore, as part of the PRACTISE study, Giraffe will be used as the online exercise programme with part personalised online exercise programme, delivered and recorded through the platform five times per week. The physiotherapist will access the participant's online exercise diary for review and modification.

The Goal setting and Action Planning (G-AP) framework has been developed to support person-centred, goal-setting practice in rehabilitation settings. It involves working in partnership with participants to agree specific and meaningful goals, developing action plans to achieve these goals and supporting ongoing goal pursuit, attainment and (if necessary) adjustment. Physiotherapists will utilise G-AP to facilitate appropriate goals to help manage participants rehabilitation progress allowing participants to set their own goals and manage their rehabilitation. The aim of G-AP is to empower participants with the skills to create personal goals; establish actions plans that lead to the goal; identify potential barriers; and coping plans. Therefore, when there is less direct oversight from the physiotherapist as the intervention progresses, participants have the self-efficacy and mastery to still engage their rehabilitation.

The supported self-management component involves strategies support participants to achieve their goals and build their self-management skills e.g. integrating therapy into their daily life and dealing with barriers. Supported self-management is a collaborative discussion and mutual understanding between physiotherapist and participant to help people to develop the skills and confidence to self-manage well. Conversations with therapists will be supplemented with educational awareness components via a participant workbook that will support the participant with strategies to achieve their goals and build their self-management skills e.g. how to integrate therapy into their daily life, dealing with barriers, identifying social support networks.

Study procedure - Control

Participants randomised to the control group will receive usual multi-disciplinary rehabilitation from their care team (e.g., physiotherapist, Occupational Therapists, Speech and Language Therapists) as per their NHS Health boards care plan. Usual care, in the context of this study is defined as routine or standard treatment and care that an individual would typically receive. Usual care in the context of stroke may differ between individuals based on their symptoms. Typical individuals will be seen clinical by physiotherapists, Speech and Language Therapists or Occupational Therapists. Usual care will be recorded (described below) as part of the study.

Participants

Inclusion criteria

There will be three different sets of participants.

1. Individuals who have experienced a stroke.
2. Carers or family members of individuals who have experienced a stroke.
3. Treating physiotherapists who will deliver the PRACTISE intervention.

1. Individuals who have experienced a stroke.

Inclusion criteria:

- Over 16 years old
- Within THREE months of first stroke
- Requiring community physiotherapy and discharged home from in-patient care
- Scores 2-4 on the modified Rankin Score on discharge
- Able to use a computer/tablet or mobile phone with/without help from carers' (participants who lack digital connectivity skills/ Products will be assisted through AbilityNet)
- Able to understand/communicate in English
- Capacity to provide informed consent

Exclusion criteria:

- Participating in another physical interventional research study
- Discharged to a nursing home or other long-term care facility
- Absolute contra-indication to exercise

2. Carers or family members of individuals who have experienced a stroke.

Inclusion criteria:

- Significant other/carer of an individual who is part of the PRACTISE study either as a control participant or as an intervention participant
- Over the age of 16 years
- Able to join and contribute to an interview, either in-person or via a video conference platform, in English.

3. Treating physiotherapist who will deliver the PRACTISE intervention.

Inclusion criteria:

- UK-based Physiotherapist who has delivered the PRACTISE intervention

- Able to join and contribute to an interview via video conference platform or in person
- Over the age of 18 years

Sample sizes

The study aims to recruit 60 participants who have experienced a stroke, up to 60 carer/significant and up to 15 treating physiotherapists.

Individuals who have experienced a stroke.

This study aims to recruit 60 participants who have experienced a stroke. 30 participants will be randomised to the intervention, with 30 participants randomised to the control. An equal split of participants will be recruited to control and intervention arms across sites.

14 (10 intervention and 4 control) individuals who have experienced a stroke and have taken part in the study will be recruited to take part in interviews to assess fidelity, acceptability and adherence of the study. Maximum variation sampling will be employed taking into consideration factors such as the site, sex, level of disability.

Carers or family members of individuals who have experienced a stroke.

The study aims to up to 60 carer/significant other of the consented stroke participant. They will also be invited to take part and complete the Caregiver Strain Index (CSI).

14 participants from this group (10 intervention and 4 control) will be recruited to take part in an interview to assess fidelity, acceptability and adherence. Maximum variation sampling will be employed taking into consideration factors such as the site, sex, level of disability of their significant other.

Treating physiotherapist who will deliver stroke rehabilitation care.

The study aims to recruit up to 15 treating physiotherapists who will deliver the intervention arm of PRACTISE. They following therapists will be invited to take part in an interview and recording of sessions to assess fidelity of the delivery.

Recruitment, consent and randomisation

Recruitment and consent

It will be clearly stated to all sets of participants, that they are free to withdraw from the trial at any time for any reason without prejudice to future care, without affecting their legal rights and with no obligation to give the reason for withdrawal.

Individuals who have experienced a stroke

Individuals who have experienced a stroke and currently receiving care as an inpatient will be approached by a Research Nurse, a member of the clinical team or a member of the study team (e.g., Study Co-ordinator). The Research Nurse, a member of the clinical team or a member of the Study team will give potential participants a Participant Information Sheet's (PIS) and will answer any questions they might have. Participants will be given at least 48 hours to consider participating in the study. The Research Nurse, a member of the clinical team or a member of the study team will then take informed consent from participants when they are close to discharge. If participants have capacity to give verbal consent, but lack physical capability to sign consent forms, a carers or family member of individuals can provide written consent. Individuals who have experienced a stroke will be asked to provide informed consent for the main study and asked if it is okay to be approached towards the end of the study period to take part in the

process evaluation interviews. The Study Co-ordinator will approach those who agreed to be approached to take part in interviews towards the end of the 16-week study period. The Study Co-ordinator will recap the PIS, answer any questions, allow 48 hours of consideration before taking informed consent for interviews.

Carers or family members of individuals who have experienced a stroke

If appropriate, carers or family members of individuals who have consented to take part in PRACTISE will be approached initially by the Research Nurse, a member of the Clinical team or a member of the Study team when they are visiting their significant other as an inpatient. The Research Nurse, a member of the clinical team or a member of the study team will explain the caregiver strain index component of the study to the individuals and provide them with a PIS. Carers or family members will be asked to provide informed consent for the caregiver strain index. On this consent there will be a line asking if it is okay to be approached at a later date to be asked about taking part in a process evaluation interview. If it has not been appropriate for the Research Nurse, a member of the clinical team or a member of the study team to consent the significant to the caregiver strain index component of the study (e.g., due to timings or lack of presence of significant other), this task will be completed by the Study Co-ordinator. The Study Co-ordinator will approach consented stroke survivors and inform them of the caregiver strain index component of the study and ask the stroke survivor to inform their main carer-giver of this element of the study. The study Co-ordinator will follow the same process as the Research Nurse would have; providing a PIS, allowing time for questions and for the participant time to think over their choice and being asked if they are happy to be approached later in the study for an interview.

Individuals who have provided consent to be approached to be informed about the process evaluation interviews will be consented by the Study Co-ordinator. The Study Co-ordinator will approach those who provided consent to be approached, towards the end of the study. The Study Co-ordinator will provide the PIS, answer any questions, allow 48 hours of consideration before taking informed consent.

Treating physiotherapist who will deliver stroke rehabilitation care

The Study Co-ordinator will approach the known treating physiotherapist via site contacts and provide potential participants a PIS. They will answer any questions they might have and allow 48 hours to consider participating in the study. The Study Co-ordinator will then take informed consent from participants that they are happy to deliver the PRACTISE intervention, have some of these sessions recorded to assess intervention fidelity and to take part in a process evaluation interview. Treating physiotherapist will be invited to provide age, ethnicity, sex, grade / band, years of experience in working in stroke rehabilitation.

Randomisation

The Research Nurse will inform the Study Co-ordinator when a consented individual who has experienced a stroke, is discharged home. At this point, the Study Co-ordinator will inform the Centre for Healthcare Randomised Trial, University of Aberdeen that a participant at a site has been consented. Here the participant will be randomised 1:1 via a web-based remote randomisation system to the intervention or control group and stratified by centre. The Study-coordinator will inform the site if the participant is control or intervention.

Data collection measurements and collection points

Participant demographics

For individuals who experienced a stroke, the Research Nurse, a member of the clinical team or a member of the study team will collect participant demographic data from the participants medical notes at the point of consent. Data to be collected are age, sex, ethnicity, highest level of education, first half of

postcode. In addition, stroke details will be recorded, date of stroke, stroke type, sub-type and location and co-morbidities (Charlson comorbidity index). The Charlson comorbidity index will be used to record co-morbidities but not used to predict mortality. In terms of screening the Research Nurse will record the Modified ranking Scale (mRS) which is a single item global outcomes rating scale of functional independence which ranges from 0 – no symptoms to 5 - Severe disability. If not available from the participants medical notes the Research Nurse will also complete the Oxford Cognitive Screen (OCS). The OCS is a stroke-specific and domain-specific cognitive screening tool which can be delivered at the bedside in acute stroke. The OCS is easy to administer and score and importantly is inclusive for patients with aphasia and neglect. The OCS domains assessed are Language, Praxis, Number, Memory, Spatial and Controlled Attention. Figure 2 provides a visual representation of data collection point.

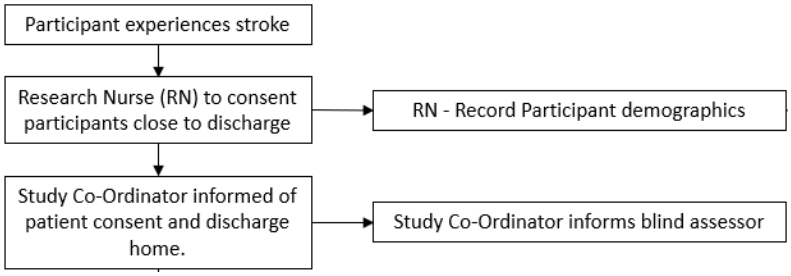


Figure 2: Diagram of main collection point for Research Nurse for Individuals who have experienced a stroke in the control and intervention arms.

Clinical outcome measures

An Assessor, blind to the group allocation, will visit participants home on four occasions (prior to the start of the intervention, Week's– 8, -16 and Week-24 which is a 2-month follow up) and carry out practical and written assessments. (see figure 3) for individuals who have experienced a stroke. To reduce potential assessment burden, written assessments will be completed out with the assessment session; completed online via Microsoft forms or posted out to participants ahead of the session, depending on preference, allowing a few days for them to be completed before the assessor visit. If the participant is unable to complete the questionnaires independently, they can be assisted by a carer/significant other, or the assessor during the assessment visit.

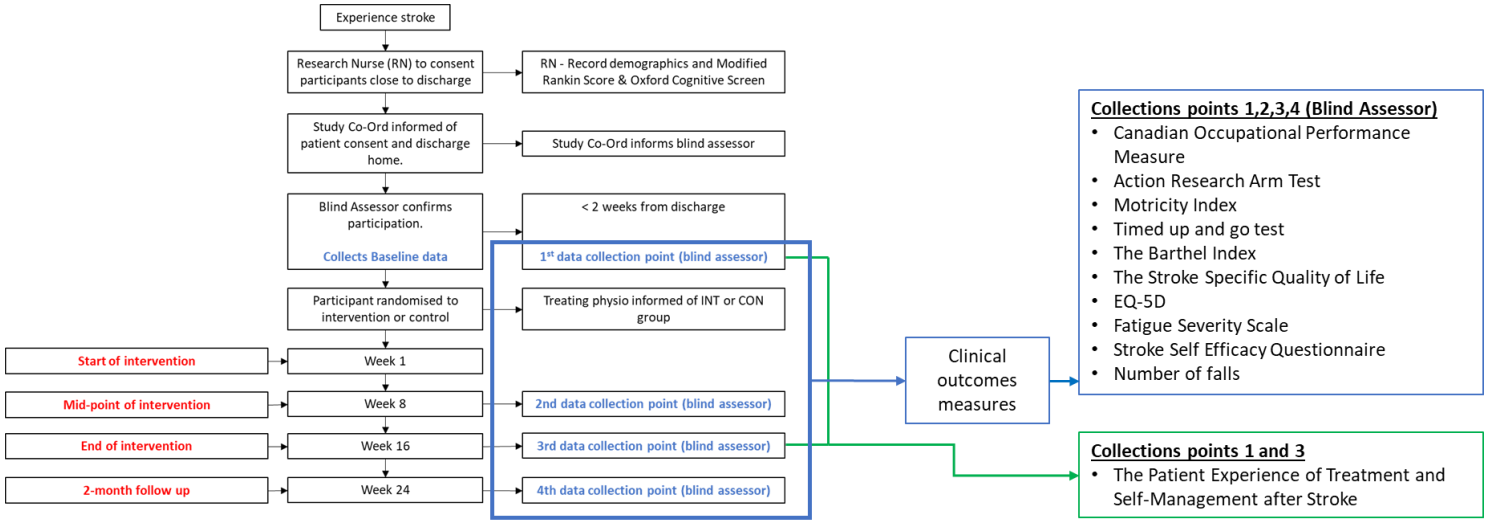


Figure 3: Diagram of clinical outcome measurement collection points.

At each collection point the assessor will collect data on the following measurements:

Canadian Occupational Performance Measure:

In the Canadian Occupational Performance Measure (COPM) the participant identifies up to five problems they face in self-care, productivity and leisure. They then prioritise the activities and rate their current level of performance and satisfaction with each. The COPM is generally a reliable, valid, and acceptable tool for researchers with satisfactory test-retest reliability specifically in stroke. COPM results will be given to physiotherapist of intervention participant. This will allow discussion between the participant and physiotherapist to agree specific, and meaningful goals using the G-AP framework.

Action Research Arm Test:

The Action Research Arm Test (ARAT) is a 19-item measure with 4 sub-tests (grasp, grip, pinch, and gross arm movement) each item scored on a four-point scale from 0 (can do no part of the test) to 3 (performs the test normally). Subjects are first asked to perform the most difficult task within a subscale. If a subject performs the task adequately with normal movement, they are scored a 3 on this item and all remaining items within that subscale. A score between 0-2 on the first item suggests that the second task (least difficult) must be evaluated. Subjects scoring 0 on the second task item are unlikely to be successful on subsequent scale items and are scored 0 for remaining tasks within a category. Remaining moderate level tasks within a subscale are thus not evaluated. Otherwise, all test items within a category must be performed. Consequently, subjects may be asked to perform anywhere from 4 tasks to 19 tasks depending on their performance. Scores on the ARAT may range from 0-57 points, with a maximum score of 57 points indicating better performance. There is no cut off scores as this assessment is continuous and based on a subject's observed mobility. The ARAT can be used to predict the functional recovery of the upper extremity in stroke rehabilitation. Scores of less than 10 points, between 10-56 points, and 57 points correlate with poor, moderate, and good recovery respectively.

Motricity Index:

Motricity Index assesses motor impairment and muscle strength of the upper and lower limbs and involves three upper limb activities; shoulder abduction, elbow flexion and pinch grip and three lower limbs; hip extension, knee extension and ankle dorsiflexion. The maximum score is 100 for the upper limb and for the lower limb. These scores are then added together before being divided by 2 for a final score of 0-100 for the test. The test has excellent reliability and excellent reported construct and concurrent validity.

Timed Up and Go test:

Timed up and go test (TUG) assesses mobility, balance, walking ability, and fall risk. The participant stands from a chair, walks 3 metres at a comfortable pace, turns around, walks back to the chair and sits down. The time to complete the test is recorded and walking aids are used as required. The test will be conducted three times with the average score being calculated and used as the final measure.

The Barthel Index:

The Barthel Index is a patient reported outcome of the ability to perform 10 activities of daily living (ADL), with each activity scored out of 10, with a maximum of 100. The Barthel Index scale demonstrates good reliability and sensitivity to changes in ADL ability. The modified Barthel Index can predict instrumental ADL performance at 6-months post-stroke, including the likelihood an individual will achieve continence after a stroke, falls risk in individuals after stroke, functional recovery after stroke, length of stay in acute care after a stroke.

Written assessments can be sent (mail or electronically) to participants beforehand. If deemed appropriate the assessor can complete them with the participant at the visit. Or they can be completed before the visit and collected by the assessor. The written assessments include:

The Stroke Specific Quality of Life:

The Stroke Specific Quality of Life questionnaire consists of 49 items each assessed on a 5-point scale. The domains covered include mobility, energy, work and productivity, mood, self-care, language, thinking and personality. Scores range from 49 to 245 with higher scores associated with higher quality of life.

EQ-5D-5L:

EQ-5D-5L evaluates health-related quality of life with one question for each of the five dimensions mobility, self- care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 score levels: 1) no problems, 2) slight problems, 3) moderate problems, 4) severe problems and 5) extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. While a score of 11111 indicates no problems across the five dimensions, a score 55555 would indicate extreme problems across all dimensions. The EQ VAS records the patient's self-rated health on a vertical visual analogue scale where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The VAS will be used as a quantitative measure of health outcome that reflects the patient's own judgement with higher scores indicating higher perceived health.

Fatigue Severity Scale:

Fatigue Severity Scale is 9-item scale, that is self-reported by participants. The scale measures the severity of fatigue and its effect on a person's life against 9 statements. Each item is scored on a scale of 1 (strongly disagree) -7 (strongly agree). Scores range from 9 to 63 with higher scores indicating more severe fatigue.

Stroke Self Efficacy Questionnaire:

Stroke Self Efficacy Questionnaire (SSEQ) is a self-report scale of self-efficacy post stroke that demonstrates good internal consistency and criterion validity. It is a 13-item patient reported outcome where participants rate their confidence with stated tasks from 0 not at all confident to 10 very confident. The SSEQ total score can potentially range from 0 to 130 with higher scores indicating higher levels of self-efficacy.

The Patient Experience of Treatment and Self-Management after Stroke (week 0 and week 16 only):

The Patient Experience of Treatment and Self-Management was developed to measure treatment burden in people with multi-morbidity and/or complex self-management regimens. However, it omits stroke-specific burdens. Therefore, the Patient Experience of Treatment and Self-Management after Stroke (PETS-STROKE) PETS-STROKE is a 34-item patient reported measure that captures the workload of healthcare and impact on wellbeing experienced by the stroke survivor.

Number of falls

The number of falls since the previous assessment will be self-reported, with a fall defined as 'an unexpected event in which the participant comes to rest on the ground, floor or lower'. As the intended outcome of the intervention is to increase functional activity this may increase risk of falls.

Burden outcome measure

Recruited carers/significant others will be asked to provide contact information to facilitate delivery of assessments. Additionally, they will be invited to provide age, sex, relation to the stroke survivor, employment, ethnicity, highest level of education.

They will be asked to complete the Caregiver strain index (CSI) at each of the four assessment points (Base line data collection point, Week-8, Week-16 and Week-24). This is a written test and will be sent to participants either via post or electronically or completed when the Assessor is visiting. The CSI is a 13-item questionnaire which assesses the level of stress experienced by informal caregivers, answered with - Yes (2), Sometimes (1) or No (0). The maximum score is 26.

Adherence/dose-response measure

Care delivered by physiotherapists, occupational therapists and speech and language therapists, for both groups will be recorded by the therapist using a short checklist which will be either in the PRACTISE workbook for the intervention or in a separate folder for the control group. This will include, date of appointment, duration of appointment, who the appointment was with (e.g., physiotherapist, speech and Language), and content via a checklist of usual care interventions. This will be completed for each therapy appointment

Exercise diaries will be completed by participants either in the Giraffe platform (intervention) or paper (control). This information will be used to determine the weekly dose of exercise from which dose/response will be calculated for the clinical outcomes.

Feasibility outcomes measures

Data from screening, recruitment and follow-up logs will be used to generate realistic estimates of eligibility, recruitment, consent and follow-up rates, reasons for drop-out and adverse events. Outcome measure completion and missing data will also be recorded. Figure 4 provides an overview of type of feasibility outcome measure and where the data will be collected. Research Nurses will record data on number potentially eligible participants; number approached, number declined (reason why) and number consented. This will be recorded and held locally and communicated to the Study Co-ordinator. The Blind Assessor at appointments will record data on number started, declined (since initial consent), number of dropout (when & reason why), number and type of adverse events and number complete. In conjunction with the Blind Assessor and via clinical outcome measures, the Study Co-ordinator will record quality and quantity of outcome measures and any missing data.

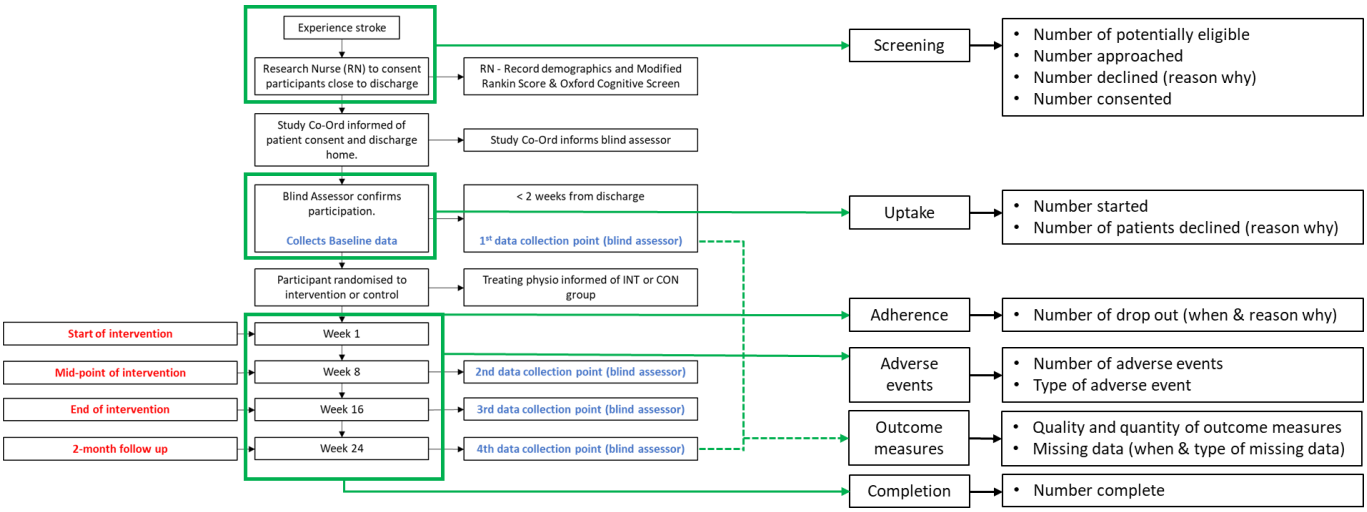


Figure 4: Diagram of data collection points and type of data to assess feasibility outcomes.

Process evaluation

To understand fidelity of PRACTISE, 20 audio recordings of PRACTISE sessions between a physiotherapist and a participant will be made. This will include 5 on session-1 (week 1), 5 on session-5 (week 4), 5 on session-6 (week 6) and 5 on session-9 (week 16) (Figures 1). Physiotherapists will record these sessions via a Dictaphone. Equal representation will be sought across site locations.

Interviews will be conducted to assess fidelity, acceptability and adherence. Interviews will be conducted with 1) individuals who have had experienced a stroke, 2) carer or significant others and 3) treating physiotherapist. These will be conducted after the 16-week intervention period for individuals who have experienced a stroke and for carers or significant others. Therapist interviews will be conducted when their involvement in the study is complete.

Economic outcome measures

The economic analysis will focus on the feasibility and acceptability of collecting resource use and Quality of Life (EQ-5D- 5L as described above) data required to conduct a full economic evaluation in a future trial from a healthcare and societal perspective. It will also evaluate the feasibility of collecting data to inform any environmental impact of online versus in-person rehabilitation post-stroke (e.g., carbon footprint of streaming versus travel to clinical services). Item completion rates will be presented to assess data completeness. Data on the delivery of the PRACTISE intervention and usual care will be recorded by health care professionals during appointments with individuals who have experienced a stroke (described above).

Individuals who have experienced a stroke (control and intervention) will be asked to document resources accessed and purchased in a record book on a weekly or as required basis during the 16-week period via a structured survey. This will include any planned and/or unplanned healthcare contacts in the last week (which services, frequency, and if related to their stroke), any new medication to treat their stroke or stroke symptoms (prescribed and over the counter), and any equipment purchased for rehabilitation. Travel time to attend face-to-face physiotherapy appointments, associated costs (e.g., parking fees), and carer/companion time spent assisting with rehabilitation (including attending appointments) will also be recorded.

Data on intervention device use (devise type, e.g., smart phone) and access (internet connection costs) will be collected for participants on the intervention arm. The Giraffe platform will record minutes of accessing online content for each participant. Participants will record any assistance required from carers/friends when using the online content. The participant will record the duration of any difficulties in accessing the Giraffe content, and frequency of technical support services utilisation.

Participants without digital skills or capabilities to access the Giraffe platform will receive assistance from the AbilityNet charity via referral by the Study Co-ordinator. This will allow data collection on number of participants requiring internet access (installation and data), and technical support.

Statistical analysis

The primary outcome of the COPM will be analysed in two ways. Firstly, we will analyse the 24-week COPM data and estimate the between group mean from an ANCOVA model adjusting for baseline COPM and design covariates. To gain extra precision, we will analyse the COPM using repeated-measures mixed-effects regression model correcting for baseline score and time as a categorical fixed effect and centre, and participant as a random effect. The repeated measures will be assessed at week 8 and 16 and week 24 (follow-up) with treatment effect, which is the difference in means at each time point, estimated from the time-by-treatment interaction, presented with 95% confidence intervals. The remaining clinical outcomes

will be analysed in a similar manner using a generalised linear model suitable for the distribution of the outcome.

The statistical analysis of the feasibility outcomes will be descriptive.

Analysis of interviews will follow the Framework Analysis Approach and will be managed within Nvivo. Analysis will be informed by Normalisation Process Theory (NPT). Specifically, the four components of NPT (coherence, cognitive participation, collective action, reflective monitoring) will be applied to deepen understanding of implementation for future evaluation. Audio-recordings of therapy sessions will be analysed against checklist of known and anticipated components of the intervention delivery.

Economic Item completion rates will be presented to assess data completeness. Costs will be attached to health care resource use using standardised unit costs where available. Market values for year of data collection will be applied to the costs of the online intervention, over the counter medication, and equipment purchases. Aggregated and disaggregated costs will be descriptively compared between intervention arms. The feasibility of estimating carbon emissions from participant-reported travel times (where private transport was used to access clinical services) and device use will be reported and presented where available data allows.

Study progression

This study aims to conduct a feasibility randomised controlled trial with embedded process evaluation to assess the feasibility of delivering a 16-week, personalised, home-based physiotherapy programme supplemented with telerehabilitation, goal setting, and self-management approaches to increase rehabilitation time and improve motor recovery (PRACTISE). Specifically, this feasibility study will evaluate whether the intervention can be delivered as planned, identify barriers and facilitators to delivery, and offer preliminary insights into its potential to engage participants in their rehabilitation, improve functional outcomes and reduce disability, thereby informing the design of a larger definitive trial. Therefore, progression criteria have been established, with data being drawn from across a spectrum of measures from the study. Appendix 2 provides a detailed overview of the progression criteria from which progression to a definitive trial is based.

Training and development

Physiotherapy staff and Blind Assessors will attend a separate training event with the study team. Physiotherapy staff will be training on the study outline, the key components of PRACTISE and what is expected of them during the study delivery. Training is anticipated to take no longer then ¾ of a day. To prevent study contamination, it is preferable that physiotherapy staff who provide PRACTISE sessions do not see control participants within the study (described below). Therefore, depending on staff availability and numbers vs workload demand of patients, separate training days might be delivered to allow staff to ‘come on board’ to the study at different points. If required, additional training days can be delivered for any new staff who may join the service during the study period.

Blind Assessors will be trained separately to treating physiotherapists. Training will cover the outline of the study for awareness, before introducing Assessors to the outcome measures that will be completed. This will include direction on the order assessments are to be completed, including documentation to record assessments. Assessors will also be trained on how documents can be securely transported to the study team.

Ethical and logistical considerations

After approval from The School of Health and Life Sciences Ethics committee at Glasgow Caledonian University, this will be submitted to NHS (west of Scotland) ethical approval board and relevant Health Board Research and development Departments. Ethical and logistical considerations are addressed below.

Participant consent.

Consent of participants will be completed either by a Stroke Research Nurses, a member of the in-patient clinical team, or a member of the study team (e.g., study co-ordinator). The Stroke Research Nurse or a member of the clinical team working within in-patient services will approach stroke survivor and make them aware of the study. Research Nurses / member of the clinical team will use their clinical judgement on the appropriate time to approach relevant patients who may be become eligible participants for the study. If due to staff constraints a Research Nurse / member of the clinical team is not able to take consent, a member of the study team (e.g., study co-ordinator) who will have a research passport for the NHS site will take guidance from the clinical team on who might be eligible to be approached. Either the Study Co-ordinator, the Research Nurse or a member of the clinical team will explain the study and answer any questions and leave at least 48hrs before taking consent. Aphasia friendly versions of information sheets and consent forms will be available for any participants that may have communication difficulties as a result of their stroke. If a participant lacks physical capabilities to sign a consent form, but is still able to provide informed consent, a significant other can sign on their behalf.

Research Burden

Due to the nature of the feasibility trial there is a large volume of data being collected. Stroke survivor participants will receive visits from an assessor at four points across the study and be asked to complete both physical and written outcome assessments. Every effort will be made to reduce the burden on an individual stroke survivors time around these time points. For example, stroke survivors can complete written assessments at a different time to practical assessment. The research team will send relevant written assessments ahead of time to be completed prior to assessor visits if appropriate.

Written instructions on assessments provide guidance on the estimated time an assessment will take to complete allowing participants prior knowledge of the commitment required. Instructions further state that assessments do not need to be completed in one go and breaks can be taken. Lastly, instructions also state that assistance from a significant other to complete the form is permitted.

Stroke survivors will also be invited to share their views in an interview after the study has ended. Participants will be made aware that not opting into the interviews or recording of appointments for fidelity will not exclude them from participating in the main study component.

Significant others who are participants will be made aware that if they opt not to complete any aspect of the study (interviews or care giver strain index) it will not influence their significant others participation in the study. Similarly, significant others also are consented at separate times for their two elements (interviews or care giver strain index), allowing them to choose what they commit to.

Confidentiality:

The Research Nurse team, member of the Clinical team or member of the study team (e.g., study Co-ordinator) will collect names of participants during the consent process and their contact details to facilitate future research and assessor visits. These data will be recorded separately from data recorded the Case Report Form (CRF), on which only anonymous data will be recorded. Only the study team will have access to these data. Only individuals who will see a participant as part of their care, e.g, NHS staff

members, or those involved in collecting data (e.g., blind assessor and study co-ordinator when undertaking interviews) will know the name of a person to facilitate visits. No other member of the study team will have access to personal data.

Participants will be anonymised after randomisation. The study team will adhere the United Kingdom Data Protection Regulation (UK GDPR), tailored by the Data Protection Act 2018, and with GCU's data security guidelines. For analysis, paper records will be transcribed into MS documents (e.g., word, excel) and saved on Glasgow Caledonian University secure OneDrive storage. Anonymous data will be stored on OneDrive for 10 years, after which it will be deleted and CRFs will be shredded as confidential waste.

Data storage and transfer

Personal data and special category health information will be collected as part of the study. All participants will be made aware of legal basis that the data is being collected under. Research Nurses, a member of the study team or a clinical team member who completes consents and takes demographics will initially be completed on paper forms. If consent is completed by a member of the study team they will be taken straight back to Glasgow Caledonian University for storage in locked cabinets within a lockable room. If a Research Nurse or member of the clinical team takes consent and demographics, they will be stored in accordance with local NHS policies and procedures. That is kept in locked filling units. The Research Nurse or member of the clinical team will then scan a copy of the paper documentation and password protect the document. The document will then be sent via secure encrypted email to a study email inbox, which only the study co-ordinator and chief investigator have access too. This prevents the data being misplaced in a personal email inbox or being sent to person with a similar sounding name. Encrypting an email message in Microsoft Outlook means it's converted from readable plain text into scrambled cipher text. Only the recipient who has the private key that matches the public key used to encrypt the message can decipher the message for reading. Any recipient without the corresponding private key sees indecipherable text. An alternative option will be for local NHS staff to enter relevant details into the research software, REDCap. REDCap is commonly used within clinical trial studies as a medium of transferring data between research sites. REDCap is a secure web application for building and managing online surveys and databases. REDCap is specifically geared to support online and offline data capture for research studies and operations.

Similarly, Blind Assessors will also follow the same process when collecting anonymised data from one of the four assessment points. This would allow the Research Nurse, member of the clinical team or Blind Assessor to send participant consent and relevant information to the study team securely.

Data collected from recordings of sessions or interviews to assess fidelity and process evaluation will be completed via an encrypted Dictaphone audio-recorder (e.g., Olympus DS-9500 which uses AES-256 key encryption). The encrypted recorder will make use of Advanced Encryption Standard (AES). The most secure version of AES, AES-256 uses a 256-bit key and is virtually immune to brute-force attacks with current technology. AES-256 is widely used in sectors requiring top-level security, like healthcare and financial services. In addition to the 256-bit encryption the device will also make use of a 4-digit PIN lock, adding an extra layer of protection by restricting access to the device itself. All recordings will be removed at the earliest opportunity and recordings will be deleted from the device after transfer.

All data from the study once in the possession of the Study team at Glasgow Caledonian University will be stored in accordance with the Universities data security and data protection/GDPR legislation. Any paper copies of documents or study material will be stored within a locked storage unit, within a lockable room. Paper copies will be scanned into GCU secure Microsoft OneDrive storage. All computer files will be stored within password protected folders within Microsoft OneDrive storage. Storage of personal and research data in will be in separate locations to prevent any potential data cross contamination. All research data will be anonymised.

Staff treating control participants

Prior to delivering PRACTISE appointments, Physiotherapy staff will undergo training in the online telerehabilitation platform, Giraffe, G-AP and approaches to support self-management. In order to prevent study contamination, those physiotherapists trained to deliver PRACTISE will be asked not to treat any control PRACTISE study members. This might create logistical scheduling around staffing. However, the study will not prevent this happening if no suitable alternative is available. The study team will be made aware if a PRACTISE trained physiotherapist treats a control participant. While control participants will not have access to the telerehabilitation platform, the PRACTISE manual or the G-AP paperwork for self-practice it will get noted and taken into consideration for analysis.

Blind Assessor aware of intervention arm

Participants and treating Physiotherapist will not be blinded to the group allocation. They will be requested and reminded to not tell the Assessor which arm they are in. However, if they Assessor is made aware by accident, they will be requested to inform the Study Co-ordinator of this. This will be annotated in the findings (e.g., when they were made aware) as a limitation and be considered for statistical investigation on potential bias to occur. The therapists involved in delivering the PRACTISE intervention will not deliver therapy to participants in the control arm of the study to avoid contaminating the interventions received.

Lone working

The Blind Assessor or any members of the study team visiting participants in their home to conduct assessments or interviews will be asked to follow the NHS sites lone working policy. This will include checking in with the Study Co-ordinator prior to and after the completion of a visit. In any situation where an induvial is operating alone and feels unsafe, they must remove themselves from that situation immediately and report the incident. In any situation where an any individual associated with the study or volunteer is operating alone and an incident (e.g., accident, fire, health emergency (this is not exhaustive)) occurs, this must be reported as soon as possible. If an assessor feels there is a need to report any concerns around the participant, they will do this through the NHS community Physiotherapy team who have care of the participant.

Risk of falls

Falls will be recorded as adverse events as the intended outcome of the intervention is to increase functional activity which may increase risk of falls. Falls will be specifically monitored and the number and consequence of any falls at each assessment time point will be recorded. Stroke survivor participants will be made aware that their GP will be told that they are a study participant. Subsequently, if there is a situation where participant see's their GP due to a fall, there is an appropriate trail. At all-time points in the study, participants will be under the supervision of NHS community team. If there is a need to withdraw the participant from the study as a result of any fall, this will be discussed in conjunction with the care team and chief investigator.

Participant withdrawal

It will be clearly stated that the participant is free to withdraw from the trial at any time for any reason without prejudice to future care, without affecting their legal rights and with no obligation to give the reason for withdrawal.

During the course of the trial a participant may choose to withdraw at any time. This may happen for a number of reasons, including but not limited to:

- The occurrence of what the participant perceives as an intolerable adverse event.

- Inability to comply with trial procedures.
- The participant's personal decision.

Participants may choose to stop treatment and/or study assessments but may remain on study follow-up.

Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely. Participants can withdraw completely from the study. However, any data collected up until the point of withdrawal may still be used in the study analysis. In addition, the study team / Blind Assessor may discontinue a participant from the study at any time if it is deemed necessary for any reason including, but not limited to:

- Ineligibility (either arising during the trial or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with treatment regimen or study requirements
- An adverse event which requires discontinuation of the intervention or results in inability to continue to comply with trial procedures
- Disease progression which requires discontinuation of the intervention or results in inability to continue to comply with trial procedures
- Lack of cognition to comprehend what the study entails.

If a participant is in the intervention arm of the study, the treating physiotherapist will be made aware. Because the nature of the intervention incorporates usual clinical care, participants will continue to be seen by the physiotherapy service and receive their required care.

Adverse events

Adverse events and Serious Adverse Events will be monitored in both intervention and control groups. It will be left to joint discussion between treating physiotherapist, local PI and Study PI using clinical judgment to decide whether or not an adverse event is of sufficient severity to require the participant's removal from treatment. A participant may also voluntarily withdraw from treatment due to what they perceive as an intolerable adverse event. If either of these occurs, the participant will be given appropriate care under medical supervision until symptoms cease, or the condition becomes stable. Annex 1 provides a detail account of the process for adverse events and serious adverse events.

Data management and storage

Because this is a feasibility trial there is no separate data management group or separate Data Management document in use for the trial. However, a PPIE group and a Trial Steering Committee has been established and will provide governance of the study. Both groups have external members to the project. These groups will meet 5 times over the course of the study and provide independent guidance to the study. This is inclusive of, but not limited to data management concerns, participant safety.

The data controller is Glasgow Caledonian University. Information is being processed on the basis of Article 6(1)(e) of the General Data Protection Regulation to perform a task carried out in the public interest. Additionally for special category data, under GDPR Article 9(2)(j), scientific or historical research purposes or statistical purposes.

Data transfer from NHS sites to GCU will be completed via encrypted and secure electronic mail or the research software REDCap. Data recorded by the Research Nurse or member of the clinical team as part of either screening and recruiting or treatment will be stored locally in the local investigator Site File. These will be stored in accordance with local NHS storage policies. Upon completion, they will be sent to the Study Co-ordinator via a secure transfer in accordance with both the local NHS site policy and that of GCU.

Personal data and special category health information will be collected as part of the study. All participants will be made aware of legal basis that the data is being collected under. The Research Nurse or member of the clinical team will then scan a copy of the paper documentation and password protect the document. The document will then be sent via secure encrypted email to a separate study email inbox, which only the study co-ordinator and chief investigator have access too. This prevents the data being misplaced in a personal email inbox or being sent to person with a similar sounding name. Encrypting an email message in Microsoft Outlook means it's converted from readable plain text into scrambled cipher text. Only the recipient who has the private key that matches the public key used to encrypt the message can decipher the message for reading. Any recipient without the corresponding private key sees indecipherable text. This would allow the Research Nurse or member of the clinical team to send participant consent and relevant information to the study team securely.

Anonymised data collected by the Blind Assessor will be entered directly into a local investigator Site File (Blind Assessor Version) which is in paper format. Where practicable, arrangements will be made for the assessor to directly hand files to the study co-ordinator. Alternatively, scanned documents (password protected) can be sent in via the same encrypted secure Microsoft email to the study Co-ordinator with paper copies stored with the NHS facility under local NHS storage policies.

All data collected by members of the Study Team (e.g., consents, demographics, interviews with participants) will be directly brought back to the University. Here they will either be downloaded from recording devices or transcribed into electronic Microsoft forms on the university's secure electronic file system (Microsoft 365 system) into password protected files.

Data received (paper and electronic copies) from the Blind Assessor and NHS sites will be stored within GCU secure electronic file system (Microsoft 365 OneDrive) or in locked filing storage units in lockable rooms.

On all trial-specific documents, other than the signed consent forms and contact information, the participant will be referred to by the trial participant number/code, not by name. The participants will be identified by a unique trial specific number and/or code in any database. The name and any other identifying detail will NOT be included in any trial data electronic file.

All data will be stored in accordance with GCU data security and data protection/GDPR legislation. The research team will adhere the United Kingdom Data Protection Regulation (UK GDPR), tailored by the Data Protection Act 2018. Anonymised research data will be stored on GCU's One Drive for 10-years, after which it will be deleted. Personal data will be kept only as long as is required to facilitate the study before being destroyed.

GDPR also gives study participants the right to ask for their personal data to be erased. If you would like us to stop using your personal data. Any enquiries specifically relating to data protection should be made to the University's Data Protection Officer (DPO). The DPO can be contacted by email: dataprotection@gcu.ac.uk. If individuals are unhappy with the response from the University, they have the right to lodge a complaint with the Information Commissioner's Office (ICO). The ICO can be contacted by email: casework@ico.org.uk.

Results and publications

Our dissemination strategy will be shaped by our PPIE group, and we will work with the Stroke Association on refining our strategy but would include regular updates through the stroke association (e.g., newsletters) and social media platforms, especially Bluesky, LinkedIn and Facebook which has specific stroke groups. This may include asking Stroke Association, Chest, Heart and Stroke Scotland and National Stroke Voices to post a plain English summary on their websites. We will also work with The Stroke

Association to produce aphasia friendly reports. We will also disseminate to younger stroke survivors by contributing to the Different strokes https://differentstrokes.co.uk/ newsletter. We will host a hybrid engagement event in GCU for stroke survivors and their families, who will be able to join in person or online. We will also look to share findings through clinical networks to ensure stroke therapists and other relevant health care professionals are aware of the findings.

As the funder, The Stroke Association expects that all findings from funded research are published in open access journals and data is deposited in open data platforms. We will ensure publications are publicly available in GCU's research repository PURE (https://www.gcu.ac.uk/currentstudents/essentials/library/research/pure). Data will be deposited in an external repository; OSF (https://osf.io/), which allows researchers to host structured datasets and associated documentation. Datasets in OSF receive a DOI which we will reference in publications, the PURE record and other dissemination activities. Findings will also be shared via academic conferences such as the UK Stroke Forum, European Stroke Organisation Conference or similar conferences.

Conflicts of Interest

Giraffe Healthcare is a not for profit, community interest company which is a start-up company from Glasgow Caledonian University. It was incorporated as a CIC in April 2018 (SC595189). Professor Lorna Paul and Dr Elaine Coulter, applicants on this ethics application are the co-founders of Giraffe Healthcare which was set up following a programme of research within GCU. To ensure it was sustainable a registered company was required so that health care providers such as the NHS could contract directly with Giraffe Healthcare CIC. Giraffe Healthcare has a formal arrangement with Glasgow Caledonian University, where there is no revenue sharing and the intellectual property sits within Giraffe Healthcare however GCU retain rights to use the Giraffe platform for research and teaching purposes.

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Annex 1 Adverse and Serious Adverse Events

Definitions

Term Standard definition

Related

It resulted from administration of any of the research procedures (e.g., directly related to exercise prescription).

Unexpected

The type of event is not listed in the protocol as an expected occurrence.

Adverse Event (AE)

Any untoward medical event affecting a study participant. A medical event that is beyond what is expected after stroke or physiotherapy exercise, non-responsive to simple measures and impactful on activities of daily living and that requires a visit to a primary care health professional (e.g., general practitioner), will be considered an adverse event.

Serious Adverse Event (SAE)

an untoward occurrence that

- results in death
- is life threatening (i.e. the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe)
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- is otherwise considered medically significant by the investigator

Adverse events are not

- continuous and persistent disease or symptom, present before the study, which fails to progress
- signs or symptoms of the disease being studied

Hospitalisations for treatment planned prior to randomisation and hospitalisation for elective treatment of a pre-existing condition will not be considered as an AE. Complications occurring during such hospitalisation will only be considered an AE or SAE if it is related to the study interventions.

Study specific considerations

In this study, all related AEs will be recorded (see above definition of “related”). All serious related AEs will be recorded as SAEs. All deaths (any cause) will also be recorded as SAEs. Furthermore, pre-existing conditions and any pre-planned hospitalisations (e.g. elective surgery) not associated with clinical deterioration will not be classed as Serious Adverse Events.

PRACTISE specific potential adverse and serious adverse events

The PRACTISE study involves a physiotherapy intervention to increase functional activity, which is a well-established approach in clinical practice. Potential adverse events (although unlikely) arising from PRACTISE are considered:

- Non injurious trips and falls
- Any other injury attributed to a fall
- Muscle soreness or pain (e.g., shoulder pain, other joint pain) that is beyond what is expected after stroke or physiotherapy exercise, non-responsive to simple measures and impactful on activities of daily living.
- Fatigue that is above and beyond stroke related fatigue symptoms
- Dizziness / Syncope

Potential serious adverse events (although unlikely) arising from PRACTISE are considered:

- Subsequent stroke
- Fracture attributed to a fall
- Heart attack

Identifying Adverse events

All AEs and SAEs meeting the criteria for recording within the PRACTISE study (see above) are recorded from the time a participant consents to join the study until the last study follow-up. Clinical staff, blind assessors or any member of the study team who interact (e.g. clinical treatment, assessments, ad hoc calls) with the participant across the period of the study intervention will be prompted to enquire about any adverse events that have occurred since the participant's previous appointment. It is also possible that participants may contact clinical staff or members of the study team between appointments and self-report symptoms that could be classed as an adverse event. In all cases, where a related (or presumed to be related) adverse event is identified, then an entry should be made onto PRACTISE Adverse Events Log. Multiple events for the same participant can be added to the same log.

Evaluating adverse events

A discussion is to be held between chief investigator and local principal investigator (or delegate) for assessing seriousness and causality of each event on the log.

Assessment of relatedness (causality) and expectedness

The chief investigator and local Investigator must assess whether the AE/SAE is likely to be related / and or expected, to treatment according to the following definitions:

- Related: resulted from administration of the research procedures.
- Unrelated: where an event is not considered to be related to the research procedures.

Alternative causes such as natural history of the underlying disease, concomitant therapy, other risk factors and the temporal relationship of the event to the treatment should be considered.

Recording AEs and SAEs

Adverse events will be recorded locally within case report forms and reported back to the Study Co-ordinator within 48 hrs. Any event considered as serious should be completed locally and sent onto Study Co-ordinator, local principal investigator and Chief Investigator for completion. SAE are to be reported within 24 hours Death for any cause (related or otherwise) is recorded on the SAE form.

Reporting SAE

Once the local Investigator becomes aware that an SAE has occurred in a study participant, they must report the information to the Study team/Chief Investigator within 24 hours (within a working week) of becoming aware of the event as per the Sponsor guidance.

The SAE form must be completed as thoroughly as possible with all available details of the event and signed by the local Investigator or designee. If all the required information is not available at the time of reporting, the Investigator must ensure that any missing or follow-up information is provided as soon as this becomes available. It should be indicated on the report that this information is follow-up information of a previously reported event.

To report an SAE to the study team, individuals can complete a hard copy of the SAE form and email it to the Study Co-ordinator. If, in the opinion of the local principal investigator and/or the chief investigator, the event is confirmed as being serious but not related, or serious, related and expected, expedited reporting to Sponsor is not required.

Rather these will be summarised and reported to Sponsor, REC, Funder, Trial Steering Committee in their regular progress reports.

Reports are only expedited if serious, related and not expected event.

Reporting responsibilities of the study team

The Study Co-ordinator or Chief Investigator will notify the Sponsor within 24 hours of receiving the signed SAE notification if the event is serious, related and not expected. The sponsor will provide an assessment of the SAE. A Sponsor cannot downgrade an assessment from the local principal investigator and/or the chief investigator. Any disparity will be resolved by further discussion between these parties and documented in the study master file.

The Chief Investigator or delegate reports any SAEs that are related to study procedures and not expected to the REC within 15 days of becoming aware of it using the HRA SAE form (Report of Serious Adverse Event (non-CTIMP)). All SAEs are summarised and reported to the Ethics Committee, the Funder, and the Study Steering Committee in their regular reports.

Follow up procedures

After initially recording and reporting an SAE, the local Investigator is required to follow each participant as indicated by clinical practice. Follow up information on an SAE should be reported to the Study Co-ordinator. The Trial Office will notify the Sponsor about any follow-up information.

Adverse Event log

This log is cumulative and captures adverse events of all participants throughout the study. Each Participant should be asked about the presence/absence of AEs at every study visit.

Study Intervention Relationship	**Action Taken Regarding Study Participation**	**Outcome of AE**	**Was this expected?**	**Does this need to be upgraded to a Serious Adverse Event (SAE)**
1= Not related 2 = Unlikely related 3 = Possibly related 4 = Probably related 5 = Definitely related	1 = None 2 = Study intervention modification 3 = Study intervention discontinued 4 = Subject withdrawn from study 6 = Hospitalisation 7 = Other	1 = Resolved 2 = Recovered / resolved with sequelae 3 = Ongoing/Continuing treatment	1 = Yes 2 = No (AE is not listed as a characteristic of the study condition or side effect in protocol)	1 = Yes (complete SAE Form) 2 = No

Date	**Participant ID**	**Adverse event description**	**Start date**	**Stop date**	**Study Intervention Relationship**	**Action taken**	**Outcome**	**Was this expected?**	**SAE**

Serious Adverse Event (SAE) Report Form

Site ID _____

Participant ID _____

Participant initials _____

Participant Date of Birth _____

Date of report _____

Name and job role of person creating report _____

Type of report (please circle)

- Initial
- Follow-up
- Final

SAE Onset Date _____ **(dd/mmm/yyyy)**

SAE Stop Date _____ **(dd/mmm/yyyy)**

What was the date the site became aware of SAE_____ **(dd/mmm/yyyy)**

What are the criteria for reporting this as a serious adverse event (please circle)

- Resulted in Death
- Life threatening
- Hospitalisation or prolongation of existing hospitalisation
- persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect
- Other

If other, please indicate_____

Please provide details of the nature of the serious adverse event (attach description if more space needed):

_____
_____
_____
_____
_____
_____

Please provide details of the location of serious adverse event (e.g. at study site or elsewhere)

_____
_____

_____

_____

Was study intervention discontinued due to event? (please circle)

- Yes
- No

What steps were taken to treat serious adverse event?

_____

_____

_____

_____

List any relevant information, tests, laboratory data, history, including preexisting medical conditions that are relevant.

_____

_____

_____

_____

Signature of person reporting incident: _____

Study Team use

The following is to be determined by the Principal Investigator / Chief investigator

Relationship of event to intervention (please circle)

- Unrelated (clearly not related to the intervention)
- Possible (maybe related to intervention)
- Definite (clearly related to intervention)

Is this event considered expected (please circle)

- Yes
- No

If the event is considered serious, related and not expected this must be reported to the sponsor

Date and time reported to the sponsor _____

What are the next steps to be followed (please detail)

_____

_____

_____

_____

Annex 2 Progression criteria for a future definitive trial

Progression criteria for a future definitive trial				
Variable	**Criteria (%) (n)**			**Notes**
	Red (stop)	**Amber (modify)**	**Green (go)**	
Initial consent	<10%	11-19%	>20%	Eligible participants who fit the inclusion criteria and go onto to consent to study. This is calculated as a percentage of eligible cohort that are approached and subsequently consent to study. This would be monitored regularly (e.g., monthly) in conjunction with recruiting staff to identify any barriers or facilitators that have been identified.
Recruitment (n=60)	<20% N= <12	21-79% N= 13 - 47	>80% N=48>	Total study recruitment, across three sites with 20 participants per site at the end of the study.
Attendance at scheduled session sessions (intervention participants only N = 30)	<20% N= <6	21-79% N= 7 - 23	>80% N= 24>	There are nine sessions within the PRACTISE intervention protocol. Seven out of nine session (77%) attended is used as the progression criteria per person. Therefore, for progression to be green on attendance for total intervention cohort we would expect to see 80% (24 out of 30) of intervention participants attend at least 77% (n=7 out of 9) of their allocated appointments.
Adherence to unsupervised exercise sessions (intervention participants only N = 30)	<15%	16-39%	>40%	On average what percentage of the weekly unsupervised exercise sessions do participants complete. Reporting to highlight those who completed 100% of exercise sessions will be reported to provide context.
Data quality completeness	<20%	21-79%	>80%	A minimum of 80% completion rate of primary outcome measure (Canadian Occupational Performance Measure) across all 4 time points (start, mid-point, end, and follow-up) and as a total in both control and intervention participants.
Intervention fidelity	<20%	21-59%	>60%	Fidelity is measured via audio recording of 20 appointments across intervention participants. Sessions will be assessed against pre-determined checklist of expected delivery. It is expected that at least 60% of items are delivered within the checklist across 20 audio-recordings.