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Sensory stimulation of the foot and ankle early post-stroke

Submission date 08/03/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/04/2016	**Overall study status** Completed	
Last Edited 06/12/2021	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
A stroke is a serious medical condition that occurs when the blood supply to part of the brain is cut off. Most stroke survivors have difficulty balancing and walking, especially if the feeling or movement in the foot has altered. Therapists use stretching, movement, and stimulation of joints, muscles and skin of the foot and ankle to improve standing and walking after stroke. Sometimes textured insoles are also used to increase feeling in the foot during walking exercises. However, these treatments have not been formally tested with stroke patients. The aim of this study is to find out whether mobilization and sensory stimulation to the foot improves stroke survivors' ability to balance and walk.

Who can participate?
Stroke survivors aged 18 or older, 6-16 weeks after their stroke.

What does the study involve?
Participants are randomly allocated to be treated with stretching, movement and stimulation of the foot and ankle and walking exercises; or to be treated with textured insoles in their shoes and walking exercises. Both groups are treated for twenty sessions, lasting up to one and a half hours, over six weeks. The ability to feel the foot, move, balance, and walk is measured by a therapist unaware of the treatment given to each participant, before, during and after the treatment. Participants are asked to keep a daily diary of how their leg changes during the six weeks, and are invited to a focus group to discuss their experiences. Each participant is involved in the study for up to four months.

What are the possible benefits and risks of participating?
Patient and Public Involvement (PPI) volunteers felt this research was worthwhile and that the extra therapy could potentially be beneficial to participants. They felt that being able to feel the feet properly was important for function, for example for walking and to prevent falls. The intensive nature of the interventions and potential for discomfort has been considered during the protocol development phase, with input from both stroke survivors and clinicians. The mobilization and tactile stimulation (MTS) and task-specific gait (walking) training are part of routine, conventional daily stroke rehabilitation. The potential discomfort of wearing a textured insole has been considered; however, work undertaken with people affected by multiple

sclerosis has shown the general acceptability of this intervention. Participants will be in control of how long they wear the textured insoles for each day. Participants will be asked to record all experiences in their daily diaries as part of the feasibility trial. There is a small risk that participating in extra therapy, either MTS or task-specific walking training, might result in an overuse syndrome, which presents as pain in the leg/foot and/or fatigue. At the beginning of each therapy session, therefore, the research therapist will check for onset/increase of leg/foot pain and onset/increase of fatigue. Fatigue will be accounted for as it would in usual therapy rehabilitation, for example by reducing the number of exercises undertaken, or the time of the intervention. Pain or fatigue will be addressed by the therapist adjusting the therapy as appropriate or, if indicated, stopping the extra therapy on either a permanent or temporary basis. There is, to date, no evidence that diagnostic ultrasound has produced any harm to humans, including the developing foetus. The diagnostic portable ultrasound machine will be used in accordance with the guidelines for the safe use of diagnostic ultrasound equipment. The research therapist/sonographer is fully trained in the machine's safe and proper operation, and has extensive experience in performing arterial imaging for research. Cross-infection of participants by the ultrasound transducer is a possible risk; therefore, the transducer will be cleaned between each participant. The risk of cross-infection from contact with the plinth will be minimized by wiping the plinth with an anti-bacterial agent between participants and by all members of the research team undertaking a thorough hand-washing between participant data collection sessions. Participants may well be receiving stroke rehabilitation, if this is the case it will be ensured participation in the study does not interfere with the stroke survivor's routine rehabilitation, by working in collaboration with the rehabilitation team involved.

Where is the study run from?
Staffordshire and Stoke on Trent Partnership NHS Trust and Keele University (UK)

When is the study starting and how long is it expected to run for?
April 2015 to March 2018

Who is funding the study?
NIHR Research Trainees Coordinating Centre (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2013-338

Study information

Scientific Title
Sensory stimulation of the foot and ankle early post-stroke: a feasibility study

Acronym
MoTaStim-Foot

Study objectives
Primary Research Aim:
1. To explore the feasibility of delivering treatment designed to increase the feeling within the foot after stroke in a randomized trial. The treatments being evaluated are Mobilization and Tactile Stimulation (MTS) with TSGT versus wearing of Textured Insoles (TIs) plus TSGT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Solihull Research Ethics Committee, 04/03/2016, Ref: 16/WM/0080

Study design
Feasibility study with a mixed-methods design, involving both quantitative (experimental) and qualitative (diaries and focus groups) methods

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
The intervention phase will be 20 treatment sessions delivered within a 6-week period, after the completion of baseline measurements. Interventions will follow the agreed protocols, and research therapists will be appropriately trained to ensure they follow the protocol. If participants are receiving routine therapy, this will continue alongside the Mobilization and Tactile Stimulation (MTS) / textured insoles (TIs) research schedule, which will therefore be in addition to routine therapy. Fatigue will be accounted for as it would in usual therapy rehabilitation.

Arm A: Mobilization and Tactile Stimulation (MTS) Group:
Prior to each standardized Task Specific Gait Training (TSGT) session (30 minutes), each participant will receive 30-60 minutes of MTS treatment to the lower limb, to prepare the sensorimotor system, prior to TSGT. The MTS schedule has been developed with clinician and PPI input. The specific content of each treatment session will be individualised for each participant according to need e.g. to address a hypersensitive foot and to take into account tolerance, and will be recorded by ticking boxes on a treatment schedule e.g. Hunter et al 2006. A research therapist will deliver the standardized MTS treatment. The schedule for the TSGT (for both groups) has also been developed with input from clinicians and will also be available prior to commencement of the trial. A research therapist will deliver this intervention and will be appropriately trained so it can be ensured the same treatment is given to each group. A log will be kept regarding which research therapist delivers which session, and an exploratory analysis undertaken.

Arm B: Textured Insole (TI) Group
This group of participants will be encouraged to wear the TI on the hemiparetic side (and a smooth insole on the opposite side), as much as possible (to 'augment' the sensorimotor system), during the 4-6-week period of intervention, apart from when the outcomes are being assessed. In addition to wearing the TIs participants will also receive 20 sessions of TSGT (30 minutes for each session), during the 4-6-week intervention period. If help is required to put the TIs into shoes and put on footwear (and no family support is available), a research therapist will assist. The specific content of each treatment session will be documented and daily diaries will inform the researcher of the extent of wearing of the TIs. Outcome measurements will be undertaken without the participant wearing TIs, so that conditions are the same as for the MTS group.

Intervention Type
Other

Primary outcome measure
The study outcomes include assessment of whether the way participants are recruited is effective, the number of people who consent to participate, the willingness of participants to be randomized, how acceptable the treatments are, how many participants drop out, and to work out how many people would need to be recruited in a future larger trial.

As this is a feasibility trial one of the objectives is to identify which measure should be the primary outcome measure for future trials.

Secondary outcome measures

1. Characterization of clinical presentation of participants (to give an overview of the participants to assist with evaluation of the interventions) using the following measurement tools:
1.1. National Institutes of Health Stroke Scale (NIHSS) - This includes assessment of the level of consciousness, vision, motor activity (face, arm and leg), coordination, sensation and speech. Timepoint: Baseline
1.2. Functional Ambulation category, which assesses walking ability and categorizes according to basic motor skills necessary for functional walking. It is anticipated that the step test will exclude people who would achieve a FAC level 6, requiring assessment on uneven surfaces and stairs. Timepoints: Baseline, on completion of the twenty treatments and at one-month follow up.

2. Sensorimotor impairment:
The following outcome measurements will be undertaken at baseline, after 5, 10, 15 and 20 treatments and one-month (+/-7 days) after last treatment (treatment number 20).
2.1. Pressure under the feet during stance phase of walking (measured with insoles). This is important to measure because in order to walk there is a dependence upon the interaction between the feet and the environment.
2.2. Ankle range of motion (dorsiflexion and plantarflexion) during stance phase. This will be measured by an electrogoniometer (an electronic piece of equipment), in stance phase of walking.
2.3. Touch/pressure sensory thresholds (sole of foot) (the ability to feel at different points on the sole) of the foot
This will be measured using Semmes Weinstein Monofilaments. This involves touching the sole of the foot using a monofilament nylon wire which exerts a force when bowed into a C shape against the skin for 1 second.
2.4. Lower Extremity Motricity Index. This will measure motor impairment (strength) of hip flexors, knee extensors and ankle dorsiflexors (moving the foot upwards). This will be undertaken with the participant in sitting with the hip and knee at 90 degrees.
Regular outcome measurements are being recorded to ascertain at what stage any changes are seen, to inform the dose (duration) of the intervention for the subsequent trial.

3. Lower limb function and balance:
Measures 3.1. and 3.2. will be collected at baseline, on completion of the twenty treatments and at one month follow up.
3.1. Walking speed 5 metre walk test (self-selected walking speed), gives an indication of the overall walking ability of stroke survivors. To enable more detailed analysis, the 5 metre walk test will be videoed.
3.2. Modified Rivermead Mobility Index. The test involves eight tasks including bed mobility, sitting and standing balance, transfers, walking and stairs. A rating is given relating to the amount of assistance the person requires.

4. Measurements of blood flow:
4.1.1. Peak systolic velocity (PSV) (cm/s) (an indicator of blood flow) and vessel diameter (mm) of the posterior tibial and the dorsalis pedis artery, measured using a portable ultrasound machine (MyLabFive, Esoate). Left- and right-limb measures will be undertaken to determine if effects are local or systemic, possibly indicating altered sympathetic vasoconstrictor nerve activity. Timepoints: Baseline, on completion of the twenty treatments and at one-month follow up.

4.1.2. In order to ascertain the effects of one individual treatment (acute effects), participants in the MTS group will have PSV and arterial diameter measured before and immediately after one of the first 10 MTS treatments.
4.2. Blood pressure, height and weight – Resting blood pressure will be taken before each measurement of blood flow. Participant's height and weight will be measured at baseline to allow calculation of Body Mass Index (BMI).

Overall study start date
01/04/2015

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Able to provide written informed consent
2. Adult stroke survivors (aged 18 years or older), male or female, with anterior or posterior circulation stroke, occurring 42-112 days (6-16 weeks) earlier
3. Ability to walk independently prior to stroke
4. Participants must also be able to follow simple commands and imitate actions, using the non-paretic upper limb (the arm that has not been affected by the stroke)
5. Participants must be unable to step on and off a 7.5 cm high block more than 12 times in 15 seconds with either their paretic (affected) or non-paretic leg (Step test, Hill et al 1996)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
34

Total final enrolment
34

Key exclusion criteria
1. Pre-existing conditions affecting sensation (feeling) of the foot and lower limb e.g. diabetic neuropathy, polyneuropathy (degeneration of the peripheral [not in the brain and spinal cord] nerves), peripheral nerve lesion [injury to a peripheral nerve], previous stroke affecting sensation of the lower limb
2. Fixed contracture of the tendoAchillis, assessed by being unable to achieve 90 degrees dorsiflexion at the ankle, either actively or passively with the knee extended

3. Pressure sores or ulcers on the foot or ankle (hemiparetic limb)
4. Deep vein thrombosis, because some of the MTS techniques would be contraindicated
5. Other conditions that affect the blood supply to/from the foot e.g. heart failure with peripheral oedema
6. Botulinum toxin injections to the lower limb in the previous six months
7. Pain sufficient to prevent delivery of treatments or outcomes
8. Known HIV, Hepatitis non-A or related condition

Date of first enrolment
01/04/2016

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Staffordshire and Stoke on Trent Partnership NHS Trust
Haywood Hospital
High Lane
Burslem
Stoke on Trent
United Kingdom
ST6 7AG

Study participating centre
Keele University
Keele
United Kingdom
TF10 7JQ

Sponsor information

Organisation
Keele University (UK)

Sponsor details

Keele
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England
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Sponsor type
University/education

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
Research Trainees Coordinating Centre

Alternative Name(s)
NIHR Research Trainees Coordinating Centre, TCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists intend to publish the protocol in 2016. Other publications related to the trial are expected to be published in 2019.

Wide dissemination utilising a variety of arenas from professional forums to general public resources is planned. PPI representatives will be funded to be involved with informing an appropriate audience of the results of the study, this has been built into the funding. Further details regarding publication will be confirmed at a later date.

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
Not provided at registration.

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Description of PPI activities	04/12/2021	06/12/2021	Yes	No
Results article		05/07/2021	06/12/2021	Yes	No
HRA research summary			28/06/2023	No	No