

Teaching carers to deliver therapy for the arm and hand post stroke

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Registration date 21/07/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/07/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In the UK, around 100,000 people have a stroke each year, and over 1.3 million people are living with stroke. Stroke commonly affects the arm and hand, reducing the ability to do daily activities, such as gripping, picking up and using objects like hairbrushes and forks. This impacts people's independence, often requiring long-term health and social support. Scientific research has shown that therapy involving hand massage, moving and stretching joints and muscles in the hand, and supporting reaching movements, can improve arm and hand strength and function, many months, even years, after stroke. However, the reality is that access to therapists to provide this therapy is limited, and most people with stroke receive very little therapy after being discharged from the hospital. This study wants to see if informal carers (family members or friends – known as CarePartners) of stroke survivors (SSs) can be taught to provide ongoing arm and hand therapy at home, improving the opportunity for better recovery over time. This work will help to decide whether it is worth doing a larger, more expensive trial of the carer-delivered treatment at home.

Who can participate?

Informal carers, stroke survivors (SSs) and therapists

What does the study involve?

This study will work with stakeholders to develop a training programme that teaches CarePartners how to provide arm and hand therapy at home. Physiotherapists will use the training package to train CarePartners to provide arm and hand treatment every day for six weeks. During that time, they will be asked to record exactly what treatment they give, how often and for how long, and to note any reactions to the treatment, overall feelings about the treatment and its effects. Support from a physiotherapist will be available during that time. The strength, feeling and function of the SS's arm, and quality of life for both SSs and Care Partners will be measured before treatment starts, at the end of the six weeks and three months (follow-up). This study will explore whether delivering this treatment places an excessive burden on CarePartners. The SSs and CarePartners will be invited to a group discussion to give feedback on the training, the treatment at home, and the tests used. Their feedback will inform whether the training, treatment and tests have the potential to improve arm and hand movement in real life / real NHS services. Therapists' views will be sought through interviews.

Patient and public involvement (PPI) supported the development of this research proposal. Project progress and budget will be monitored by a patient and public advisory group and study management group, which will include a public member.

Findings will be published and shared with local stroke services and participants, and at regional and national conferences.

What are the possible benefits and risks of participating?

Stroke survivors may benefit from receiving the extra MTS therapy; this has been the experience in other studies, but there is no evidence yet available to be sure there will be any benefits from receiving the extra treatment. Although there is no expectation that delivery of MTS is continued at the end of the study, the CarePartner will have been appropriately trained and have received copies of the MTS training materials, so they could choose to continue treatment at home. The information gained from the study may also help improve the treatment of other people who have survived a stroke.

MTS is a treatment which is often delivered as part of routine therapy after stroke; therefore, the level of risk for this study is low. There could be a risk that CarePartners could cause harm or discomfort through the delivery of MTS. However, the training programme for CarePartners, which will be developed in Phase 1, will be comprehensive. The research team will ensure that CarePartners know how much pressure to use and how to stretch joints and soft tissues when doing the MTS treatment. They will also ensure it is appropriate for their SS. CarePartners will work with an experienced therapist who will help the CarePartners practice how to do MTS and ensure they understand the purpose of each part of the treatment and how to do it correctly. CarePartners will be given as much support as they need, and the research team will ensure they feel confident before the six-week treatment period begins. CarePartners' own needs will also be considered. During the six-week treatment period, a research therapist will visit the 'pair' every week to check the quality of what they are doing and advise any changes. If required, extra training will be given to ensure CarePartner-delivered MTS is safe and that both the CarePartner and stroke survivor are happy with the treatment. Participants will also be provided with contact details for their research therapist so they can reach out to them between visits if required.

Where is the study run from?

Keele University, UK

When is the study starting and how long is it expected to run for?

June 2025 to November 2027

Who is funding the study?

The National Institute for Health and Care Research (NIHR), UK

Who is the main contact?

Dr Ali Aries, a.m.aries@keele.ac.uk

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

341844

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 61540, NIHR207153

Study information**Scientific Title**

Teaching carers to deliver physical therapy for the upper limb post Stroke (TaPpS): a feasibility study

Acronym

TaPpS

Study objectives

Aim: To assess feasibility (including acceptability and fidelity) of CarePartner-delivered MTS, and appropriateness and statistical properties of proposed outcome measures.

Research question: Is it feasible (acceptable, achievable) to teach unpaid carers (e.g. family members) to deliver specific aspects of physical therapy that aim to improve somatosensation, range of movement and functional activity in the UL following stroke, to their stroke survivor (SS), at home, whilst maintaining fidelity and adherence to the intervention, and without adversely affecting carer burden and quality of life?

Research objectives: This study will focus on preparatory work necessary before taking CarePartner-delivered MTS to a full trial, specifically addressing delivery and feasibility uncertainties:

1. Develop a training programme for CarePartners to learn how to deliver MTS for the UL of SSs at home, competently and safely, that is acceptable to all stakeholders.

2. Assess the feasibility of CarePartner-delivered MTS for the UL post stroke and assess trial progression criteria, including CarePartner burden.

3. Following RFPB guidance for feasibility studies, if a subsequent full trial is considered feasible, develop a proposal and prepare a funding application for further NIHR funding. This study is a feasibility study and not a randomised controlled trial. The primary objective is to assess the feasibility (including acceptability and fidelity) of CarePartner-delivered MTS, and appropriateness and statistical properties of proposed outcome measures.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 02/07/2025, West Midlands - Solihull Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8191; solihull.rec@hra.nhs.uk), ref: 25/WM/0082

Study design

Mixed methods feasibility study with two phases

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community, Home, Hospital, University/medical school/dental school

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied

Stroke

Interventions

The study is a mixed-methods feasibility study with two phases:

Phase 1: Co-design workshops actively collaborating with stakeholders to design a training programme for CarePartners to deliver mobilization and tactile stimulation (MTS).

Phase 2: Feasibility study

Upper limb therapy, including the delivery of mobilization and tactile stimulation (MTS).

Following the development of the MTS programme (adapted for carers to deliver) in Phase 1 of the study, carers will deliver MTS to their stroke survivor daily for six weeks. Each treatment is anticipated to take approximately 45 minutes.

Intervention Type

Mixed

Primary outcome measure

The Action Research Arm Test (measuring hemiparetic upper limb activity limitation) is anticipated to be the primary outcome measure; however, as this is a feasibility study, one of the purposes of the study is to ascertain the most appropriate primary outcome measure to take forward to a larger study in the future. The primary outcome will be assessed at baseline, after the six-week intervention and at three months

Secondary outcome measures

The following secondary outcomes are assessed at baseline, after the six-week intervention and at three months:

Walking (activity limitation) will be measured using:

1. Able to walk 10 m independently (walking aids permitted)? Y/N
2. Timed 10 m walk test, at a comfortable pace, if able to walk 10m independently

Body function and structure will be measured using:

Motricity Index (arm section)

Hemiparetic hand sensation will be measured using:

Nottingham Sensory Assessment – tactile and kinaesthetic subsections only

CarePartner burden will be measured using:

Zarit burden interview

Overall study start date

01/06/2025

Completion date

30/11/2027

Eligibility

Key inclusion criteria

Phase 1: Months 0-6

1. Adult (18 years old or more) stroke survivors (SSs) with ongoing self-reported UL dysfunction, discharged from hospital inpatient care. Interpreters will be sourced as required
2. Adult (18 years old or more) informal carers of SSs discharged from hospital care. Interpreters will be sourced as required.
3. Physiotherapists at NHS Band 6 or above who have two or more years' experience working in community or outpatient stroke services

Phase 2: Feasibility study - months 6-30

1. Adult (18 years of age or more) SS and CarePartner pairs, where:

- 1.1. The SS has ongoing UL dysfunction because of stroke (score of <33; the maximum score representing 'normal' strength, i.e. comparable to 'nonparetic' limb on the Motricity Index UL section, measuring muscle strength at shoulder, elbow and hand)
- 1.2. SS discharged from inpatient care
- 1.3. SS willing to receive CarePartner-delivered MTS
- 1.4. Both SS and CarePartner are willing and have the capacity to consent to participating in the trial

1.5. CarePartner willing and able to be trained

1.6. CarePartner willing to commit to deliver MTS to their SS's UL at home, according to protocol

Participant type(s)

Patient, Health professional, Carer

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

Planned Sample Size: 102; UK Sample Size: 102

Key exclusion criteria

Phase 1: Months 0-6

1. SSs who have severe aphasia, meaning they are unable to contribute to discussions unless they have an alternative means of communicating effectively (e.g. communication board, technology, signing)

2. Informal carers who are unable to contribute to discussions unless they have an alternative means of communicating effectively (e.g. communication board, technology, signing)

Phase 2: Feasibility study - months 6-30

1. SS-CarePartner pairs if one of the pair does not consent, or if the SS has no CarePartner available to take part

2. SS-CarePartner pairs if the CarePartner has significant health conditions, e.g. upper-limb dysfunction (from a neurological, orthopaedic, e.g. severe OA or RA of the hands, or other condition that might be exacerbated) affecting their ability to deliver MTS

The study will record the number and nature of exclusions to inform future plans for greater inclusivity

Date of first enrolment

21/07/2025

Date of final enrolment

31/03/2027

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St Georges Hospital

Midlands Partnership University NHS Foundation Trust
Trust Headquarters
Corporation Street
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United Kingdom
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Sponsor information

Organisation

Keele University

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Sponsor type

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Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Findings will be published and shared with local stroke services and participants, and at regional and national conferences. In addition, peer-reviewed journal publications are anticipated.

Intention to publish date

30/04/2028

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available on request from Dr Ali Aries (a.m.aries@keele.ac.uk).

IPD sharing plan summary

Available on request