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STEPS II Study
Summary Participant Information Sheet
V1

Short project title: Assessment of electrical stimulation to improve movement for people who have Parkinson's disease (PD).

Introduction

You are being invited to take part in the STEPS II study as you have been identified as a person with Parkinson's Disease (pwPD) who has some difficulty walking due to your PD. This Summary introduces the study. If you are interested in taking part, please read the Detailed Participant Information Steet for further information. You do not have to take part if you do not wish, and you could withdraw from the study at any time.

Functional Electrical Stimulation (FES) is a non-invasive procedure that involves wearing a battery-operated device on the leg that applies small electrical impulses to the nerves, to help encourage movement in muscles that are not working properly. It is commonly used by people who have had a stroke or have multiple sclerosis to help improve their walking, as FES can make walking easier, safer, and faster. We would like to find out if FES could produce similar benefits in pwPD.

A small version of this study (known as a feasibility study) has already been completed to see if pwPD are happy to take part and find the assessments and FES device acceptable. This small study also showed us that pwPD are able to walk faster after using FES. However, this study was too small to determine if FES is a useful treatment for PD, how it works and other benefits it may have to pwPD.

To answer these questions, we are carrying out the STEPS II study. This is a Randomised Controlled Trial (RCT), which means that participants will be randomly assigned to be in one of two groups: usual care (Group 1) or FES with usual care (Group 2). This is because we need an accurate record of usual care and how people respond to it, to compare with the new treatment. Seven NHS Trusts in the UK are taking part and 234 pwPD will be involved in the study for a period of 22 weeks.

What will happen to me if I take part?

If you are assigned to Group 1 (usual care):
You will continue with your usual care. In addition, will have the following:

- **x1 telephone appointment**, lasting around 15 minutes, to answer questions to check you are suitable to take part in the study.
- **x1 face-to-face screening appointment**, lasting around 65 minutes, to provide consent, answer questions about your condition and complete a

walking test. At the end of the appointment, you will be told if you are suitable to take part in the study.

- **x5 face-to-face assessment appointments,** lasting up to 2 hours, to complete questionnaires and physical assessments. These appointments will take place over a 22 week period (at weeks 0, 2, 6, 18 and 22).
- Wear a pedometer around your ankle for 7 days, on 3 different occasions.

If you are assigned to Group 2 (FES with usual care):
You will continue with your usual care and use the FES device daily for 18 weeks. You will have the same appointments as Group 1, detailed above. In addition, you will have:

- **x4 face-to face FES appointments**, lasting around 60 minutes, with a FES specialist to show you how to use the device and complete walking tests. At the last appointment, you will also complete questionnaires. These appointments will take place at weeks 1, 2, 6 and 18, on a different day to the assessments detailed above.

The FES device
The FES device is called the ODFS Pace and was developed by researchers at Salisbury District Hospital. It consists of a small battery powered control box, sticky patches (called electrodes), a leg strap, and a small pressure switch, which is placed in the shoe. It works by stimulating the nerve on the side of the leg (called the common peroneal nerve), which then causes the muscles that lift the foot to contract. The stimulation is turned on and off using the pressure sensitive footswitch, helping to lift the foot at the correct time when walking.

Are there any risks associated with FES treatment?
There are no known serious risks from using FES, but there are some possible minor risks:

- The stimulation feels a bit like pins and needles. Most people become used to it quickly, but some people may find sensation too uncomfortable and decide not to use the device. Similarly, turning the stimulation up too high may be uncomfortable, but not dangerous.
- Skin irritation from the sticky patches may occur in some cases.
- Some people who have epilepsy could have an increase in symptoms in response to the electrical stimulation.

Will expenses be reimbursed?
Some travel expenses may be claimed back. Participants will also be offered a £20 voucher for each stage of the study they complete. This applies to assessment appointments that take place at weeks 0, 2, 6, 18, and 22.

What next?
Thank you for reading this summary. If you think that you may be interested in taking part, please read the enclosed Detailed Participant Information Sheet, which provides more information on what taking part in the study will involve and how your information would be used. Contact details are provided at the end of this to register your interest.