Torbay Medical Research Fund

UNIVERSITY OF PLYMOUTH

FES in Cerebral Palsy

Guardian or Parent information sheet

IRAS ID: 347391

V1 31/07/2024

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

We would like to invite your child to take part in our research study. Before you decide whether your child may want to take part, we would like you to understand why the research is being done and what it will involve. One of our team will go through this information with you and your child and answer any questions you may have. Take time to decide whether you want to take part and talk to other people about the study if you wish. The main researcher is Harriet Hughes, a physiotherapist who works with children and young people with cerebral palsy. She is doing this study as part of her PhD and her research team is Prof John Marsden (University of Plymouth) and Prof Cherry Kilbride (Brunel University, London).

What is the purpose of the study?

The purpose of the study is to learn more about the use of Functional Electrical Stimulation (FES) in the management of crouch gait in children with bilateral cerebral palsy. FES is a small battery powered device which helps your muscles switch on when walking (see figure 1). We want to find out whether FES when applied to either a muscle in the thigh (quadriceps) or a muscle in the lower leg (Tibialis anterior) can improve the degree of knee bend in children and young people with cerebral palsy and crouch gait. Crouch gait is a walking pattern associated with bilateral cerebral palsy and is characterized by excessive knee bend when walking (see figure 2), it is a tiring walking pattern, and if left untreated it may lead to chronic knee pain and difficulty with walking.

Fig 1: FES device

Fig 2: Image of Crouch Gait

Why has you child been chosen?

Your child has been chosen because they are aged between 8-18 years old and have bilateral cerebral palsy. Before your child can begin the study, we will need to ask you some questions to see if they are eligible to participate. Some young people with cerebral palsy won't be able to take part, if for example, they are unable to walk more than 20 metres or go up and down steps.

Does my child have to take part?

No. It is up to you and your child, whether to participate or not. Before you decide, a member of the research team will explain the study and go through this information sheet with you. If your child decides to take part and is under 16 years old, we will ask you to sign a consent form allowing participation. You will be given a copy of the information sheet and the signed consent forms to keep for your records. You and your child are free to withdraw at any time, without giving a reason. This will not affect the standard of care your child receives in the future.

What will my child have to do if we choose to take part?

If you and your child decide to take part the researcher will arrange a convenient time to discuss the study over the phone or via a video call (according to your preference) and to screen whether your child is eligible to participate in the study.

Before your child can start the study, you will need to complete a written consent form for your child if they are under 16 years of age. Young people over the age of 16 can give their own written consent. We ask your child to try not to start any new sporting activities or physiotherapy programs for the duration of the study. If you do start a new activity, we would ask you to inform the team as it could affect the results of the study.

The study is then divided into two phases, phase A: Your child's 'Usual' physiotherapy and Phase B: 'FES' intervention (see figure 3). Both phases of the study last 8 weeks, with a two-week gap in between to allow for the FES set up.

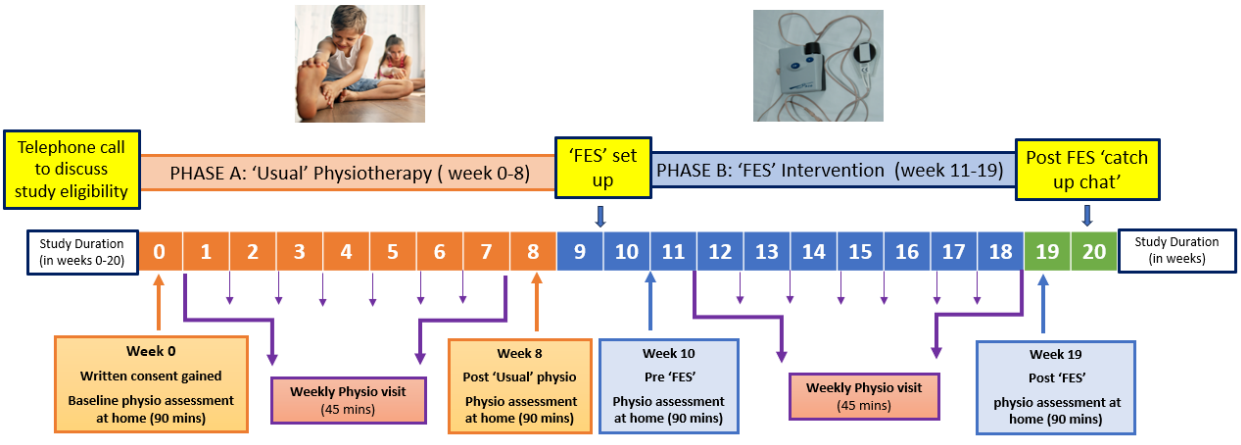


Figure 3: Study timeline of both phase A; Usual Care and Phase B; FES intervention

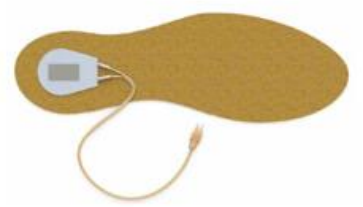
Phase A starts at week 0 and is 8 weeks of usual care with some additional measures. At the start of Phase A (Week 0) your child will have a physiotherapy assessment at your home, lasting 90 minutes. During this assessment the Physiotherapist will measure how your child moves their legs using a goniometer (see figure 4a), measure your child's leg strength using a Dynamometer (See figure 4b) and ask you and your child to complete a questionnaire about their walking. The researcher will also watch your child walk on the level, up and downstairs and measure how much your child bends their knees when walking using an electric goniometer (see figure 4c).

(a) (b) (c)

Figure 4: Baseline assessment measurements. (a) leg measurements using a goniometer, (b) Leg strength measurements using a dynamometer (C) Measuring knee bend when walking using electric goniometer

The physiotherapist will then continue to visit your child at home each week at a time that is convenient for you, for 7 weeks to repeat a series of measurements. This will include re-measuring the movement in your child's legs, your child's leg strength and how much your child bends their knees when walking on the level. The physio will also ask you to complete a short questionnaire with your child about how your walking has been over the last week. This session will last 45 minutes each week. At the end of phase A (week 8) the physiotherapist will visit your child at home and repeat all the measures taken in the initial baseline assessment. This session will last 90 minutes. For a diagram of phase, A: 'Usual' physiotherapy, please see figure 6.

Phase B of the study will start at week 9 (see figure 3). The physio will visit your child at home and show them how the FES device works. The FES will then be set up by the physiotherapist on one of your child's leg muscles. Your child will then be given the FES devise to practise with at home to enable them to get use to the sensation of it on their skin. Alongside being given the FES device, your child will also be given a pouch to hold the FES device and enable them to clip it to their pocket or waistband. They will also be given a small air-tight bag to store the FES electrodes in and if needed a cork insole for their shoe to attach the FES foot switch to (see figure 5).



A

Figure 5. **A** FES foot switch in the heel of a cork insole.

On week 10 the physio will re-visit you and your child at home again and check how your child is using the FES. They physiotherapist may adjust the FES if required. Your child will then be given another week to practise wearing and using the FES device and build up to using it for between 2-4 hours a day.

On week 11, the physiotherapist will come to your home and complete a full base line assessment of measures with your child, lasting 90 minutes. During this assessment the Physiotherapist will measure how your child moves their legs using a goniometer (see figure 4a), measure your child's leg strength using a Dynamometer (See figure 4b) and ask you and your child to complete a questionnaire about their walking. The researcher will also watch your child walk on the level, up and downstairs and measure how much your child bends their knees when walking using an electric goniometer (see figure 4c) with both the FES turned ON and turned OFF as well as with an usual ankle splints (orthoses).

Your child will then be given a new set of FES electrodes to use and will be asked to wear the FES daily for up to 4 hours a day, 6 days a week. This can be during school or before and/or after school, whichever is manageable for you and your child. During this time, your child will be asked to complete a diary to record your daily use of FES.

Each week that your child is using the FES (Week 11-19) the physiotherapist will visit you and your child at home at a time that is convenient for you. During this weekly home visit the physiotherapist will re-measure the movement in your child's legs, the leg strength and the degree of knee bend when walking on the level with both the turned FES ON and OFF. The physio will also ask you to complete a short questionnaire about how your walking has been over the last week. The FES device will log the number of steps you have taken and how long it has been worn for and each week the physiotherapist will record this information off the FES device. This session will last 45 minutes each week. In addition to this at week 14 your child will be given another new set of electrodes to use, as they typically have a shelf life of 4 weeks.

On week 19 the FES intervention is finished. The physiotherapist will visit you at home for the last time and repeat all the measurements taken at the start of the FES intervention. The physio will also collect the FES device. This session will last 90 minutes.

On week 20 the physio will arrange a video call with both you and your child to catch up and chat about the FES. We will ask you and of your child questions about your experiences using the FES device and taking part in the study. For a diagram of phase B: 'FES' intervention, please see figure 7.

Figure 6. Flow chart of Phase A of the study: 'Usual Physiotherapy'

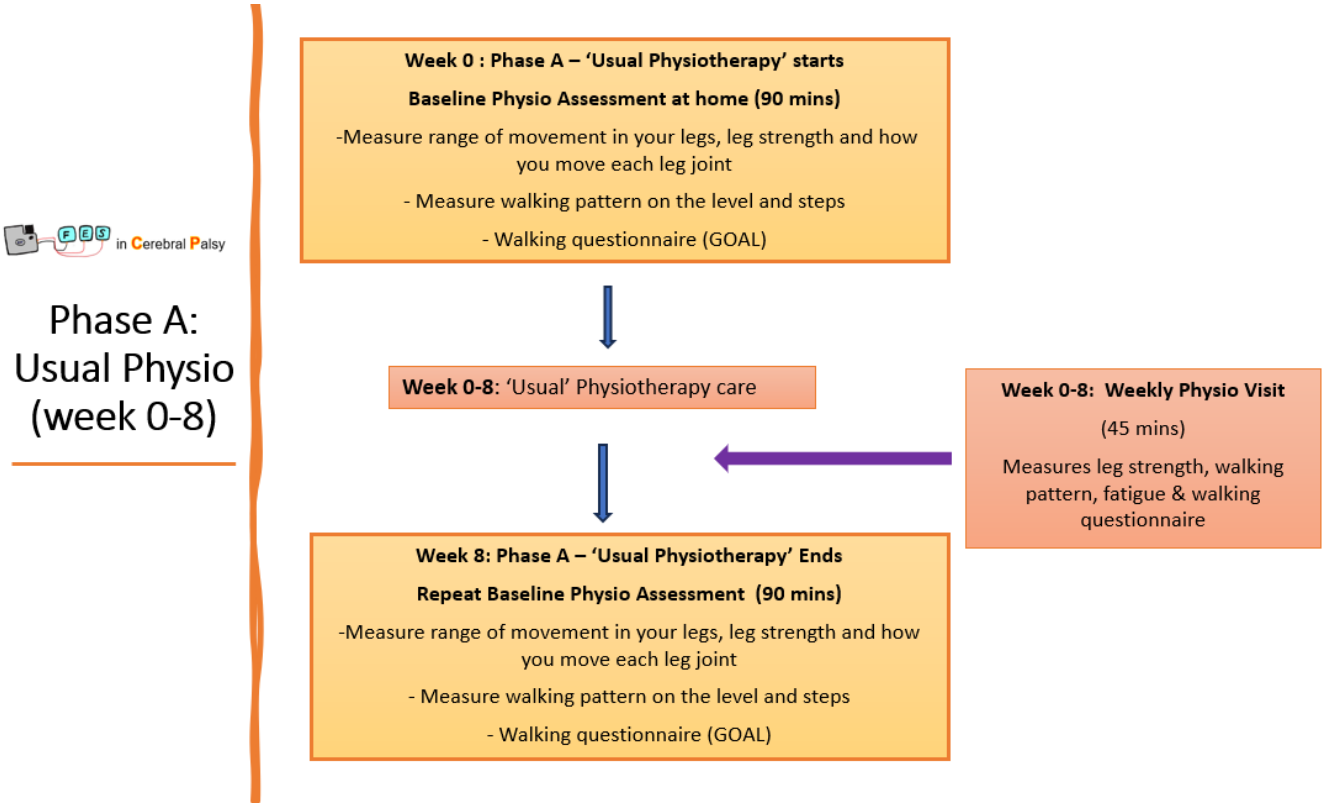
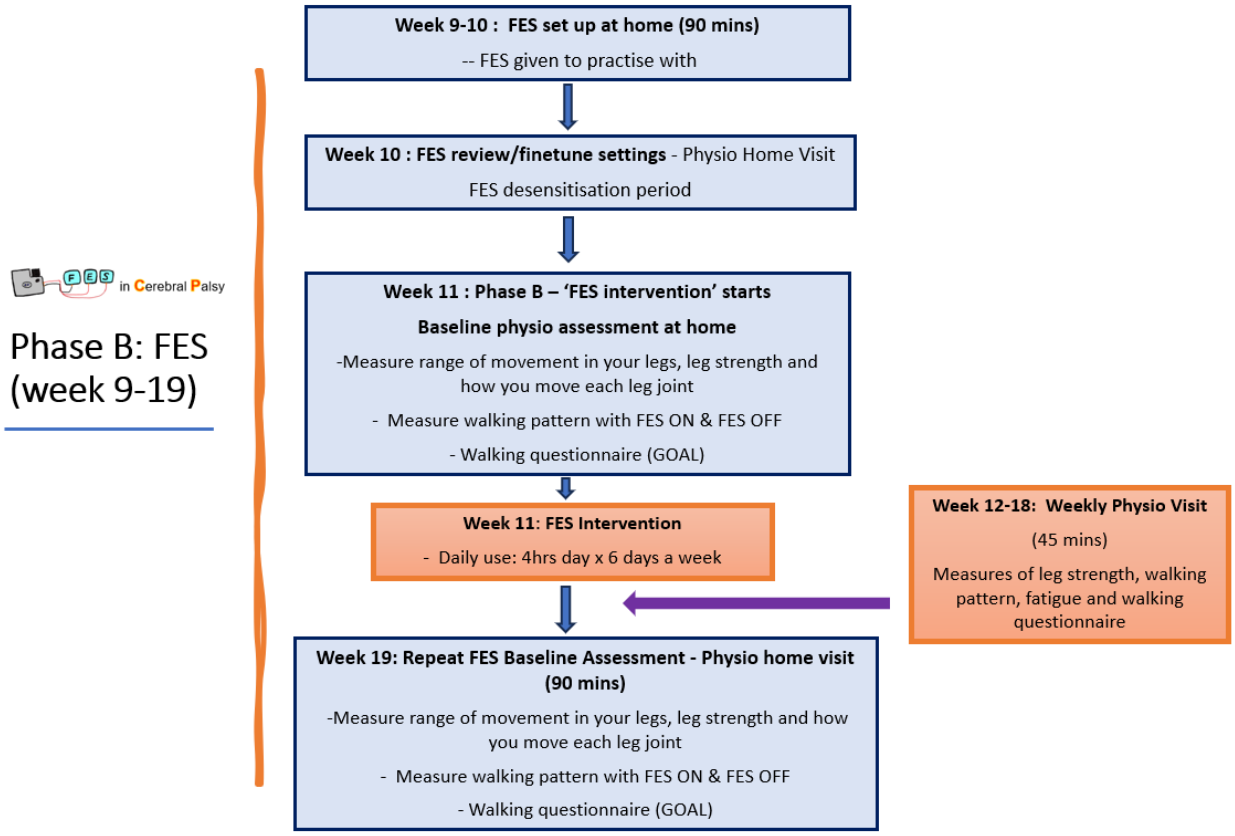


Figure 7. Flow chart of Phase B of the study: 'FES Intervention'



Are there any side effects from using the FES and taking part in the study?

Doing the walking assessment on the level and up and down steps may make your child feel tired. Your child's muscles may feel tired and a bit sore the next day. You child can take a break during the assessments and stop if they want to.

Sometimes the FES sticky pads which are placed on your child's skin can cause 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, the physiotherapist will ask you stop using the electrodes and inform the study co-ordinator.

Sometimes FES can cause a 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.

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

What are the possible benefits of taking part?
The FES may improve your child's walking and they might find it easier to walk with the FES on. You are also helping to improve our understanding of FES and whether it may be beneficial treatment for the management of crouch gait in children and young people with Cerebral Palsy. This study will be used to inform larger clinical studies across the UK.

What happens when the research study stops?
You will need to return the FES device, but if your child liked using it and you both feel that it improved their walking then we can discuss this with your physiotherapy team and see if we can refer your child for their own FES device.

We will analyse the study information and then tell people about what we found, by writing about it in a scientific journal.

We can send you a summary of the study. This study will help us to plan a future study looking at using FES to help with crouch gait.

How will we use information about you and your child?
We will need to store you and your child's initials/ name/ contact details for the study duration and afterwards if you want a study summary. This will allow us to contact you to arrange appointments and send you study reports. Your personal details will only be seen by the immediate research team.

The data gathered from the pre and posts 'usual' physiotherapy and 'FES' intervention will be analysed. We will assess whether the FES intervention had an impact on your child's measures of leg strength, range of movement and the degree of knee bend when walking on the level and up and down stairs. We will also compare these measures to other children with cerebral palsy who have participated in the study, so we can see if FES has a similar effect on each child taking part.

The film from the video cameras will be used to assess your child's selective movement ability. We will pixelate the video so your child will not be identifiable in this video. The research team will use the videos to grade your child's movement ability.

We will keep all information about your child safe and secure. People who do not need to know your child's information, will not be able to see their name or contact details. Your child's data will have a unique code number instead. Once we have finished the study, we will keep some of the anonymised data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

What are your choices about how your information is used?
Your child can stop being part of the study at any time, without giving a reason. This will not affect their medical care or participation in other studies in anyway. If your child wants to stop during the measurement session, we would like keep information about you that we already have. After the study the data is anonymised, and we cannot withdraw the data.

Where can you find out more about how my child's information is used?

In this research study we will use information from your child. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study to contact you to arrange appointments. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it and for future research.
We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this. The information pack is at the end of this sheet.

What will happen if we don't want to carry on with the study?
You and your child can withdraw from the study at any time without giving a reason. Whatever decision you make will not affect the care you in anyway. Should your child decide to withdraw from the study, the measurements we have collected up to that point will be kept and used in analysis of the results unless you ask that they are also withdrawn. You can withdraw your child during the assessments of the FES intervention if they become upset or distressed or no longer want to participate for any reason.

Who has funded and reviewed the research?
This research has been funded by the Torbay Medical Research Fund and it has been reviewed by independent experts external to University of Plymouth. Ethics approval has been gained for this study from the Health Research Authority and the University of Plymouth.

What should I do if we are interested in taking part?
If you and your child are interested in the study, please return the reply slip or contact Harriet Hughes via email or phone (contact details are given at the end of the sheet). She will then contact you to see if you have any further questions. If you are happy to participate, we will arrange for the physiotherapy to visit you at home and take your written consent and start the study assessments.

What if there is a problem?
In the unlikely event that your child is harmed by taking part in this study, there are no special compensation arrangements. However, neglectful harm will be covered by the insurance scheme of the University of Plymouth which is leading on this study. If you are harmed due to someone's negligence, you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about this study, the normal National Health Service complaints mechanisms are available to you.

If you are unsure about any aspect of this study, you should speak to the research team who will do their best to answer your questions.

- Harriet Hughes

Study Co-ordinator and Physiotherapist
University of Plymouth PL4 8AA
Email: Harriet.hughes-5@postgrad.plymouth.ac.uk Work Tel: 07971246605

• Professor Jon Marsden
Chief Investigator
University of Plymouth
Email: jonathan.marsden@plymouth.ac.uk Work Tel: 01752 587 590

If you would like independent advice about the study you can contact the University faculty of health administrators by e mail using FOHEthics@plymouth.ac.uk
Contact for further information If you would like any further information about this study, please contact:
Prof Jon Marsden
Professor of Rehabilitation
School of Health Professions
Faculty of Health Science
University of Plymouth,
Email jonathan.marsden@plymouth.ac.uk

You should be given a copy of this information sheet and a signed consent form to take home.

Thank you for reading this and considering whether to take part in the project. If you are interested in taking part in this study and you are happy for the researcher to contact you, then please complete the attached contact reply form. Alternatively, you can email, phone, or send a whatsapp message/text to:

Harriet Hughes.
Study Co-ordinator and Physiotherapist
University of Plymouth PL4 8AA
Email Harriet.hughes-5@postgrad.plymouth.ac.uk:
Work Tel: 07971246605

Appendix: Information pack about data storage

How will we use information about you?

- We will need to use information from your child for this research project. This information will include you and your child's name and contact details. We will store the data we gather under a unique non-identifiable code. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

- All information will be handled in compliance with the General Data Protection Regulations (2018). The University of Plymouth is the sponsor for this study based in the UK. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.
- Individuals from the University of Plymouth and regulatory organisations may look at your research records to check the accuracy of the research study. The research team will pass these details to the regulatory organisations along with the information collected from you. The only people in the University of Plymouth who will have access to information that identifies you will be people who need to contact you to arrange an appointment or to provide a summary of study findings or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/

- by asking one of the research team using the contact details at the end of the information sheet
- by sending an email to the University Data Protection Officer at dpo@plymouth.ac.uk

The University of Plymouth privacy notices can be assessed at https://www.plymouth.ac.uk/your-university/governance/information-governance/privacy-notices.