Keele UNIVERSITY

Full title: Mobilization and tactile stimulation (MTS) to improve unilateral neglect post stroke: a pilot and feasibility study

Short title / acronym: Somatosensory Stimulation for Unilateral Neglect (SSUN) Post stroke

Chief Investigator	Dr. Ali Aries
Sponsor	Keele University, Keele, Staffordshire ST5 5BG Email: Research.governance@keele.ac.uk
Funder	
Funding reference number	N/A
Project registration	The study will be registered on ClinicalTrials.gov or the ISRCTN registry
IRAS ID	353466
Version Number and Date	3.0 27/03/2026

SIGNATURE PAGE

The Sponsor must be notified of all amendments to the protocol, both substantial and non-substantial. Authorisation of amendments by the Sponsor will act as the confirmation that the sponsor confirms approval of the amended protocol.

This protocol has been agreed and accepted and the Chief Investigator agrees to conduct the research in compliance with the approved protocol, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

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

The CI will make the findings of the research project publicly available through publication or other dissemination tools without any unnecessary delay and an honest accurate and transparent account of the research will be given; any discrepancies from the research project as planned in this protocol will be explained.

Chief Investigator:

Signature:  Date: 30/03/2026

Name (please print): DR ALI ARIES

CONTENTS

List of Abbreviations

ADL	Activities of Daily Living
AE	Adverse Event
BIT	Behavioural Inattention Test
BLS	Basic Life Support
CBS	Catherine Bergego Scale
CI	Chief Investigator
CRF	Case Report Form
CRN	Clinical Research Network
CTU	Clinical Trials Unit
EHR	Electronic Health Records
FIM	Functional Independence Measure
GCP	Good Clinical Practice
HRA	Health Research Authority
HSCR	Health and Social Care Research
ICSS	Integrated Community Stroke Service
IRAS	Integrated Research Application System
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Numbers
MBI	Modified Barthel Index
MI	Motricity Index
MPFT	Midland Partnership Foundation Trust
MTS	Mobilization and Tactile Stimulation
NICE	The National Institute for Health and Care Excellence
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PPIE	Patient and Public Involvement and Engagement
QA	Quality Assurance
QC	Quality Control
REC	Research Ethics Committee

SDV	Source Data Verification
SMF	Study Master File
S/PMG	Study/Project Management Group
SMS	Short Messaging Service
SOP	Standard Operating Procedure
SSI	Site Specific Information
UL	Upper Limb
UN	Unilateral Neglect
USN	Unilateral Spatial Neglect

KEY STUDY CONTACTS

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RESEARCH SUMMARY

Study Title	Mobilization and tactile stimulation (MTS) to improve unilateral neglect post stroke: a pilot and feasibility study	
Short Title / Acronym	Somatosensory Stimulation for Unilateral Neglect (SSUN) Post stroke	
Study Design	Mixed methods feasibility study involving quasi-experimental, single- system (n=1) studies with A-B-A design and qualitative group interviews	
Study Treatment / Intervention	Mobilization and Tactile Stimulation (MTS)	
Treatment / Intervention duration	45-60 minutes (per session for 5 sessions a week, for 6 weeks)	
Participants	Stroke survivors and informal carers (e.g. family members / friends) of stroke survivors	
Planned Sample Size	12-16 (6-8 stroke survivors and 6-8 carers)	
Number of participating sites / PICs	1	
Follow up duration	No follow up	
Planned Research Period	18 months	
	Objectives	**Outcome / Outcome Measures**
Primary	To assess feasibility of delivering MTS as an intervention for UN post-stroke	1. Catherine Bergego Scale (CBS) 2. Fluff Test 3. Letter cancellation test
Secondary	1. Investigate potential effectiveness or signal of effect of MTS in treating personal UN post stroke. 2. Assess the interrater reliability of carer-collected outcome measure (CBS). 3. Assess the acceptability	1. **For secondary objective number one**: CBS/ Fluff test 2. **For secondary objective number two**: Carer-collected CBS and researcher-collected CBS 3. **For secondary**

	to carers of carer-collected outcome measures. 4. Assess acceptability of the dose (intensity/duration/frequency) of MTS.	**objective number three**: carer-reported acceptability of being part of the study, including collection of the CBS outcome measure. This will be explored through qualitative data (semi-structured interview) 4. **For secondary objective number four**: Participant (stroke survivor) and carer-reported acceptability of MTS dose through qualitative data (semi-structured interviews)

INTRODUCTION

BACKGROUND

Stroke is one of the most frequent causes of permanent disability in adults. More than 113,000 people are affected by stroke each year in the UK (King et al., 2020). Stroke can cause various physical, psychological and perceptual disorders that persist for a long-time post stroke. Of the impairments, unilateral neglect is recognized as a major debilitating disorder associated with stroke (Wu et al., 2013).

Unilateral spatial neglect (USN), also known as unilateral neglect (UN) or neglect syndrome, is defined as cognitive disorder that affects the ability to attend and respond to stimuli, including visual, somatosensory, and auditory stimuli, presented in the contralesional hemispace following brain lesion, like stroke (Azouvi et al., 2017; Rode et al., 2017). This failure is not related to the presence or absence of sensory or motor deficits (Pierse and Buxbaum, 2002; Rode et al., 2017).

UN negatively affects functional recovery post stroke and is known to be a predictor of poor functional outcome (Mizuno et al., 2011). It limits the ability to perform activities of daily living (ADL) from the perception and motor aspects. For instance, some patients with neglect are unable to eat food on the left side of the dish or dress the left part of the body (Fassotti and Van Kessel, 2013). Upon discharge, the Functional Independence Measure (FIM) and the modified Barthel Index (MBI) of patients with UN are substantially lower despite receiving more therapy than patients with no UN (Johannsen et al., 2003). Some patients with UN recover partially or completely after one month due to spontaneous recovery that occurs after stroke; however, one-third of stroke survivors experience persistent symptoms up to the chronic phase post stroke, despite participating in active rehabilitation (Ringman et al., 2004).

Different treatment approaches have been developed to address UN. This includes but is not limited to mobilization and tactile stimulation (MTS). MTS is a module of current routine therapy for the treatment of the contralesional Upper Limb (UL) after a stroke (Hunter et al., 2006). It involves hands-on physical therapy techniques that provide somatosensory stimulation (specifically touch and proprioception) of the hand and forearm: joint mobilization (passive movements, accessory movements through anatomical range); massage and soft tissue mobilisation/stretch; specific sensory input (e.g. compression, touch including textures); and isolated / selective joint movement including placing the hand (Hunter et al., 2006).

MTS is commonly used to treat UL complications after stroke such as limitation or loss of range of motion, and loss of sensation. MTS has also been reported to be used in the treatment of perceptual problems such as UN following stroke (Hunter et al., 2006). Additionally, in a case report of 64-year-old patient with right stroke, lack of functional movement of the UL as well as apparent UN behaviour such as right-ward directed attention and right-turned head, the patient was treated with MTS and showed improvement in UN behaviours after only one session of MTS and that improvement was maintained in the withdrawal phase (Hunter, 2018). As a participant in a single-system experimental study with an A-B-A design, this patient received MTS for the paretic UL on five days per week for up to one hour for six weeks. In addition to improvement in UL function (Action Research Arm Test) and muscle strength Motricity Index (MI), immediate improvement in the patient's UN behaviour was observed. However, as UN had not been the outcome of interest in that study, UN was not formally assessed with a valid and reliable outcome measure but was based on the therapist's subjective assessment and observation of ADL and communication (Hunter, 2018). As a result, research evaluating the effect of MTS on UN after stroke using valid and reliable tests of UN is warranted. Improvement in UN behaviour could be related to the subsequent improvement in UL functions that may have increased awareness and activation of the neglected side. However, it is difficult to establish a relationship between the factors in this n=1 study with a single subject, which emphasises the need to repeat this study with a larger number of participants (Hunter, 2018). In conclusion, this study provides insight into exploring the potential impact of MTS in the treatment of post- stroke UN.

RATIONALE FOR RESEARCH PROJECT

There is emphasis to further explore the most effective rehabilitation interventions to treat UN, including the different subtypes of neglect, using both measures of neglect and functional outcomes. In the absence of strong evidence for a single treatment intervention for different types of UN, it is suggested that further clinical studies are warranted to evaluate effectiveness of interventions likely to reduce different types of UN due to the high incidence of UN as well as its negative effect on the rehabilitation process (Bailey et al., 2002). For instance, and in particular, robust studies exploring effectiveness of treatment of personal neglect (which is defined as the lack of exploration of the contralesional part of one's body or face, characterised by a deficit in grooming or dressing the contralesional side of the body) post stroke are limited. In particular, evaluating the effect of a commonly used physiotherapy intervention, namely MTS, in the treatment of UN is

suggested, using valid and reliable UN outcome measures; this has never been explored before despite some albeit limited observational evidence and reported experience of expert clinicians suggesting that it may be effective.

RESEARCH OBJECTIVES

OBJECTIVES

Primary Objective

The main aim of this research is to pilot and assess feasibility of delivering MTS as an intervention for UN post-stroke in a series of single-system (n=1) studies with A-B-A design.

Secondary Objective

1. Evaluate potential effectiveness or signal of effect of MTS in treating personal UN post stroke.
2. Assess the interrater reliability of carer-collected outcome measure (CBS).
3. Assess the acceptability to carers of carer-collected outcome measures.
4. Assess acceptability of the dose (intensity/duration/ and frequency) of MTS.

STUDY DESIGN

The design of this study will be a mixed methods feasibility study involving quasi-experimental, single-system (n=1) studies with A-B-A design and qualitative semi-structured interview or group interview, where appropriate. In the A-B-A design, the first A phase represents the baseline phase for comparison with subsequent phases (e.g., no intervention). Initial outcome measures are recorded at regular intervals in this phase and the participant's performance should be stable. The B phase acts as the intervention phase, and the final A phase is the withdrawal phase (i.e., no intervention). Throughout all the phases, outcome measurements are recorded regularly (e.g. Sim & Wright, 2000). In the B (intervention) phase, the researcher will deliver the MTS intervention to the participants' hemiparetic UL for 45-60 minutes daily, on five days per week, for six weeks. This dose was chosen because an average daily MTS dose of between 37 and 66 minutes was found to be suitable for subsequent evaluation in a dose-response MTS study (Hunter et al., 2011), and this is the evidence-based dose used in previous MTS studies (Hunter et al., 2008; Winter et al., 2013). The researcher will deliver MTS to the participant at their home or in an appropriate hospital-based room if this was more

convenient for the participant and the content and duration of each session will be noted on a treatment schedule.

The single system ABA design selected is believed to be the most appropriate design for many reasons. Firstly, it allows detailed examination of individual responses to the intervention as well as offering distinctive perspectives on treatment responses that might not be visible in a group study. Additionally, using single system design studies is especially helpful in modelling early therapy evaluation, and assessing complex behaviour, such as those found following stroke (Barlow & Hersen, 1984). It is especially useful for therapists when assessing or investigating the effectiveness of a treatment (Riddoch and Lennon 1994). Some disorders are not suitable for evaluation through RCTs due to the difficulty in finding a large, homogeneous sample of patients. In such cases, a single-system design is appropriate. It is known that UN is characterised by heterogeneous symptoms and patients may present with different types of UN (Williams et al., 2021). Given the heterogeneity of the syndrome and the difficulties in recruiting a large homogeneous sample, the study of UN behaviour in patients with stroke and their response to the intervention lends itself to evaluation by a single-system design study. Finally, this design has been adopted successfully in the other literature exploring effects of limb activation on UN treatment (Robertson et al., 1998; Bailey et al., 2002; Maddicks et al., 2003)

In the semi-structured or group interviews, which will be conducted by a member of the research team, participants and carers will be asked to provide their feedback and opinion on various topics including: the intervention (MTS), challenges they faced, changes they noticed and acceptability of carer-collected outcome measures. If the participants or carers do not want to take part in a group interview, or there are no other participants available at that time, a separate interview will be arranged.

Topics of discussion with the participants in an interview will specifically include:

1. Acceptability of the intervention: dose/frequency/comfort.
2. Acceptability of the therapist coming to their home daily.
3. Challenges/ barriers to completion they faced during the research study.
4. Changes observed (perceived benefits).

Topics of discussion with the carers in an interview will include:

1. Acceptability of carer-collected outcome measures: daily collection/ training
2. Challenges/ barriers experienced in outcome measure’s daily collection
3. Acceptability of the frequency of MTS.
4. Changes observed in participants.

The interview will take place shortly after completion of the ABA study with each participant. If two participants begin and end the study at the same time, a group interviews will be offered and conducted including two participants and two carers (i.e. one group interview with two participants, and one group interview with two carers); however, if there is only one participant (and, if appropriate, the carer), a single semi structured interview will be conducted with the participant and, if appropriate, the carer. The semi-structured interview or group interviews (if appropriate) will be conducted either in person or online depending on participants/ carers preference.

The design of the qualitative part of the study was chosen as a semi-structured interview for a number of reasons. Firstly, interviews are known to be a useful means of gathering people's opinions and experiences, which is one of the secondary aims of this research study. Both open and close ended questions will be asked to participants and carers on topics related to MTS dose (intensity, frequency, and duration), and comfort and outcome measure to ultimately assess the feasibility and acceptability of MTS, which emphasises the use of a semi-structured interview as a method of data collection (Matthews and Ross, 2014). .

RESEARCH SETTING

As the participants will be stroke survivors in the late subacute/ chronic phase (12 weeks post stroke), the intervention (MTS) will be delivered to the participants at their home or in an appropriate hospital-based room if this was more convenient for the participant (e.g. Bradwell hospital therapy outpatients). Meetings have been held with this clinical team who have agreed to be the recruitment site, and further agreement has been provided by the Research Governance team at Midlands Partnership Foundation NHS Trust (MPFT).

STUDY POPULATION

NUMBER OF PARTICIPANTS

6-8 stroke survivor and carer pairs

INCLUSION CRITERIA FOR STROKE SURVIVOR

INCLUSION CRITERIA FOR CARERS

1. Adult stroke survivor (≥18 years of age) with a clinical diagnosis of UN, in the late subacute-chronic phase of stroke (≥ 12 weeks post stroke)

2. Ability to consent to participate in the study, assessed by their understanding of the study when it is explained to them.
3. Sufficient cognitive and physical ability to allow inclusion in this study, assessed by the ability to follow a simple one-stage command with the non-paretic limb.
4. Able and willing to receive and engage with regular therapy (MTS) (e.g. at home).

INCLUSION CRITERIA FOR CARERS

1. Adult (≥18 years of age) who is an informal carer (e.g. family member / friend of the stroke survivor) who is willing and able to assist with the research. This includes carrying out simple daily outcome measures such as observational assessments of activities of daily living.

2. Ability to consent to participate in the study, assessed by their understanding of the study when it is explained to them.

3. Sufficient cognitive and physical ability to complete the simple daily outcome measures in this study.

EXCLUSION CRITERIA FOR STROKE SURVIVOR

1. Stroke survivor with major communication problems (e.g receptive aphasia) that affect their understanding of the treatment, their ability to follow instruction, or ability to consent to participate.
2. Participants who do not speak/understand English and who do not have access to an interpreter.

EXCLUSION CRITERIA FOR CARERS

1. Communication problems that affect: understanding of the study, ability to carry out daily outcome measures, or the ability to consent to participate.

2. Carers who do not speak and understand English and who do not have access to an interpreter.

PARTICIPANT SELECTION, RECRUITMENT AND ENROLMENT

IDENTIFYING PARTICIPANTS

Following NHS ethical approval and Health Research Authority (HRA) approval (through the integrated research application system (IRAS)), stroke survivors will be recruited through the MPFT Integrated Community Stroke Service (ICSS). Stroke survivors meeting the inclusion criteria will be identified by the clinical team and interested stroke survivors will be invited to give permission to be approached by a member of the research team, who will explain the study in full and provide

them with the participant information sheet (PIS). Those who want to enrol in the study will be asked to complete a consent form and screened for eligibility.

The researcher will have access to the identifiable personal information of the participants like name, gender, age, time since stroke. This information will only be offered after verbal consent is sought for a member of the research team (who will have a valid research passport) to look at their medical notes and stage 1 of the screening process (case note review) will occur to determine whether the potential participant is eligible for the study (i.e. to check: [1] age, [2] time since stroke, [3] type of stroke and [4] presence of UN). No expenses will be paid as the research intervention (MTS) will be given in their home environment or in an appropriate hospital-based room if this was more convenient for the participant (e.g. if the participant has an appointment/ follow up/ test) in Bradwell hospital. Travel expenses - Participants will not receive payment for taking part in this research. It will, however, be ensured that participants will not be out of pocket because of taking part in a research study. Travel expenses will be re-reimbursed to the participants, if travel is necessary, for example for outcome measurements to be undertaken, or to come to the interviews. Any reimbursement will be at the rate according to Keele University rates or taxi fares if necessary.

Approaching Potential Participants

A member of the potential participant's existing MPFT ICSS clinical care team will approach first. Verbal consent will be sought prior to a member of the research team having access to any identifiable information or healthcare records.

PROCESS in details (This will take place either in the potential participant's clinical setting within an NHS organisation or at their place of residence, as appropriate.)

1) In keeping with GCP and data protection act standards, a member of the potential participant's existing clinical care team in the MPFT Integrated Community Stroke Service (ICSS) will advise if they think a potential participant meets the inclusion criteria for the study.
2) A clinical team member will approach potential participants (stroke survivors with unilateral neglect and their carers) to establish whether they would like to find out more about the study. Verbal consent will be sought for a member of the research team (e.g. research therapist) to look at their medical notes and stage 1 of the screening process (case note review) will occur to determine whether the potential participant is eligible for the study (i.e. to check: [1] age, [2] time since stroke, [3] type of stroke and [4] presence of UN).
3) Interested potential participants will be approached by one of the research team (e.g. researcher; PhD student Maryam Mohammad) who will:

introduce herself and discuss the study; explain the purposes of the study; clearly delineate what is research and what is clinical practice; explain potential benefits and risks and go through the PIS. Any questions the potential participant may have will be answered. The potential participant will then be left with a PIS to read and consider further and discuss with their family / carer (expected to be 24–48 hours). A record will be kept of the contact and leaving of the PIS, and members of the clinical team will also be informed either verbally or in writing.

4) The researcher will return (after the potential participant has been given as much time as they need, expected to be at least 24-48 hours), establish if the participant wishes to take part in the study, answer any questions about the study and participation, and take consent if appropriate. This contact and the decision regarding participation will be recorded and also communicated either verbally or in writing (in the participant's medical notes) to members of the clinical team.
5) Those who want to enrol in the study will be asked to complete a consent form and undertake cognitive screening to check for eligibility.

CONSENTING PARTICIPANTS

Informed Consent Process

Informed consent must be obtained prior to the participant undergoing any activities that are specifically for the purposes of the research project. The researcher is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate verbal and written information; appropriate participant information and informed consent forms will be provided. The verbal explanation to the participant will be performed by the Investigator or qualified delegated person and must cover all the elements specified in the PIS and consent form.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

Participants meeting the inclusion criteria will be identified by the clinical team and interested participants will be invited to give permission to be approached by a member of the research team, who will explain the study in full and provide them with the PIS. Those who want to enrol in the study will be asked to complete a consent form. At this point they will be given a consent form, which they are able to take away if requested to further consider their participation. Once confirmed, they will be screened for eligibility. Consent forms will be on printed A4 pages. The participants will be given up to 1 week to consider the information provided and ask for more information or clarify any point before consenting. It will be clearly explained verbally and in the PIS that the participants may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

It will be ensured that all potential participants, whether they have a communication impairment or not, are given sufficient time to assimilate information, understand information and ask questions. It will be ensured that the participant understands the information about the study and potential consequences of being involved in a study before asking a potential participant to provide written informed consent.

* Various communication strategies will be employed including: verbal, hand gestures, demonstrations, and diagrammatic presentation of information and checking retention and comprehension by asking closed questions, selection of written words or pictures and confirmatory checks such as repeating and rewording verbal communication. These strategies have proved to be useful in other trials even when potential participants do not have a communication impairment.

A brief screening assessment will be completed to check that participants are able to follow simple commands and imitate actions using ability to imitate test (attached), using the non-paretic upper limb (the arm that has not been affected by the stroke) to ensure patients have adequate cognition to understand the information relating to the study and give informed consent. The ability to imitate test (attached) involves the potential participant copying actions being performed by the assessor e.g. opening a bottle, drawing a line etc. with their unaffected upper limb. Some participants may have dominant arm weakness and difficulty signing the form, or speech problems. If this is the case an independent witness will be used to sign the consent form, if required, on behalf of the participant. This may be a family member or one of the clinical team working with the patient, but not a member of the study team. Consent and the means by which consent occurs (i.e. if there is an independent witness) will be documented in the participant's medical notes. Throughout the consent and study processes it will be made clear to participants that they will be free to withdraw from the study at any stage.

A full explanation of the study and an opportunity to ask questions will also be given to participants' carer/partner as carers prior to them also completing a consent form to enable them to undertake daily observational outcome measure (CBS) as part of the research study.

The research therapist (or delegated member of the research team) and the participant will sign and date the consent form(s) to confirm that consent has been obtained. The participant will receive a copy of this document, and a copy filed in the Investigator Site File (ISF) and participant's healthcare records (if applicable).

Loss of Capacity following informed consent

If a participant's situation changes and there is a change in capacity following consent (for example, if they had a further stroke) another discussion with the participant's clinical team will take place and, if required, capacity will be assessed using the ability to imitate test (attached) prior to continuing in the study. If capacity is deemed to be insufficient, the participant will be withdrawn.

ENROLMENT

Withdrawal of Research Participants

Participants will be free to withdraw from the research at any time without giving reasons and without affecting their care.

Participants may also be withdrawn at the discretion of the Investigator, if it is considered to be in their best interests. The participants will be made aware that withdrawal will not affect their future care.

Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected up until that date will not be erased, in accordance with the University's Research Privacy Notice and information given in the PIS and may still be used in the final analysis.

Participants will be given a participation number in chronological order from when they joined the study, starting from participant 01 and onwards. This will allow for information collection of reason for withdrawals to be collected.

The circumstances when participants may discontinue treatment temporarily or permanently include the occurrence of adverse reactions like pain. Pain will be considered to be an adverse reaction if (i) a participant reports the onset or increase of paretic upper limb pain (verbally or behaviourally), and (ii) the pain is sustained over four consecutive therapy sessions and (iii) if the research therapist and clinical team are unable to account for this in any other way than involvement in this study. This will be addressed by the research therapist adjusting the therapy

as appropriate or, if indicated, stopping the extra therapy on either a permanent or temporary basis. The date of adverse reaction will be the date of the fourth consecutive therapy session on which pain was apparent.

Pain as described above is not an expected adverse reaction as our previous studies of MTS for the upper limb and lower limb have not incurred any such adverse reactions (Hunter et al., 2006; Hunter et al., 2008; Winter et al., 2013; Aries et al., 2021).

Additional circumstances when participants may withdraw from the research include the occurrence of adverse event and the participant or carer wanting to discontinue for any other reason.

RESEARCH ASSESSMENTS

SCHEDULE OF ASSESSMENTS

Once consent is obtained, a date to screen and start the research study will be set. Once a date is agreed, the research therapist will arrive at the set time to conduct the research study at the participant's home.

Research assessments will involve the letter cancellation test, CBS, and Fluff test.

In the letter cancellation test, which is part of behavioural inattention test (BIT) (Halligan et al., 1991) patients are seated at a table and asked to allocate a target on a sheet of paper placed on a table in front of them and cross it out from a background of different letters. It consists of 34 upper case letters and 40 targets evenly distributed on both sides of the page. The maximum score is 40 and the total number of target letters omitted is calculated and their location is determined (Plummer et al., 2003).

The CBS (Azouvi,1996), which involves a 10-item checklist used by the therapist or by the carer to observe and evaluate the presence as well as the severity of UN in the personal, peri-personal, and extra-personal space, will also be used in this study. It requires a 30-minute direct observation of the stroke survivor in 10 everyday activities like grooming or shaving the left part of the face, eating food on a plate, mouth cleaning, gaze orientation and knowledge of left sided parts of the body. UN is scored on a 4-point scale: mild (1), moderate (2), severe (3), or absent (0). A total score ranging from 0 to 30 is obtained with 0 = no behavioural neglect, 1-10 = mild behavioural neglect, 11-20 = moderate behavioural neglect, 21-30 = severe behavioural neglect.

In the Fluff test (Cocchini et al., 2011), participants are asked, while blindfolded, to detach 24 stickers stuck to the left side of their body or front of their clothes, using

their ipsilesional/nonparetic hand. The 24 stickers are identical circles made of white cardboard 2cm in diameter, with Velcro on one side to attach the sticker to the clothes. The patient is seated with their eyes closed / blindfolded and the stickers are attached to their clothes by the assessor who does not tell them how many stickers have been attached. To avoid the potential for bias by patients counting the stickers, the assessor distracts the patient with simple conversation during attachment of stickers. Once the stickers are all attached (three on each side of the anterior trunk, six on the anterior aspect of each leg, and six on the anterior aspect of the neglected arm) the patient is asked to remove them. There are no time restrictions and the test finishes when the patient collects or reports that all the stickers have been removed. The number and percentage of stickers collected from each side of the body is recorded from a total of 9 on the non-paretic side and 15 on the paretic side. The cut-off score is 13 stickers detached out of the 15 on the neglected side. Each A phase will last for two weeks, and the B phase will last for six weeks. The participant's carer / family member / friend, if available (who will have consented and been trained to do this) will conduct daily assessments using the CBS, throughout the three phases (ABA). In addition, in the initial A (baseline) phase, the researcher will conduct assessments using the CBS, letter cancellation, and Fluff test, every Monday (+ or – one day) and Friday (+ or – one day) each week giving four additional baseline data points for each test to check against the carer-collected scores. In the B (intervention) phase, the researcher will continue to assess the participants using the CBS, letter cancellation and Fluff tests. In the B (intervention) phase, the researcher will deliver the MTS intervention to the participants' hemiparetic upper limb for 45-60 minutes daily, on five days per week, for six weeks. In the final A (withdrawal) phase, the carer will continue to complete daily assessment of CBS. Additionally, the researcher will complete the CBS, letter cancellation and Fluff tests every Monday (+ or – one day) and Friday (+ or – one day) of the weeks in the final A phase. The figure below provides a summary of the timeline of the data collection period

Assessment	Screening
Assessment of Eligibility Criteria	X
Written informed consent	X

	Phase A (control)					Phase B (intervention) (MTS)					Phase A (withdrawal)				
	2 weeks					6 weeks					2 weeks				
	Week 1-week 2					Week 3-week 4-week 5-week 6-week 7- week 8					Week 9-week 10				
Intervention	Day 1	Day 2	Day 3	Day 4	Day 5	Day 1	Day 2	Day 3	Day 4	Day 5	Day 1	Day 2	Day 3	Day 4	Day 5
MTS						×	×	×	×	×					
OUT COME MEASURMENT															
CBS- (Carer)	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
CBS– (researcher)	**X (week1 +week 2)**				**X (week 1+week 2)**	**X (in each week)**				**X (in each week)**	**X (week 9+ week 10)**				**X (week 9+ week 10)**
Letter cancellation test – (researcher)	**X (week 1 + week 2)**				**X (week 1 + week 2)**	**X (in each week)**				**X (in each week)**	**X (week 9+ week 10)**				**X (week 9+ week 10)**
Fluff test- (researcher)	**X (week 1 + week 2)**				**X (week 1 + week 2)**	**X (in each week)**				**X (in each week)**	**X (week 9 +week 10)**				**X (week 9 +week 10)**

Figure 1 overview of study phases

LONG TERM FOLLOW UP ASSESSSMENTS

Nil

DATA COLLECTION

Once the ABA part of the study has started, it will take 10 weeks to complete for each participant. The study consists of three phases (ABA), each A phase will last for two weeks, and the B phase will last for six weeks. Data will be collected throughout the three phases by the research therapist, and/ or a research assistant, and the carer/ family member of the participant. A research therapist (physiotherapist) will do the assessment/ deliver the intervention (MTS), the carer/ or family member of the participant will be trained to carry out a daily simple assessment e.g. the observational assessment in the CBS.

At the end of the ABA study (after 10 weeks for each participant), a semi-structured interview or group interview (if appropriate) will be conducted by a member of the research team with the participants and carers to provide their feedback and opinions on various topics including: the dose (frequency, intensity, duration) and comfort of the intervention (MTS), challenges they faced, changes they noticed / perceived benefits of the MTS, and the acceptability of carer-collected outcome measures, including the carer-collected CBS. Group interviews (or semi-structured interviews where appropriate) will be conducted either in person on online, using Microsoft Teams and audio recorded and subsequently transcribed verbatim. Audio recording devices will be used for the group interviews, or semi-structured interviews. On transcription, pseudonyms will be used to maintain anonymity. When the work is written up for publication all direct quotations will be anonymous.

The interview questions will be developed from the topics (see above) by the research therapist and reviewed / agreed by supervisors. Data will be stored on a Keele password encrypted computer.

SOURCE DATA DOCUMENTATION

Electronic data collection will be merged onto excel or IBM SPSS statistical software, for analysis, this will be stored on a Keele University OneDrive account and accessed through a Keele password protected computer.

CASE REPORT FORMS / QUESTIONNAIRES / DATA COLLECTION TOOLS

Consent forms will be stored in locked cupboard within a member of the research team's office at Keele University.

DATA MANAGEMENT

Data management will be carried out in accordance with Keele University Health and Social Care Research (HSCR) Standard Operating Procedures (SOPs). The research data will be stored on Keele University storage servers within the UK and protected by industry standard security tools. All confidentiality arrangements adhere to relevant data protection regulations and guidelines (Data Protection Act 2018, UK General Data Protection Regulation (UK GDPR), Caldicott, General Medical Council (GMC)) and the Chief Investigator and the Data Custodian have responsibility for the use, security and management of all data generated by the study.

All information collected during the course of the research will be kept strictly confidential. Information will be held securely on paper and managed electronically by Keele University, in compliance with data protection regulations:

- Appropriate storage, restricted access and disposal arrangements for participant personal and health-related details
- Personal data can only be linked to research data by individuals with appropriate permissions.
- Where applicable: Consent from participants for access to their healthcare records by responsible individuals from the research staff or from regulatory authorities, where it is relevant to research participation.
- Consent from participants for the anonymous data collected for the research to be used to evaluate safety and develop new research.
- Where applicable: All data collection forms that are transferred to and from Keele University will be coded with a participant research number.

PERSONAL DATA

The following personal data will be collected as part of the research:

- Age, gender, time since stroke, type of stroke
- Name on consent form
- Email address should a participant contact the team with a query
- Telephone number
- Race/ethnicity
- Home address

Personal data will be stored by the research team on a Keele password protected computer, with only the research team to have access, on a need-to-know basis. Personal data will only be kept for as long as is necessary. Consent forms will be stored in a locked cupboard within a team office at Keele University.

All Investigators and research site staff involved with this study will comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act) regarding the collection, storage, processing and disclosure of personal information.

Published results will not contain any personal data and be of a form where individuals are not identified, and re-identification is not likely to take place.

We will seek your consent to inform the relevant medical team, as appropriate that you are taking part in the study. For example, this could be your consultant, nurses and therapists in the clinical team and your General Practitioner.

DATA INFORMATION FLOW

Data collected will be anonymised on recruitment to the study, with all participants given a number in chronological order from when they joined the study. The participants' names will not appear on any data set and will only be collected on the consent form. Date of birth, gender, time since stroke, type of stroke will

appear on the data set, as, where appropriate, the group mean will be calculated for reporting purposes.

TRANSFER OF DATA

Data collected or generated by this research project (including personal data) will not be transferred to any external individuals or organisations outside of the Sponsoring organisation(s).

DATA BREACHES

Any data breaches will be reported to Keele University's Data Protection Officer (DPO) who will onward report to the relevant authority according to the appropriate timelines if required. If these data breaches also meet the definition of a protocol non-compliance or a potential serious breach, they will also be reported as such.

ACCESS TO THE FINAL STUDY DATASET

Only the study team (CI/ study supervisors) will have full access to the data; this will include the site investigators via a relevant request and explanation of use.

ARCHIVING

At the end of the research, data will be securely archived in line with the Sponsor's procedures for 10 years after end of study declaration and until the Sponsor authorises destruction. Archiving will be carried out in accordance with Keele University SOPs.

STATISTICS AND DATA ANALYSIS

SAMPLE SIZE CALCULATION

In the single system A-B-A study, single cases rather than a group of cases are studied. To show a causal effect of the intervention, replicated results in at least four or more cases are needed (Barlow & Hersen, 1984). Accordingly, purposive sampling of between six and eight participants is planned in this study. Once ethical approval is granted, recruitment period will start. According to the meeting that was held with clinical team, recruiting 6 to 8 participants is achievable.

PROPOSED ANALYSES

Data for each participant will be analysed using visual analysis primarily to identify changes in UN behaviour between phases. Stability of the baseline will be assessed and, specifically, changes in trend, level and slope of the data, particularly at the transition between one phase, to the other will be calculated.

Visual analysis is the most used and recognised method of data analysis in a single subject experimental design study (Barlow & Hersen, 1984).

Group interviews (or semi-structured interviews where appropriate) will be conducted either in person or on online, using Microsoft Teams. Group interviews (or semi structured interviews where appropriate) will be recorded, raw data will be transcribed verbatim, coding and thematic analysis (Braun and Clarke, 2022) will be undertaken by the researcher (PhD student) and another independent researcher to analyse the data. Inductive and deductive approaches will be used, with some a priori themes related specifically to acceptability of the intervention and outcome measures, burden, and perceived effects of the intervention. NVivo may be used to aid data management. Data will be stored on a Keele password encrypted computer.

We will use The Transcription Company UK to transcribe the audio recordings. The sound files will be sent by uploading to their secure server. No data will be shared until the formal contract is in place. Transcriptions will be anonymised, with pseudonyms used, prior to being stored on a personal computer or laptop. When the work is written up for publication all direct quotations will be anonymous and no-one should be identifiable.

SAFETY REPORTING PROCEDURES

Definitions

Term	Definition
Adverse Event	An adverse event is: • any unintentional, unfavourable clinical sign or symptom • any new illness or disease or the deterioration of existing disease or illness
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing

	• hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant 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.
Related Unexpected Serious Adverse Event (RUSAE)	The National Research Ethics Service (NRES) defines related and unexpected SAEs as follows: • 'Related' – that is, it resulted from administration of any research • procedures; and • 'Unexpected' – that is, the type of event is not listed in the protocol as • an expected occurrence

Adverse event may include: if the participant has a further stroke (deterioration of existing disease), this will be dealt with using the local policy and arrangement within the NHS. Through the PIS the participants are advised to contact their GP or local out of hours service and attend A&E in an emergency and in accordance with usual clinical pathways.

Risk of research procedures or withholding standard procedure:
No standard procedures will be withheld. Researchers will work with therapists and the multidisciplinary team to ensure routine rehabilitation is not affected by the study.

The MTS therapy commonly takes place in routine clinical practice. The risk of related unexpected serious adverse events resulting from MTS is low. The intensive nature of the interventions and potential for discomfort has been considered during the protocol development phase. There is a small risk that participating in an intensive therapy, like MTS, might result in an overuse syndrome, which presents as pain in the arm.

All occurrences of pain will be recorded. At the beginning of each therapy session, therefore, the research therapist will check for onset /increase of arm pain. Pain will be accounted for as it would in usual therapy rehabilitation, for example by reducing the number of exercises prescribed, or the time of the intervention. Pain will be considered to be an adverse reaction if (i) a participant reports the onset or increase of paretic upper limb pain (verbally or behaviourally), and (ii) the pain is

sustained over four consecutive therapy sessions and (iii) if the research therapist and clinical team are unable to account for this in any other way than involvement in this study. This will be addressed by the research therapist adjusting the therapy as appropriate or, if indicated, stopping the extra therapy on either a permanent or temporary basis. The date of adverse reaction will be the date of the fourth consecutive therapy session in which pain was indicated.

The intensive nature of the interventions and potential discomfort have been considered and discussed with clinicians and with PPI volunteers. Thirty sessions of daily visits, plus regular outcome measures are proposed; this means there is a potential burden of time for participants involved in the study. Although this does mean increased time and input for the participants, the overall impression from clinicians was that the extra treatment will be beneficial for the stroke survivors. The PPI group advised that 45 min of MTS daily is fine and acceptable and would not cause fatigue.

Intrusion:

As the treatments (MTS) will occur in the participant's own home environment, the research therapists will treat both the environment and the participant with respect.

The procedures for monitoring and safeguarding lone workers will be established as will a process to allow researchers to report any harm that occurs to them. As part of routine project management practice, and in keeping with GCP, risk to the research team will be appropriately considered.

The research therapist's supervisors are experienced in conducting research of this type, in these settings, and with this population. No potential risks have been identified. The Arthritis Research UK Primary Care Centre at Keele has a long history of conducting home interviews with research participants, and guidelines have been developed, incorporating various safety procedures associated with lone working. These guidelines will be followed in order to minimise the risk to research staff engaged in the current study.

Other issues:

There will be the usual manual handling issues in relation to working with stroke survivors. It will be ensured that all mandatory training is up to date, including manual handling, and Basic Life support (BLS).

Risk of breach of confidentiality:

Personal details collected will be kept securely in a locked cabinet at Keele University or MPFT, on a password- protected computer or password-protected Keele OneDrive account.

Possible misunderstanding:

Simple screening procedures will be used to make sure the potential participants can follow simple commands and undertake a task involving imitating actions

Staff not available due to sickness/ annual leave:

If required, an additional research physiotherapist will be recruited to support this study as a member of the research team. Therefore, cover will be available in the event of sickness/ annual leave.

OPERATIONAL DEFINITIONS

Expected Adverse Events / Serious Adverse Events (non-reportable)

As above, this is a low-risk study and SAE/SAR incidences are not anticipated as a result of taking part in this study. Should an adverse event, such as a cardiac symptom, fainting or nausea occur it will be dealt with using the local policy and arrangement within the NHS. Through the PIS the participants are advised, if necessary, to contact their GP or local out of hours service and attend A&E in an emergency and in accordance with usual clinical pathways. The Chief Investigator will be informed immediately of any SAE.

Related and Unexpected SAEs – expedited reporting

All RUSAEs occurring from the time of start of study treatment until one day post cessation of study intervention must be recorded on the adverse event form and emailed to the Chief Investigator within 24 hours of the research staff becoming aware of the event.

All RUSAEs will be reviewed by the CI and will be subject to expedited reporting to the Sponsor and the main REC within 15 days.

Responsibilities

- Local Principal Investigator
  - Checking for SAEs when participants attend for treatment / follow-up.
  - Judgement in assigning:
    - Seriousness
    - Relatedness
    - Expectedness
  - Ensuring all RUSAEs are recorded and reported to the CI within 24 hours of becoming aware and to provide further follow-up information as soon as available.
  - To report RUSAEs to local committees in line with local arrangements.
- Chief Investigator
  - Assigning relatedness and expected nature of SAEs where it has not been possible to obtain local assessment.

- Undertaking SAE review.
- Review all events assessed as Related / Unexpected in the opinion of the local PI. In the event of disagreement between local assessment and the CI, local assessment may be upgraded or downgraded by the CI prior to reporting to the main REC.
- Preparing annual safety reports to main REC and periodic safety reports to TSC and DMEC as appropriate.
- Notifying Investigators of Related Unexpected SAEs which compromise participant safety.
- Expedited reporting of Related Unexpected SAEs to the main REC and within required timelines.

OVERSIGHT ARRANGEMENTS

Research oversight Groups

Study management group: Keele PhD team (research therapist/ supervisors) and the Principal Investigator (Margurite O'Mara) or another representative therapist from the Midlands Partnership Foundation Trust (MPFT) Integrated Community Stroke Service (ICSS)

INSPECTION OF RECORDS

Investigators and institutions involved in this research project will permit related monitoring and audits on behalf of the Sponsor, REC, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the Sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

STUDY MONITORING AND AUDIT

The study will be managed in accordance with Keele University SOPs. The study Chief Investigator (CI) is responsible for the conduct of the study and will convene a study management group comprising Keele PhD team (Research therapist (PhD student)/ supervisors) and the Principal Investigator (Margurite O'Mara) or another representative therapist from the Midlands Partnership Foundation Trust (MPFT) Integrated Community Stroke Service (ICSS). Regular meetings of the research management group will take place throughout the study (at least every 4 to 6 months). It will oversee the protocol completion, obtaining regulatory approval and site set-up and software development. They will be responsible for the delivery of the study, data collection and the ongoing management. The study management group will monitor recruitment procedures, review against timelines and complete regulatory reporting requirements. In addition, they will also oversee the analyses

and the interpretation of the results. The group will also ensure there is sufficient staffing support available for the study.

Study monitoring will be carried out in accordance with a risk proportionate Study Monitoring and Data Management Plan and Keele University SOPs which lay out the procedures for monitoring the data collection, protocol compliance and data management procedures.

In accordance with their standard operating procedures, the Sponsor may conduct audit(s) of the study. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

ETHICAL AND REGULATORY CONSIDERATIONS

Health Research Authority (HRA) approvals will be applied for and obtained before the study commences. HRA Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, with independent Research Ethics Committee opinion provided through the UK Department of Health's Research Ethics Service.

ETHICAL CONDUCT

Before the start of the study, a favourable opinion will be sought from an appropriate Research Ethics Committee (REC) for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

Substantial amendments that require review by the REC will not be implemented until the REC grants a favourable ethical opinion for the amendment (note that amendments may also need to be reviewed by NHS R&D departments before they can be implemented in practice at sites).

All correspondence with the REC will be retained in the Study Master File.

The Chief Investigator will notify the Sponsor and REC of the end of the study.

If the study is ended prematurely, the Chief Investigator will notify the Sponsor and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

PEER REVIEW

This study protocol has been subject to internal peer review as a part of a PhD.

Patient and Public Involvement

A workshop was held with Patient and Public Involvement (PPI) advisors, attended by the research therapist, the lead supervisor (CI), a stroke survivor and two carers (partners). The workshop included discussions on topics such as: plain English summary, PIS, study phases, outcome measures, the need for their involvement, discussion about: intensity of treatment/ home session/ risk/ burden for participants and caregivers/ qualitative aspect of the study. The PPI workshop helped to refine the details of the planned research. For example, useful suggestions were made regarding the home visit, the number of participants, the study site and possible adverse reaction like overuse syndrome or pain. The qualitative aspect of this study was also discussed at the PPI workshop and focus groups or interviews were considered appropriate. In the PPI workshop, which was also attended by the caregivers of stroke survivors, the feedback on the involvement of caregivers in the daily collection of observational outcome measure (CBS) was positive and no burdens were identified in this context. There was also positive feedback on the daily dose of MTS, which was felt to be "*good, acceptable and appreciated*" by the PPI advisors. Some useful suggestions made, for consideration during the protocol development stage, regarding timing of the therapist coming to the participant's home each day were made. This included the suggestion to give participants a timetable of when the researcher will come and start each session.

The PPI advisors will assist in revising the PIS to ensure that it is written in lay language as it relates to future PPI involvement.

Regulatory Compliance

The study will be conducted in accordance with the principles of Good Clinical Practice (GCP) in research studies and the UK Policy Framework for Health and Social Care Research. Keele University has a quality management system in place containing standard operating procedures which will be adhered to in the conduct of the research.

STUDY CONDUCT RESPONSIBILITIES

PROTOCOL AMENDMENTS

Any changes in research activity or approved documents, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, will be reviewed and approved by the Chief Investigator.

Amendments will be submitted to the Sponsor in accordance with their processes for review and authorisation before being submitted in writing to the appropriate REC and HRA (as applicable) for approval, prior to implementation.

MANAGEMENT OF PROTOCOL NON-COMPLIANCE

The research will be conducted in compliance with this protocol and GCP guidelines. Deviations from study protocols and GCP occur commonly in health and social care research. The majority of these instances are technical non-compliances that do not result in harm to the participants and do not compromise data integrity, or significantly affect the scientific value of the reported results of the research.

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the Sponsor and, therefore, will not be implemented, except where necessary to eliminate an immediate hazard to a participant or participants as an Urgent Safety Measure (USM).

Protocol non-compliance (deviations, violations) must be reported to the Chief Investigator at a.m.aries@keele.ac.uk and will be recorded and monitored by the research team and escalated to the Sponsor in accordance with their requirements.

Deviations and violations are non-compliance events discovered after the event has occurred.

SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, a Principal Investigator or a member of the research team or participating site, the Sponsor (research.governance@keele.ac.uk) must be notified within 24 hours. In collaboration with the CI, the Sponsor will assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

STUDY RECORD RETENTION

All study documentation will be kept for 10 years from the protocol defined end of research point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the Sponsor.

END OF RESEARCH

The end of this research project is defined as collection of the last data (interview) from the last participant and carer.

The end of the research will be reported to the REC and Sponsor within 90 days, or 15 days if the study is terminated prematurely. The Chief Investigator (or their delegate) will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. The end of study notification will be reported to the Sponsor via email to research.governance@keele.ac.uk.

A Final Summary Report of the study will be provided to the REC within 1 year of the end of the research.

CONTINUATION OF TREATMENT FOLLOWING THE END OF STUDY

There will not be a continuation of treatment after this study. The patient will continue with their usual care, which will not be affected by the outcome of the findings.

INSURANCE AND INDEMNITY

The Sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and research staff.

The following arrangements are in place to fulfil the Sponsor's responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the Sponsor and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The Sponsor requires individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity. Agreements between the Sponsor and participating NHS organisations detailing study conduct and the responsibilities to be honoured by each party will be fully executed before the study can start at the any participating site.

REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

DISSEMINATION PLAN

Ownership of the data arising from this research project resides with the research team.

A Final Summary Report of the study will be provided to the REC within one year of the end of the study.

Dissemination will be via publications with Maryam Mohammad as first author and conference presentations, with all papers aiming to be reviewed and published within 12 months of conclusion of the study. The study is not limited by funding restrictions, all results will be made available to the Midlands Partnership Foundation Trust (MPFT) Integrated Community Stroke Service (ICSS) team who will display the findings via their social media channels. If the participants specifically request results, the results will be shared with them after the final study report had been compiled or after the results have been published. The full report will be available in in a peer-reviewed journal.

AUTHORSHIP

Authorship will be available to those who fulfil the International Committee of Medical Journal Editors (ICMJE) criteria. No-one who fulfils the ICMJE criteria should be excluded from authorship credit and, of equal importance, no-one who fails to fulfil the four criteria should receive authorship credit. This includes academic staff and students as well as research managers, administrative, informatics, IT and nursing staff, and patient/public representatives where they fulfil all four criteria above. However, individuals have the right to choose not to be an author on a particular paper.

Staff heavily involved in the practicalities of study operationalisation and delivery, including dedicated research co-ordinators, will be considered for co-authorship of protocol papers on the condition they can contribute to critical revision of drafts, approve the final version, and be accountable for the content.

There is no intention to use professional writers.

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AMENDMENT HISTORY

Amendment No.	**Protocol Version**	**Protocol Version Date**	**Brief details of changes**

AM01 NSA0	2.0	7/11/25	1. Flexibility for outcome measures to be one day after or before the Friday or Monday. 2. Participants could still be recruited even if they do not have a carer. Change from group interviews to individual interviews with the participants and carers.