We will be using information from you in order to undertake this study and Glasgow Caledonian University will act as the data controller for this study. This data will contain your name, age, contact details and data collected throughout the trial. Your contact details will be used to send you study related materials (such as bowel diaries). Your personal data will not be shared with any other research bodies.

This means that the Glasgow Caledonian University is responsible for looking after your information and using it properly. Glasgow Caledonian University will keep identifiable information 5 years after the study has finished in a secure location. After this time, all information will be securely destroyed. We will also notify your GP about your study participation.

Legal basis for processing data

As part of the project we will be recording personal data relating to you. This will be processed in accordance with the General Data Protection Regulation (GDPR); **Article 6(1)e.** Under GDPR the legal basis for processing your personal data will be the official authority of the university.

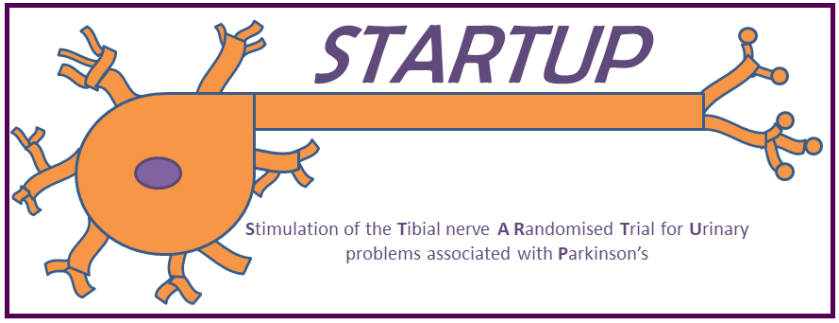
Who is organising and funding the study?

This study is sponsored by Glasgow Caledonian University and funded by The Dunhill Medical Trust and Parkinson's UK.

To take part

If you wish to participate please complete the expression of interest form and return in the envelope provided. The researcher will then call you to discuss further.

Thank you for reading this and considering taking part in this study.



A study to assess if transcutaneous tibial nerve stimulation (TTNS) will help with urine leakage in people who have Parkinson's

Patient Information Leaflet

A multicentre randomised trial of Stimulation of the Tibial Nerve for Urinary problems associated with Parkinson's

General Patient Information Leaflet: Version 2.0 04.05.2018 (GDPR)

Introduction

We'd like to invite you to take part in our research trial. Before you decide it is important that you understand why the research is being done and what it would involve for you. If you are interested a researcher will go through this information sheet with you, to help you decide and answer any questions. This should take about 10-15 minutes. Please feel free to talk to others about the research if you wish.

Why are we doing this research?

Bladder problems, including having to go to the toilet frequently and urgently, especially during the night, sometimes leading to urine leakage (incontinence), is common in people with Parkinson's. These symptoms impact significantly on the ability to socialise or get a good night's sleep. Unfortunately, there are few treatment options to help with these symptoms but transcutaneous tibial nerve stimulation, also called TTNS, is a treatment which has helped many men and women to reduce their bladder problems. However, this treatment has not been tested in people with Parkinson's. We want to investigate if TTNS helps people with Parkinson's who have bother with their bladder.

Why have I been chosen?

You are invited to take part in this research because you are a person with Parkinson's and you have bladder problems.

Do I have to take part?

No, it is up to you to decide to take part or not. If you decide you would like to take part you are free to withdraw at any time without giving a reason. This will not affect your care in any way. You may also want to talk to your family about it before making your decision.

If you have any further questions about the study at any stage, please feel free to contact:

Professor Doreen McClurg
Chief Investigator STARTUP Trial
NMAHP RU
Glasgow Caledonian University
G4 0BA
0141 331 8105
Doreen.McClurg@gcu.ac.uk

or

Susan Stratton
STARTUP Trial Manager
NMAHP RU
Glasgow Caledonian University
G4 0BA
0141 331 3504
susan.stratton@gcu.ac.uk

Your Rights

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information using the following links:

https://www.gcu.ac.uk/dataprotection/
https://www.hra.nhs.uk/information-about-patients/

Alternatively, you can contact the following office:

Data Protection Officer
Department of Governance
Glasgow Caledonian University
Cowcaddens Road
G4 0BA
Tel: 0141 332 8392
dataprotection@gcu.ac.uk

If you remain unhappy and wish to complain formally, you can do this by contacting the complaints department at your local NHS Board.

Taking part in this study does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS (which includes professional indemnity insurance for negligence).
If you become unable or unwilling to continue with TTNS, we would withdraw you from the research. We would retain, confidentially and with your consent, the relevant information that we had already collected about you, for the purposes of this research only.

Who is organising and funding the research?

This research is funded by the Dunhill Medical Trust & Parkinson's UK It is sponsored by Glasgow Caledonian University and includes experienced healthcare researchers from 6 universities and the NHS.

Who has approved the research?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. The East of Scotland Research (REC2) has scrutinised and examined this proposal for medical research on humans, and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records. be made available for scrutiny from monitors from the sponsor (Glasgow Caledonian University) and the local NHS whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What should I do now?

Please return the Expression of Interest form to us in the envelope provided. If you do not want to take part then we will know not to contact you again and no information about you will be stored. If you are interested we will contact you by telephone on receipt of your form.

What will happen to me if I take part?

Once the Expression of Interest form has been received by the researchers at Glasgow Caledonian University or by your local hospital, they will telephone you. During the telephone call they will explain more about the study and answer any questions you may have. If, after discussing the study you do not want to take part that is fine, no further contact will be made. If you want to take part then you will be asked some questions to make sure you are eligible to take part in the study and if you are, then you will be given an appointment to see a clinician at a time and place convenient to you, or in some cases they may visit you (less common). This may be with your Parkinson's nurse, a Research Nurse or a continence nurse depending on the way the study is running in your area.

At this appointment you will be asked to sign a consent form and because this is a research trial, half of the participants will be randomised to be in either the intervention group or the placebo group. We have no control over which group you will be allocated too, this is done using an on line system especially designed for the trial. If you agree to participate you will not know which group you are in until the research is finished.

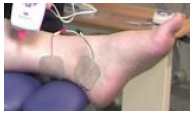
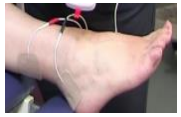
At this appointment you will also be given a 3-day bladder frequency chart which you will need to complete before you start using the stimulation and a booklet with some questionnaires which you also need to complete.

Following your visit to the clinic to be shown how to use the device, the researcher from Glasgow will telephone you again to make sure you understand how to complete the bladder frequency chart and some questionnaires asking about your bladder symptoms and your quality of life. If you want, they will help you to complete the questionnaires. To complete the bladder frequency chart you will be asked to tick the approximate time you go to the toilet for 3 days and indicate if you have leaked or not, and how urgent it was.

Once these have been completed a start date to use the device will be agreed, the researcher will make sure you are happy with how to use the unit, and a date and time for a weekly phone call will be arranged to make sure you are having no problems will be made.
At the end of the 6 weeks of using the device (twice a week for 30 minutes), you will be asked to complete the bladder frequency chart and questionnaires, and this will be repeated 6 weeks after that. Devices will be returned to the research office by posting in a pre-paid jiffy bag.
To summarise the total length of time of your involvement with the study is 13 weeks, this includes one appointment at the start, 6 weeks of device use and the completion of questionnaires 6 weeks later

The TTNS and placebo treatment

Everyone will be shown you how to use the small hand held stimulator and where to put the adhesive electrodes. The machine and electrodes looks like this:


Once this is switched on, you may feel a tingling sensation but it does not hurt. Some people do not feel anything and this is quite normal. Each treatment lasts 30 minutes. You will use this unit twice a week, for 6 weeks.

After the TTNS and placebo treatment

After you have finished all 12 treatments (2, 30 minute treatments for 6 weeks), we need to repeat what happened before you started to use the device to see if anything has changed.

- We will repeat the bladder frequency chart that recorded how often you pass urine for 3 days and nights
- We will ask you the same questions about your bladder symptoms and quality of life.

We will do these on three occasions: before you start treatment, as soon as your TTNS or placebo treatment finishes and 6 weeks after that. Some of the questions may be quite sensitive and if they are upsetting please contact the researcher or your PD clinician.

What are the possible benefits of taking part?

We cannot guarantee any specific benefits for you, if you do take part. You may find that you go to the toilet less often, have less sudden urgency, get up less to the toilet at night, leak less urine and have better bowel habits.

What are the possible risks of taking part?

There are no serious side-effects associated with any part of this research. Some people may experience mild itchiness on their ankle during or after the treatment for a few minutes.

Will my taking part in the study be confidential?

Yes. All information which is collected about you will be kept confidential in a locked cupboard at Glasgow Caledonian University. Computerised information will be kept on password protected computers. Only those involved in the research will be permitted access to the information. When the research results are published, this will be done in such a way that you will not be personally identifiable.

With your permission we will tell your GP that you are taking part in the research.

Relevant parts of your care records and information collected during the research may be looked at by responsible individuals from regulatory authorities where it is relevant to your taking part in this research.

What if something goes wrong?

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 study, please contact:

The Chief Investigator, Professor Doreen McClurg
Tele-0141 331 8105
email-Doreen.mcclurg@gcu.ac.uk