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Can electrical stimulation of muscles be used to improve walking for people with Parkinson's disease?

Submission date
27/03/2017

Recruitment status
No longer recruiting

Registration date
05/04/2017

Overall study status
Completed

Last Edited
16/08/2022

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a long-term medical condition which is caused by the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). People with Parkinson's disease (PD) often have difficulty in walking, which causes them to walk slowly and fall, leading to a reduced quality of life. Functional Electrical Stimulation (FES) is a technique which uses low energy electrical impulses to trigger useful movements in underactive muscles through small battery powered device worn on the leg. Previous studies have shown that patients with PD have been able to walk faster and have reduced symptoms after using FES. In order to carry out a large 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, it is important to run a small study to ensure the dull study is designed properly. The aim of this study is to look at the feasibility of conducting a study looking at the effectiveness to FES to see if a larger study would be possible.

Who can participate?
Adults with Parkinson's disease who have walking difficulties.

What does the study involve?
Participants are first screened for their suitability for the study. If suitable they are invited back for an initial assessment which takes about 2 hours. Participants are then randomly allocated to one of two groups. Those in the first group continue to receive their usual care only for the duration of the study. There particiapnts return for follow up appointments after six, eight and 22 weeks at which the initial assessments are repeated. Those in the second group are invited to attend two appointments to learn how to use the equipment and followed up by the FES clinician at 6 and 18 weeks. At the 18 week appointment the FES device is returned to the clinic.

As with those in the first group, these participants are also asked to attend assessment sessions at six, 18 and 22 weeks. At the end of the study, the number of participants who took part and those who completed all assessments is recorded to see if a larger study would be possible.

What are the possible benefits and risks of participating?
At the start of this study it is not known if people with Parkinson's disease will benefit from using FES but reports from small short term studies indicate that walking may be made easier, faster and safer. While the long term safety of the technique has not been assessed for people with Parkinson's, the technique has been extensively used in other patients groups such as multiple sclerosis and stroke. No serious side effects have been reported. The only regularly reported side effect from using FES is skin irritation under the electrodes (sticky pads via which the electric current is administered), effecting between 2.5% to 5% of device users.

Where is the study run from?
1. Salisbury District Hospital (UK)
2. The National Hospital for Neurology and Neurosurgery (UK)

When is the study starting and how long is it expected to run for?
April 2016 to April 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Paul Taylor
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30475

Study information

Scientific Title
The effectiveness of peroneal nerve functional electrical stimulation (FES) for the reduction of bradykinesia in Parkinson’s disease: A pragmatic feasibility study for a single blinded randomised control trial (STEPS)

Acronym
STEPS

Study objectives
The aim of this study is to investigate the feasibility of conducting a randomised controlled trial to demonstrate that functional electrical stimulation (FES) applied to the common peroneal nerve while walking has a beneficial effect for people who have Parkinson's disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Cornwall & Plymouth Research Ethics Committee, 18/07/2016, ref: 16/SW/0041

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.odstockmedical.com/knowledgebase/steps-participant-information

Health condition(s) or problem(s) studied
Specialty: Dementias and neurodegeneration, Primary sub-specialty: Parkinson's Disease; UKCRC code/ Disease: Neurological/ Other disorders of the nervous system

Interventions
Sixty-eight people with gait deficit due to idiopathic PD will be recruited. All participants will continue with usual care. In general, this comprises medication, attendance at medical clinics or

visits from PD nurses. Exercise therapy may be accessed by individuals although this is not routinely prescribed. Participants will record usual care during the 22 week study.

The participants will be randomly allocated using computer generated randomisation to one of two groups.

Group 1 (control group): Participants will not receive any additional intervention over their usual care.

Group 2 (FES): Participants will use the device in addition to their usual care. FES will be delivered using a device called the ODFS Pace. Self-adhesive electrodes are placed over common peroneal nerve at its most superficial point just below the head of fibula. Stimulation is timed to the gait cycle using a pressure sensitive footswitch placed in the shoe and cause a contraction in the muscles that lift the foot and stabalise the ankle. As the foot is brought forward. The stimulator will be used daily when walking, throughout the intervention period. Participants will be taught to use the device over two clinic appointments with follow up 6 and 18 weeks.

Both groups will be assessed at weeks 0, 6, 18 and 22, (4 weeks after withdrawal of the device from group 2), by an assessor blind to the group allocation.

Intervention Type
Other

Primary outcome measure
1. Recruitment rate is determined by comparing the number of people with PD in each service, the number of people approached and issued with and information sheet and the number of people who come forward for assessment with the number of people who are consented on to the study at baseline
2. Willingness to be randomised will be assessed by recording the number of people who drop out of the study because of what they consider unfavourable group allocation will be recorded, and through qualitative interviews with potential participants who do not wish to take part at or around baseline
3. Loss-to-follow rates will be determined by comparison of the number of participants who are consented for the study with the number of participants who complete the 22 week assessment
4. Participant views on obstacles to recruitment and retention in study using semi structure qualitative interviews at the beginning and end of the study
5. Participant views on what would constitute a meaningful primary outcome measure using semi structure qualitative interviews at the beginning and end of the study and study questionnaire at week 18

Secondary outcome measures
No secondary outcome measures.

Overall study start date
01/04/2016

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Aged 18 years and above (no upper age limit)
2. Idiopathic Parkinson's disease
3. Hoehn and Yahr stages I to IV under medication
4. Difficulty with gait (clinical observation by experienced clinician):
4.1. Reduced dorsiflexion or eversion at any point in the swing or weight acceptance phase of gait,
4.2. Bradykinesia demonstrated by a measured 10m walking speed of less than 1.25ms-1
4.3. Festination demonstrated by walking with short rapid strides
4.4. Akinesia demonstrated by exhibiting freezing episodes while walking. This may be in restricted areas such as doorways.
4.5. Hypokinesia demonstrated by walking with a short stride length
5. Able to walk 10m with appropriate walking aids but without assistance from another person
6. Able to obtain standing from sitting without the assistance of another person.
7. Medically stable defined as no significant changes in the participants condition over the last 3 months
8. Able to understand and comply with the treatment and assessment procedures
9. Able to give informed consent
10. Able to start using FES within 2 weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 68; UK Sample Size: 68

Total final enrolment
64

Key exclusion criteria
1. Able to walk 10m in less than 8s (walking speed >1.25ms-
1) indicating non limited functional walking
2.
Other treatment than standard drug therapy (FES, deep brain stimulation, duodopa, apomorphine)

3.
Atypical or secondary parkinsonism or parkinsonism related to other neurodegenerative diseases
4. Dropped foot due to any neurological condition other than Parkinson's Disease
5. Untreated or refractory epilepsy
6. Pregnancy
7. Cardiac pacemaker, or other active medical implanted devices
8. Denervation of the common peroneal nerve

9. Malignancy or dermatological conditions in the area of the electrodes
10. Major cognitive impairment or dementia

Date of first enrolment
01/05/2016

Date of final enrolment
20/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
The National Hospital for Neurology and Neurosurgery
Queen Square
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Sponsor information

Organisation
Salisbury NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ja2ye75

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned submission of a research report to the journal of Movement Disorders.

Intention to publish date
30/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Paul Taylor (p.taylor@salisburyfes.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results			12/08/2022	No	No
Protocol file	version 2.6.0	05/04/2017	12/08/2022	No	No
Results article		01/12/2020	12/08/2022	Yes	No
Statistical Analysis Plan	version 1		16/08/2022	No	No
HRA research summary			28/06/2023	No	No