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A study to look at using electrical stimulation for leg weakness early after stroke

Submission date
14/08/2025

Recruitment status
Not yet recruiting

Registration date
18/08/2025

Overall study status
Ongoing

Last Edited
18/08/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke can cause weakness on one side of the body, making it hard or impossible for people to walk. This can lead to further muscle wasting (getting smaller), limiting a person's ability to walk and stand. Physiotherapists use electrical stimulation, a safe and painless treatment. It involves applying electrical currents (using sticky pads on the skin) to help muscles contract. This study will investigate whether electrical stimulation can stop the leg muscles from wasting after a stroke. This could help people get back to walking and doing everyday activities sooner. Before running a full study, the first step is to run a small study to see if: i) the study design works well, ii) people with a stroke want the treatment and the treatment is of benefit to them, and iii) the method of treatment and measurement are acceptable to people with a stroke.

Who can participate?
Patients aged 18 years and over who have had a stroke within the last 2 weeks who are well enough to take part

What does the study involve?
People taking part in the study will be randomly assigned to receive their usual care with or without electrical stimulation to their affected leg muscles three times a week for 12 weeks. Participation in the study will last six months and involves four visits where researchers will assess physical function (including walking ability, grip strength, leg strength) and ask about quality of life and what hospital services participants have used via questionnaires. Those assigned to use electrical stimulation will be shown how to use the device at home and asked to keep a usage diary. Some participants may also be invited to take part in a short interview about their experience in the study.

What are the possible benefits and risks of participating?
The electrical stimulation may help people get back to walking after having a stroke. It is not possible to guarantee that taking part in the study will directly benefit participants, but the information we gather will increase the understanding of how best to treat leg muscle weakness after stroke.

There are no significant risks to taking part in this study. Some people may have skin irritation from the sticky pads used for electrical stimulation, but this is rare. Some participants may find the tests tiring, but the research teams will do their best to accommodate their needs.

Where is the study run from?
The study is being run by teams based at University Hospitals Dorset, Bournemouth University and University of Exeter, UK.

When is the study starting and how long is it expected to run for?
August 2024 to May 2026

Who is funding the study?
The National Institute for Health and Care Research (NIHR)'s Research for Patient Benefit (RfPB) programme, UK

Who is the main contact?
Dr Katey Collins (Chief Investigator), kcollins@bournemouth.ac.uk
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332116

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

CPMS 69406, NIHR206227

Study information

Scientific Title
Using surface neuromuscular electrical stimulation for lower limb weakness early after stroke: A randomised controlled feasibility study

Acronym
STIM-STROKE

Study objectives
Primary Objective:
Assess the feasibility and acceptability of surface neuromuscular electrical stimulation (SNMES) started within 2-weeks after stroke and applied for 12-weeks to the weakened lower limb muscles, and provide necessary data to inform the design of a future definitive RCT testing whether SNMES started within two weeks after stroke prevents muscle wastage and improves recovery of strength, walking and quality of life in people with severe lower extremity weakness.

Secondary Objectives:
1. Determine the feasibility and acceptability of the SNMES intervention started within 2 weeks in people after stroke.
2. Estimate screening, recruitment and attrition rates, and reasons for declining participation or leaving the study early (where possible).
3. Estimate adherence/engagement to the SNMES protocol, including the number of sessions completed/total sessions in the treatment protocol
4. Determine the acceptability of the outcome measures, data collection methods, and data completeness
5. Collect data to inform sample size for a definitive trial
6. Determine whether the protocol can be incorporated within routine clinical practice
7. Assess the feasibility of delivering SNMES in a range of settings eg. hospital, rehabilitation, home.
8. Determine if the participant sample is representative of the local areas of recruitment and of national stroke survivors to develop and implement an inclusive recruitment strategy for the next stage
9. Identify, measure, and value resources required to deliver the SNMES intervention
10. Pilot data collection tools to measure resource use in the follow-up period to inform the design of a future within-trial economic evaluation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/07/2025, North West - Haydock Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048138; haydock.rec@hra.nhs.uk), ref: 25/NW/0208

Study design
Randomized controlled feasibility study with a nested qualitative and economic component

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Internet/virtual, Telephone

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
A surface neuromuscular electrical stimulation (SNMES) protocol for people with leg weakness within 2 weeks after a stroke

Interventions
This study will be a randomised controlled (RCT) feasibility study with a nested qualitative and economic component. A feasibility study is being used to explore recruitment, data collection methods, suitability of outcome measures, as well as the acceptability and feasibility of a surface neuromuscular electrical stimulation (SNMES) protocol for people with leg weakness within 2 weeks after stroke. Through our patient and public involvement and engagement (PPIE), this was deemed to be an important area to explore. The stroke survivors and their carers felt that recovering walking and standing was an essential part of their recovery and that they would be open to using electrical stimulation.

This study and the design will provide necessary data to inform the design of a future definitive RCT testing whether SNMES started within two weeks after stroke prevents muscle wastage and improves recovery of strength, walking and quality of life in people with severe lower extremity weakness.

The study design includes:

1. An RCT comparing a control group of usual care (n=30) versus an intervention group receiving usual care plus SNMES to the weakened leg muscles after stroke (n=30). The methodology was informed by PPIE discussions to have a usual care control group, as well as discussions with methodologists and statisticians. These methods will be able to be scaled for a large-scale definitive trial.

2. A nested qualitative component which includes:

a. Semi-structured interviews with participants with stroke, control group (n=8), intervention group (n=12). The interviews will not exclude participants with communication or cognitive changes. It was felt by the PPIE group that everyone's voice was important, and supporting people with communication and cognitive changes to take part in an interview was vital to a holistic understanding of the intervention.

b. Semi-structured interviews with caregivers to the participants in the SNMES intervention group (n=10).

c. Focus groups with clinicians who have helped to support the study and participants to use the SNMES (n=10).

Study Setting

This study is set in acute care hospital trusts, University Hospitals Dorset (UHD) and a second site (awaiting confirmation). The therapy teams at both sites will support the delivery of the intervention. The therapy teams will be provided with an in-person training session on the electrical stimulation machines, troubleshooting, setup, removing electrodes at the end, stimulation machine/electrode storage, and putting on and taking off the leg braces. The project manager will be available for support if needed.

Research Timetable

The whole project will be conducted over 24 months.

Months 0-5: Preparation for study, study documents, participant documents, ethics

Months 5-17: Recruitment, intervention period, data collection

Month 21: End of intervention period

Months 5-23: Data collection

Months 21-24: Data analysis, project write-up

Months 24+: Dissemination of findings

Intervention

Intervention Group:

Participants who are randomised to receive SNMES will use SNMES three times a week for 12 weeks. SNMES will target only the stroke-affected leg muscles of the thigh (hamstring, quadriceps, triceps surae) and calf (anterior tibialis, gastroc soleus). The SNMES intervention will be delivered alongside and in addition to usual care.

Treatment with SNMES is provided using a commercial constant current a 2-channel battery-operated electrical stimulation device.

Participants receiving SNMES will be provided with

SNMES stimulator unit

Knee immobiliser brace (if needed)

Ankle foot orthosis (if needed)

4 large electrode pads

4 small electrode pads

An extra 9-volt battery

SNMES diary (in the format of their choice, written or digital)

The treating therapist will teach the participant and their family/caregivers how to use the knee and ankle braces (if using), apply the electrodes, set up the stimulator, carry out stimulation, remove the electrode pads, and store the electrode pads and stimulation devices. Participants and caregivers will be provided with an instructional booklet containing written information and videos explaining how to use the electrical stimulation unit, electrodes, troubleshooting, and when to stop electrical stimulation. Participants and caregivers will also be provided with a diary to track their stimulation sessions and reasons for not doing a session (paper or digital, depending on the participant's preference). The general procedure that will be used on each muscle/joint is described below.

1. The locations for the electrodes (motor points) for the appropriate muscle will be identified by the therapist. The therapist will mark this spot on the skin with a permanent marker for future sessions. This will help to ensure consistent stimulation.

2. The gel electrode is placed on the muscle motor point of the weak leg (stroke-affected leg).

3. The stimulator leads are connected to electrodes.

4. For participants using the braces, the limb is positioned into a standard lower limb (thigh and calf) brace/splint and ankle foot orthosis (AFO) in a comfortable position. This is to prevent limb movement during the stimulation. Use of the brace will be optional, depending on patient preference and achieving a good limb position.

5. The stimulator is turned on and programmed at the following settings:

a. Frequency of 50Hz

b. Pulse duration: 450 μs

c. ON:OFF time: 5:10 seconds

d. Intensity is increased until a visible muscle contraction (this is when you can see the muscle move and contract) is produced in the muscle of interest. The intensity is then increased to participant tolerance. The intensity is determined at each individual session.

6. Each muscle will be stimulated for 45 contractions, which is around 30 minutes in total for all four leg muscles (12 minutes for the thigh, 12 minutes for the calf, and 6 minutes for attaching the stimulator to the electrodes and for programming the session).

7. When the stimulation is complete, the stimulator leads are removed from the electrodes.

8 . The electrodes are removed from the skin and stored in their packaging for the next session.

9. The stimulator and electrode leads are stored in the stimulator box until the next session.

This process is repeated for each muscle/joint (quads, hamstring, gastroc soleus, and anterior tibilais).

SNMES will be carried out three times a week for 12 weeks and will be integrated into the rehabilitation of the patient after a stroke.

Study assessments

Participants in both the control and intervention groups will attend all study visits and participate in the same outcome assessments.

Visit 1- Baseline and randomisation at the hospital

Visit 2 - Week 6 (after baseline) at hospital or place of discharge if non-ambulatory

Visit 3 - Week 12 (after baseline) at hospital or place of discharge if non-ambulatory

Visit 4 - Week 24 (after baseline) at hospital or place of discharge if non-ambulatory

Interviews and Focus Group

Participants from both intervention groups, caregivers to the person with stroke in the SNMES group, will be invited to take part in a semi-structured interview. Clinicians and health care workers who supported the study will be invited to take part in a focus group discussion.

A convenience sample of 12 participants from the intervention group and 8 participants from the control group will be invited to take part in an interview. The interviews will be conducted by a member of the research team who has experience in and has been trained in interviews (qualitative methods) and is on the delegation log; they will be supported by the team. The interview location will be based on the participant's preference: in-person, online, or telephone. The interviews will last around 30 minutes. People with changes to cognition or communication will be invited to take part in the interview and will be supported with their communication needs. The interviews will take place after the end of the intervention. Purposive sampling will help to gain perspectives from people with stroke with a range of abilities and recovery.

A convenience sample of caregivers (n=10) to participants with stroke in the SNMES group will be invited to take part in an interview. The interviews will be conducted by a member of the research team who has experience in and has been trained in interviews (qualitative methods) and is on the delegation log; they will be supported by the team. The interview location will be based on the participant's preference: in-person, online, or telephone. The interviews will last around 30 minutes. The interviews will take place after the end of the intervention.

A convenience sample of clinicians and health care workers (n=10) who supported the intervention will be invited to take part in a focus group discussion lasting around 45-60 minutes. The focus group will be online or in-person, depending on the clinician and health care professional's preference. The interviews will be conducted by a member of the research team who has experience in and has been trained in focus groups (qualitative methods) and is on the delegation log; they will be supported by the team.

The focus group with clinicians will take place after month 15 of the study, when the intervention period has ended (in-person or online).

Blinding

Participants and clinicians supporting the research will not be blinded to group allocation. This is due to the clinical team supporting the intervention and the participants knowing whether they have received SNMES or usual care.

Every attempt will be made to blind research practitioners doing the outcome assessments. To explore blinding, research practitioners doing the outcome assessments will make a guess as to which group the participant was in at Visit 3. Research practitioners will record if they were unblinded to group allocation and how this happened (e.g. saw the equipment, participant told them). The findings from this feasibility study will inform the design and blinding strategy of the subsequent definitive trial.

Interim analysis

This project does not have an interim analysis.

Sample Size

We intend to recruit 60 participants over 12 months across two hospital sites, with a 2-month contingency if needed. Sample size estimation is based on feasibility parameters of recruitment uptake to a 10% margin of error for 90% 2-sided and 95% 1-sided Cl estimation and adequate precision for estimation of standard deviation (SD) for numerical scales, i.e. allows for a sufficiently precise x 1.1 inflation factor for >80% 1-sided Cl estimation of the SD.

Participant Identification and Screening

Participants with stroke

The recruitment strategy has been developed in collaboration with the Public Advisory Group (PAG).

Screening and recruitment will be from the acute stroke unit. Eligible participants will be identified through screening of all new and current stroke admissions to the trust. Screening will be completed by a research practitioner (RP), such as a research nurse or clinician. The RP will screen new admissions of people with stroke against the eligibility criteria, as well as attend ward rounds to facilitate identification of patients who meet the screening/eligibility criteria. Clinical teams that identify someone who meets the eligibility criteria will notify the research team and research practitioners. Patient data will be seen by people outside of the direct care team within the trust in order to facilitate screening by the research team.

When a patient with a stroke is identified who meets the eligibility criteria, they will be provided with a participant information sheet (PIS). The PIS will be in multiple formats to meet the needs of all people after a stroke. PIS formats include written, written easy read, and a video version. The various formats were recommended by our patient and public involvement work to meet the diverse needs of people after stroke (and their caregivers/significant others). This will provide a more equal opportunity for understanding the information and participation. The video PIS was co-created with a PAG member and is in the format of a discussion around the easy-read PIS.

A detailed screening log will be kept detailing the number of stroke admissions, individuals meeting the screening eligibility criteria, those that do not meet the criteria and why (which criteria they do not meet), those approached about the study, and reasons for declining if the participant is willing to provide a reason, they do not have to.

If a patient is screened and meets all eligibility criteria except, they are not medically or neurologically stable, they will continue to remain on the screening log and be checked on for 10 days. If at 10 days the patient is medically/neurologically stable and meets all inclusion criteria, they will be provided information about the study; if they do not meet the eligibility criteria, then they will be excluded.

Caregivers to People with Stroke

To understand a range of experiences, the team will aim to purposively sample caregivers to participants with stroke with a range of functional abilities and recovery.

Caregivers will be provided with a brief explanation of the interviews and study, and will be given a caregiver PIS at the baseline assessment (Visit 1) by a member of the research team. For caregivers who are not present at the baseline assessment, the caregiver PIS will be left for them with the person with stroke. Those who are interested will be able to contact the research team via phone or email to let them know of their interest. The research team will follow up with the caregiver at Visit 2 and Visit 3 to explore their interest in the interviews if they have not been in touch with the research team.

Interested caregivers will complete a form giving their permission to share their contact details with the research team to discuss the study and arrange a potential qualitative interview.

The interviews will take place after the intervention period, around Visit 3 (12-week follow-up).

It will be made clear that the team are not able to interview everyone who responds that is interested, but that a subgroup of those willing to take part in an interview will be interviewed. This is clear within the caregiver PIS.

Clinicians and Health Care Professionals

Clinicians and health care professionals (therapists, nurses, health care assistants) who have supported the participants with stroke to carry out the SNMES intervention will be invited to take part in a clinician focus group discussion. They will be recruited from participating NHS sites via announcements at team meetings and research project updates, in which participant information sheets will be provided to those who are interested in taking part. It will be made clear that taking part or not taking part will have no impact on their job within the NHS or their ability to continue to support the study.

Those who are interested in taking part will contact the research team and complete a form giving their permission to share their contact details with the research team to allow them to discuss the focus group discussion.

Randomisation

Once individuals/their consultees have consented to take part in the study and their baseline outcome measures have been completed, the participant will be randomised in a 1:1 ratio, stratified by site, to receive either SNMES or usual care via REDCap.

The randomisation sequence using random permuted blocks will be generated by a statistician outside of the trial team and implemented using a centralised independent web-based randomisation system set up within REDCap.

The PI at the respective site or other trained clinician (on the delegation log) will undertake randomisation.

Intervention Type
Procedure/Surgery

Primary outcome measure
The following feasibility and acceptability variables will be measured using study data at the end of the study:
1. Overall recruitment rate
2. Rate of incomplete 6-month follow-up data
3. Intervention adherence

Secondary outcome measures
1. Feasibility and acceptability of the SNMES intervention started within 2 weeks in people after stroke will be explored via interviews with people with stroke and their caregivers following their participation in the study.
2. Screening, recruitment and attrition rates, and reasons for declining participation or leaving the study early will be collated at the end of the study
3. Adherence/engagement to the SNMES protocol, including the number of sessions completed /total sessions in treatment protocol, will be monitored via the participant diary and usage records obtained from the SNMES device at the end of the study.
4. Acceptability of the outcome measures, data collection methods, and data completeness will be explored via interviews with people with stroke and their caregivers following their participation in the study.
5. The intended primary outcome for a definitive trial would be the 10-Metre Walk Test (assessed at 12 weeks and 6 months). Data will be collected to estimate the mean and standard deviation of this outcome to inform power calculation for a definitive trial.
6. Whether the protocol can be incorporated within routine clinical practice will be explored via interviews with people with stroke and their caregivers following their participation in the study.
7. Feasibility of delivering SNMES in a range of settings, e.g. hospital, rehabilitation, and home, will be explored via interviews with people with stroke and their caregivers following their participation in the study.
8. Whether the participant sample is representative of the local areas of recruitment and national stroke survivors will be explored by analysing demographics and outcome data at the end of the study to develop and implement an inclusive recruitment strategy for a definitive trial
9. Resource use will be assessed via bespoke resource use questionnaires at 6 weeks, 12 weeks and 6 months.
10. Effectiveness and ease of use of the resource use questionnaires will be assessed at the end of the study

Overall study start date
01/08/2024

Completion date
31/05/2026

Eligibility

Key inclusion criteria

The inclusion criteria for the participants with stroke are:
1. Adults >= 18 years of age within two weeks of diagnosis of acute stroke
2. Sufficiently medically stable to participate in rehabilitation/trial interventions
3. National Institutes of Health Stroke Scale (NIHSS) score of >= 3 for the lower limb (limb weakness)
4. Unable to walk or transfer independently (with/without a walking aid)

Inclusion criteria for caregivers of people with stroke:
1. Caregiver or family member to participant with stroke defined as:
1.1. An informal caregiver (hereafter referred to as caregivers) who is a family member or a close friend in a good relationship with the person with a stroke.
1.2. The caregiver will be older than 18 years of age
1.3. Able to communicate and assist the stroke survivor
2. The participant with stroke that they support was in the intervention group (SNMES)
3. Caregiver or family member has the communication skills to be able to participate in an interview

Inclusion criteria for clinicians:
1. Health care worker (e.g. but not limited to physiotherapist, occupational therapist, therapy technician/aid, nurse, healthcare assistant)
2. Supported the participants with stroke to use the SNMES during the study period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
The exclusion criteria for the participants with stroke are:
1. Inability to gain informed consent from the patient or a consultee
2. Inability to walk independently prior to the stroke (with or without a walking aid)
3. Peripheral nerve injury to lower limb muscles
4. Pregnancy
5. Lower limb joint contractures
6. Contraindications to SNMES (DVT, uncontrolled epilepsy, malignancy at site of electrode placement, unstable fracture).
7. Poor skin condition and integrity at electrode sites (e.g. skin infection)
8. Previous stroke with residual lower limb weakness from first stroke
9. Impaired circulation in lower extremities
10. Additional underlying neurological condition e.g. Multiple Sclerosis or Parkinson’s Disease
11. Cardiac pacemaker (the number of participants that have a cardiac pacemaker will be

collected during screening, this will help to inform the development of the definitive trial and the inclusion and exclusion criteria)

Date of first enrolment
01/10/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Sponsor information

Organisation
University Hospitals Dorset NHS Foundation Trust

Sponsor details
Research & Development Department
Poole Hospital
Longfleet Road
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United Kingdom
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+44 (0)300 019 8500
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Sponsor type
Hospital/treatment centre

Website

https://www.uhd.nhs.uk

ROR
https://ror.org/02pa0cy79

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of this study will be published in academic journals and presented at national and /or international conference(s)

Intention to publish date
31/08/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository.
The anonymised electronic dataset will be put onto Bournemouth University's BORDaR, which is the Bournemouth Online Research Data Repository. The data on BORDaR will be anonymised quantitative data from study outcome measures. The anonymised dataset will be in BORDaR indefinitely and will be freely available for access.
Website: https://bordar.bournemouth.ac.uk/
Consent will be obtained from participants for their anonymised data to be put on BORDaR with the potential for the data being used in other studies.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Caregiver version 1.1	29/07/2025	18/08/2025	No	Yes
Participant information sheet	Clinical version 1.1	29/07/2025	18/08/2025	No	Yes
Participant information sheet	Consultee version 1.1	29/07/2025	18/08/2025	No	Yes
Participant information sheet	Easy read version 1.1	29/07/2025	18/08/2025	No	Yes
Participant information sheet	Stroke version 1.1	29/07/2025	18/08/2025	No	Yes
Protocol file	version 1.0	30/04/2025	18/08/2025	No	No