Torbay Medical Research Fund

FES in Cerebral Palsy

UNIVERSITY OF PLYMOUTH

Young Person information sheet for 12–18-year-olds

IRAS ID: 347391

V1: 31_07_2024

FES in Cerebral Palsy

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

We would like to invite you to take part in our research study. Before you decide whether 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 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 Dr Cherry Kilbride (Brunel University, London).

What is the study about?

- This study is about Functional Electrical Stimulation or FES for short.
- 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 can improve Crouch gait in children with Cerebral Palsy.
- Crouch gait is a walking pattern which causes the knees to bend (see figure 2).

Fig 1: FES device

Fig 2: Image of Crouch Gait

Why have I been chosen?

- We are asking you to think about doing this study because you are aged between 8-18 years old, and you have cerebral palsy and crouch gait.

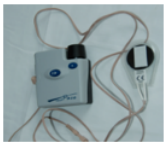
- Before you can begin the study, we will need to ask you some questions to see whether you are able to take part.
- Some young people with cerebral palsy won't be able to take part, if for example, they are unable to walk up more than 50 metres.

Do I have to take part?

- No. It is up to you, whether you take part in this study or not.
- Before you decide, a member of the research team will explain the study and go through this information sheet with you.
- If you decide to take part and are over 16 years old, we will ask you to sign a consent form allowing you to take part. If you are under 16 your parent or guardian will do this for you.
- You are free to withdraw at any time, without giving a reason. This will not affect the medical care you receive in the future.

How does the study work?

- The study has two phases, phase A: Your 'Usual' physiotherapy and Phase B: 'FES' intervention. Both phases last 8 weeks each, with a two-week gap to allow for the FES set up.
- At the start and end of both, Phase A 'Usual' Physiotherapy and Phase B 'FES' intervention, you will have a physiotherapy assessment at your home, all of which will last 90 minutes.
- Each week of both phase A 'Usual' physiotherapy and Phase B 'FES' intervention a physiotherapist will visit you at your house for 45 minutes, to re-assess you.
- At the end of both phase A: 'Usual' physiotherapy and Phase B 'FES' intervention a researcher will chat with you and your parent/guardian to hear about your thoughts and feelings of FES.



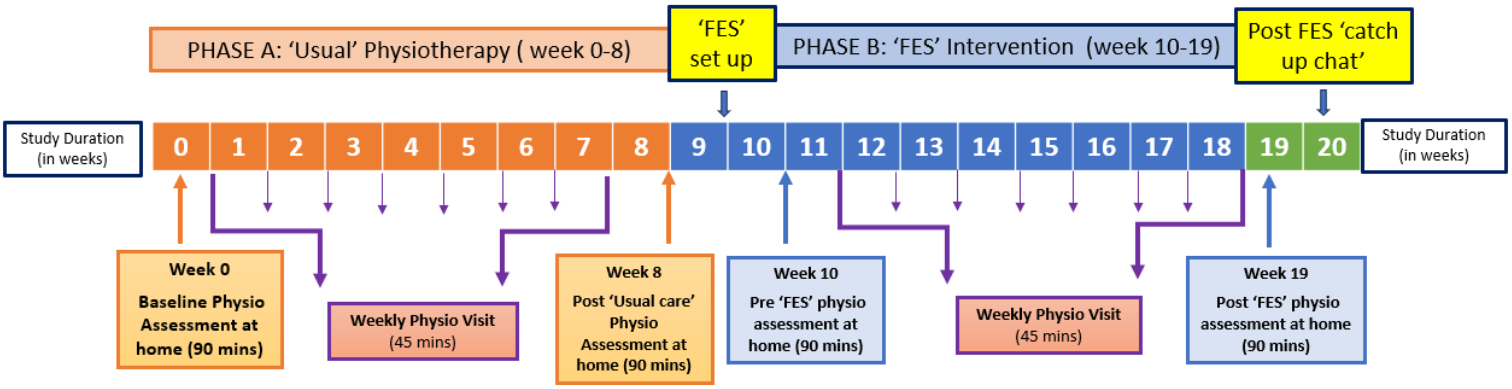


Figure 3: Study timeline of both phase A; Usual Care and Phase B; FES intervention

What will I have to do if I choose to take part?

- The researcher will talk to you about the study over the phone or via a video call. After this talk, we will see if you want to take part.
- Before you start the study, you will need to complete a written consent form if you are between 16 -18 years of age. Young people under the age of 16 years will also need their parents to fill in a form to give written consent.
- The study starts with phase A: 'Usual' care (Week 0). A physiotherapist will visit you at home and carry out a baseline assessment. During this assessment the physio will measure how you move your legs (see figure 4a), measure your leg strength using a Dynamometer (See figure 4b) and ask you to complete a questionnaire about your walking. The researcher will also watch you walk on the level, up and downstairs and measure how much you bend your knees when walking using an electric goniometer (see figure 4c). This session will last 90 minutes.

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

- As part of Phase A 'usual' physiotherapy you will need to continue with your usual physiotherapy program for 8 weeks . Each week the physiotherapist will come to your house at a time that is convenient for you and re-measure the movement in your legs, your leg strength and how much you bend you knee when you are walking on the level.. The physio will also ask you to complete a short questionnaire about how your walking has been over the last week. This session will last 45 minutes each week.
- At the end of Phase A 'Usual' Physiotherapy (week 8) the physiotherapist will visit you 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' care, please see figure 5.

- Phase B of the study 'FES intervention' then starts on week 9. The physio will visit your home and show you how the FES device works. The FES will then be set up by the physiotherapist on one of your leg muscles. You will then be given the FES devise to practise with at home.
- On week 10 the physio will visit you at home again and check how you are using the FES and make changes to the FES settings as needed. You will then be given another week to practise wearing and using the FES device.
- Then on week 11 the physio will visit you at home and carryout another baseline assessment. During this assessment the physio will measure how you move your legs (see figure 4a), measure your leg strength using a Dynamometer (See figure 4b) and ask you to complete a questionnaire about your walking. The researcher will also watch you walk on the level, up and downstairs and measure how much you bend your knees when walking using an electric goniometer (see figure 4c) both with the FES ON and the FES OFF. This session will last 90 minutes.
- You will then 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 after school, whichever is manageable for you. During this time, you will be asked to complete a diary to record your daily use of FES.
- Each week that you are using the FES (Week 11-19) the physiotherapist will visit you at home at a time that is convenient for you and re-measure the movement in your legs, your leg strength and measure your degree of knee bend when walking on the level with both the FES ON and OFF and in any usual ankle splints/orthoses. 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.
- 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 parent/guardian to catch up and chat about the FES. We will ask both of you questions about the using the FES device and taking part in the study.
- For a diagram of phase B: 'FES' intervention, please see figure 6.

Figure 5. Flow chart of Phase A of the study: 'Usual Physiotherapy'

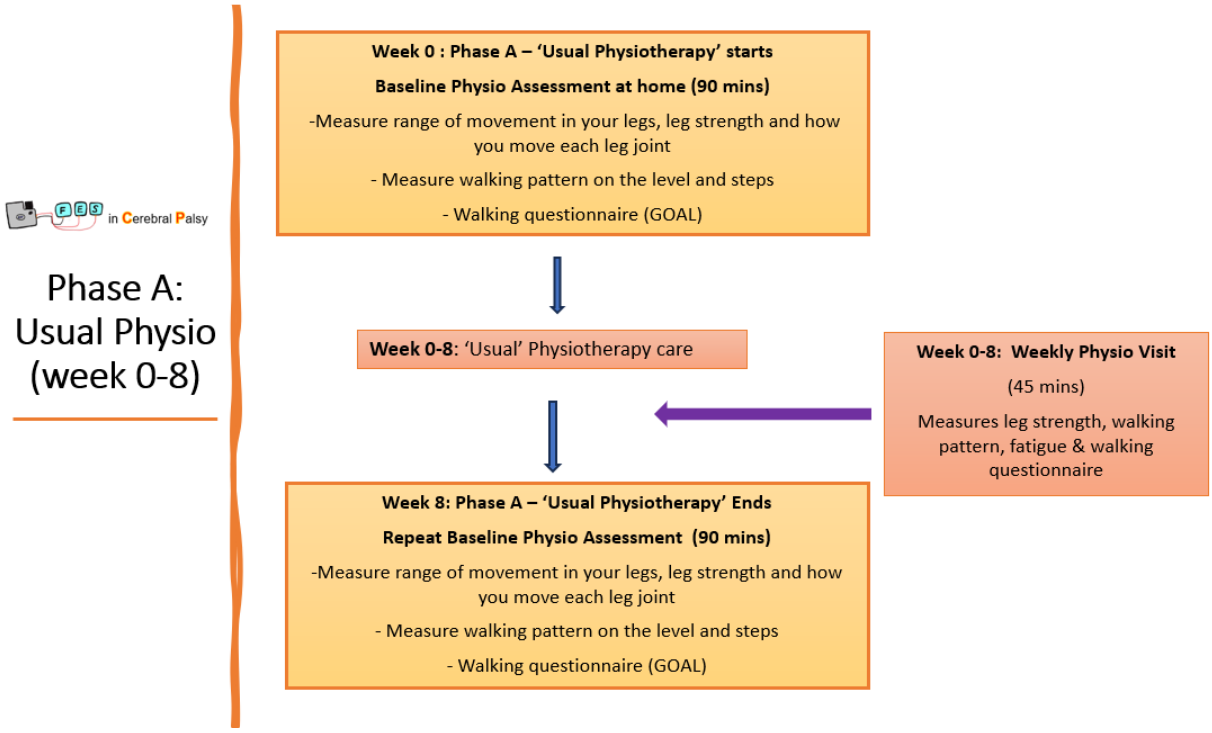
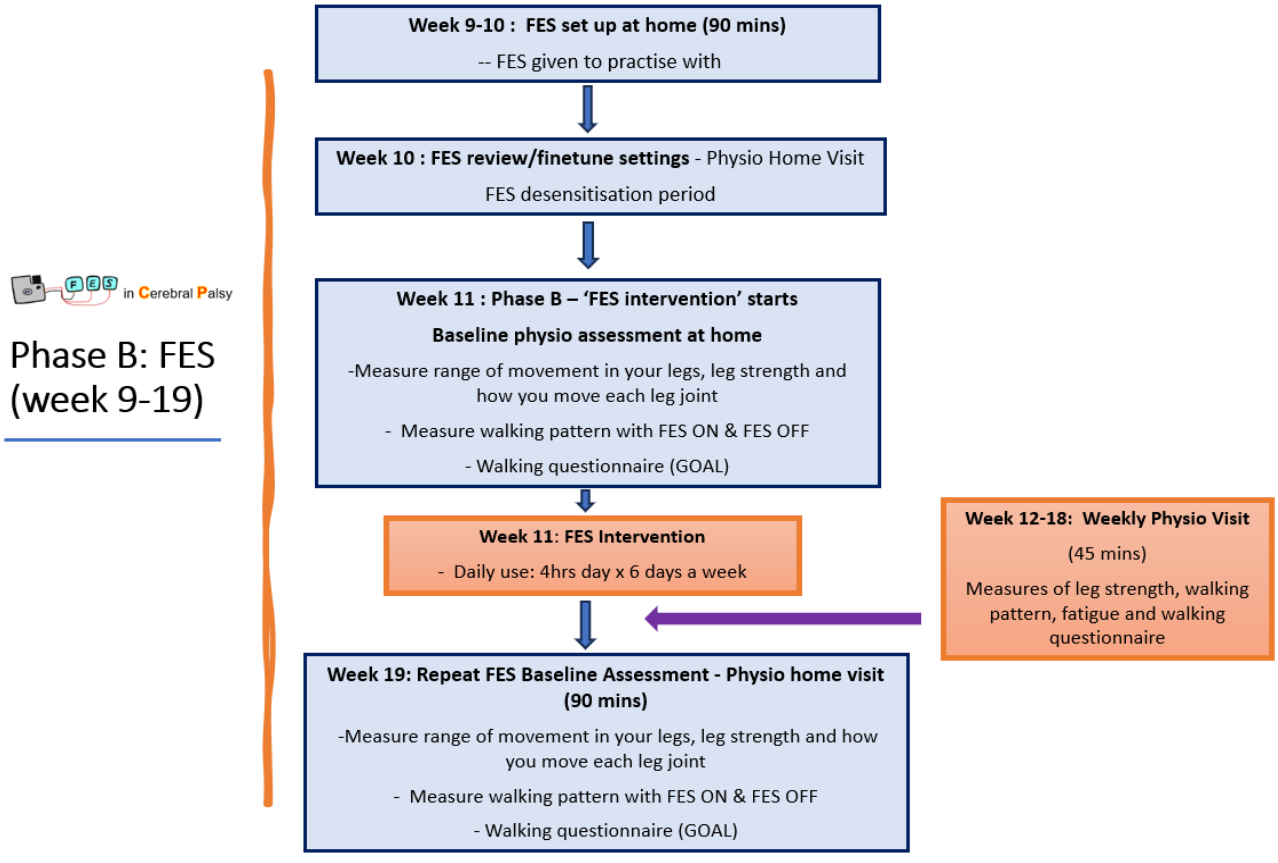


Figure 6. Flow chart of Phase B of the study: 'FES Intervention'



- Doing the walking assessment on the level and up and down steps may make you feel tired. Your muscles may feel tired and a bit sore the next day. You can take a break during the assessments and stop if you want to.
- Sometimes the FES sticky pads which are placed on your 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, you may need to take a break from using the FES or reduce the length of time you are wearing it, until your muscle has got used to it.

What are the possible benefits of taking part?

- The FES may improve your walking and you might find it easier to walk with the FES on.
- You are helping to improve our understanding of FES and whether it is a beneficial treatment for the management of crouch gait in children and young people with Cerebral Palsy

What are the possible benefits of taking part?

- The FES may improve your walking and you might find it easier to walk with the FES on.
  You are helping to improve our understanding of FES and whether it is a beneficial treatment for the management of crouch gait in children and young people with Cerebral Palsy

What happens when the research study stops?

- You will need to return the FES device, but if you liked using it and feel that it improved your walking then we can discuss this with your physiotherapy team and see if we can refer you for your 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?

- We will need to store your name and contact details (address, telephone number, email) whilst the study is taking place, this will allow us to contact you to arrange appointments.
- We will store this information after the study is complete, so we can send you the study results. After this we will securely destroy your personal information on our system.

- Your name and contact information will only be seen by the research team.
- We will keep all information about you safe and secure. People who do not need to know who you are, will not be able to see your name or contact details.
- Your data will have a unique code number. Once we have finished the study, we will keep some of the information that doesn't have your name included (anonymised data) so we can check the results. We will write about the study 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 a reason, and this will not affect your medical care or whether you can take part in other research.
- If you want to stop during the study, we would like to keep information about you that we already have.
- After the study the data is anonymised, so people cannot tell who you are, we cannot take out your information.

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

- Please see the information pack at the end of this sheet.

What will happen if I don't want to carry on with the study?

- You can stop the study at any time, and this will not affect the care you receive in any way.
- If you choose to stop taking part, the measurements we have collected up to that point will be kept and used in the results unless you ask us not to.
- You will need to return the FES device to the physiotherapist.
- You can stop taking part during the study if you feel worried or anxious.

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 Plymouth University.
- Ethics approval has been gained for this study from the University of Plymouth and the study has been reviewed by xxx Ethics Committee.

What should I do if I want to take part?

- Please send us the reply slip or contact Harriet Hughes via email or phone (contact details are given at the end of the sheet).
- She will contact you to see if you have any further questions. If you are happy to take part, she will arrange an appointment to carry out the initial study assessment.

What if there is a problem?

- In the unlikely event that you are 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 making a mistake, you may have grounds for a legal action, but you may have to pay for it.

- If you wish to complain, or have any concerns about this study, the normal National Health Service complaints process can be used.

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. You can also ask your parent or guardian to speak to us.

- 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