Keele UNIVERSITY

Impact Accelerator Unit

Keele Critically Appraised Topic (CAT Form)

Clinical Question

Is Functional Electrical Stimulation (FES) effective in the treatment of upper limb spasticity in adults and children with neurological conditions?

Clinical bottom line

There were no studies of paediatric patients that met our criteria, all studies included were of adults with stroke. None of the studies included blinding of participants or therapists or had a robust placebo control, so there is risk of bias in all studies. Given this, and the balance of evidence for and against being even, it is not possible to conclude whether FES is effective in treating spasticity in the upper limb.

Whilst we do not intend to change current practice, we do plan to improve our data collection to explore our own practice parameters and build local evidence for the use of FES in the upper limb. We also feel it will be helpful to review the other outcome measures that were used in the retrieved studies and include these in our practice if appropriate.

Why is this important?

The West Midlands Rehabilitation Centre (WMRC) FES Service regularly uses FES for the upper limb, however there was no standard pathway of care, particularly around the use for patients with spasticity. There was variability around goals, outcome measures, length of treatment and parameters. This Critically Appraised Topics (CATs) question was designed to help provide clinical evidence to guide the development of the upper limb FES Service pathway specifically regarding the FES treatment for spasticity.

Search timeframe (e.g. 2013-2013)

First search: 2010 to 16th June 2021

Second search: 16th June 2021 to 16th March 2023

Search criteria

Population Intervention Comparison Outcomes (PICO) themes	**Description**	**Search terms**
Population and Setting E.g. adults with OA, primary care	Adults and children with upper limb spasticity related to a neurological condition. Upper limb to include shoulder girdle and scapula	Upper limb: forearm or forearms or finger or fingers or clavicle or clavicles or coracoid or coracoids or "upper extremity" or "upper extremities" or "upper limb" or "upper limbs" or arm or arms or wrists or wrist or elbows or elbow or shoulder or "pectoral girdle" or "pectoral girdles" or scapula or scapulas or hands or hand or shoulders or tricep or triceps or bicep or biceps Spasticity: spasm or spasms or spasticity or tightness or dystonia or "spastic muscle" or "spastic muscles" or rigidity or hypertonic or hypertonicity or hypertonus or hypertonia or hyperreflexia or clonus Neurological: "cerebrovascular accident" or "cerebrovascular accidents" or "upper motor neuron lesions" or "upper motor neuron lesion" or "upper motor lesions" or

		"upper motor lesion" or "neurological disorder" or "neurological disorders" or "upper motor neuron diseases" or "upper motor neuron disease" or "cerebral infarction" or "cerebral infarctions" or "multiple sclerosis" or stroke or "cerebral palsy" or "cerebral palsies" or "neurological condition" or "neurological conditions" or "neurological disease" or "neurological diseases" or "primary lateral sclerosis" or "traumatic brain injury" or "traumatic brain injuries" or "partial spinal cord injury" or "partial spinal cord injuries" or "incomplete spinal cord injury" or "incomplete spinal cord injuries" or "partial spinal injury" or "partial spinal injuries" or "incomplete spinal injury" or "incomplete spinal injuries"
Intervention or Exposure (i.e. what is being tested) e.g. manual therapy	Electrical stimulation that produces a movement	Electrical stimulation "electric muscle stimulation" or "electric stimulation" or electromyostimulation or "neuromuscular electrostimulation" or "electrical muscle stimulation" or "electrical stimulation" or "functional electrostimulation"
Comparison, if any	Any other treatment including; normal/usual treatment, any other treatment, medication,	

e.g. usual care, leaflet	splints, lycra, physiotherapy, occupational therapy, exercise, therapy bands, gym, Botox	
Outcomes of interest e.g. Visual analogue scale, Range of motion	Any validated measure that includes spasticity	
Types of studies e.g. Randomised Controlled Trails, Systematic reviews	Randomised controlled trials	

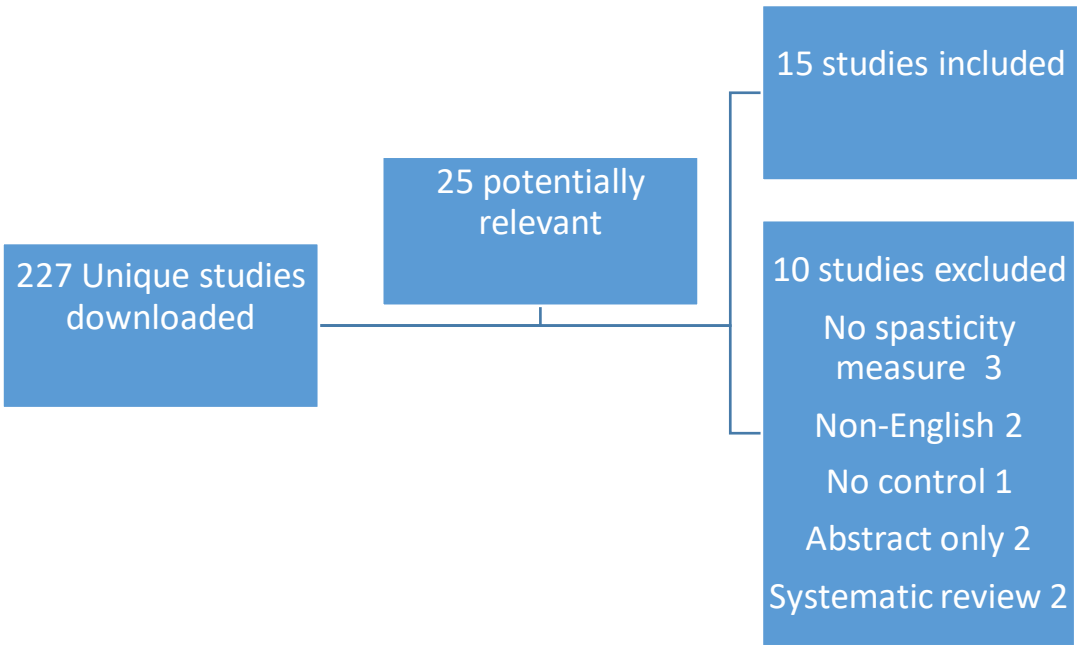
Databases searched

ovid emcare, ovid medline, ovid embase, ebsco cinahl, proquest psycinfo, cochrane, pedro

Date of search

16th June 2021 and 16th March 2023

Results of the search: include the number in each box



Quality Appraisal

The CASP Randomised Controlled Trial Standard Checklist was used to appraise the quality of studies.

There were no studies of paediatric patients that met inclusion criteria.

All 15 studies that met inclusion criteria involved adult patients with stroke (see reference list). All studies were of FES plus an adjunct intervention vs a control group so there were no studies of FES alone. Only 2 studies included a placebo control (1 used TENs and a sham stretch and 1 used FES at a sensory level). None of the studies included blinding of participants or therapists. The outcome measures that related to spasticity included; MAS, Tardieu, Leeds adult/arm spasticity impact scale, EMG activity, Spasm Frequency Scale and electrophysiological evaluation, Resistance to Passive Range of movement (REPAS) and Brunnstrom motor recovery scale.

Studies were grouped according to the intervention. There were nine studies of FES plus standard treatment compared to standard treatment alone. Five of these studies found a significant difference in favour of FES plus standard treatment, and four found no difference. Five studies explored wrist/finger extensors, the other four explored; shoulder only, shoulder plus wrist/finger extensors, wrist/finger extensors plus grip and elbow extensors. Bearing in mind threats to validity above, there was little obvious difference in quality between eight of the studies included, with one poor quality study that reported a significant difference.

There were two studies of FES plus 'shoulder' therapy, compared to 'shoulder' therapy alone. One study found a significant difference in favour of FES but this was of poor quality. The other found no significant difference. In the former, FES was applied to the forearm; in the latter, FES was applied to the shoulder.

The remaining four studies consisted of FES plus Botox versus Botox alone; FES plus 90 minutes intensive rehabilitation versus 90 mins intensive rehabilitation; sensory level FES versus active FES and FES plus passive stretching and standard treatment versus standard treatment, a sham stretch and TENs as a placebo. FES was applied to different locations in each study. Two studies found a significant difference in favour of FES and two studies found no significant difference however one of these studies was of worse quality.

Table 1- Detail of included studies

First author, year and type of study	**Population and setting**	**Intervention or exposure tested**	**Study results**	**Assessment of quality and comments**
Is it a randomised controlled trial or systematic review?	What type patients were included? Where was it undertaken? Primary Care, secondary, UK or another country? How many studies in the systematic review?	Describe the intervention briefly	Brief overview of the results	Your judgment of the quality of the studies The Critically Appraised Skills Programme (CASP) tool, may help you to generate comments **http://www.casp-uk.net**

Summary

All included studies were of adults with stroke and all exhibited important threats to validity. However, it is important to acknowledge the challenges to blinding and the difficulty identifying a suitable placebo control that are inherit in this intervention. When both quality and the balance of evidence was considered, it was not possible to conclude whether FES is effective in treating spasticity in the upper limb.

It should also be noted that there were multiple variables in the studies that it was not possible to include as part of the analysis e.g., the point at which outcome measures were taken, duration and frequency of treatment, stimulator parameters used, length of episode of treatment and stroke chronicity. Any of these could impact on effectiveness.

Implications for practice

This CAT focused only on spasticity and spasticity outcome measures rather than the secondary impact of spasticity such as patient reported function, pain and range of movement. Thus, it is important to explore these aspects which may yield different findings. Ideally, we would use FES in isolation with a placebo. The challenge of finding a suitable placebo control remains paramount and should be explored in future research.

What would you post on X (previously Twitter)?

FES for upper limb spasticity: Evidence is not consistent nor robust enough to make a conclusion. Further research using standard measures, protocol and patient cohort is required.

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Please tick the box that best reflects your clinical bottom line and include the picture on page 1

CAT image	Evidence quality	Checkbox
	Good quality evidence to support use….	☐
	Insufficient or poor quality evidence OR substantial harms suggest intervention used with caution after discussion with patient…	☐
	No good quality evidence, do not use until further research is conducted OR Good quality evidence to indicate that harms outweigh the benefits….	☐

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