ISRCTN26060261 https://doi.org/10.1186/ISRCTN26060261

A randomised trial of Sheffield Adaptive Patterned Electrical Stimulation (SHAPES) as a new therapy for post-stroke arm spasticity

Submission date
21/06/2023

Recruitment status
Recruiting

Registration date
29/06/2023

Overall study status
Ongoing

Last Edited
13/01/2026

Condition category
Nervous System Diseases

[_] 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
Following a stroke people often experience muscle stiffness (spasticity) in their arms. The study team have developed a small device that is worn on the arm which stimulates sensory nerves using gentle electrical pulses. It can give two forms of stimulation: Transcutaneous Electrical Nerve Stimulation (TENS) and Sheffield Adaptive Patterned Electrical Stimulation (SHAPES). These techniques may be able to reduce muscle spasticity. The study team want to understand if the addition of either of the two forms of electrical stimulation to usual care adds any extra benefits. The purpose of this study is to compare the effect of SHAPES and TENS on spasticity at the elbow alongside the usual treatment.

Who can participate?
Adults aged 18-100 years old who have had a stroke between 2 and 16 weeks ago and who have post-stroke arm spasticity. Only those with a certain level of arm weakness and muscle stiffness would be eligible to participate. The study is single-site and sponsored by Sheffield Teaching Hospitals. Participants will be identified from eligible stroke centres within the South Yorkshire region.

What does the study involve?
Those agreeing to participate in this trial will receive one of three types of treatment for six weeks. Participants are allocated to groups randomly.
1. Group-1 will receive the SHAPES stimulation with the usual care
2. Group-2 will receive TENS stimulation with the usual care
3. Group-3 will receive usual care without electrical stimulation

Those in all groups will be asked to do a simple rating of their level of muscle stiffness daily. Before and 6 weeks after the study treatment, all study participants will have their arm movement assessed by a therapist and be asked to complete some questionnaires about how their arm spasticity affects them. After the 6 weeks of treatment, participants will be invited for follow-up assessments with a therapist:
1. At 6 weeks

2. At 12 weeks
3. Then at 24 weeks

What are the possible benefits and risks of participating?
You are not expected to gain any benefits from taking part in this research. The information arising might help improve the treatment of people with spasticity due to stroke. The treatment may result in a temporary reduction in the spasticity in your arm. The study team will follow up at 6, 12 and 24 weeks to see if there might be reductions in your arm spasticity that continue after you finish the study.

The sensory stimulation used in this study is not associated with any known side effects. It is not anticipated that any permanent or serious adverse effects. Possible side effects include a feeling of tightness during the therapy, skin redness, discolouration, irritation and rarely pain. These side effects are transient, lasting only for few minutes. However, as there is only limited experience with SHAPES, there might be unknown side effects.

Where is the study run from?
The Sheffield Teaching Hospitals NHS Foundation Trust, from its Royal Hallamshire Hospital site, Sheffield, UK

When is the study starting and how long is it expected to run for?
May 2019 to January 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR), Invention for Innovation (i4i) Programme (Ref: 201642)

Who is the main contact?
Dr Avril McCarthy, avril.mccarthy@nhs.net

Contact information

Type(s)
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Scientific

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Additional identifiers

Central Portfolio Management System (CPMS)
52321

Integrated Research Application System (IRAS)
309757

MHRA clinical investigation registration
CI-2022-0005

Study information

Scientific Title
A new therapy for post-stroke arm spasticity: Sheffield Adaptive Patterned Electrical Stimulation (SHAPES) - a co-designed system improvement followed by a powered multi-arm randomised control trial.

Acronym
SHAPES

Study objectives
Current study objectives as of 13/01/2026:
Purpose:

This study aims to investigate the effectiveness of using the SHAPES form of sensory stimulation on an affected arm for the treatment of post-stroke elbow spasticity, with participants recruited 2 or more weeks after their stroke.

Clinical Performance:
For the purpose of the clinical investigation, the ShefStim APS device will be configured to provide sensory stimulation in one of two forms: The Sheffield Automated Patterned Electrical Stimulation (SHAPES) and emulation of standard Transcutaneous Electrical Nerve Stimulation (TENS). The clinical performance of both forms for treating elbow spasticity will be compared. When used as intended in accordance with the study protocol it is expected that both forms of stimulation will confer a reduction in elbow spasticity. For a participant to be defined as a responder to therapy a Minimal Important Clinical Difference (MCID) of an 18% improvement in spasticity measured by the NRS-S scale is required.

Hypothesis:
It is hypothesised that a significantly higher proportion of participants will respond to SHAPES plus usual care than TENS plus usual care, and usual care alone. In addition, the duration of therapeutic effect will be compared, where SHAPES is hypothesised as producing longer-lasting benefits of at least 6 weeks after the end of treatment. Although the safety of an essentially equivalent ShefStim device has been demonstrated in previous trials, monitoring of safety will be undertaken to confirm that no unexpected safety issues arise.

Claims for clinical effectiveness:
A treatment will be considered effective if it successfully confers enough benefit to the patient such that their 7-day average NRS-S improves by at least 18% between time points of interest.

Previous study objectives:
Purpose:
This study aims to investigate the effectiveness of using the SHAPES form of sensory stimulation on an affected arm for the treatment of post-stroke elbow spasticity, with participants recruited between 2 and 16 weeks after their stroke.

Clinical Performance:
For the purpose of the clinical investigation, the ShefStim APS device will be configured to provide sensory stimulation in one of two forms: The Sheffield Automated Patterned Electrical Stimulation (SHAPES) and emulation of standard Transcutaneous Electrical Nerve Stimulation (TENS). The clinical performance of both forms for treating elbow spasticity will be compared. When used as intended in accordance with the study protocol it is expected that both forms of stimulation will confer a reduction in elbow spasticity. For a participant to be defined as a responder to therapy a Minimal Important Clinical Difference (MCID) of an 18% improvement in spasticity measured by the NRS-S scale is required.

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A treatment will be considered effective if it successfully confers enough benefit to the patient such that their 7-day average NRS-S improves by at least 18% between time points of interest.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/05/2022, London Queens Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd floor, Block B, Whitefriars Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0) 207 1048225, (0)207 1048284; queensquare.rec@hra.nhs.uk), ref: 22/LO/0203

Study design
Randomized treatment education or self-management device rehabilitation health economic study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-stroke arm spasticity

Interventions
Current interventions as of 13/01/2026:
Stimulation with electrical pulses is anecdotally associated with relief from muscle stiffness (spasticity). Proof of the effectiveness of TENS stimulation is not currently available but will be tested in this study compared to usual care. One limitation of TENS is the fixed pulsation points. It is expected that moving the pulse points in a spatially varying pattern (SHAPES stimulation) will confer an increased and/or longer-lasting benefit compared to TENS and usual care.

The benefit will be measured by the change in the 7-day average NRS-S score from baseline with an 18% improvement being considered a treatment success and the proportion of successes per group being the key comparison outcome.

Each of the primary null hypotheses will take the form:
o There is no association between the treatment group and success.
Each of the primary alternative hypotheses will take the form:
o There is a significant association between the treatment group and success.

Secondary analysis for ARAT, MAS, MRC Strength, LASIS, and EQ-5D-5L will take the following hypotheses:
H0: There is no significant difference between treatment groups
HA: There is a significant difference between treatment groups

Stroke survivors with arm weakness and elbow spasticity as indicated in the trial inclusion criteria who consent to participate will be randomised into 1 of 3 groups:
1. SHAPES stimulation for 60 minutes per day for 6 weeks plus usual care

2. TENS stimulation for 60 minutes per day for 6 weeks plus usual care
3. Usual care only

Subject to meeting inclusion /exclusion criteria and giving continued consent, each participant will attend 7 visits with activities performed as summarised below:

Recruitment Initiation: Identification of potential participant. Giving Patient information leaflet, Consent to contact

Visit 1: - Consent, Screening (inclusion & exclusion criteria), review resource use, Training to record NRS-S, Randomisation

Visit 2: (Min 6 days after Visit 1) - Device training, set up, device check & adverse events/device effects check Baseline measures: 1 week of NRS-S, MAS, MRC strength, ARAT, LASIS, EQ-5D-5L, adverse events/device effects check

Visit 3: (2-4 weeks after Visit 2) - Device management check & adverse events/device effects check

Visit 4: (Min of 6 weeks after Visit 2) - End of Treatment (EOT), Repeat baseline measures & adverse events/device effects check plus review resource use

Visit 5: (6-8 weeks post EOT) - Follow up 1 Repeat baseline measures & adverse events/device effects check plus review resource use

Visit 6: (12-16 weeks post EOT) - Follow up 2 Sub-set of baseline measures & adverse events /device effects check plus review resource use (done as a virtual visit to minimise participant burden)

Visit 7: (24-30 weeks post EOT) - Follow up 3 Sub-set baseline measures & adverse events/device effects check plus review resource use (done as a virtual visit to minimise participant burden)

Previous interventions:
Stimulation with electrical pulses is anecdotally associated with relief from muscle stiffness (spasticity). Proof of the effectiveness of TENS stimulation is not currently available but will be tested in this study compared to usual care. One limitation of TENS is the fixed pulsation points. It is expected that moving the pulse points in a spatially varying pattern (SHAPES stimulation) will confer an increased and/or longer-lasting benefit compared to TENS and usual care.

The benefit will be measured by the change in the 7-day average NRS-S score from baseline with an 18% improvement being considered a treatment success and the proportion of successes per group being the key comparison outcome.

Each of the primary null hypotheses will take the form:
o There is no association between the treatment group and success.
Each of the primary alternative hypotheses will take the form:
o There is a significant association between the treatment group and success.

Secondary analysis for ARAT, MAS, MRC Strength, LASIS, EQ-5D-5L and SQoL-6D will take the following hypotheses:
H0: There is no significant difference between treatment groups
HA: There is a significant difference between treatment groups

Stroke survivors with arm weakness and elbow spasticity as indicated in the trial inclusion criteria who consent to participate will be randomised into 1 of 3 groups:
1. SHAPES stimulation for 60 minutes per day for 6 weeks plus usual care
2. TENS stimulation for 60 minutes per day for 6 weeks plus usual care
3. Usual care only

Subject to meeting inclusion /exclusion criteria and giving continued consent, each participant will attend 7 visits with activities performed as summarised below:

Visit 0: (week 0) Identification of potential participant. Giving Patient information leaflet, Consent to contact

Visit 1: (week 1) - Consent, Screening (inclusion & exclusion criteria), review resource use, Training to record NRS-S, Randomisation

Visit 2: (week 2) - Device training, set up, device check & adverse events/device effects check Baseline measures: 1 week of NRS-S, MAS, MRC strength, ARAT, LASIS, EQ-5D-5L, SQoL-6L, adverse events/device effects check

Visit 3: (week 5) - Device management check & adverse events/device effects check

Visit 4: (week 8) - End of Treatment, Repeat baseline measures & adverse events/device effects check plus review resource use

Visit 5: (week 14) - Follow up 1 Repeat baseline measures & adverse events/device effects check plus review resource use

Visit 6: (week 20) - Follow up 2 Repeat baseline measures & adverse events/device effects check plus review resource use

Visit 7: (week 32) - Follow up 3 Repeat baseline measures & adverse events/device effects check plus review resource use

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ShefStim APS

Primary outcome(s)
Elbow muscle spasticity measured using a daily self-reported Numerical Rating Scale for Spasticity (NRS-S) for 7 days prior to Visits: 2 (Baseline), 4 (at 6 weeks (end of treatment-EOT)), 5 (6 weeks after EOT), 6 (12 weeks after EOT), and 7 (24 weeks after EOT)

Key secondary outcome(s))
Current key secondary outcomes as of 13/01/2026:
The following secondary outcomes are assessed at visits 2 (Baseline), 4 (at 6 weeks (end of treatment-EOT)), 5 (6 weeks after EOT), 6 (12 weeks after EOT), and 7 (24 weeks after EOT):

1. Elbow muscle tone measured using the Modified Ashworth Scale (MAS) given by a therapist
2. Elbow muscle strength measured using the Medical Research Council (MRC) Strength test given by a therapist
3. Arm function measured using the Action Research Arm Test (ARAT) given by a therapist
4. Passive and low-level active arm function measured using a semi-structured interview using the Leeds Adult Spasticity Impact Scale (LASIS)
5. Generic Quality of Life measured using EuroQol's EQ-5D-5L instrument

Previous key secondary outcomes:
The following secondary outcomes are assessed at visits 2 (Baseline), 4 (at 6 weeks (end of treatment-EOT)), 5 (6 weeks after EOT), 6 (12 weeks after EOT), and 7 (24 weeks after EOT):
1. Elbow muscle tone measured using the Modified Ashworth Scale (MAS) given by a therapist
2. Elbow muscle strength measured using the Medical Research Council (MRC) Strength test given by a therapist
3. Arm function measured using the Action Research Arm Test (ARAT) given by a therapist
4. Passive and low-level active arm function measured using a semi-structured interview using the Leeds Adult Spasticity Impact Scale (LASIS)
5. Generic Quality of Life measured using EuroQol's EQ-5D-5L instrument
6. Spasticity-related Quality of Life, including spasticity-associated pain and fatigue,measured using the SQoL-6D measure

Completion date
31/01/2028

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 13/01/2026:
1. Age 18 to 100 years
2. 2 or more weeks after stroke
3. Weakness of elbow extension of MRC grade 4 below
4. Spasticity of the elbow, of grade 1 or more on the modified Ashworth scale of elbow flexion

Previous participant inclusion criteria as of 08/01/2025:
1. Age 18 to 100 years
2. 2-26 weeks after stroke
3. Weakness of elbow extension of MRC grade 4 below
4. Spasticity of the elbow, of grade 1 or more on the modified Ashworth scale of elbow flexion

Previous participant inclusion criteria:
1. Age 18 to 100 years
2. 2-16 weeks after stroke
3. Weakness of elbow extension of MRC grade 4 below
4. Spasticity of the elbow, of grade 1 or more on the modified Ashworth scale of elbow flexion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 13/01/2026:
The following criteria will be reviewed and a final judgement made based on clinical experience by medically qualified study team investigators. Eligibility will be confirmed before randomization. The threshold for meeting criteria 1, 2, 3, 4, and 6 will be the degree to which, in the opinion of the investigator, it could significantly interfere with participation in the study:

1. Dermatological, rheumatologic, orthopaedic illnesses or muscle contractures of the affected arm interfering with elbow movement
2. Pre-existing severe systemic disorders like cardiovascular disease, active cancer or renal disease, end-stage pulmonary or cardiovascular disease, psychiatric illness including severe alcohol or drug abuse and depression
3. Inability to perform the baseline assessments
4. Severe tactile hypersensitivity
5. Participation in other spasticity-related studies
6. Uncontrolled epilepsy
7. All forms of implanted electrical/electronic device
8. Pregnancy
9. Confirmed inability to provide informed consent
10. Pre-existing upper limb spasticity unrelated to stroke
11. Previous acute contact dermatitis and/or known allergy to acrylates

Previous key exclusion criteria:
The following criteria will be reviewed and a final judgement made based on clinical experience by medically qualified study team investigators (Neurologists at Consultant or Registrar level). Eligibility will be confirmed before randomization. The threshold for meeting criteria 1, 2, 3, 4, and 7 will be the degree to which, in the opinion of the investigator, it could significantly interfere with participation in the study:
1. Dermatological, rheumatologic or orthopaedic illnesses of the affected arm interfering with elbow movement
2. Pre-existing severe systemic disorders like cardiovascular disease, active cancer or renal disease, end-stage pulmonary or cardiovascular disease, psychiatric illness including severe alcohol or drug abuse and depression
3. Inability to perform the baseline assessments
4. Severe tactile hypersensitivity
5. Participation in other spasticity-related studies

6. Within 12 weeks of receiving Botulinum toxin injections
7. Uncontrolled epilepsy
8. All forms of implanted electrical/electronic device
9. Pregnancy
10. Inability to provide informed consent
11. Pre-existing upper limb spasticity
12. Previous acute contact dermatitis and/or known allergy to acrylates

Date of first enrolment
22/05/2023

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
S10 2JF

Study participating centre
Barnsley Hospital NHS Foundation Trust
Gawber Road
Barnsley
England
S75 2EP

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Kendray Hospital Lodge
Doncaster Road
Barnsley
England
S70 3RD

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
England
DN2 5LT

Study participating centre
The Rotherham NHS Foundation Trust
Moorgate Road
Rotherham
England
S60 2UD

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/11/2024	20/11/2024	Yes	No
Other publications	Overview of the usability engineering process	24/08/2022	28/06/2023	Yes	No
Participant information sheet	version 6	04/05/2022	28/06/2023	No	Yes
Participant information sheet	version 3	05/05/2022	28/06/2023	No	Yes
Participant information sheet	Patient information leaflet version 4	04/05/2022	28/06/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes