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Stimulation of the Tibial nerve – A Randomised Trial for Urinary problems associated with Parkinson's disease (STARTUP)

Submission date
15/06/2018

Recruitment status
No longer recruiting

Registration date
22/07/2018

Overall study status
Completed

Last Edited
23/08/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a combination of movement complaints (such as slow and restricted walking, tremor or shaking), and problems with the bladder, such as having to get to the toilet quickly, or getting up often at night to go to the toilet. These bladder symptoms are a major cause of distress and have a large impact on health-related costs and quality of life.
Previous studies have shown that using a mild electrical stimulation (similar to a TENS machine) to a nerve in the lower ankle can improve bladder problems in some people and thus improve their quality of life. However, we do not know if using such a device will help the bladder symptoms in patients with Parkinson's disease. The STARTUP trial aims to find out if using the device will reduce bladder symptoms in patients with Parkinson's. The device works by placing electrodes (patches) near the ankle to stimulate a nerve that has connections with the bladder.

Who can participate?
Adults patients, both male and female, who have been diagnosed with Parkinson's disease and who also have bladder problems.

What does the study involve?
208 participants will be are asked to join this study. Participants will be asked some questions to make sure they are suitable and if they are and they want to take part then they will be randomly allocated to one of two groups (an active treatment group and a dummy treatment group). At their local clinic the participants will be shown how to use the device, but they will not know if they are getting the stimulation in the right way, or not.
Following this clinic visit the participant will be given a pack to take home with them containing a 3-day frequency bladder diary (with simple instructions) and a questionnaire booklet. The participant is asked to complete the frequency bladder diary during the next 3 days (starting with the first morning urination), before starting to use the stimulation. During these 3 days at home, the research office will telephone the participant to make sure they are completing the bladder diary and completes the these are posted to the research office. The participants then starts to use the device.

What are the possible benefits and risks of participating?
There are no risks of taking part in the trial. The possible benefits are that those in the active group may see an improvement in their bladder symptoms, and we will have confirmation of an effective treatment for people with Parkinson’s who have bladder issues.

When is the study starting and how long is it expected to run for?
May 2018 to April 2021

Who is funding the study?
The Dunhill Medical Trust and Parkinson's UK.

Who is the main contact?
1. Professor Doreen McClurg (scientific)
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2. Susan Stratton, STARTUP Trial Manager (public)
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Study website
https://www.parkinsons.org.uk/research/startup-trial-stimulation-tibial-nerve-trial-urinary-problems-associated-parkinsons

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18/ES/0042

Study information

Scientific Title
A multicentre randomised trial of the effectiveness of transcutaneous tibial nerve stimulation (TTNS) to reduce lower urinary tract symptoms in people with Parkinson’s

Acronym
STARTUP

Study objectives
Will transcutaneous (i.e. using a surface electrode) tibial nerve stimulation (TTNS) reduce lower urinary tract (LUT) symptoms in people with Parkinson’s (PwP) significantly more than placebo stimulation?

Ethics approval required
Old ethics approval format

Ethics approval(s)

NHS East of Scotland Research Ethics Service, 11/12/2017, ref: 18/ES/0042
Grant application RPGF1711\16

Study design
Double-blind placebo-controlled randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
https://www.parkinsons.org.uk/sites/default/files/2019-02/Participant%20info%20sheet%20D%20McClurg.pdf?utm_source=Adestra&utm_medium=email&utm_term=&utm_content=label%3A%20info%20sheet&utm_campaign=Feb%202019%20TP-%20Doreen%20McClurg%20Glasgow

Health condition(s) or problem(s) studied
Parkinson's disease with lower urinary tract symptoms

Interventions
Current intervention as of 27/03/2019:
The settings of the device will be pre-set and locked by the clinician. The participant will be shown how to apply the two adhesive electrodes to the lower leg and how to connect to the device and set to the appropriate intensity. All participants will use the stimulator for two sessions a week for 6 weeks, each session is 30 minutes in length. It is preferable to have 2-4 days between stimulation sessions. When the device is returned compliance of use will be downloaded.

Previous intervention:
The previous intervention text has been removed on the request of the investigator.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
1. Urinary leakage assessed using ICIQ-UI Short Form questionnaire. The ICIQ-UI SF provides a brief and robust measure to assess the impact of symptoms of urinary incontinence (UI) on

quality of life and outcome of treatment. It is validated in both males and females with 4 questions measuring frequency of UI, amount of leakage, overall impact of UI and a self-diagnostic item. Overall Grade A validity, reliability and responsiveness established with rigour on one data set. Scores range from 0-21 overall score with greater values indicating increased severity.
2. Bladder overactivity assessed using International Prostate Symptoms Score (IPSS). The IPSS is based on the answers to seven questions concerning urinary symptoms and has been validated for use in men and women. The questions refer to the following urinary symptoms:
2.1. Incomplete emptying
2.2. Frequency
2.3. Intermittency
2.4. Urgency
2.5. Weak stream
2.6. Straining
2.7. Nocturia
2.8. Patient's perceived quality of life. Each question is assigned points from 0 to 5 indicating increasing severity of the particular symptom. The total score can therefore range from 0 to 35 (asymptomatic to very symptomatic). Although there are presently no standard recommendations into grading patients with mild, moderate or severe symptoms, patients can be tentatively classified as follows: 0-7 = mildly symptomatic; 8-19 = moderately symptomatic; 20-35 = severely symptomatic.
The outcome measures are applied at baseline, at 6 weeks (following intervention period) and at 12 weeks.

Secondary outcome measures
1. Urinary symptom-related quality of life assessed using Qualiveen, an 8-item self-administered questionnaire validated in patients with neurological disorders at baseline, at 6 weeks (following intervention period) and at 12 weeks
2. Parkinson's disease-specific quality of life assessed using PDQ-8 questionnaire at baseline, at 6 weeks (following intervention period) and at 12 weeks
3. Frequency of micturition, leakage episodes and urgency assessed using a 72-hour bladder diary recorded during the week post-randomisation before commencing the use of the device at home (Week 0), week 7 and week 11. Participants will be advised to start the diary in the morning (first void of that day) following their clinic visit
4. Compliance: Locked compliance within the stimulation unit will record how often and for how long the participant has used the unit during the 6 weeks of intervention and will be downloaded on at clinic on receipt of the unit
5. Concomitant medication assessed using a form completed at the weekly telephone interview and at week 12. All medications that are taken by the patients are considered as concomitant medications in clinical trials and they are critical for proper monitoring of patient safety and well-being
6. Resource use (including visits to the doctor/nurse/hospital, medications bought/prescribed or not prescribed, purchases such as incontinence pads) assessed using a questionnaire completed at 6 and 12 weeks
7. Participation experience and protocol fidelity assessed at 6 weeks using a brief self-completion questionnaire

Overall study start date
22/05/2018

Completion date

22/04/2021

Eligibility

Key inclusion criteria
1. Diagnosis of Parkinson's disease with self-reported problematic LUT symptoms
2. Capacity to consent/complete self-report outcome measures
3. Ability to apply TTNS (or placebo) independently or has carer who can apply for duration
4. Stable Parkinson’s medication, treatment naïve, treatment failed or continuing treatment with anti-muscarinic medication (group allocation will be minimised to account for these groups).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
A sample size of 208 randomised evenly to the two arms

Key exclusion criteria
1. Pacemaker or implanted electrical device
2. Ulceration or broken skin in area of pad placement
3. History of gynaecological, urological cancer, prostate cancer
4. History of peripheral vascular disease, epilepsy or current urinary tract infection (as per dip stick analysis)
5. Pace-maker, sacral nerve stimulator, receipt of Botox or PTNS within the last year
6. Severe prostatic enlargement as determined by treating clinician

Date of first enrolment
01/08/2018

Date of final enrolment
12/02/2020

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre

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Sponsor type
University/education

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Not defined

Funder Name
The Dunhill Medical Trust

Funder Name
Parkinson's UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The dissemination plan is designed to achieve maximum study exposure and impact amongst a range of beneficiaries (PwP and carers, healthcare professionals, national/local decision makers, professional bodies, patient/carer organisations and the academic research community). Specific dissemination strategies will include:
1. Presentations at a range of Parkinson's/Dementia/Neurology and continence (bladder and bowel) related professional and research conferences. The Chief Investigator (CI) has extensive experience in presenting at such conferences including the International Continence Society which has a specific Neuro-urology stream, Parkinson's UK Research Conference, etc. In addition, she has been an invited speaker at several international Neuro-urology Workshops held at the Institute of Neurology at Queens Square London. She has also taken part in several initiatives organised by IMPRESS an NIHR funded project to develop pilot and early-stage research projects on technology for incontinence as well as a workshop on continence research hosted jointly by a host of charities e.g. Parkinson's UK, Age UK, etc. and clinical and patient representatives. There are therefore significant links and opportunities for dissemination of findings and opportunities to plan implementation.
2. A dedicated study website with project findings and regular updates (including recruitment rates)
3. The final report will be submitted to Dunhill Medical and Parkinson's UK. A summary of the findings will be provided to all study participants (if requested on consent form). The main results paper will target a high-impact journal (e.g. BMJ, Movement Disorders). Other papers (e. g. methodology, health economics) will target relevant open access journals. Authorship and time scales will be agreed by the project management team.
4. Findings will be provided to NICE for guideline updates for bladder and bowel dysfunction, diagnosis and management of Parkinson's in primary and secondary care. These national guidelines will feed into local guidelines and care pathways.
5. Findings will be included in relevant Cochrane Review protocols and updates.
6. We will use Twitter to share study news and exploit other relevant social media to raise awareness of study progress and the findings, as well as press releases to news media.
7. We will revise the treatment handbook in the light of findings regarding acceptability and utility from our patients.
8. The CI is a past Chair of the Association for Continence Advice and currently sits on the Education Committee. Should the results show effectiveness, training in the use of TTNS will be

targeted at continence nurses. Such training will include all aspects of continence care in the elderly, especially those with neurological conditions, and then on TTNS which is largely a self-management tool.

Intention to publish date
31/07/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		17/02/2020	23/08/2023	Yes	No