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Functional electrical stimulation (FES) in cerebral palsy

Submission date
31/07/2024

Recruitment status
No longer recruiting

Registration date
03/12/2024

Overall study status
Completed

Last Edited
02/09/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
This is a single case series exploring the impact of an intervention called Functional Electrical Stimulation in children with cerebral Palsy and crouch gait, aged 8-18 years old. Functional Electrical Stimulation (FES) is a small pocket device, which allows for precisely timed muscle activation during walking.
The aim is to find out how FES affects the degree of knee bend when walking in children with crouch gait and cerebral palsy.

Who can participate?
Children with cerebral palsy and crouch gait, aged 8-18 years old

What does the study involve?
The study will be 20 weeks duration. Children will start with an 8-week period of Usual physiotherapy care (phase A). This is followed by a 1 week period of getting used to using FES and then an 8-week intervention phase (phase B) when FES is used every day. Before and after each phase assessments of muscle strength and walking will take place. There will be additional 45-minute weekly assessments of fatigue, muscle strength and walking.

What are the possible benefits and risks of participating?
The FES may improve walking patterns in children or young people with cerebral palsy, it may help their knee to be more straight they might find it easier and less effortful to walk with the FES on. This study may also improve our understanding of FES and whether it may be a beneficial treatment for the management of crouch gait in children and young people with Cerebral Palsy. This study may also be used to inform larger clinical studies on FES across the UK.
Doing the walking assessment on the level and up and down steps may make the children and young people (CYP) feel tired.
Sometimes the FES sticky pads which are placed on the CYP skin, to stimulate a muscle contraction can cause redness of the skin. This is a normal reaction to increased circulation and should fade within 2 hours.
Sometimes the FES can cause a skin rash (little red spots). This can occur weeks, months or even years after starting FES treatment. If this happens the CYP will be asked not to use electrodes over the skin rash and should inform the study co-ordinator straight away.

Sometimes the muscle being stimulated by the FES may feel tired or ache after using the FES. This is normal as the FES is causing the muscle to work harder. The CYP may need to take a break from using the FES or reduce the length of time they are wearing it for, until their leg muscle has got used to it.

Where is the study run from?
University of Plymouth (UK)

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

Who is funding the study?
Torbay Medical Research Fund (UK)

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
347391

Protocol serial number
V217/07/2024, 5649

Study information

Scientific Title
Functional electrical stimulation for the management of crouch gait in children with cerebral palsy

Study objectives
Functional Electrical Stimulation applied to either the quadriceps during stance phase of gait or tibialis anterior during swing phase of gait over an 8-week period has a therapeutic effect on variations of knee flexion at initial contact and midstance in children with crouch gait and cerebral palsy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/11/2024, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224558458; gram.nosres@nhs.scot), ref: 24/NS/0123

Primary study design
Interventional

Study design
Intervention study of single case series design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cerebral palsy

Interventions
The intervention phase of this study is FES, a battery-powered, pocket electrical device combined with a foot switch to allow precisely timed muscle stimulation while walking. This will be compared to their usual care.

The intervention period is 8 weeks and each CYP will be asked to use the FES device for between 2-4 hours a day, 6 days a week. This duration has been guided by PPI feedback on the study protocol and a RCT on the use of FES in drop foot in children with CP [26]. The FES can be worn

at home and or at school depending on the preferences of the CYP. The CYP will be asked to avoid starting any new physical activities or sports during the period of FES intervention but may continue with their usual physiotherapy routine.

The FES intervention including the frequency, pulse width and amplitude is tailored to the individual. It will be based on the clinical judgement of the SC, in accordance with the CYP muscle response to stimulation and in order to optimise gait performance.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Functional Electrical Stimulation

Primary outcome(s)
Measured at week 0 (prior to starting Usual' Physiotherapy), week 8 (post 'Usual' Physiotherapy), week 10 (prior to starting FES intervention) and week 19 (post FES intervention)
1. Popliteal Angle and Hamstring Spasticity (Modified Tardieu Scale)
2. Passive Ankle Range of Motion and Gastrocnemius spasticity (Modified Tardieu Scale)
3. Duncan Ely and Rectus Femoris spasticity (Modified Tardieu Scale)
4. Passive Hip Flexor Range of Motion (Thomas test)
5. Tibialis Anterior Strength (Hand- Held Dynamometer)
6. Quadriceps strength (Hand- Held Dynamometer)
7. The Goal Questionnaire
8. Extensive Walking Assessment – Measuring knee flexion at Initial contact and Midstance using an Electro goniometer.
9. Stairs Assessment - Measuring knee flexion using an Electro goniometer
10. SCALE tool - Selective Control Assessment of the Lower Extremity (SCALE)

Assessed at Week 0 only
11. Foot Posture established with the CYP in standing and barefoot. Hind foot position whilst weight bearing and the presences of a midfoot break will be recorded using the CPIP manual as a guide

Key secondary outcome(s)
Assessed weekly during 'Usual Care' and 'FES intervention' from Week 1 – 18
1. Self-report Neuro-QOL paediatric fatigue form
2. 12- Item Walking Scale (Walk 12-G)
3. FES Activity Logger - This data includes the number of steps taken and the duration of use in HH:MM
4. Tibialis Anterior Strength (Hand- Held Dynamometer)
5. Quadriceps strength (Hand- Held Dynamometer)
6. Hamstring, Gastrocnemius and Rectus Femoris Spasticity (Modified Tardieu Scale)
7. Weekly Walking assessment - Measuring knee flexion at Initial contact and Midstance using an Electro goniometer
8. Weekly Stairs Assessment - Measuring knee flexion using an Electro goniometer

Completion date

02/04/2026

Eligibility

Key inclusion criteria
1. Diagnosis of spastic CP (GMFCS level I-III), affecting one or more muscle groups in both lower limbs, and aged 8 - 18 years
2. The ability to follow simple instructions
3. The ability to adhere to the FES protocol
4. The ability to walk 20 metres of more with or without a walking frame

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
1. Dystonic or Athetoid CP as the sole presentation (CYP with dystonia / athetosis co-occurring with a spastic presentation can be included)
2. Selective dorsal rhizotomy or Multi level orthopaedic surgery within the last 6 months
3. Soft tissue surgery in lower limbs in the last 6 months
4. Anti-spasticity botulinum toxin injections within 3 months
5. Moderate to Severe Cognitive Impairment and/or Learning difficulties that may limit the use of FES consistently or appropriately
6. Poorly controlled epilepsy
7. Bilateral Fixed Knee Flexion deformities > 10 degrees
8. Bilateral contractures of the tendon Achilles which means they are unable to achieve plantigrade (90 degrees) in both ankles by passive movement when the knee is bent. (please note that CYP with one contracted tendon Achilles may still be considered appropriate for FES intervention)
9. CYP with a Cardiac Pacemaker
10. CYP with a malignant Tumour in the area that FES stimulation is taking place I.e., the thigh or lower leg

Date of first enrolment
02/02/2025

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Torbay and South Devon NHS Foundation Trust
R&D Department, Horizon Centre, Torbay District General Hospital
Torquay,
United Kingdom
TQ2 7AA

Study participating centre
University of Plymouth
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Sponsor information

Organisation
University of Plymouth

ROR
https://ror.org/008n7pv89

Organisation
Torbay Medical Research Fund

Funder(s)

Funder type
Charity

Funder Name
Torbay Medical Research Fund

Alternative Name(s)
TMRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The Chief Investigator will act as Data Custodian and will ensure that the location of the data and access to that data is shared with the Sponsor. Data will be collected and stored in accordance with the Data Protection Act 1998/General Data Protection Regulation 2018. Data generated from this study will be available for inspection on request by the participating research team, University of Plymouth representatives, the REC, local R&D Departments, and the regulatory authorities. This is in accordance with the university of Plymouth's Research Data Management Policy which can be found here: https://plymouth.libguides.com /researchdatamanagement

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	12 - 18 years old version 1	31/07/2024	27/08/2024	No	Yes
Participant information sheet	8 - 11 years old version 1	31/07/2024	27/08/2024	No	Yes
Participant information sheet	Parent version 2	31/07/2024	27/08/2024	No	Yes
Protocol file	version 3	18/09/2024	23/01/2025	No	No