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PATIENT INFORMATION SHEET

April 18th 2016 V1.6.1

- *You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.*

Thank you for reading this information sheet.

Project scientific title:

The Effectiveness of Peroneal Nerve Functional Electrical **ST**imulation (F**E**S) for the Reduction of Bradykinesia in **P**arkinson's Disease: A Pragmatic Feasibility **S**tudy for a Single Blinded Randomised Control Trial **(STEPS).**

A short title for the project is: Can Electrical Stimulation of Muscles be Used to Improve Walking for People with Parkinson's Disease?

What is the purpose of the project?

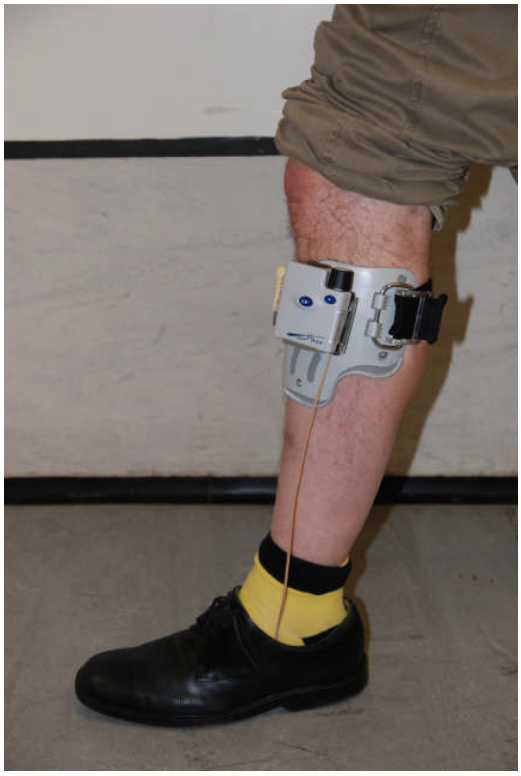
This is a project to test a new device that aims to improve walking for people who have Parkinson's disease (PD). People with PD often have difficulty in walking, which causes them to move slowly (Bradykinesia) and fall, leading to a reduced quality of life. Functional Electrical Stimulation (FES) can be used to produce useful movements in under active muscles, by applying small electrical impulses to their nerves, using a small battery powered device worn on the leg.

In previous small studies, we have shown that patients are able to walk faster and have reduced PD symptoms after using FES. We want to carry out a larger study to investigate whether FES would be beneficial to patients in the longer term when compared to routine care and whether it would be value for money for the NHS. Before setting up a larger study, we need to run a smaller study to ensure we design the full study properly. We especially want to know how many people will complete the study and the reasons why some people don't. We also want to determine if we are asking the right questions, and if the study methods are acceptable. We will interview participants to find out what they think about the study and whether there are things we should improve.

Sixty-eight people who have PD will be randomly allocated to have either FES with routine care or routine care alone. Over 22 weeks we will measure the changes in walking speed, falls, quality of life and PD symptoms.

What is Functional Electrical Stimulation (FES)?
FES is a none-invasive treatment that uses small electrical impulses to activate weak or paralysed muscles and so produce useful movement. The electrical impulses work by exciting the nerves leading to the muscles. Self–adhesive patches (electrodes) held in place using a leg cuff are placed on the skin close to the nerve supplying the muscle. Leads connect the electrodes to a stimulator (ODFS Pace) that produces the impulses. Electrical stimulation feels like pins and needles and most people quickly become used to the sensation.

The ODFS Pace is a FES device developed by researchers at Salisbury District Hospital. It consists of a small battery powered control box, which is worn on a leg cuff, placed around the leg just below the knee. The stimulation activates a nerve called the common peroneal nerve and this causes the muscles that lift the foot to contract. The stimulation is turned on and off using a small pressure sensitive footswitch placed in the shoe. This ensures the stimulation only acts when the wearer wants to lift their foot from the ground.



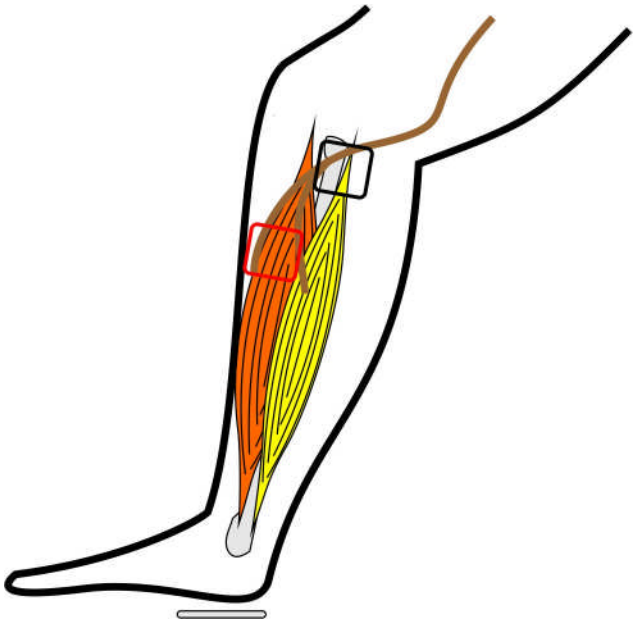


Figure 1a. **1b.**
a) The ODFS Pace and leg cuff, b) the cuff mounted electrodes relative to the underlining common peroneal nerve, fibula bone and muscles.

Why have I been chosen?
You have been identified as someone who has walking that may be affected by PD. However, before you can be offered a place on the study, your suitability will be assessed against the following criteria:

Inclusion criteria summary

- difficulty with one or more aspects of your walking
    - reduced movement of the foot and ankle while walking
    - slow walking
    - short rapid strides
    - freezing while walking
    - short stride length
- able to walk 10m with appropriate walking aids but without assistance from another person

Exclusion criteria summary

- treatment other than standard drug therapy
- pregnancy
- cardiac pacemaker, or other active medical implanted devices
- other medical conditions that affect walking
- malignancy or skin conditions in the lower leg area.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. During the project, you are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from The National Hospital for Neurology and Neurosurgery.

What if I do not wish to take part?

That's Fine. However, we would be very interested to know your reasons for not taking part. This is so we can improve the design of our future study. We would therefore like to invite you to complete the reply slip at the end of this information and contact the study centre to take part in a short telephone interview. No effort will be made to change your mind, only to understand your reasons for not taking part. This is totally voluntary.

How long will I be involved with the project if I take part?

The study lasts 22 weeks in total of which 18 weeks (group 2 only) is spent using the treatment at home.

What will happen to me if I take part?

If you decide to take part, your suitability for the study will be assessed by a researcher. This will involve a timed 10m walk test, a physical examination of your lower limbs, some questions about your medical history and a short questionnaire. Please bring a repeat prescription listing any medication you take.

If you are eligible, you will be offered an appointment to begin the study. This may be on the same day as the initial screening appointment. This appointment will take 60 to 90 minutes during which you will complete further questionnaires, assessments and walking tests. You will also be given a diary to fill in each day to record any falls or contacts with medical services.

Once all the assessments have been completed, the next step is to be allocated to either group 1 (normal care) or group 2 (FES). This is done using a computer randomisation

system and is completely out of the control of the researchers. If you are allocated to group1 (normal care) you will be given an appointment to attend the next assessment session, which will be 6 weeks later. If you are allocated to group 2 (FES) you will be given an appointment to start FES treatment.

Clinical Assessment Sessions
For both groups there will be three further assessment sessions; one at 6 weeks, one at 18 weeks and a final one at 22 weeks. The 22 week assessment is 4 weeks after group 2 have stopped using FES. At each session the measurements taken at the first session, will be repeated.

All of the outcome measures will be performed by a clinician who is "blinded" to which group each participant is in. This is so they cannot be biased in the way they make the assessments. It is **very important** that you do not tell the clinician which group you are in. Assessment sessions will take 60 to 90 minutes.

Normal Care (group 1)
Participants allocated to group 1 will continue with their normal care. Although they will not receive the FES, their role in the study is equally important as group 2. This is because we need an accurate record of normal care and the way people respond to it, in order to make a comparison with the new treatment.

FES Treatment (group 2)
If you are allocated to group 2 (FES) you will be invited to two clinic sessions, in the same week, to begin treatment. At the first session the FES device will be set up for you and you and if appropriate, your partner or carer will be shown how to use it. At the second session your use of the device will be checked and any further adjustments made if required. You will also be asked to complete a timed 10m walk test with and without FES.

You will be asked to take the FES device home and use it daily. At first your use will be limited to short walks. The amount you use FES will be increased daily over a three week period at which point you will be able to use it whenever you walk.

You will be asked to return to the FES clinic 6 weeks later where the device and your use of it will be checked. Any further adjustments will be made if required and further instruction in its use given. The timed 10m walking test will be repeated.

The final visit to the FES clinic will be at week 18 (12 weeks after the 6 week visit). At this visit the timed 10m walk test will be repeated and you will be asked to complete a short questionnaire about you experience of using FES. You will be asked to return the equipment to the clinic.

Each clinic appointment takes about 60 minutes. Where possible they will be on the same day and immediately after the Clinical Assessment sessions.

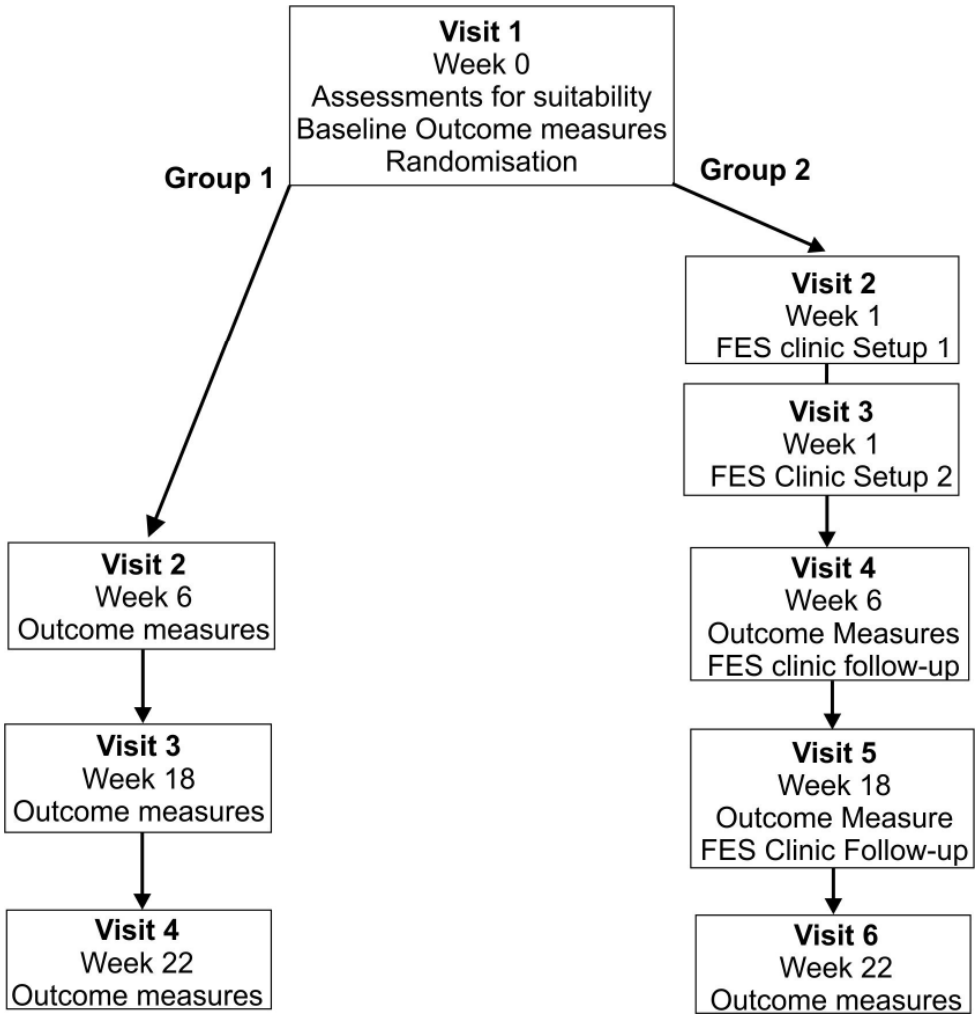


Figure 2. Study visits

What clothes should I wear?
Wear what you feel comfortable in. We will need to have access to your lower legs for the physical examinations and if you are allocated to group 2, we will need to put electrodes on your legs. Loose trousers, a skirt or shorts would be ideal. Tights or stockings should not be worn if you are in group 2 (FES)

Telephone Interviews
In order to find out what the study participants think about their mobility, the study and FES, 24 participants will be invited to take part in two short telephone interviews. The first will be at the beginning of the study, before group 2 have begun FES. The second will be at the end of the study. We will also ask permission to contact and interview people who leave the study early to find out their reasons. All interviews will be confidential and identifiable information will not be reported or feedback to either the assessor or treating clinician. Interview will be carried out by a researcher in the University of Southampton. If appropriate, a limited number of interviews may be carried out face-to-face at the participant's home or other location. Interviews will be digitally recorded and analysed later.

What facilities does your department have?
There are limited disabled parking facilities outside the hospital but good public transport links. Within the department there is a toilet suitable for wheelchair users and we have facilities to enable privacy when changing, placing electrodes or measuring equipment.

What are the possible disadvantages and risks of taking part?
There are no known serious side effects from using FES, but there are some minor risks.

The stimulation feels a bit like pins and needles. Most people quickly become used to it, but it is possible that you may find the sensation too uncomfortable and may decide too not to use the stimulator. Similarly, turning the stimulation up too high may be uncomfortable, but not dangerous.

In some cases skin irritation can occur. If this happens, then you are asked to contact us. We will provide advice on how to solve the problem.

Some people who have epilepsy can have an increase in symptoms in response to electrical stimulation.

The ODFS Pace, the device used in this study, has been extensively used by people who have other neurological conditions such as Multiple Sclerosis and stroke. No serious adverse effects from using the device have been recorded.

What are the possible benefits of taking part?
Although it has not yet been scientifically proven, our preliminary evidence indicates that FES can improve walking speed, reduce falls and may reduce the overall impact of PD. If we produce good evidence for these effects, the study may lead to a new treatment being available within the NHS.

What if new information becomes available?
Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, we will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

With your permission, we will contact your doctor and, where appropriate, your medical consultant before you start on the trial. If you do start the trial and there is any new information from your doctor, consultant or one of the researchers that could affect you continuing on the project, we may ask you to withdraw from the project. In reaching any decision we will discuss it fully with you and consider your best interests at all times.

Will I have my expenses reimbursed?
You are entitled to claim travel expenses which will be reimbursed at 24 pence a mile up to a maximum of 100 miles for each return trip. Public transport fares may also be reimbursed. A claim form will be provided at the end of your participation in the study.

What happens when the research project stops?
You will be asked to return the equipment to the hospital. If you have found FES of benefit and wish to continue its use after week 22 this will be offered to you however this will only be provided by the London site.

What if something goes wrong?
If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then 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 any aspect of the way you have been approached or treated during the course of this project, the normal National Health Service complaints mechanisms will be available to you. For information about how to complain please contact: Patient Advice and Liaison Service (PALS), Box 25, The National Hospital for Neurology and Neurosurgery, Queen Square, London, NC1N 3BG, tel: 0203 448 3237, e-mail: PALS@UCLH.NHS.UK

Will my taking part in this project be kept confidential?
All information collected about you during the course of the research will be kept strictly confidential. Each patient on the project will be given a unique code that does not contain any personal details. The study information will be stored on computers at Plymouth University for a period of one year following completion of the project. Only members of the research team and the Peninsula Clinical Trials Unit (PenCTU) at Plymouth University will have direct access to the study information. Non person identifiable records will be stored by Salisbury District Hospital for a period of 10 years following the completion of the projects.

In the consent form, we will ask for your permission to allow restricted access to your medical records. This access will only be by the named researchers who are members of NHS staff within this department.

What will happen to the results of the research project?
A report will be submitted to the National Institute of Health Research, which is funding this work. The results will be used for planning the next stage of research. Findings may also be published in scientific and medical journals, at conferences and at training days for clinicians. Confidentiality and patient anonymity will always be maintained. If you are interested, we would be pleased to discuss the results and conclusions from the project with you.

Who is organising and funding the research?
The study is organised by the Dept. of Clinical Science and Engineering at Salisbury District Hospital and funded by the National Institute of Health Research as part of their Research for Patient Benefit funding stream. The money is to cover research expenses associated with the project, including part of the salaries of the research staff. No payment is made to your referring doctor.

Who has reviewed the project?
This project and information sheet were prepared in consultation with the STEPS project Patient Advisory Group. All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by South West Cornwall and Plymouth Research Ethics Committee.

Contact for further information
If you need further information about the project, please contact:

- **Paul Taylor.** Chief Investigator
- **Trish Sampson.** Researcher

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Telephone. 01722 429119. / 01722 439561
E-mail p.taylor@salisburyfes.com

- **Val Stevenson.** Principle Investigator
- **Coralie Seary.** Clinical Specialist Physiotherapist
- **Benjamin Beare.** Researcher

Department of Therapies and Rehabilitation, National Hospital for Neurology and Neurosurgery, Queen Square, London, WC1N 3BG
Telephone 0203 448 3194
E-mail Benjamin.Beare@uclh.nhs.uk
E-mail Val.stevenson@uclh.nhs.uk

If you wish to participate in this project or would like to report your reasons for not taking part, please complete the form at the end of this information and return it in the stamped addressed envelope provided.

Thank you for reading this information sheet.

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RESEARCH PROJECT REPLY SLIP
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April 18th 2016 V1.6.1

If you do not have further questions and have made a decision about taking part in the study, please read the statements below and tick the box that applies to you and return in the pre-paid envelope enclosed in this pack:

- I am interested in taking part in the study and I am happy for you to contact me to talk about it. ☐
- I do not want to take part in the study, but I am happy to take part in an interview to discuss my reasons and to help with future research in this area ☐
- I do not want to take part in any part of the study (please note you do not need to return the reply slip) ☐

Please provide your details:

Name: ……………………………………………………………………

Address: ………..…………………………………………………………………………………...

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Telephone Number: ……………………………………………

Email: ……………………………………………………………….

Please send to:
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