

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

<b>Submission date</b> 21/06/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/06/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/07/2025	<b>Condition category</b> 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

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](mailto:avril.mccarthy@nhs.net)

### **Study website**

<https://fundingawards.nihr.ac.uk/award/NIHR201642>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Dr KP Sivaraman Nair

### **ORCID ID**

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**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
309757

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
CPMS 52321, IRAS 309757

## 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**

**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.

**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.

**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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Home, Hospital

**Study type(s)**

Treatment

## **Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

Post-stroke arm spasticity

## **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 SQuoL-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, SQuoL-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

### **Pharmaceutical study type(s)**

Not Applicable

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

ShelStim APS

### **Primary outcome measure**

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)

### **Secondary outcome measures**

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

### **Overall study start date**

31/05/2019

### **Completion date**

31/01/2028

## **Eligibility**

### **Key inclusion criteria**

Current 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

### **Age group**

Mixed

### **Lower age limit**

18 Years

### **Upper age limit**

100 Years

### **Sex**

Both

### **Target number of participants**

Planned Sample Size: 297; UK Sample Size: 297

### **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**

31/07/2025

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Royal Hallamshire Hospital**

Glossop Road

Sheffield

United Kingdom

S10 2JF

**Study participating centre**

**Barnsley Hospital NHS Foundation Trust**

Gawber Road

Barnsley

United Kingdom

S75 2EP

**Study participating centre**

**South West Yorkshire Partnership NHS Foundation Trust**

Kendray Hospital Lodge

Doncaster Road

Barnsley

United Kingdom

S70 3RD

**Study participating centre**

**Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust**

Doncaster Royal Infirmary

Armthorpe Road

Doncaster

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DN2 5LT



**Study participating centre**  
**The Rotherham NHS Foundation Trust**  
Moorgate Road  
Rotherham  
United Kingdom  
S60 2UD

## **Sponsor information**

**Organisation**  
Sheffield Teaching Hospitals NHS Foundation Trust

**Sponsor details**  
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+44 (0)114 2265941  
dipak.patel12@nhs.net

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.sth.nhs.uk/>

**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

**Publication and dissemination plan**  
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**  
31/07/2026

**Individual participant data (IPD) sharing plan**  
The data-sharing plans for the current study are unknown and will be made available at a later date

**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?
<a href="#">Other publications</a>	Overview of the usability engineering process	24/08/2022	28/06/2023	Yes	No
<a href="#">Participant information sheet</a>	version 6	04/05/2022	28/06/2023	No	Yes
<a href="#">Participant information sheet</a>	version 3	05/05/2022	28/06/2023	No	Yes
<a href="#">Participant information sheet</a>	Patient information leaflet version 4	04/05/2022	28/06/2023	No	Yes
<a href="#">Protocol article</a>		09/11/2024	20/11/2024	Yes	No