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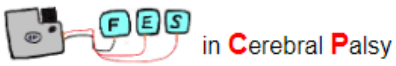

TRIAL PROTOCOL:

Full title: Functional Electrical Stimulation for the Management of Crouch Gait in Children with Cerebral Palsy.

Short title: FES in Cerebral Palsy

PROTOCOL VERSION NUMBER: V3

DATE: 18/09/2024

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This protocol has regard for the HRA guidance and order of content

RESEARCH REFERENCE NUMBERS:

IRAS number: 347391

/ CO-SPONSORS / JOINT-SPONSORS

TRIAL REGISTRY NUMBER AND DATE:

SPONSOR number: 5649

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be explained.

For and on behalf of the Trial Sponsor:

Signature: ..... Date: ...../...../.....

Name (please print):

University Sponsor Representative.

Signature: ..... Date: ...../...../.....

Name: (please print): XXX

Chief Investigator

Signature: ..... Date: ...../...../.....

Name: (please print): XXX

KEY STUDY CONTACTS

Chief Investigator	Prof Jon Marsden University of Plymouth PL4 6AB jonathan.marsden@plymouth.ac.uk
Study Co-ordinator	Harriet Hughes University of Plymouth PL4 8AA Harriet.hughes-5@postgrad.plymouth.ac.uk 07894167532
Sponsor	Sarah.C. Jones University Sponsor Representative Research and innovation Drake Circus Plymouth PL6 8AA Plymouth.sponsor@plymouth.ac.uk
Funder	Torbay medical research Fund admin.torbaymrf1@nhs.net

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Contents

LIST OF ABBREVIATIONS

AE	Adverse Events
CDC	Child Development Centre
CI	Chief Investigator
CP	Cerebral Palsy
CRF	Case Report Form
CYP	Children and young people
EMG	Electromyography
FES	Functional Electrical Stimulation
GMFCS	Gross Motor Function Classification System
ICF	Informed Consent Form
MRC	Medical Research Council
MTS	Modified Tardieu Scale
NHS	National Health Service
PIS	Participant Information Sheets
PI	Principal Investigator

PROM	Passive Range of Motion
REC	Research Ethics Committee
SAE	Serious Adverse Event
SCALE	Selective Control Assessment of the Lower Extremity
SHP	School of Health Professions
SMC	Selective Motor Control
SMG	Study Management Group
SOP	Standard Operating Procedure
SC	Study Co-ordinator
SSC	Study Steering Committee
TDC	Typically Developing Children

TRIAL SUMMARY

Study Title	Functional Electrical Stimulation for the Management of Crouch Gait in Children with Cerebral Palsy	
Internal ref: **Short Title**	Sponsor No: FES in Cerebral Palsy	
Study design	Single case study design	
Study participants	Children with Cerebral Palsy and Typically Developing Children aged 8-18years	
Planned Sample size	12	
Study Duration	20 weeks	
Planned Study Period	2nd February 2025– 2nd April 2026	
Study End Date	2nd April 2026: This is the date by which the the last study participant will have completed their semi structured interview and marks the end of data collection.	
	Primary Objectives	Primary Outcome Measures
1.	To explore the therapeutic impact of 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 on variations of knee flexion at initial contact and midstance in children with crouch gait and cerebral palsy.	• Knee flexion angle at initial contact and midstance using an Electric Goniometer when walking on a 5-meter level walkway at self-selected and fast speeds and going up and down the stairs
		Secondary Outcome Measure
		• Quadriceps and Tibialis Anterior strength using a dynamometer • Passive range of motion of knee flexion (popliteal angle), ankle dorsiflexion and hip flexor length using a goniometer • Hamstring, Gastrocnemius and

		Rectus femoris spasticity measured by Modified Tardieu Scale (MTS) • Completion of the Selective Control Assessment of the Lower Extremity
	Secondary Objectives	Secondary Outcome Measure
2.	To explore the immediate Orthotic effect of Functional Electrical Stimulation applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait on variations of knee flexion at initial contact and midstance in children with crouch gait and cerebral palsy.	• Knee flexion angle at initial contact and midstance using an Electric Goniometer
3.	To explore how 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 affects parents' perception of gait and child's perception of fatigue and gait in children with cerebral palsy and crouch gait	• Parent and Child completion of the Gait Outcomes assessment List (GOAL) questionnaire • Child completion of the Neuro-QOL paediatric fatigue short form and 12-Item Walking Scale • Post FES Semi structured interview with parents and children/young people exploring perception of FES intervention on gait function and mobility.

3.	To explore the acceptability of FES intervention and study participation	• Semi-structured interviews informed by the constructs described in the Theoretical Framework of Acceptability
4.	To monitor adherence to a an 8-week FES intervention with FES being applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait in children with cerebral palsy and crouch gait.	• FES activity logger recordings of duration of use (HH:MM) and number of steps taken. • Post FES Semi structured interview with parents and children/young people exploring barriers to adherence to FES intervention.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
Torbay Medical research Fund admin.torbaymrf1@nhs.net	Financial Support of the study via a clinical doctoral fellowship which includes the cost of the backfill for my clinical hours.
University of Plymouth	Academic Support

ROLE OF TRIAL SPONSOR AND FUNDER

The Sponsor organisation is University of Plymouth. The Sponsor Representative is Sarah Jones - . The sponsor's responsibilities are as defined in the UK policy framework for health and social care research (version 3.3 2017).

Tasks associated with meeting various sponsorship responsibilities have been delegated to the CI or by way of formal agreement.

Torbay Medical Research Fund, funds this study as part of a Clinical Doctoral Fellowship. The role of the funder is to fund the trial. The Sponsor nor funder have no direct role in trial design, data analysis and interpretation, manuscript writing or dissemination of results.

ROLES AND RESPONSIBILITIES

Study Steering Committee and study management group

The Study Steering Committee (SSC) will consist of Harriet Hughes' supervisory team, Prof Jon Marsden, Dr Cherry Kilbride and Rachel Rapson, a patient representative and an independent specialist physiotherapist with research training.

The study management group will consist of Harriet Hughes' supervisory team, Prof Jon Marsden, Dr Cherry Kilbride and Rachel Rapson.

Frequency of Meetings

The SSC will meet on a 3 monthly basis

The study management group will meet on a monthly basis .

Responsibilities

The SSC will meet on a 3 monthly basis (via Microsoft teams or face to face) and provide oversight of the study (adverse events , withdrawals and/or declines, adherence to planned timelines, finances and recruitment rates and dissemination plans).

The study management group will meet on a monthly basis and discuss the everyday running of the study as well as adverse events.

Protocol Contributors

Harriet Hughes is the Study Co-ordinator and Doctoral Research Fellow and has shared responsibility for the implementation of this study in conjunction with the Chief investigator, Prof Jon Marsden. Harriet Hughes (SC) has responsibility for preparing the protocol, writing, and submitting the ethics and HRA applications, preparing periodic reports, recruitment, and clinical oversight of the safety of patients participating in the study, including an ongoing review of the risk and/or benefits. She

will also take the lead on data analysis and article publication. She is an experienced Paediatric Physiotherapy Clinician undertaking doctoral-level studies while employed by the NHS and the University of Plymouth.

Jon Marsden is Professor of Rehabilitation University of Plymouth and is the Chief Investigator of this study. He will be first supervisor for the part-time PhD studies of Harriet Hughes the Study Co-ordinator (SC) and will provide guidance on the protocol; management of the study, data collection and analysis and write up and dissemination

Professor Cherry Kilbride, Brunel University, London. She will act as a co-investigator to the trial and overall, as a second supervisor for the part-time PhD studies of Harriet Hughes. She will also provide guidance on the protocol; management of the study, data collection and analysis and write up and dissemination.

Dr Rachel Rapson, is a Clinical physiotherapy Manager and post-doctoral researcher, Torbay and South Devon NHS Trust. She will act as a co-investigator to the trial and overall, as a third supervisor for the part-time PhD studies of Harriet Hughes. She will also provide guidance on the protocol; management of the study, data collection and analysis and write up and dissemination.

Patient representative will provide advice on the study protocol, patient/public facing documentation, recruitment, timelines, adverse events and finances and dissemination

The independent academic physiotherapist will provide advice on the study protocol, recruitment, and timelines, adverse events and finances and dissemination.

KEY WORDS

1.BACKGROUND

Cerebral Palsy is a neuromotor disorder that affects the developing fetal or infant brain and has prevalence of between 2 and 3 per 1000 births worldwide [1]. Although the injury to the brain is non-progressive the functional impairments associated with CP are progressive in nature, resulting in interrelated neuromuscular

impairments such as muscle weakness, spasticity, contracture and reduced selective motor control; these significantly impact on a child's walking pattern and community participation [2].[3]

The functional ambulatory status of children with CP is assessed using the Gross Motor Function Classification System (GMFCS). This is a five-level scale; children with GMFCS level I-II walk independently with some limitations, children with GMFCS level III use a walking aid and children with GMFCS level IV and V are reliant on a wheelchair [4]. This study will focus on ambulant Children with CP, GMFCS level I to III.

Crouch gait is the most common gait problem, affecting 72-76% of ambulant children with bilateral CP [5]. This highly inefficient, tiring gait pattern is characterized by excessive knee flexion during stance phase of gait and if left untreated can lead to chronic knee pain [6]. The cause of crouch gait and the degree of knee flexion is unclear and multifactorial in nature, with potential factors including but not limited to, knee extensors weakness, excessive tibial torsion, knee flexor spasticity and contracture and impaired Selective Motor Control (SMC) [5,7]

Over time crouch gait leads to higher rates of joint pain, degenerative arthritis and if not adequately treated there is progressive gait deterioration. Once 30^{o} knee flexion while walking is reached, the degree of crouch rapidly progresses leading to the child requiring wheelchair use for mobility [7]. Although crouch gait may affect relatively small numbers of children, its impact is felt across a child's lifespan, placing a heavy burden on their quality of life long into adulthood. Furthermore, the management of crouch gait spans from childhood to old age, requiring multidisciplinary intervention from physiotherapists, orthotist, and Orthopaedic surgeons, at a significant cost to the NHS.

At present, the treatment of crouch gait is dominated by surgical interventions with hamstring lengthening being the most frequently used approach [8]. This is usually performed in the later stages of childhood to prolong independent ambulation and when conservative treatment options are exhausted. However, computer modelling has identified that short hamstrings may not be the primary cause of crouch gait and hamstring lengthening surgery may further weaken already weak muscles, increase

anterior pelvic tilt and contribute towards back pain [8]. Furthermore, rates of hamstring lengthening revision are high, due to its limited effectiveness and a return of the crouch gait pattern [8]. This places a heavy financial burden on the NHS and is costly to both children and parents alike, who experience disruptions to their home and school life.

Conservative approaches to the management of crouch gait include botulinum toxin injections to the hamstrings, strength training of the lower limb extensor muscles and/or the prescription of orthosis such as Ground reaction ankle foot orthotics [7]. Evidence suggests that any benefit of conservative interventions to reduce the degree of knee flexion are usually short term, with inconsistent and/or variable outcomes on crouch [7]. The limited availability of successful conservative interventions for children with crouch gait means that surgery is almost inevitable, particularly if these children are to remain ambulatory into adolescence and even then, the rate of ambulatory decline in adults with CP is prolific [7].

The lack of successful conservative intervention and high rates of ambulatory decline in children with crouch gait, highlight the need for further research into new novel treatment approaches such as Functional Electrical Stimulation.

2.RATIONALE

The focus of the proposed study is Children with GMFCS I-III, who comprise of around 67% of the population (about 23,400) of children with CP in the UK. Crouch gait is one of the most common gait deviations found in this population, affecting 72-76% of ambulant children with bilateral CP with the risk of it occurring increasing with age [9]. Over time crouch gait leads to higher rates of joint pain, degenerative arthritis and if not adequately treated there is progressive gait deterioration, loss of functional mobility and increasing reliance on a wheelchair for mobility. Although crouch gait may affect relatively small numbers of children, its impact is felt across a child's lifespan and places a heavy burden on a child's quality of life. Furthermore, the management of crouch gait spans from childhood to old age, requiring multidisciplinary intervention from physiotherapists, orthotist and Orthopaedic surgeons, at a significant cost to the NHS.

The lack of successful intervention and high rates of ambulatory decline in children with crouch gait, highlight the need for this research into FES. FES is a pocket electrical device combined with a foot switch to allow precisely timed muscle stimulation while walking. There is substantial evidence for the use of FES to manage ankle weakness (drop foot) in CP [10] and its use in this way is recommended in clinical practise by NICE [11] . In comparison, the evidence for using FES to address other gait abnormalities, such as crouch remains poor [7].

The use of FES to address crouch gait in children with CP has only been examined in two case studies [12, 13]. Both case studies reported that FES used to stimulate the quadriceps muscle increased knee extension during stance phase of gait and alleviated crouch.

At present the exact cause of crouch gait is unknown and believed to be multifactorial in nature [6] and although FES is unable to address all the factors affecting crouch there is rationale to suggest that it may be able to address factors such as knee extensor weakness, impaired selective motor control (SMC) and hamstring spasticity during the gait cycle. A prior observational study (IRAS 313063 ISRCTN14187957) by the research group in children with CP have confirmed the importance of these measures in causing crouch gait.

So far FES when applied to activate tibialis anterior in children with CP and a drop foot gait, has been found to increase muscle fibre diameter, size and strength [10], suggesting similar potential effects could be seen with FES when applied to the quadricep muscles in children with crouch gait. There is also evidence to suggest that electrical stimulation applied to tibialis anterior in children with Cerebral palsy and drop foot, can reduce spasticity in the opposing plantar flexor [14]. Thus, indicating that FES, when applied to the quadriceps in children with crouch gait, could have the potential to reduce spasticity in the opposing hamstring antagonist. Finally, FES may be able to compensate for impaired SMC in children with crouch gait, as it can produce a precisely timed quadricep activation, enabling knee extension to take place, when the hip is flexed at initial contact, thus diminishing the synergistic flexor movement pattern frequently seen in crouch gait [15]

Although there is a clear rationale for the potential effectiveness of FES in the management of crouch gait in children with CP, there is limited evidence [12, 13] to support its use in this way. Our study aims address the shortcomings of previous research and will examine the effect of FES applied to the quadriceps in children with cerebral palsy and crouch gait using a single case study series. The aim is that this will inform a future randomised controlled trial.

3.OBJECTIVES

3.1 To explore the impact of FES applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait over an 8-week period to the most affected limb on knee flexion angle at initial contact and midstance, in children with crouch gait and cerebral palsy.

3.2 To explore the impact of FES applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait over an 8-week period to the most affected limb on impairment profile (quadriceps and tibialis anterior strength, passive range of hip flexion; knee flexion and ankle dorsiflexion, selective motor control), in children with crouch gait and cerebral palsy.

3.3 To explore how FES applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait, over an 8-week period, affects parents' perception of gait and child's perception of fatigue and gait in children with cerebral palsy and crouch gait

3.4 To explore acceptability, study participation and adherence to an 8-week FES intervention with FES being applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait in children with cerebral palsy and crouch gait.

4. STUDY DESIGN

Using SCS we aim to examine the effect of FES applied to the quadriceps muscles for 2-4 hours a day, 6 days a week, over an 8-week period in children with CP who have a crouch gait. The FES application and stimulation parameters will follow previous work [16].

The effects of FES will be investigated using an AB single case study design. There will be an initial 8-week baseline period over which serial outcome measures (walking, muscle strength and perceived walking ability and fatigue) will be taken (figure 1). The FES will be issued in week 9 with a one-week period to determine the optimal simulation parameters. There will then be 8 weekly assessments while the FES being used (week 10-18). There will be a final assessment at week 20 where a semi-structured interview will occur (figure 1). At the start and end of each phase (weeks 1, 8, 10, 19) there will be a more in-depth assessment of impairment (muscle strength, passive range of motion and selective motor control).

The research question can be framed as follows:

Population: Ambulatory Children with bilateral Cerebral Palsy, age 8-18 years old, GMFCS level I-III

Intervention: Functional Electrical Stimulation applied to the quadriceps during stance phase of gait or Tibialis anterior during the swing phase of gait for 2-4 hours a day, 6 days a week

Time: 8 weeks FES intervention

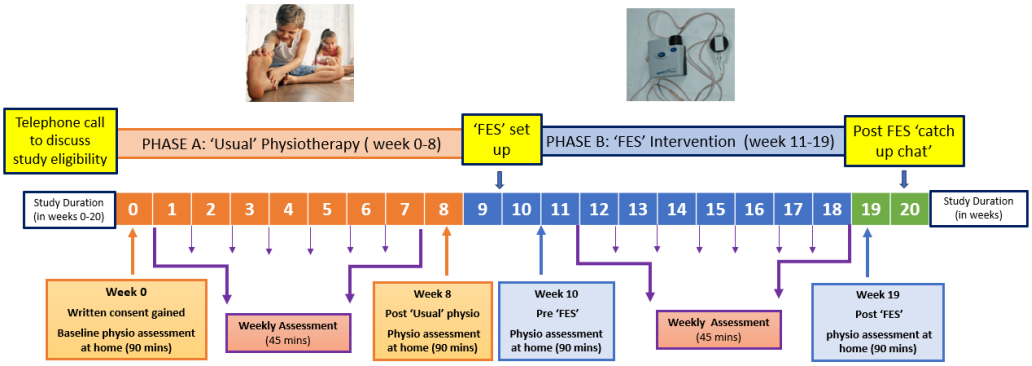
Outcome:

Primary: The effect of FES on knee flexion angle during mobility tasks (walking on the flat and up/downstairs), as measured by an electric goniometer at initial contact and midstance.

Secondary: Effect of FES on:

- Muscle strength, passive range of motion, selective motor control.
- Parents' perception of gait and child's perception of fatigue and gait
- Acceptability of FES as an intervention for crouch gait using semi structured interviews with parents and children/young people.

Figure 1. Study timeline diagram



5. STUDY SETTING

- The study will recruit children with CP from Child Development Centres (CDCs) and community settings. These include Torbay and South Devon NHS Trust, Plymouth Hospitals NHS Trust, Royal Cornwall Hospitals NHS Trust, Royal Devon University Healthcare NHS Trust.
- Community paediatric Physiotherapists and Occupational Therapists will recruit children from their caseloads and Orthopaedic consultants will recruit from their clinic list.

6. PARTICIPANTS ELIGIBILITY CRITERIA

6.1 Inclusion Criteria

1. Diagnosis of spastic CP (GMFCS level I-III), affecting one or more muscle groups in both lower limbs, and aged 8-18years

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.

6.2 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.

7.STUDY PROCEDURE:

7.1 Methods/ Data collection

7.1.1 Participant characteristics

The participant's GMFCS level and CP classification and distribution will be established during the initial phone assessment, using the screening tool (see Appendix 5), this will also identify the participant's age and gender and will ensure they meet the study eligibility criteria. During this telephone consultation the parent and child will be given the option of whether they want their assessments, pre and

post ‘usual’ physiotherapy care and FES intervention, to take place at home, a clinic centre or the University.

7.2 Procedure

Once the participant has been screened as eligible to participate, they will be invited for the initial baseline assessment. This can take place either at the home, local clinic room or the University. The same setting will need to be used for each assessment point (n=20).

At the baseline assessment consent will be obtained to participate in the study from parents/guardians and young people over the age of 16 years old. Time will be given for the participants and/or parent/legal guardian to ask questions. Prior to initiating any measures, we will obtain assent from children under the age of 16 years old. Throughout the measures of impairment and initial FES set up the Child/ Young person (CYP) will be given the opportunity to take comfort breaks. We will also ‘check in’ with the CYP during each measure, to ensure they are comfortable, to ask whether they may need a drink or a snack or the opportunity to go to the toilet as well as to check that they are happy to continue with the study. We will inform the CYP that they can withdraw their participation at any point during the study.

During the initial baseline assessment, we will measure the participant’s height and weight. If the CYP is happy to do so, we will then ask them to change into shorts. The child will the begin the clinical measures of impairment listed below, which will last approximately 90 minutes.

7.3 Clinical Measures of Impairment Battery

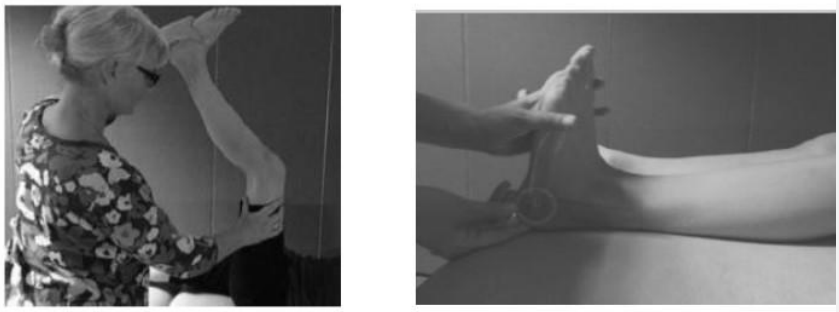
This battery of clinical measures of impairment will be taken at week 0 (prior to starting Usual’ Physiotherapy), week 8 (post ‘Usual’ Physiotherapy), week 10 (prior to starting FES intervention) and week 19 (post FES intervention) (see figure 1).

7.3.1 Passive Range of Motion (PROM) and Modified Tardieu Scale (MTS)

7.3.1 (I) Popliteal Angle and Hamstring Spasticity

The popliteal angle (assessment of hamstring length) will be obtained from both lower limbs with the participant positioned in supine lying on the plinth. The SC will flex the participants hip to 90 degrees and extend the knee, the research assistant will then record the popliteal angle using a goniometer, in accordance with Cerebral Palsy Integrated Pathway (CPIP) measurement guidelines [17]. This will then be repeated 3 times on each leg (see figure 3 A).

To establish hamstring spasticity this same movement will then be repeated on each leg at a fast speed termed R1, in the Modified Tardieu Scale (MTS) [18]. When the examiner feels a 'catch' during the movement a goniometer measurement will be taken to establish the spasticity component within the hamstrings muscle (see CPIP measurement guidelines [17])



A B

Figure 2 A Measurement of popliteal angle B Measurement of ankle angle

7.3.1 (II) Passive Ankle Range of Motion and Gastrocnemius spasticity

The participant will be positioned in supine on a plinth. The SC will extend the knee and dorsiflex the ankle (assessment of Gastrocnemius length), whilst the research assistant measures the degree of ankle dorsiflexion. This will then be repeated with the knee flexed (assessment of soleus length). Both goniometer measurements will

be repeated 3 times, so that an average measure of gastrocnemius and soleus length is obtained for each lower limb (see figure 2B and CPIP manual [17]).

To establish gastrocnemius spasticity, the ankle, with the knee extended will be dorsiflexed quickly, where a catch is felt (R1) and measure of gastrocnemius spasticity will be taken using the goniometer. This will be repeated once on both ankles in accordance to the CPIP manual [17]

7.3.1 (III) Duncan Ely and Rectus Femoris spasticity

To establish passive rectus femoris muscle length the child will be positioned prone, the knee will be flexed slowly and the heel brought towards the child's bottom, the goniometer is placed over the child's knee and a measure of this range of motion is taken. This will be carried out in accordance to the CPIP manual [17] and the measure will be repeated three times on each lower limb.

To measure rectus femoris muscle spasticity the movement above will be repeated but the examiner will flex the knee quickly, where a catch is felt by the RC a measure of rectus femoris spasticity will be taken (R1) using the goniometer (see CPIP manual [17])

7.3.1 (IV) Passive Hip Flexor Range of Motion (Thomas test)

Passive hip range of motion will be established with the CYP in supine, pelvis in neutral, with the opposing knee over the edge of the bed to accommodate knee flexor contractures. The goniometer will then be placed over the hip to measure the degree of hip flexion. This will be carried out in accordance to the CPIP manual [17] and the measure will be repeated three times on each lower limb.

7.3.1 (V) Modified Tardieu Scale (MTS) and establishing Spasticity.

Spasticity in the Gastrocnemius, Hamstrings and Rectus Femoris bilaterally will be calculated using the MTS [18]. Where spasticity in the muscle is the difference between R2 (Slow passive muscle range of motion as measured by a goniometer) and R1 (fast passive range of motion, where goniometer measurement is taken at

the angle of muscle reaction 'catch'). The difference between these two measures (R2-R1) helps differentiate muscle spasticity from muscle passive stiffness [18].

7.3.2 Muscle Strength Testing

7.3.2 (i) Tibialis Anterior Strength

With the participant positioned in supine on a bed or plinth, with hip and knee at 0 degrees if possible. The thigh is fixed by the participants parent or a strap; to stop the knee bending and the handheld dynamometer is placed just proximal to the metatarsophalangeal joint on the dorsum of the foot [19]. The participant positions their foot in plantigrade (90^{o} at the ankle) and is then asked to lift their foot upwards and the maximal force will be recorded, if the child is unable to achieve ankle plantigrade a score of 0 is given [19]. Three measures will be taken of each leg and the maximal reading used, normalised to body weight.

7.3.2 (ii) Quadriceps strength

The participant will be positioned in sitting, back supported by a chair, the knee is firstly positioned by the SC at 30 degrees flexion using a goniometer and rested on a stand (see figure 3) [19-21]. A handheld dynamometer will then be placed on the distal tibia and the participant will be asked to push their leg straight [19-21]. The maximal force will be recorded. The test is repeated with the knee at 90 degrees. For each test three measures will be taken of each leg and the maximal reading used, normalised to body weight and the same adjustable chair will be used for each participant to standardise the measurement.

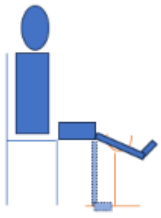


Figure 3: Position of the CYP for handheld dynamometer testing of quadricep strength.

7.3.3 Foot Posture

Foot posture will be 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 [17] A review of Foot posture will only take place at the initial baseline assessment 'usual' care, so that its effect as predictor on outcomes can be examined .

7.3.4 GOAL Questionnaire

The GOAL questionnaire will be issued to both Parent and Child. The GOAL consists of 48 items grouped into seven domains; domain A: activities of daily living and independence; domain B: gait function and mobility; domain C: pain, discomfort and fatigue; domain D: physical activities, sports and recreation; domain E: gait pattern and appearance; domain F: use of braces and mobility aids; domain G: body image and self-esteem and takes approximately 10 minutes to complete [22].

7.3.5 Walking Assessment

The walking assessment will take place across a 5-metre level walkway either in the child's home, local clinic room or University lab. The same setting will be used for each walking assessment pre and post usual physiotherapy and FES intervention. An electric goniometer will be placed over the knee joint (see figure 4) to measure the degree of knee flexion at initial contact and midstance in the most affected leg. An additional electrogoniometer will record ankle dorsi-/plantar-flexion and an accelerometer placed on the tibia to aid in the detection of initial contact while walking. Signals are sent via Bluetooth to a recording unit (Biometrics, DataLITE, UK) and analogue signal outputs are AD converted using a 1401 (CED electronics, Cambridge, UK) and recorded using Spike 2 software (version 6 CED electronics, UK).

To calibrate the electrogoniometer the output signal will be recorded while the participant is supine or sitting and the knee is passively positioned to 0 degrees and 90 degrees respectively (as confirmed using a manual goniometer). The most affected leg will be established through assessment of muscle length, spasticity and strength, taken during measures of impairment. At the pre 'Usual' physiotherapy care baseline assessment (Week 0) and the post 'Usual' physio care assessment (week 8) the CYP will be asked to complete an extensive walking assessment in the following three conditions 1.wearing their AFO's (if present) and normal footwear, 2. wearing their AFO and the FES pocket box (FES turned off and not connected to either lower limb muscle group), 3. Wearing No AFO (if safe to do so) and the FES pocket box (turned off and not connected to either lower limb muscle group), with each three conditions repeated three times (see figure 5A). In the pre 'FES' intervention and post 'FES' intervention assessment the CYP will be asked to complete the walking assessment in the following three conditions. 1. Wearing normal footwear and AFO, 2.FES ON and wearing normal footwear, 3. FES Turned off and wearing normal footwear , with each condition repeated three times. (see figure 5B).

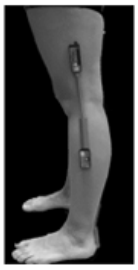


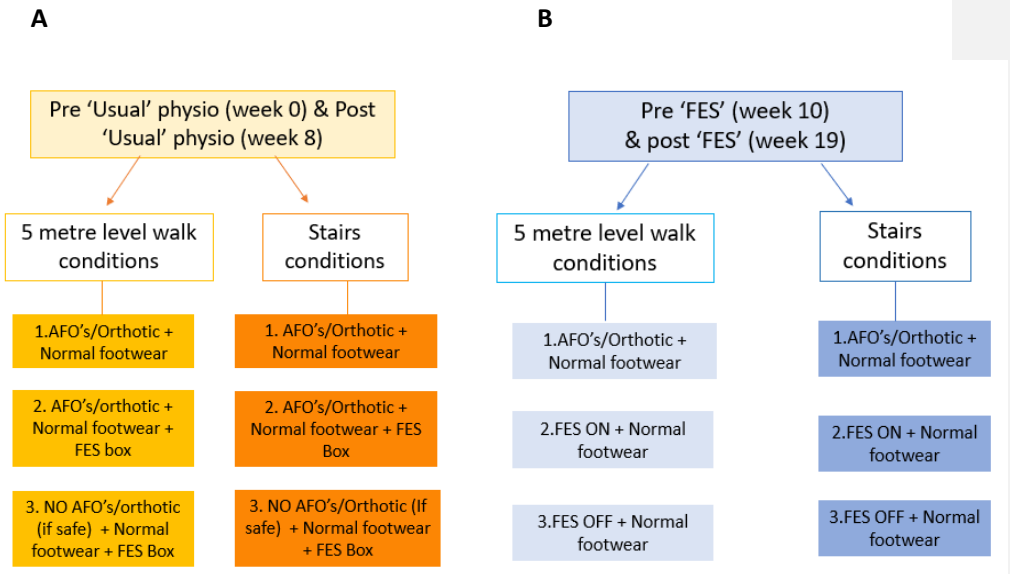
Figure 4. Electric goniometer placement for walking and stairs assessment

7.3.6 Stairs Assessment

For the stairs assessment the CYP will be asked to walk up and down a flight of stairs using their preferred method, but not exceeding one step at a time as carried out in a similar FES case study on children with CP [12]. If the baseline assessment is being carried out at the participants home this will be on their flight of stairs, alternatively this may be stairs at a local clinic or the university if this is a preferred location for the CYP and family to have their baseline assessments, but the flight of

stairs will remain the same for each individual participant for the duration of the study. During the stairs assessment the child will wear and electric goniometer over the knee joint (see figure 4) to record the degree of knee flexion. A video recording of the child ascending a descending the stairs will be taken and a tick box form will be used for the SC to describe their technique and the stairs being used (see appendix 6). The stairs assessment will be carried out pre – 'Usual' physiotherapy (week 0) with AFO's/Orthotics and again post 'Usual care' (week 8). It will then be repeated pre-FES intervention (week 10) and post- FES intervention, with AFO's/Orthotics and with FES On and normal footwear and FES OFF and normal footwear (See figure 5)

Figure 5: A) Diagram of the walk and stairs conditions during 'Usual' physiotherapy care.
B) Diagram of the walk and stairs conditions during the FES intervention



7.3.7 Selective Motor Control (SMC)

SMC will be assessed using the validated, Selective Control Assessment of the Lower Extremity (SCALE) tool [3]. This tool was developed by Fowler *et al.* (2009) for health professionals to clinically assess SMC in the entire lower limb in patients with spastic CP. The SCALE assessment will be completed by the SC with participants positioned in sitting, except for the assessment of the hip, which will be performed in side-lying. The assessment will be filmed using 2 static cameras set up to give a lateral and frontal view and the video footage will be used by the SC to calculate the SCALE score for each participant's lower limb. The SCALE will take place at the baseline assessment on Week 0, post usual care assessment (week 8), pre FES intervention assessment (week 10) and post FES intervention (Week 19) (see figure 1)

8. USUAL PHYSIOTHERAPY CARE

Once the baseline assessment has been completed (Week 0) the child is asked by the SC to continue with their 'Usual' Physiotherapy care. During this time, they are asked to avoid starting any new sports or joining a new physical activity club, but instead to continue with their usual physical activity routine. This 'Usual' care period will last for a duration of 8 weeks (see figure 1). During the usual care period the SC will visit the child once a week in their own home to carry out a weekly physiotherapy assessment

9. WEEKLY MEASURES

Weekly measures will take place at the child's home, it will last approximately 45 minutes and will take place weekly throughout the duration of 'Usual' physiotherapy and 'FES' intervention (see fig 1). In total across the whole study the CYP will receive 16 sessions of weekly measures with the SC. The weekly measures will include measures of muscle strength, walking on the level and up and down stairs on

the leg most affected by CP as well as patient reported outcomes of perceived fatigue and walking ability. We will now outline each of these in more detail.

9.1 Weekly clinical measure of impairment

9.1.1 Tibialis Anterior Strength

This will be carried out in the same way as during the baseline assessments using a handheld dynamometer, but this time it will only focus on the leg most affected by CP (see section 7.3.2 (i)) Three measures will be taken of each leg and the maximal reading used, normalised to body weight.

9.1.2 Quadriceps strength

This will be carried out in the same way as during the baseline assessments using a handheld dynamometer, but this time it will only focus on the leg most affected by CP (see section 7.3.2 (ii)) Three measures will be taken of each leg and the maximal reading used, normalised to body weight.

9.1.3 Spasticity

Spasticity in the Gastrocnemius, Hamstrings and Rectus Femoris of the most affected leg will be measured weekly using the MTS.

9.1.4 Weekly walking measure

Weekly walking assessments will be carried out in the same place each week, either at the CYP's home, local clinic or Plymouth university laboratory and this will be at the choice of the CYP and parent.

During the weekly walking assessment an electric goniometer will be placed over the knee joint (see figure 4) to measure the degree of knee flexion at initial contact and midstance in the most affected leg (for more detail see section 7.3.4). The child will then be asked to walk 5 metres on the level at a self-selected speed. During 'Usual' physiotherapy the walking assessment will be repeated three times for each condition, with the child wearing their AFO/Orthotic provision and with just their normal footwear. For the weekly walking assessment taking place during 'FES' intervention period, walking assessments will take place in the following conditions

and repeated 3 times, with FES ON and normal footwear, with FES OFF and normal footwear and with AFO/Orthotic and normal footwear. Each week the order in which the walking conditions take place will be altered.

9.1.5 Weekly Stairs measure

As above the electric goniometer will be placed over the knee joint (see figure 4) to measure the degree of knee flexion in the most affected leg as the child ascends and descends the stairs. As outlined in 7.7 of this protocol a video recording of the child ascending a descending the stairs will be taken and a tick box form will be used by the SC to describe their stair technique each week. The weekly stairs measure will be carried out with AFO's/Orthotics and their normal footwear during 'Usual' care. During FES intervention weekly stairs measures will take place with FES On/normal footwear, FES OFF/normal footwear and the CYP wearing their AFO's/Orthotics and normal footwear (See figure 5B)

9.2 Weekly Patient Reported Outcome Measures

9.2.1 Fatigue

Fatigue will be measured each week using the self-report Neuro-QOL paediatric fatigue form, which is design to measure the domain fatigue in children across a range of neurological children [23]. It consists of 11 questions regarding symptoms of fatigue experienced 'in the past 7 days' , frequency of symptoms experience is then rated on a 5 point Linkert scale ranging from 'None of the time' to 'All of the time' and will take less than 5 minutes to complete [23].

9.2.2 12 Item Walking Scale

Limitations in the participants walking over the past week will be measured using a patient reported outcome measure called the 12- Item Walking Scale (Walk 12-G). It consists of 12 questions which are then rated on a Linkert scale, it is a useful measure of walking ability in people with neurological conditions [24]

9.2.3 FES activity logger

Each week during FES intervention the SC will collect data stored on the FES activity logger. This data includes the number of steps taken and the duration of use in HH:MM.

10. INTERVENTION

The intervention phase of this study is FES using either the Odstock Dropped Foot Stimulator (ODFS®) Pace or the ODFS® Pace XL device depending on CYP preference and availability. Both FES devices are a battery powered, pocket electrical device combined with a foot switch to allow precisely timed muscle stimulation while walking.

The FES devices are CE marked and approved by NICE. Both devices are described in detail (see appendix 8) using the Template For Intervention Description and Replication (TIDIieR).

Before FES intervention can begin a clinical decision will be made whether FES is going to be used to stimulate the Tibialis Anterior muscle or the Quadricep muscle in the most affected leg. This will be based on, clinical outcomes of the baseline physio assessment and will be guided by a clinical decision-making tool (see Appendix 7). FES application, training and usage is according to current paediatric UK guidance and local usual practice [25].

10.1 FES Set Up (week 9)

Once a decision is made about the muscle group being stimulated by FES the participant will be set up with an Odstock Dropped Foot Stimulator ODFS® Pace or if the participant prefers, the wireless version ODFS® Pace XL FES device. FES set will take place in week 9 with the SC at the participant preferred location (see figure 1). For Tibialis anterior stimulation, FES set up will take place with the participant in sitting. The SC will place two, 50mm x 50mm PALS Plus® square electrode pads (see figure 6A) on the lower leg, one over the head of the fibula and the other over the muscle belly of Tibialis Anterior, in accordance to the ODFS® Pace and ODFS® Pace XL manual (see figure 6B). In participants with smaller legs, the electrodes may need to be cut down to size for an accurate muscle stimulation. The SC will then turn up the FES current until a contraction is observed in the muscle and the foot begins to dorsiflex and evert.

A B

Figure 6 : **A** PALS® Plus square electrode 50mm x 50mm **B** FES electrode placement for Tibialis Anterior stimulation

If the participant is being set up with FES to stimulate the quadriceps the SC will place two PALS Plus® round electrodes of either size 25mm or 32 mm (depending on the size of the child's leg) over the distal vastus medialis oblique and proximal lateralis, in accordance to the manual (see figure 7B). With the participant sat up on a bed and the knee straight, the SC will gradually increase the FES current until a contraction is observed in the quadricep muscle belly.

Figure 7: **A** PALS round electrodes **B** FES electrode placement for quadricep stimulation

During FES Set Up, the participant will experience the sensation of FES activating the muscle for the first time, for some CYP this can be uncomfortable to begin with. They will be given time to get used to the sensation and can stop for comfort breaks if required. If the CYP is unable to tolerate the sensation, they can ask to stop the session and may wish to withdraw from taking part in the study. Once the FES device is set to a level that a contraction is observed in either Tibialis Anterior or the Quadricep, the SC will stick the foot switch into a cork insole, which can then be placed in the child's shoe. In most cases the foot switch will be placed in the heel of the insole (see figure 8A), but if the child is not achieving a heel strike at initial contact, the foot switch will need to be placed under the head of the first metatarsal (see figure 8B). Once the foot switch is connected to the FES device the participant is ready to trial using the FES when walking. For FES tibialis anterior set up, the FES device will be set to activate tibialis anterior when the heel or forefoot rises off the floor and through swing phase of gait. For FES quadricep set up the device will be set to activate the quadricep at initial contact and early stance phase of gait. Once the child is walking with the FES the SC may have to make further adjustments to the timing and speed of the muscle activation for optimal gait performance

10.2 Intervention Training

The CYP and their parent will receive training on using their FES device. General training will include donning and doffing of the FES device, use of the FES, care of the electrode, electrode placement and potential adverse skin reactions to electrode pads. All of this will be documented in an information leaflet (see Appendix 4) for them to take home with their FES device. Participants will be taught how to monitor possible training effects of FES such as; transient muscle fatigue, and post exercise muscle soreness, which are normal physiological responses to walking practise whilst wearing FES.

A **B**

Figure 8. **A** Placement of foot switch in the heel of cork insole. **B** Placement of the foot switch on the 1st metatarsal head

Once FES training is complete the CYP will be issued with the FES devices and bag of accessories to take home.

- FES device and battery
- FES set of electrode wires and foot switch wire
- 1 Set of Electrodes
- Airtight bag to store electrodes.
- User Instruction Manual
- Cork Insole and foot switch
- FES pouch, to hold FES device when wearing it.
- FES supporting leaflets.

Following FES training the CYP will be asked to use the FES daily, this should start in and around the house, but building up confidence to wearing it in the community setting or at school. The aim is to build up over 1 week to wearing the FES for between 2-4hours a day in preparation for starting the FES intervention phase of the study at week 11. One week after receiving FES training (Week 10), the participant will receive a home visit from the physiotherapist to check the CYP has been using it correctly and to make any changes required to optimise gait.

10.3 SC Training

The SC is trained Children's Physiotherapist with over 8 years of experience working with children with CP. She completed the OML® FES training course for the lower limb in 2019 and uses FES regularly for the treatment of drop foot in CYP with CP at Torbay Hospital CDC.

10.4 FES intervention

FES Intervention will begin in week 10, once the pre-FES assessment has taken place and the FES desensitisation period is complete (see figure 1). FES intervention will end in week 18.

Each CYP will be asked to use the FES device for between 2-4 hours a day, 6 days a week, for 8 weeks. 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.

10.4 Pre and Post FES assessment

Before FES intervention can begin the participant will need to complete their pre-FES physio assessment (week 10) (see figure 1). This will last approximately 90 minutes and will take place at the participants' home, local clinic or University laboratory, depending on parent and child preference with the SC. The pre-FES

assessment will consist of the clinical measures of impairment, GOAL questionnaire and kinematic measures of walking outlined in 7.3 of this protocol.

Once FES intervention is complete the CYP will receive a post FES assessment (week 19) with the SC (see figure 1). This will consist of the clinical measures of impairment, GOAL questionnaire and kinematic measures of walking outlined in 7.3. Once the post FES assessment is complete the CYP will need to return the FES device to the study co-ordinator.

11 QUALITATIVE EVALUATIONS

11.1 CYP and Parent Interviews

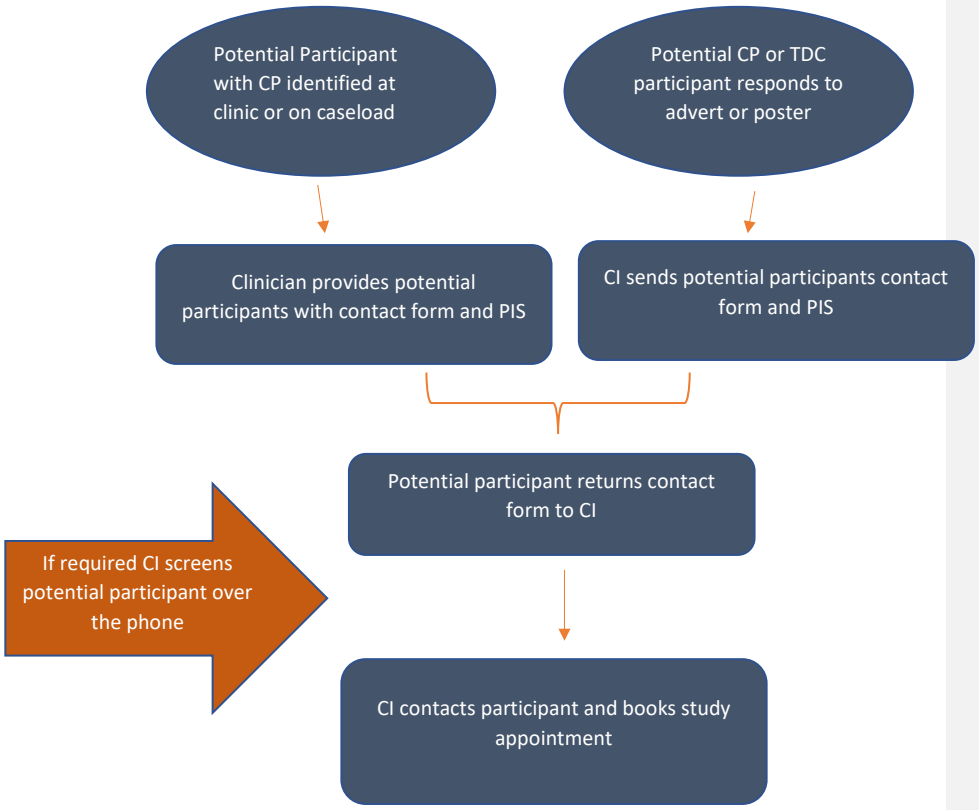
Interviews will be conducted in person or over video call at the end of FES intervention (week 20) (see figure 1). In person interviews will be in the CYP home with their permission. The interviews will be conducted by the SC following topic guides developed from the TFA. Each interview will last approximately 45 minutes and will follow the interview schedule outlined in Appendix 5.

12.RECRUITMENT

Recruitment will take place simultaneously across each Child Development Centres (CDCs) and Community Paediatric Outpatient physiotherapy services. These include Plymouth Hospitals NHS Trust, Torbay and South Devon NHS Trust, Royal Cornwall Hospitals NHS Trust and Royal Devon and Exeter NHS Trust. The study will be advertised via interest groups, University of Plymouth website and charity / support group websites (e.g Cerebra). In preparation for recruitment, the SC will visit each site to familiarise physiotherapists with the eligibility criteria and study procedures.

Potential study participants will be identified, screened, and recruited as shown in Figure 9.

Figure 9. Diagram of recruitment



- Recruitment will take place simultaneously in each NHS trust, the university of Plymouth and via social media
- In preparation for recruitment the SC will visit each recruiting sites to familiarise recruiting clinicians with eligibility and study procedure.
- Once a child has been recruited and identified as a suitable candidate to participate in the study the SC will contact their parents to arrange an appointment for them attend the study assessment at the University of Plymouth.

12.1 Estimation of recruitment rate

There are an estimated 1460 children with CP within the targeted age range and severity distribution in the South West of England, based on published prevalence data and population estimates from the Office for National Statistics (2015). Of these 71% of children are predicted to be ambulant, i.e. GMFCS levels I-III. We anticipate that within each NHS trust locality there will be approximately 150 children with a diagnosis of CP (Cerebral Palsy Integrated Pathway South West, 2017 unpublished data). Therefore, we predict that approximately 60-80 ambulant children with CP may be eligible in each NHS trust locality.

We aim to recruit 12 participants with CP across the three sites in Devon and Cornwall over a 6-month period. An estimated recruitment rate of two to four children per month over a maximal 10-month period has been calculated based on the population and previous experience.

12.2 Participant identification

Recruitment will primarily occur through clinical teams at 4 NHS Trusts: These include Plymouth Hospitals NHS Trust, Torbay and South Devon NHS Trust, Royal Cornwall Hospitals NHS Trust and Royal Devon and Exeter NHS Trust.

Participants will also be recruited via posters and adverts. These will be distributed in local newsletters of groups such as APCP (Association of Paediatric Chartered Physiotherapists) and PenCru (Peninsula Childhood Disability Research Unit). As well as online via social media sites such as facebook, Instagram and twitter on pages that are relevant to our study population, such as Cerebral Palsy UK, Cerebra, CP sport and SCOPE .

- Physiotherapists, occupational therapists, paediatricians and orthopaedic surgeons will identify potential participants during clinics and via their caseload lists. Clinicians may approach children on their caseloads by telephone before sending out an information pack to those who are interested in taking part. The information pack contains a contact reply slip, prepaid envelope and information sheet.

- Posters and leaflets will be produced for clinicians to distribute to potential participants. They will also be issued for clinicians to put up in departments and waiting rooms where children with CP may have appointments.
- Potential participants can contact the research team via contact details on posters / adverts or via a contact reply slip and prepaid envelope which is part of the information pack.
- When potential participants contact the research team they will be contacted via their preferred route (eg telephone / e mail) and the participant information sheet (PIS) will be sent out and later discussed to ensure that the parents / guardian and children understand the study prior to volunteering. The PIS will be available for parents and young adults (16-18 years) and an easy read version will be available for children.
- Consent forms will be provided to parents and, young adults, and assent forms provided to children when attending the appointment.
- Participants / guardians and or parents will be issued with PIS at least 24 hours prior to their study appointment so that they have time to discuss the trial with the research team before participating.

12.3 Screening

The local PI will use a study-specific screening log to record numbers of children eligible, ineligible, the numbers of children approached, and numbers of study information packs given out at each site. Potential participants who respond to the invitation and will be screened for suitability using a telephone questionnaire to check diagnosis, age, GMFCS level, neuromusculoskeletal involvement and distribution and the child's ability to follow simple instructions.

12.4 Payment

Travel expenses (up to £30/visit) will be reimbursed for all assessment sessions taking place outside of the home. Travel expenses above this amount will be discussed on a case-by-case basis.

12.5 Consent

- Potential participants/parents and/or guardians will be issued with a PIS.
- Discussions will take place between the potential participant, their parent and/or legal guardian and a member of the research team. This will cover the nature of the study, the study procedure, the possible risks associated with participation, as well as their right to withdraw from the study at any time. Potential participants/parents and/or guardians will also be given the opportunity to ask questions.
- According to the Medicines For Human Use (Clinical trials) regulations, children under the age of 16 are prohibited from taking part in a clinical trial without the consent of a parent or legal guardian or representative. Therefore, in children under the age of 16 years old, the child's parents or their legal guardian will be responsible for signing and completing the written consent form. Assent from the child will be obtained through discussion with their parent or legal guardian and the CI.
- Young person's participating between 16 and 18 years of age who are considered capable of giving consent according to the Health Research Authority will have the opportunity to complete their own written consent form.
- Written informed consent and assent will be recorded at the start of the child's study appointment by the CI, before any study investigations can begin.

12.6 Withdrawal

Participants can withdraw at any point in the study without giving a reason. It will be emphasised that this would not affect their healthcare or potential involvement in another research. At the point of withdrawal from the study CYP data up to that point will be used for data analysis unless the CYP and/or parent express that they would like this data to be destroyed.

13 ASSESSMENT AND TESTING

13.1 Baseline data

- GMFCS level

- Distribution of lower limb weakness
- Date of Birth
- Medical and surgical history
- Height, Weight,
- Presence and site of any pain
- Foot posture

13.2 Outcomes

The study objectives will be measured using the Outcome measures listed in the table below.

Objectives	Outcome Measures to be Completed
Primary Objective	
1. To explore the therapeutic impact of 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 on variations of knee flexion at initial contact and midstance in children with crouch gait and cerebral palsy.	• Knee flexion angle at initial contact and midstance using an Electric Goniometer when walking on a 5-meter level walkway and going up and down the stairs • Quadricep and Tibialis Anterior strength using a dynamometer • Passive range of motion of knee flexion (popliteal angle), ankle dorsiflexion and hip flexor length using a goniometer • Hamstring, Gastrocnemius and Rectus femoris spasticity measured by Modified Tardieu Scale (MTS) • Selective Motor Control as measured by the Selective Control Assessment of the Lower Extremity tool (SCALE)
Secondary Objectives	
2. To explore the immediate Orthotic effect of FES applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait on variations of knee flexion at initial contact and	• Knee flexion angle at initial contact and midstance using an Electric Goniometer.

midstance in children with crouch gait and cerebral palsy.	
3. To explore how FES applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait effects strength of the Quadriceps and Tibialis anterior and spasticity in the hamstrings, gastrocnemius and rectus femoris	• Hamstring, Gastrocnemius and Rectus femoris spasticity measured by Modified Tardieu Scale (MTS) • Quadricep and Tibialis Anterior strength measured using a hand held dynamometer
4. To explore how FES applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait effects selective motor control	• Completion of the Selective Control Assessment of the Lower Extremity
5. To explore how FES applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait over an 8-week period effects parents perception of gait and CYP's perception of fatigue and gait in children with CP and crouch gait	• Parent and Child completion of the Gait Outcome Assessment List (GOAL) questionnaire • Child completion of the Neuro-QOL paediatric fatigue short form and 12-Item Walking Scale • Post FES Semi structured interview with parents and children/young people exploring perception of FES intervention on gait function and mobility.
5. To explore the acceptability of FES intervention and study participation	• Semi-structured interviews informed by the constructs

	described in the Theoretical Framework of Acceptability
6. To monitor adherence to a an 8-week FES intervention with FES being applied to either the Quadriceps during stance phase of gait or Tibialis Anterior during swing phase of gait in children with cerebral palsy and crouch gait.	• FES activity logger recordings of duration of use (HH:MM) and number of steps taken. • Post FES Semi structured interview with parents and children/young people exploring barriers to adherence to FES intervention.

13.3 Outcome Measures

13.3.1 Primary Outcome Measures

Knee flexion at initial contact and midstance, measured by the Electrogoniometer when walking.

13.3.2 Secondary Outcome Measures

- Knee flexion, as measured by the Electrogoniometer, when ascending and descending the stairs
- PROM of the ankle, in a flexed and extended knee position using a goniometer
- PROM Popliteal angle of the knee using a goniometer.
- PROM of Rectus Femoris (Duncan Ely Test) using a goniometer
- MTS measuring spasticity in Hamstrings, gastrocnemius and rectus femoris
- Strength in the Quadriceps and Tibialis anterior using a handheld dynamometer.
- GOAL -Gait Outcome Assessment List
- Neuro-QOL paediatric fatigue
- 12 Item walking scale
- SCALE - Selective Control Assessment of the Lower Extremity

14. DATA MANAGEMENT

14.1 Data Collection Tools and source document identification

Study data will be recorded on the trial specific case report forms. The Case report Form (CRF) will be a printed paper document. Data captured on the CRF will be considered source data. The baseline date and outcome measures that will be recorded are outlined in the data management plan.

The study co-ordinator will complete a CRF form for all participants. Completeness of data will be maximised by:

- Checking all forms at the end of the study to ensure no missing items
- Where possible, arranging another assessment session should the participant not attend the scheduled study appointment.

Once each study appointment is completed the CRF forms will be signed and dated by the SC.

14.2 Participant Numbering

Each participant will be issued a unique participant number once registered onto the study.

14.3 Archiving

Paper and electronic formats and essential study documentation (i.e content of Study Master file) will be store in a secure location for a minimum of 10 years after the end of the study. Archiving will be authorised by the Sponsor following submission of the end of study report. No essential documents should be destroyed unless or until the Sponsor gives authorisation to do so. This is in accordance with the University of Plymouth Research Data Management Policy which can be found here: https://plymouth.libguides.com/researchdatamanagement

14.4 Access to Data

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

15. STATISTICS AND DATA ANALYSIS

15.1 Quantitative data Analysis

Serial data (n=16) gathered across phase A and B will be analysed using multiple-methods including an extended celeration line (ECL), a percentage of overlapping data (PND) and a Two Standard Deviation Band Method .

The ECL or split middle line method can control for positive or negative trends in the A Phase. Here the Phase A data is divided into two halves and the median calculated for each half. The two median points obtained will be joined to form the ECL. The ECL is then extend through Phase B to predict any trend in the continuation of data. The number of intervention phase B data points above trend line will be counted and divided by total Phase B data points to calculate a percentage/ratio. A chance-level score is considered 50%, or 4 out of 8 intervention data points above the trend line [27].

The PND method is calculated by locating the highest data point plotted in the baseline phase A and then counting the number of intervention phase B data points that exceed it. This value is then divided by the total number of intervention phase B data points to calculate a percentage. A PND < 50% would mark no observed effect, PND = 50–70% signifies a questionable effect, and PND > 70% suggests the intervention was effective [28].

The two Standard Deviation Band Method involves calculating the mean and standard deviation (SD) from Phase A. The SD value will then be multiplied by two and then added to the mean to give the +2 SD band and subtracted from the mean to give the -2 SD band. A significant change in performance occurs when, within

Phase B, at least two consecutive data points fall outside the 2SD range within the intervention phase [29].

Data gathered at the start and end of each phase (n=4) will be summarised using descriptive statistics (median, range, inter-quartile range) and plotted. The graph will provide visual analysis and interpretation of trends, which will be compared alongside findings from serial measurement data analysis.

15.2 Qualitative data

To determine the feasibility, acceptability and safety of the intervention interviews will be analysed using the five iteratives stage of the Framework Analysis method (familiarisation, thematic framework identification, indexing, charting, mapping and interpretation) [30]. This method incorporates both deductive and inductive coding and provides a strong audit trail of the analytical process from original transcripts to final themes, including illustrative quotes [31], and enables trial processes and positive as well as negative participant experiences to be explored and reported. Deductive trial factors will include factors relating to feasibility, acceptability and adoption of technology which will be informed by the theoretical framework of acceptability [32] and the NASSS Framework [33].

15.3 Sample size calculation

As a single case design, no formal sample size has been calculated through statistical analysis. The total sample size of 12 has been estimated based on the length of the study design, access to measurement and intervention resources and the set time frame of 15 months to complete the study. Each single case study lasts for 20 week (4.5 months). There are x4 FES units available at any one time. We intend to recruit x2-4 people / month. Therefore, we should be able to recruit to target within 15 months.

16.SAFETY AND MANAGEMENT OF RISK

16.2. Clinical measures

The SC has training and experience from a previous observational study in carrying out the SCALE, PROM and MTS, MTS using a goniometer, Hand Held Dynamometer and in using the electrogoniometers. The participant will also be given a verbal explanation of what will happen during the clinical measures, and they will have the opportunity to stop the assessment at any time. For the clinical measures the participant will position themselves in sitting or lying in accordance to what is required for the assessment. This will be on a height adjustable plinth if taking place in a clinic setting or at home on a bed if. If taking place on a plinth the CI and SC to raise the plinth to a suitable height during the assessment, thus reducing manual handling risks. If taking place at home the SC will need to be mindful of their own posture and position when carrying out assessments and make adjustments as required to minimise any manual handling risks. If a participant has difficult moving themselves from lying to sitting or transferring onto a plinth or bed, they will be assisted by the CI and SC using appropriate risk assessed, manual handling techniques. The CI and SC will have up to date manual handling qualifications and training in place.

CYP will be accompanied during the walking and stairs measures to prevent and reduce the risk of falls. The stairs will either be the ones situated in their own home, which they are familiar with, or ones situated within the university or clinic setting with handrails.

16.3 Loan working in the community setting

CYP and parents will have the choice to be seen at home for their baseline and weekly assessments or within a clinic or university lab setting. The site chosen will remain the same for the CYP for the study duration. If CYP selects the community setting, which could be either the CYP home or local clinic, the SC will inform the CI of the date and time of each appointment as well as the CYP home address. The SC will also telephone or text the CI at the end of the appointment to inform them that they are safe. The SC will have their mobile phone on them with them for the

duration of the study appointment so If they feel unsafe during a home visit they can make contact with the CI or the emergency services.

16.4 RISK Level

A risk assessment has been completed, (please refer to the Risk assessment document). This suggest that the study is of 'Low Risk' category and the appropriate steps will be taken to mitigate any potential risks posed to participants and no further action is required.

17. ADVERSE EVENTS

17.1 Recording and reporting of AEs

An adverse event (AE) is defined as any unfavourable and unintended sign that develops or worsens during the period of the trial, whether or not it is considered to be related to the trial. The risks of taking part in this trial have been assessed to be low.

Any new or worsening problems, which participants perceive to be related to participation in the study and occur at the single visit and within the following 48 hrs will be captured.

Examples of AEs that require reporting include:

- Aches and pains in the leg muscles following FES stimulation, lasting over 1 hour following cessation of the stimulation or requiring pain relief
- Fatigue following FES intervention lasting more than 1 day
- Injury related to the study procedure or data collection
- Red marks or a reaction on the surface of the skin because of contact with FES electrode pads, which last for more than 10 minutes after data collection is complete.

Participant's parent and or guardian will be asked to report any AE's that occur for the duration of the study to the CI/ SC. These will be gathered during the weekly face-to-face measurement sessions. Recorded AEs and SAEs will be presented at a

Study management Group (SMG) meeting for review. The SMG will refer concerns to the Study Steering committee (SSC) for further review if required. AEs considered related to study participation will be followed until resolution or the event is considered stable. If the AE occurs during the study assessment the Study Co-ordinator (SC) in discussion with the participant parents/Guardian will take responsibility as to whether an AE is of sufficient severity to withdraw the participant from the study. The participant may also voluntarily stop participating in the study if he or she perceives an incident to be an intolerable AE.

17.2 Recording and reporting of SAEs

Participants and the SC will be asked to report any SAEs directly to the CI as soon as possible via e-mail / Telephone call. A serious adverse event (SAE) is defined as an untoward occurrence that:

(a) results in death;

(b) is life-threatening;

(c) requires hospitalisation (where hospitalisation is any admission leading to an overnight inpatient stay, or any day case appointment, or any ED attendance) or prolongation of existing hospitalisation;

(d) results in persistent or significant disability or incapacity;

(e) consists of a congenital anomaly or birth defect; or

(f) Is otherwise considered medically significant by the investigator.

SAEs will be recorded until the date the participant completes follow-up or withdraws from the study. SAEs may be volunteered by the participant or discovered by the SC through questioning, physical examination or other investigation, or as a result of direct reporting (e.g. by telephone) by the participant, independent clinician or other informant. Participants will be asked to report any SAEs directly to the CI as soon as possible via e-mail / Telephone call.

SAEs will be followed until resolution/stable condition is reached. It is not anticipated that there will be any SAEs related to this study. Any SAE will be reported within 24 hours of the research team becoming aware of it. Any Unexpected Serious Related Events will be reported to REC within 15 days of CI being informed.

17.3 Responsibilities

Study Co-ordinator (SC):

- Checking for AEs when participant attends study day.
- Ensuring that all SAEs are recorded and reported to the sponsor and CI within 24hrs of becoming aware of the event and provide further follow-up information as soon as available.
- Completion of the SAE form must include the PI's assessment of causality i.e. whether there is a reasonable causal relationship between the SAE and attending the study appointment. If incomplete information is available at the time of reporting, all appropriate information relating to the SAE should be forwarded to the CI as soon as possible.

Chief Investigator (CI) / delegate or independent clinical reviewer:

- Clinical oversight of the safety of patients participating in the study, including an ongoing review of the risk / benefit.
- Ensuring that SAEs are sent to the sponsor within 1 working day of initial reporting. Using medical judgement in assigning the SAEs seriousness, causality and whether the event was anticipated where it has not been possible to obtain local medical assessment.
- Review of specific SAEs in accordance with the trial risk assessment and protocol.
- Central data collection and verification of AEs, SAEs, according to the study protocol onto study database.

18. MONITORING, AUDIT & INSPECTION

The research team will devise a monitoring plan specific to the study, based upon an initial pre-trial risk assessment, which will be updated as required throughout the study. The monitoring plan will include both central monitoring strategies and site set up reviews as appropriate and will be regularly reviewed. Monitoring will include oversight of processes relating to the safety of participants and the integrity/reliability of the study data, including adverse events reporting, participant enrolment, consent, eligibility, and adherence to study protocol and policies to promote the accuracy, and timeliness of data collection.

All study procedures will be conducted in accordance with the protocol and according to the principles of GCP.

19. ETHICAL AND REGULATORY CONSIDERATIONS

19.1 Research Ethics Committee (REC) review & reports

The study will not be initiated before the protocol, informed consent forms, Participation Information Sheets and other relevant documents (e.g. GP information letters, exit questionnaire and invites to participate) have received ethical approval from the REC, HRA, the University of Plymouth Faculty of Health Research Ethics and Integrity Committee and the respective NHS R&D departments.

Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed study documents (if appropriate) have been reviewed and received approval from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible, and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of ICH Good Clinical Practice, and the UK Policy Framework for Health and Social Care Research v3.3 07/11/17. All correspondence with the REC will be retained in the Study Master File/Investigator Site File

An annual progress report will be submitted to the REC within 30 days of the anniversary date on which the original favourable opinion was given, and annually until the trial is declared, ended. If the study is ended prematurely, the CI will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the CI will submit a final report with the results, including any publications/abstracts, to the REC and HRA.

19.2 Peer review

This protocol has been reviewed by a team of independent clinicians and clinical academics as part a successful application to Torbay Medical Research Fund.

19.3 Public and Patient Involvement

- Design of the research: Families have been consulted on the design of the study especially the daily use of FES and the duration and location of baseline assessments.
- The protocol, adverts and patient information sheets have been reviewed by an expert parent and a teenager and altered to make the information more accessible to families and young people.
- Dissemination of findings: The patient representative will advise on appropriate dissemination of the results to reach families in the most accessible way.
- Payment for PPI will be in line with NIHR guidance.

19.4 Regulatory Compliance

Before any site can enrol patients onto the study, the CI will apply for NHS permission from the site's Research & Development (R&D) department. For any

amendment that will potentially affect a site's NHS permission, the Chief Investigator/ Study Co-ordinator or designee will confirm with that site's R&D department that NHS permission is ongoing (note that both substantial amendments, and amendments considered to be non-substantial for the purposes of REC may still need to be notified to NHS R&D).

19.5 Protocol compliance

Planned protocol deviations, non-compliances, or breaches which are departures from the approved protocol are not allowed under the UK regulations on Clinical Trials and will not be used e.g. subjects will only be enrolled if they meet the eligibility criteria.

Accidental protocol deviations will be documented on the relevant forms and reported to the Chief Investigator immediately.

19.6 Notification of Serious Breaches to GCP and/or the protocol

The sponsor will be notified immediately of any case in which any of the following are compromised during the study conduct phase:

a) The safety or physical or mental integrity of the study participants

b) The scientific value of the study

c) The conditions and principles of GCP in connection with the study

The sponsor will be notified within 7 days of becoming aware of any accidental breach / amendment to the study protocol. The sponsor will be required to adjudge amendments prior to submitting these to REC/HRA.

19.7 Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 and General Data Protection Regulations (2018) concerning the collection, storage, processing, and disclosure of personal information and will uphold the Act's core principles.

- Data will be collected on the CRF, kept secure in a locked filing cabinet in the Research office of the CI.

- The participant's data will be stored using a unique participant identifier.
- The participant's personal data and identification key will be stored on the secure study database. This will be stored for the duration of the study to allow contact with the participants (e.g. to clarify missing data and/or send study summaries). After this personal data will be destroyed.
- Electronic trial records will be stored in a secure encrypted, password protected database.
- Only the research team will have access to the data.
- The number of individuals necessary for quality control, audit, and analysis will be kept to a minimum.
- The confidentiality of data will be preserved when the data are transmitted to a co-investigator
- The CI is the data custodian for the duration of the study. Once the study is completed, the CI is responsible for the long-term storage of data in accordance with University of Plymouth regulations.

19.8 Financial and other competing interests

There are no financial or competing interests for the CI, TC at each site and committee members for the overall trial management.

19.9 Indemnity

The University of Plymouth has appropriate indemnity cover for all activities in this study, the certificates and details of the cover can be accessed here: https://www.plymouth.ac.uk/about-us/university-structure/service-areas/procurement/insurance-certificates

19.10 Amendments

Any amendments of the protocol will be submitted to the Sponsor, HRA, and REC for approval. Amendments will not be implemented until the REC/HRA grants a favourable opinion. All correspondence with the REC and HRA will be retained in the Study Master File and Investigator Site Files.

19.11 Post Study care

Where the SC identifies that treatment is required beyond the study appointment, the SC will liaise with their local therapy provider / GP to ensure that the patient is able to access care.

20. DISSEMINATION POLICY

- The data arising from the trial will be owned by the University of Plymouth research team
- On completion of the trial, the data will be analysed and tabulated, and a final study report prepared.
- Study findings will be published in peer reviewed academic journals and presented at National and International conferences.
- TMRF funding will be acknowledged within the publications.
- Participants will be notified of the outcome of the trial using a lay summary that will be sent via post or e-mail in accordance with participant preference.
- If a participant specifically requests results from the CI this information would be provided after the results had been published
- It is hoped that the anonymised participant level data set will be made available 1 year after the end of the trial via the Rehabilitation Research Group (University of Plymouth) website. Interested parties will also be able to contact the research team to request access to the anonymised data set.

20.1 Authorship eligibility guidelines and any intended use of professional writers

The CI and SC will have authorship on the final trial report

21 APPENDICES

21.1 Appendix 1 – Authorisation and Participating sites

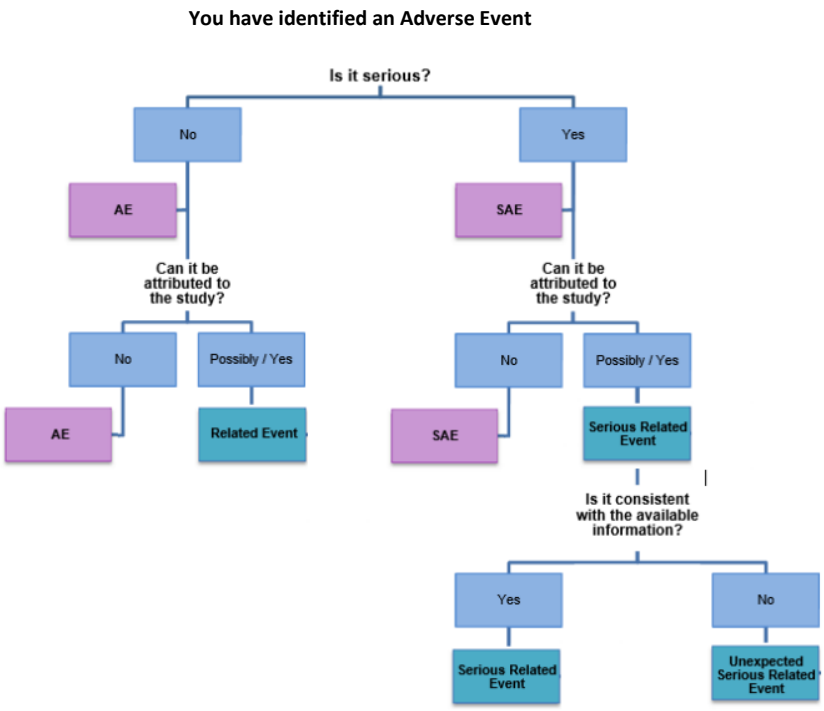
These will be attached following ethical/ R and D approval

21.1.1 Local documentation required prior to initiating a participating site.

To be inserted into the Trial Master File and each site file by the CI once these have been gathered:

- CVs of the research team
- GCP certification of the research team
- Site Specific Approval Site Specific
- R and D Approval

21.2 Appendix 2 – Safety reporting Flow Chart



21.3 Appendix 3 – FES intervention leaflets

Torbay Medical Research Fund

FES in Cerebral Palsy

UNIVERSITY OF PLYMOUTH

V1: 11/01/2024

PATIENT FACTSHEET – ELECTRODE CARE

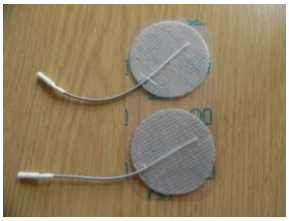
Following this advice should ensure that electrodes last 4-6 weeks or the duration of this research study.

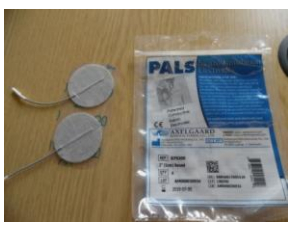
Handling of electrodes

- When opening the pack of electrodes use the 'zip' perforated in the plastic to ease opening.
- When lifting the electrode from the plastic or your skin always use the edge of the electrode and not the wire.

Storage of electrodes

- Keeping your electrodes as clean as possible is important to prevent bacterial growth and possible skin irritation - lightly wash over the surface of the electrode with warm water to remove any debris or dead skin.
- When not in use always store the electrodes on the plastic sheet provided and place in the electrode pack (see photos below). Place a few drops of water on the plastic before replacing the electrodes.
- Keeping the electrodes moist retains their stickiness for longer but do not make them too wet.
- Do not place your bag near radiators as this causes heat damage to electrodes and leads.





Electrode problems to look out for

- If the electrodes become too dry at the edges and will not stick on your skin then replace them with new ones.
- If the gel of the electrode becomes pitted (holes appear in the surface of the gel) then replace the electrode with a new one and throw the pitted electrode away.

Hypoallergenic electrodes

Some people develop a skin allergy to the electrodes which shows as a skin rash (see Patient Fact Sheet on Skin Care). If this should happen to you, you will be provided with hypoallergenic electrodes which are blue in colour.

It is very important that you only use the 'blue' electrodes in the future. Do not be tempted to use the grey electrodes again - if you do use the grey electrodes again you will immediately come out in a rash which can take a while to heal and prevent you using your stimulator.

Who to contact if you have a problem with your Electrodes.

- I you have any problems or concerns with your FES electrodes during the research study then please contact the Study Co-ordinator
- Study Co-ordinator: Harriet Hughes. Email: harriet.hughes-5@postgrad.plymouth.ac.uk or telephone: 07971246605.

Your Sincerely

Harriet Hughes. Bsc (Hons) Phys, MSc, MCSP
Study Co-ordinator
Clinical Doctoral Research Fellow

ICP building,
Plymouth Railway Station
North Road, Plymouth
PL4 6AB
Email: Harriet.hughes-5@postgrad.plymouth.ac.uk
Website: https://www.plymouth.ac.uk/research/raincoat-study
Tel: 07971246605

PATIENT FACTSHEET – SKINCARE

Looking after your skin where the electrodes are positioned is very important when using functional electrical stimulation.

Skin care to ensure effective stimulation

Skin creams can reduce the conductivity of the electric current from the stimulator. Wash your skin with water only before placing the electrodes. Alternatively use Dermol wash and pat dry.

Shaving

It is advised never to use a razor to shave the area of skin under the pads. If you do, wait 24 hours before applying the electrodes. This is because shaving causes small scratches which can cause pain and skin irritation when stimulation is applied.

Closely monitor skin

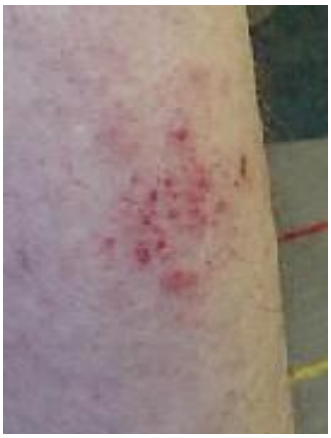
When first applying the electrodes to your skin, gradually build up the time they are on over a period of a week (never wear them at night) and look out for any skin changes such as…

Redness of the skin – this is a normal reaction to increased circulation and should fade within 2 hours. **If it lasts more than 2 hours, stop using the electrodes and inform the study co-ordinator**.

Cuts, spots, grazes – do not position electrodes over these as it will cause pain and will prevent healing of the injured skin if the stimulator is used. **Allow the skin to completely heal**.

Skin rash (little red spots) – this can occur weeks, months or even years after starting FES treatment. **Do not use electrodes over a skin rash and inform the study co-ordinator**. Blue hypoallergenic pads can be issued in the future – once you start using the blue hypoallergenic pads, do not return to using the standard grey ones.
Ensure the skin is completely healed before using any of the electrodes – Hc45 or Eumovate cream can be bought over the counter and used.

NHS
Health Research Authority



WARNING!

Risk of blisters and broken skin if you continue to use electrical stimulation over a rash.

This is painful and can lead to infection.

THE SOONER YOU INFORM US, THE BETTER – long term skin irritation can be a contraindication to electrical stimulation.

What to do if you have a problem with your skin following electrode use?

- Follow the guidance above.
- If you continue to have a problem or further concerns please contact the research study co-ordinator.
- Research study co-ordinator Harriet Hughes. Email: harriet.hughes-5@postgrad.plymouth.ac.uk or telephone: 07971246605.

Your Sincerely

Harriet Hughes. Bsc (Hons) Phys, MSc, MCSP
Study Co-ordinator
Clinical Doctoral Research Fellow

ICP building,
Plymouth Railway Station
North Road, Plymouth
PL4 6AB
Email: Harriet.hughes-5@postgrad.plymouth.ac.uk
Website: https://www.plymouth.ac.uk/research/raincoat-study
Tel: 07971246605

21.4 Appendix 4 – Interview Schedule

FES in CP: Interview schedule

Questions will not necessarily be asked in this order nor phrased in the way presented here.

Consent

- Discuss purposes of the interview:
  - to find out you and your parents view on the FES study, how it went for you, whether you or your parent think it made any difference, and how we can improve it.
  - To learn what you thought about taking part in the research study.
- So it is important to be as honest as you can so we know what works and what needs to change. You don't have to answer any question, and can stop whenever you want
- I'll record the interview so I can listen to you properly. What you say will remain confidential to the research team. Anything you say about the study will be anonymised to protect your identity.
- Any time limitations or other issues with being interviewed now? It may last up to about an hour and a half.
- Obtain written consent.

Overview of condition

- Briefly, when you started the study what issues did you face when walking?
  - Prompts: tiredness, difficulties walking far, walking more slowly than your friends, tripping/difficulty walking on uneven surfaces/difficulties up and down slopes and stairs
- How have these changed over the last 8 weeks? Has anything about your walking improved or got worse?
- Were any other illnesses/conditions an issue for you in the last 8 weeks?

Preparing to take part in FES in CP study

- Why did you want to take part in this study?
  - What were you hoping for from taking part in the FES study?
  - Prompts: goals
- Did you know enough about what was involved in the study before you took part?
- Did you have any concerns about taking part? If so, what were these?

Preparation for Intervention

- At the start of the study your received training on with FES. How did you find the training?
    - Prompts:
        - What did you find helpful / unhelpful in the way you were trained?
        - How well did they take account of your own needs/ circumstances (therapeutic alliance, fatigue)
        - At the end did you have enough knowledge to use FES?
        - How confident did you feel to use the FES?
- What did you understand the purpose of the FES to be?

Questions regarding the FES (bring device used as visual prompt)

- How able were you to put on and use the device by yourself?
    - If no, what aspects did you need help with?
- What would make it easier to put it on?

Using the FES

In your own words can you tell me about your experience of using FES as part of this study?

Prompt questions

- How did you feel using the FES?
- Did your feelings about using the FES change from the beginning of the study to the end?
- Was there anything you liked / disliked about the FES?
- How much effort did you have to make to use FES?
- How did you find recording your daily use in the diary?
- Did you suffer from any problems/adverse effects while using the FES (Skin soreness/muscle aches and pains/tiredness?)
    - If anything, that can we change to prevent these from happening?
- How did you find putting on and off the electrodes and caring for the electrodes?
- Do you think the FES has had any impact on your walking?
- Do you think using the FES for 8 weeks had any effect on your leg or walking ability? If so, can you describe the main effect you felt it had?
- Was there anything that put you off using FES?
- If the opportunity arose would you want to keep the FES? Why?

Commented [HH1]: No diary now just FES stepp and duration tracker

External Support

- During the study did you receive support from anyone/where else with using the FES?
  Prompts:
  - Friends or family
  - Physiotherapist/private therapist
- And what support did they give you with using the FES?
- What did you think about the technical support offered? Was it adequate/lacking?

General question inpatient and home use

- How did it using the FES compare to your usual physiotherapy routine? (tiredness enjoyment, time taken)
-

Taking part in the research

Questions regarding the study:

How did you find the assessment and researchers taking different measurements?

- Meeting with the assessor
- Performing the different assessments

- How did you find the research team (Harriet)?
- Is there anything we could have done differently to make it a better experience for you?
- Would you be willing for us to contact you again in the future about this study or other studies related to CP?
- Would you like to receive a report of this study?
- Is there anything else you would like to say about FES or this study?

Conclusion

Thank them for their time.

21.5 Appendix 5 – Screening Checklist

17/07/2024 V1

Study Number/IRAS ID:

FES in Cerebral Palsy Screening Checklist

CYP NAME: **AGE:** **GENDER:**

Each of these criteria MUST be answered YES for the participant to be included in the study	**YES**	**NO**
Does the CYP have a diagnosis of spastic CP?		
Is the CYP aged 8-18 years?		
Is the CYP able to follow simple instructions?		
Is the CYP able to travel to the University of Plymouth or a local clinic if you don't want to the researcher to visit your CYP in the home? (travel expenses will be provided up to a limit of £30).		

Each of these criteria MUST be answered NO for the participant to be included in the study	**YES**	**NO**
Does the CYP present with repetitive involuntary twisting motions and muscle contractions in the arms or legs (Dystonic CP)? (CYP with dystonia co-occurring with a spastic presentation can be included)		
Does the CYP present with slow writhing movements particularly in the fingers and face (Dystonic CP)? (CYP with Athetoid CP co-occurring with a spastic presentation can be included)		
Has the CYP had a Selective Dorsal Rhizotomy or Multi level orthopaedic surgery within the last 6 months?		
Has the CYP had soft tissue surgery in lower limbs in the last 6 month?		
Has the CYP had anti-spasticity botulinum toxin injections within the last 3 months?		
Does the CYP have poorly controlled epilepsy?		
Does the CYP have a Cardiac pacemaker fitted?		
Does the CYP have a malignant tumour in either lower limb?		
Moderate to Severe Cognitive Impairment and/or Learning difficulties that may limit the use of a small battery powered pocket device?		

PRINT Name: …… Date……

Signature (of person completing screening tool) ……..

Establishing GMFCS Level

GMFCS Family Report Questionnaire: Children Aged 6 to <12 Years

Read the following to parent of Child and mark the box beside the description that best represents their child's ability to move.

My child…

- ☐ **Has difficulty sitting on their own and controlling their head and body posture in most positions**
  and has difficulty achieving any voluntary control of movement
  and needs a specially supportive chair to sit comfortably
  and has to be lifted or hoisted by another person to move

- ☐ **Can sit on their own but does not stand or walk without significant support**
  and therefore relies mostly on wheelchair at home, school and in the community
  and often needs extra body / trunk support to improve arm and hand function
  and may achieve self-mobility using a powered wheelchair

- ☐ **Can stand on their own and only walks using a walking aid** (such as a walker, rollator, crutches, canes, etc.)
  and finds it difficult to climb stairs, or walk on uneven surfaces
  and may use a wheelchair when travelling for long distances or in crowds

- ☐ **Can walk on their own without using walking aids, but needs to hold the handrail when going up or down stairs**
  and often finds it difficult to walk on uneven surfaces, slopes or in crowds

- ☐ **Can walk on their own without using walking aids, and can go up or down stairs without needing to hold the handrail**
  and walks wherever they want to go (including uneven surfaces, slopes or in crowds)
  and can run and jump although their speed, balance, and coordination may be slightly limited

Available from *CanChild* Centre for Childhood Disability Research (www.canchild.ca), McMaster University
GMFCS modified with permission from Palisano et al. (1997) Dev Med Child Neurol, 39, 214-223.

GMFCS-E&R Family Report Questionnaire: for Young People Aged 12 - 18 Years

Read the following to parent of CYP and mark the box beside the description that best represents their CYP ability to move.

My child…

❑ **Has difficulty sitting on their own and controlling their head and body posture in most positions**
and has difficulty achieving any voluntary control of movement
and needs a specially adapted chair to sit comfortably and be transported anywhere
and has to be lifted or hoisted by another person or special equipment to move

❑ **Can sit with some pelvic and trunk support but does not stand or walk without significant support**
and therefore always relies on wheelchair when outdoors
and can achieve self-mobility using a powered wheelchair
and can crawl or roll to a limited extent to move around indoors

❑ **Can stand on their own and only walks using a walking aid** (such as a walker, rollator, crutches, canes, etc.)
and finds it difficult to climb stairs, or walk on uneven surfaces without support
and uses a variety of means to move around depending on the circumstances
and prefers to use a wheelchair to travel quickly or over longer distances

❑ **Can walk on their own without using walking aids, but needs to hold the handrail when going up or down stairs**
and therefore walks in most settings
and often finds it difficult to walk on uneven surfaces, slopes or in crowds
and may occasionally prefer to use a walking aid (such as a cane or crutch) or a wheelchair to travel quickly or over longer distances

❑ **Can walk on their own without using walking aids, and can go up or down stairs without needing to hold the handrail**
and walks wherever they want to go (including uneven surfaces, slopes or in crowds)
and can run and jump although their speed, balance, and coordination may be limited

Available from *CanChild* Centre for Childhood Disability Research (www.canchild.ca), McMaster University
GMFCS-E&R modified with permission from Palisano et al. (2008) Dev Med Child Neurol, 50(10), 744-750.

GMFCS-E&R Self Report Questionnaire: for Young People Aged 12- 18 Years

Read the following to the CYP and mark the box beside the description that best represents the CYP ability to move.

I...

- ☐ **Have difficulty sitting on my own and controlling my head and body posture in most positions**
  and have difficulty achieving any voluntary control of movement
  and need a specially adapted chair to sit comfortably and be transported anywhere
  and have to be lifted or hoisted by another person or special equipment to move

- ☐ **Can sit on my own but do not stand or walk without significant support**
  and therefore always rely on wheelchair when outdoors
  and can achieve self-mobility using a powered wheelchair
  and can crawl or roll to a limited extent to move around indoors

- ☐ **Can stand on my own and only walk using a walking aid** (such as a walker, rollator, crutches, canes, etc.)
  and find it difficult to climb stairs, or walk on uneven surfaces without support
  and use a variety of means to move around depending on the circumstances
  and prefer to use a wheelchair to travel quickly or over longer distances

- ☐ **Can walk on my own without using walking aids, but need to hold the handrail when going up or down stairs**
  and therefore walk in most settings
  and often find it difficult to walk on uneven surfaces, slopes or in crowds
  and may occasionally prefer to use a walking aid (such as a cane or crutch) or a wheelchair to travel quickly or over longer distances

- ☐ **Can walk on my own without using walking aids, and can go up or down stairs without needing to hold the handrail**
  and walk wherever I want to go (including uneven surfaces, slopes or in crowds)
  and can run and jump although my speed, balance, and coordination may be limited

Available from *CanChild* Centre for Childhood Disability Research (www.canchild.ca), McMaster University
GMFCS-E&R modified with permission from Palisano et al. (2008) Dev Med Child Neurol, 50(10), 744-750.

Based on the Information above please circle the GMFCS level which most closely matches response obtained in the GMFCS E & R Self-report questionnaire.

Between 6th – 12th Birthday	
GMFCS Level	Descriptor
Level I	Children walk at home, school, outdoors, and in the community. Children can walk up and down curbs without physical assistance and stairs without the use of a railing. Children perform gross motor skills such as running and jumping but speed, balance, and coordination are limited.
Level II	Children walk in most settings. Children may have trouble walking long distances and balancing on uneven terrain, inclines, in crowded areas, confined spaces or when carrying objects. Children walk up and down stairs holding onto a railing or with physical assistance if there is no railing. Outdoors and in the community, children may walk with physical assistance, a hand-held mobility device, or use wheeled mobility when traveling long distances. Children have at best only minimal ability to perform gross motor skills such as running and jumping
Level III	Children walk using a hand-held mobility device in most indoor settings. When seated, children may require a seat belt for pelvic alignment and balance. Sit-to-stand and floor-to-stand transfers require physical assistance of a person or support surface. When traveling long distances, children use some form of wheeled mobility. Children may walk up and down stairs holding onto a railing with supervision or physical assistance. Limitations in walking may necessitate adaptations to enable participation in physical activities and sports including self-propelling a manual wheelchair or powered mobility.
Level IV	Children use methods of mobility that require physical assistance or powered mobility in most settings. Children require adaptive seating for trunk and pelvic control and physical assistance for most transfers. At home, children use floor mobility (roll, creep, or crawl), walk short distances with physical assistance, or use powered mobility. When positioned, children may use a body support walker at home or school. At school, outdoors, and in the community, children are transported in a manual wheelchair or use powered mobility.
Level V	Children are transported in a manual wheelchair in all settings. Children are limited in their ability to maintain antigravity head and trunk postures and control arm and leg movements. Transfers require complete physical assistance of an adult.

CYP's GMFCS Level ……

Is the CYP eligible to take part? ……

COMMENTS:

PRINT NAME/ROLE: SIGN: DATE:

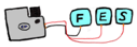
Between 12th – 18th Birthday	
GMFCS Level	Descriptor
Level I	CYP walk at home, school, outdoors, and in the community. Children can walk up and down curbs without physical assistance and stairs without the use of a railing. Children perform gross motor skills such as running and jumping but speed, balance, and coordination are limited.
Level II	CYP walk in most settings. Environmental factors (such as uneven terrain, inclines, long distances, time demands, weather, and peer acceptability) and personal preference influence mobility choices. At school or work, CYP may walk using a handheld mobility device for safety. Outdoors and in the community, CYP may use wheeled mobility when traveling long distances. CYP walk up and down stairs holding a railing or with physical assistance if there is no railing
Level III	CYP are capable of walking using a hand-held mobility device. Compared to individuals in other levels, youth in Level III demonstrate more variability in methods of mobility depending on physical ability and environmental and personal factors. When seated, CYP may require a seat belt for pelvic alignment and balance. Sit-to-stand and floor-to-stand transfers require physical assistance from a person or support surface. At school, CYP may self-propel a manual wheelchair or use powered mobility. Outdoors and in the community, youth are transported in a wheelchair or use powered mobility. Youth may walk up and down stairs holding onto a railing with supervision or physical assistance
Level IV	CYP use wheeled mobility in most settings. CYP require adaptive seating for pelvic and trunk control. Physical assistance from 1 or 2 persons is required for transfers. CYP may support weight with their legs to assist with standing transfers. Indoors, youth may walk short distances with physical assistance, use wheeled mobility, or, when positioned, use a body support walker. CYP are physically capable of operating a powered wheelchair or are transported in a manual wheelchair
Level V	CYP are transported in a manual wheelchair in all settings. CYP are limited in their ability to maintain antigravity head and trunk postures and control arm and leg movements. Assistive technology is used to improve head alignment, seating, standing, and mobility but limitations are not fully compensated by equipment

CYP's GMFCS Level ……

Is the CYP eligible to take part? ……

COMMENTS:

PRINT NAME/ROLE: SIGN:
DATE: 21.6 Appendix 6: Stairs Assessment



UNIVERSITY OF PLYMOUTH

Torbay Medical Research Fund

IRAS ID:

V1 24/07/2024

Stair Type

Number of Stairs		Number of Rails	
Height of step (cm)		Height of rails (cm)	
Depth of step (cm)			

Stair Surface
- Laminate ☐
- Carpet ☐
- Tiling ☐
- Other ☐

Comments

Stair Assessment

1. Ascending the stairs

Leading leg	Left	☐	Rail Use	Left	☐
	Right	☐		Right	☐
	Variable	☐		Bilateral	☐
				Variable	☐
Comments			Comments		

Stair Technique One foot on a step at a time ☐

Two feet on a step at a time ☐

Comments ☐

2. Descending the stairs

Leading leg Left ☐ Right ☐ Variable ☐

Rail Use Left ☐ Right ☐ Bilateral ☐ Variable ☐

Comments ☐

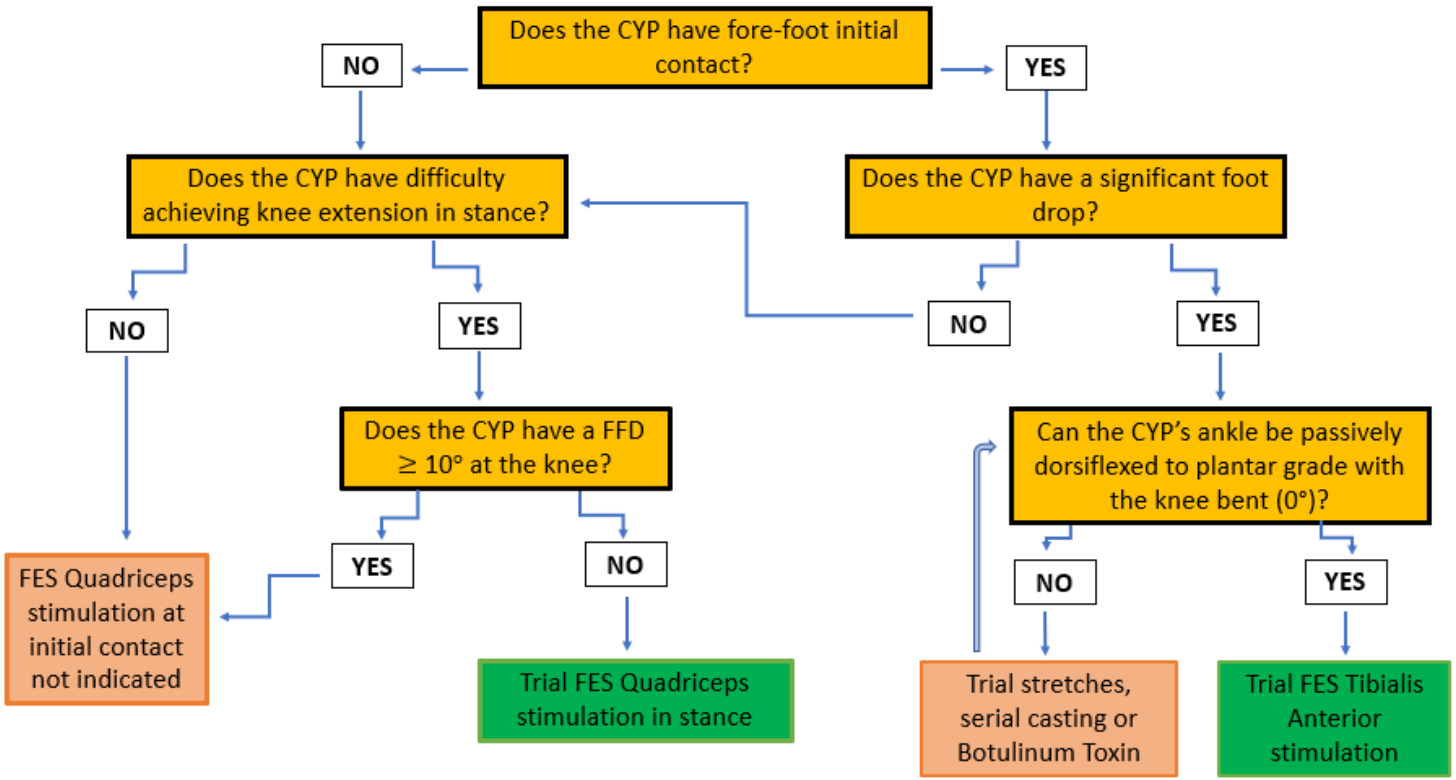
Comments ☐

Stair Technique One foot down a step at a time ☐

Two feet down a step at a time ☐

Comments ☐

21.7 Appendix 7 –FES clinical decision-making tool for muscle stimulation



21.8 Appendix 8 – TIDieR Template

Table 1. FES in Cerebral Palsy: The Template for Intervention Description and Replication (TIDieR)

TIDieR item	FES intervention
1. Brief Name provide the name or a phrase that describes the intervention	Functional Electrical Stimulation will be provided by either Odstock Dropped Foot Stimulator (ODFS ®Pace) or the ODFS ®Pace XL. Both devices are a battery powered, pocket electrical device combined with a foot switch to allow precisely timed muscle stimulation while walking. They are CE marked and approved by NICE. In contrast to the ODFS®Pace the ODFS®Pace XL has a radio link between the foot switch and the stimulator. This is called the OML LINQ™ and allows discreet stimulation triggering without a wire back to the stimulator (see link https://odstockmedical.com/patients/patients-what-is-fes/) .
2.WHY? describe any rationale, theory, or goal of the elements essential to the intervention	The lack of successful intervention and high rates of ambulatory decline in children with crouch gait, highlight the need for this research into FES. There is substantial evidence for the use of FES to manage ankle weakness (drop foot) in CP [10] and its use in this way is recommended in clinical practise by NICE [11] . In comparison, the evidence for using FES to address other gait abnormalities, such as crouch remains poor [7]. The use of FES to address crouch gait in children with CP has only been examined in two case studies [12, 13]. Both case studies reported that FES used to stimulate the quadriceps muscle increased knee extension during stance phase of gait and alleviated crouch.
3. WHAT? materials: describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention	Either the Odstock Dropped Foot Stimulator ODFS® Pace or if the participant prefers, the wireless version ODFS® Pace XL FES device will be provided to the participant. These will also come with a 9V alkaline battery, an electrode wire, a foot switch wire, a foot switch and a cork insole. Each participant will also be given a set of 50mm x 50mm PALS Plus® square electrode pads if the Tibialis Anterior muscle is being

providers. provide information on where the materials can be accessed (e.g. online appendix, url)	stimulated or PALS Plus® round electrodes of either size 25mm or 32 mm (depending on the size of the CYP) and an air-tight bag to store them in. Each Parent and CYP will be provided training on donning and doffing the FES device and switching it on and off by the SC. They will also be provided with a link to the online User manual: https://odstockmedical.com/wp-content/uploads/Patient-Manual_POML001_Software-V1.4_Doc-V4.0.pdf. Leaflets on electrode care and skin care will also be provided, see protocol appendix 4.
4. Procedures: describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities	FES set will take place in week 9 with the SC at the participant preferred location. For Tibialis anterior stimulation, FES set up will take place with the participant in sitting. The SC will place two, 50mm x 50mm PALS Plus® square electrode pads on the lower leg, one over the head of the fibula and the other over the muscle belly of Tibialis Anterior, in accordance to the ODFS® Pace and ODFS® Pace XL manual . In participants with smaller legs, the electrodes may need to be cut down to size for an accurate muscle stimulation. If the participant is being set up with FES to stimulate the quadriceps the SC will place two PALS Plus® round electrodes of either size 25mm or 32 mm (depending on the size of the child's leg) over the distal vastus medialis oblique and proximal lateralis, in accordance to the manual. With the participant sat up on a bed and the knee straight, the SC will gradually increase the FES currant until a contraction is observed in the quadricep muscle belly. Once the FES device is set to a level that a contraction is observed in either Tibialis Anterior or the Quadricep, the SC will stick the foot switch into a cork insole, which can then be placed in the child's shoe. In most cases the foot switch will be placed in the heel of the insole, but if the child is not achieving a heal strike at initial contact, the foot switch will need to be placed under the head of the first metatarsal. Once the foot switch is connected to the FES device the participant is ready to trial using the FES when walking. For FES tibialis anterior set up, the FES device will be set to activate tibialis anterior when the heel or forefoot rises off the floor and through swing phase of gait. For FES quadricep set up the device will be set to activate the quadricep during heel strike and through stance phase of gait.

	Once the child is walking with the FES the SC may have to make further adjustments to the timing and speed of the muscle activation for optimal gait performance. Following FES training the CYP will be asked to use the FES daily, this should start in and around the house, but building up confidence to wearing it in the community setting or at school. The aim is to build up to wearing the FES for between 2-4hours a day in preparation for starting the FES intervention phase of the study at week 11. One week after receiving FES training (Week 10), the participant will receive a home visit from the physiotherapist to check the CYP has been using it correctly and to make any changes required to optimise gait.
5. WHO PRIVIDED for each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given	The initial screening, physical screening and training home visits will all be provided by the Study Co-ordinator (SC). The SC is trained Childrens Physiotherapist with over 8 years of experience working with children with CP. She completed the OML® FES training course for the lower limb in 2019 and uses FES regularly for the treatment of drop foot in CYP with CP at Torbay Hospital CDC
6. HOW. describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	The initial screening for study eligibility will take place over a telephone conversation. FES set up and training will take place face to face.
7. WHERE: describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	FES set up and training will take place in the CYP home or at a preferred location such as the University of Plymouth Human Movement and Function Lab or in a clinic space situated with the child's NHS Trust Providers CDC.
8. WHEN AND HOW MUCH describe the number of times the intervention was delivered and over what period including	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

the number of sessions, their schedule, and their duration, intensity, or dose	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
9. TAILORING if the intervention was planned to be personalised, titrated, or adapted, then describe what, why, when, and how.	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 to the CYP muscle response to stimulation and in order to optimise gait performance. FES electrode pad placement for both Tibialis Anterior and Quadriceps may differ between individuals due to variations in anatomy, but electrode placement will remain the same for a CYP throughout the study.
10. MODIFICATIONS if the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Modification to the FES intervention may occur if the child has an adverse skin reaction or if they are finding it difficult to tolerate the FES stimulation
11. HOW WELL if the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	To be explored post FES Intervention

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