ELECtric Tibial nerve stimulation to Reduce Incontinence in Care homes: The ELECTRIC trial

PARTICIPANT INFORMATION LEAFLET

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. The 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.

1. Why are we doing this research?

Bladder problems, including urine leakage (incontinence), are common in older people who live in a care home. There are not many options to treat the causes and so most older people who have urinary incontinence wear absorbent pads to catch the leakage. Transcutaneous posterior tibial nerve stimulation, also called **TPTNS**, is a new type of treatment which has helped many men and women to reduce their urinary leakage and improve their bladder problems. However, this treatment has not been tested with older people who live in care homes. We want to investigate if TPTNS helps older people who live in care homes.

2. Why have I been chosen?

You are invited to take part in this research because you live in a care home and you have bladder problems which you wear pads for, but you also use the toilet.

3. 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.

4. What will happen to me if I take part?

Before starting the treatment, you will be asked to sign a consent form to say that you agree to take part.

Because this is a research trial, half of the people who agree to take part will receive the treatment and half will receive a dummy (sham) treatment allocated at random. If you agree to participate you will not know which treatment you receive until the research is finished.

We need to see how your bladder is working before you begin any treatment – this is called a 'baseline'. This will involve:

1. keeping a diary of how often you use the toilet for 3 days and nights – you can do this, or the care home staff will do it for you. For 24 hours during these 3 days we will collect all the pads you use in a water-tight bag. We will weigh the bag, which tells us how much urine you leaked.

2. a bladder scan. This is done at your care home. After you have used the toilet the scanner is placed at the bottom of your stomach for a few seconds. It looks like a little hairdryer and it does not hurt. We use this to see how well your bladder empties.

3. answering some questions about your bladder. The researcher will ask you some questions about your bladder and use of the toilet and your quality of life. This should only take a few minutes.

The TPTNS and sham treatment

One of your nurses or carers will make sure you are sitting or lying comfortably. They will place two small sticky pads near your ankle and attach a small machine. The machine looks like this:

Once this is switched on, you may feel a tingling sensation in your toes or ankle. The TPTNS does not hurt. Some people do not feel anything and this is quite normal. Each treatment lasts 30 minutes. You will receive this treatment twice a week, for 6 weeks.

After the TPTNS or sham treatment

After you have finished all 12 treatments, we need to repeat what happened at baseline to see if anything has changed. Weighing your pads is the best way to find out about any changes in your bladder leakage. It is the most important measurement we will make in this research.

- We will repeat the diary of how often you use the toilet for 3 days and nights
- We will do another scan of your bladder
- We will repeat the 24 hour pad weigh
- We will ask you questions about your bladder

We will do these on three occasions: as soon as your TPTNS or sham treatment finishes, 6 weeks after that and after another 6 weeks.

You will be asked about your quality of life when the TPTNS treatment finishes and 12 weeks after that, during the final pad weigh.

After the treatment has finished you may be asked if you are willing to talk to a researcher to tell them what you thought about your treatment. This would take about half an hour, depending on what you say.

We will also collect some information about you and your care from your medical and care home records.

5. 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.

6. 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.

7. 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 Aberdeen University and 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.

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.

8. What if something goes wrong?

Taking part does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other resident (which includes professional indemnity insurance for negligence). If you wish to complain about your health care or any aspects of this study, the normal care home mechanisms will be available to you.

If you have a concern about any aspect of the research, you should ask to speak with the research team who will do their best to answer your questions (telephone 0141 331 8012). If you remain unhappy and wish to complain formally, you can do this by contacting Glasgow Caledonian University's Research Office on 0141 331 8882 or y.glover@gcu.ac.uk

If you become unable or unwilling to continue with ELECTRIC, 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.

9. Who is organising and funding the research?

This research is funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA). It is sponsored by Glasgow Caledonian University and includes experienced healthcare researchers from 6 universities, the NHS and the independent care home sector.

10. Who has approved the research?

All research in the NHS and independent care homes is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given approval Scotland A Research Ethics Committee in Edinburgh.

Contact for further information:

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Funded by NHS National Institute for Health Research

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Funding acknowledgement: This research was funded by the NIHR HTA (15/130/73)
Department of Health disclaimer: The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health