

# Active functional electrical stimulation

<b>Submission date</b> 08/01/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/02/2023	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hand function is essential for daily living activities. People with spinal cord injury (SCI) can suffer from impaired hand functions. Conventional hand therapy is usually offered at the sub-acute stage of SCI but patients still experience significantly impaired hand function which affects their daily living activities and reduces their quality of life. A system has been developed that uses the electrical signal of the muscles to control functional electrical stimulation of the same muscles. The aim of this study is to determine the best parameters and confirm that people with SCI can adequately use the system both as a rehabilitative and assistive device.

### Who can participate?

Patients aged 18–76 with high level SCI that affects their hand function

### What does the study involve?

Each participant receives functional electrical stimulation to open and close the hand, controlled by the electrical signals of their muscles. There is a total of three sessions with each session lasting for a maximum of 2 hours.

### What are the possible benefits and risks of participating?

There are no known direct benefits to participants but the result will help in further research in the area. There is no known risk as devices are certified.

### Where is the study run from?

National Spinal Injuries Centre (NSIC), Stoke Mandeville Hospital, Buckinghamshire Healthcare NHS Trust (UK)

### When is the study starting and how long is it expected to run for?

Buckinghamshire Healthcare NHS Trust (UK)

### Who is funding the study?

January 2017 to January 2019

### Who is the main contact?

Dr Bethel Osuagwu  
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# Contact information

## Type(s)

Public

## Contact name

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# Additional identifiers

## Protocol serial number

Active FES - v1

# Study information

## Scientific Title

Feasibility of two-channel proportional Electromyogram Controlled Functional Electrical Stimulation (EMG-FES) for augmentation of finger and wrist flexion and extension for application in active neurorehabilitation in spinal cord injury

## Acronym

Active FES

## Study objectives

There is evidence that active participation is important in movement rehabilitation. One of the methods of involving active participation during rehabilitation is to control rehabilitation system with voluntary effort. For this purpose, Electromyogram (EMG) has been investigated to trigger the onset or proportionally control the intensity of functional electrical stimulation (FES). The proportional control method is very attractive because it gives a more natural control but it is more difficult to implement because of the issues associated with recording EMG simultaneously with the application of FES. Recent developments have demonstrated potentials of single channel proportional EMG controlled FES as an orthotic and rehabilitation system that can argument either tenodesis, hand flexion or extension. Here the aim is to further research and test the feasibility of a two-channel proportional EMG controlled FES system that can augment both hand and wrist flexion and extension in addition to tenodesis grasp and release

## Ethics approval required

Old ethics approval format

### **Ethics approval(s)**

Yorkshire & The Humber - Leeds East Research Ethics Committee, 06 /12/2017, REC ref: 17/YH /0416

### **Primary study design**

Interventional

### **Study design**

Single-centre feasibility study of an interventional device

### **Study type(s)**

Treatment

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

Spinal cord Injury

### **Interventions**

Each participant will receive functional electrical stimulation (FES) to open and close the hand. The FES will be controlled by the person's residual electromyogram. There will be a total of three sessions with each session lasting for a maximum of 2 hours.

### **Intervention Type**

Device

### **Primary outcome(s)**

The following tests will be measured only once for each condition in the study:

1. Hand function, measured using Toronto rehabilitation institute hand function test (TRI-HFT)
2. Hand function, measured using trapezoidal shape tracing

### **Key secondary outcome(s)**

The following tests will be measured only once for each condition in the study:

1. Physical well-being, assessed using the spinal cord independence measure (SCIM)
2. Spasticity muscle hypertonia levels, assessed using the Modified Ashworth Scale (MAS) test
3. Device usability and usefulness, assessed using a series of questionnaires including the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)
4. Functional impairment, assessed using the International Neurological Standards for Spinal Cord Injury (ASIA impairment scale)

### **Completion date**

30/08/2019

## **Eligibility**

### **Key inclusion criteria**

1. 18–76 years old
2. Sub-acute and chronic incomplete tetraplegia (neurological level C2 – T1), AIS grade B to D
3. Presence of residual EMG activity during hand flexion and extension

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Total final enrolment**

15

**Key exclusion criteria**

1. Known neurological condition, comorbidity (e.g., brain injury)
2. A person unable to understand verbal or written information in English

**Date of first enrolment**

08/01/2018

**Date of final enrolment**

30/08/2019

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Buckinghamshire Healthcare NHS Trust**

Mandeville Road

Aylesbury

United Kingdom

HP21 8AL

**Sponsor information****Organisation**

Stoke Mandeville Hospital NHS Trust

ROR

<https://ror.org/0524j1g61>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Buckinghamshire NHS Trust Charitable Funds

**Funder Name**

Stoke Mandeville Spinal Research (SMSR)

## Results and Publications

**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="#">Results article</a>		04/12/2020	27/02/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No