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Electric tibial nerve stimulation to reduce incontinence in care homes

Submission date
17/04/2018

Recruitment status
No longer recruiting

Registration date
25/04/2018

Overall study status
Completed

Last Edited
23/11/2023

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Urinary incontinence is a distressing and embarrassing condition that occurs in around 70% of older people who live in nursing or residential care homes. It is common in those who have dementia, and it can have a major impact on an older person's dignity and quality of life. There is some evidence from small-scale studies that transcutaneous posterior tibial nerve stimulation (TPTNS) is a safe and acceptable way to help bladder problems. TPTNS involves placing two sticky pads (surface electrodes) on a person's ankle and connecting these to a small, pocket sized electrical stimulator. This sends an electric pulse to the nerve near the ankle which also controls the bladder and reduces the feeling of sudden urgency, giving more time to find a toilet. TPTNS also increases the volume of urine the bladder can hold, so it does not need to be emptied as often. Better quality evidence regarding the effectiveness of TPTNS on UI is needed before it is used for everyday treatment. The aims of this study are to find out whether a programme of TPTNS is an effective treatment for urinary incontinence in care home residents, and to assess the associated costs and consequences.

Who can participate?
People living in care homes who have urinary incontinence and wear absorbent pads

What does the study involve?
Participants are randomly allocated to receive either TPTNS or dummy treatment. Twelve treatments are given over a six-week period, each treatment lasting 30 minutes. The amount of urine leaked into pads over a 24-hour period is measured after the 6 weeks and again after 3 and 5 months, to see if leakage is reduced. Participants are also asked whether they feel their bladder leakage has changed and about any impact on their quality of life. The opinions of close family members and care home staff about the impact of TPTNS on the participants are also sought. The cost of providing this treatment is compared to the costs of providing continence care and pads, and the best ways to provide TPTNS treatment, long-term, are explored with care home staff.

What are the possible benefits and risks of participating?
The benefits to participation are reduced levels of urinary incontinence and the associated improvement to quality of life that this will bring to participants. Participation is considered to

be low risk with the only side effect reported of TPTNS being mild skin irritation at the site of the electrodes. Hypoallergenic electrodes will be available for those with sensitive skin.

Where is the study run from?
1. Lillyburn Care Home (UK)
2. Mosswood Care Home (UK)
3. Stanely Park Care Home (UK)
4. New Thursby Care Home (UK)
5. Priory Court Care Home (UK)
6. Other care homes to be identified in Scotland & Northern England (UK)

When is the study starting and how long is it expected to run for?
July 2017 to June 2020

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Catriona O'Dolan
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Study website
https://w3.abdn.ac.uk/hsru/ELECTRIC/Public/Public/index.cshtml

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03248362

Secondary identifying numbers
HTA 15/130/73

Study information

Scientific Title
ELECtric Tibial nerve stimulation to Reduce Incontinence in Care homes

Acronym
ELECTRIC

Study objectives
Is a programme of transcutaneous posterior tibial nerve stimulation (TPTNS) a clinically effective treatment for urinary incontinence (UI) in care home residents and what are the associated costs and consequences?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Scotland A Research Ethics Committee, 06/11/2017, ref: 17/SS/0117
2. Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 01/12/2017, ref: 17/YH/0328

Study design
The research comprises:
1. A pragmatic, multicentre, placebo-controlled randomised parallel-group trial to compare effectiveness of TPTNS (n=250) with sham stimulation (n=250) to reduce UI in CH residents. Results from an internal pilot with 100-140 residents will determine progression to full trial
2. A longitudinal, mixed methods nested process evaluation investigating intervention fidelity and acceptability and qualitative components of the intervention and implementation support
3. Economic evaluation of TPTNS compared with usual continence care pathway

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Urinary incontinence

Interventions
Transcutaneous posterior tibial nerve stimulation (TPTNS) is a form of peripheral neuromodulation. The tibial nerve, which lies immediately posterior to the medial malleolus is stimulated electrically using a portable TENS machine and two surface electrodes. The cathode electrode is positioned behind the medial malleolus and the anode 10cm cephalad to it. Standardised stimulation parameters are applied of 10 Hz frequency, 200μs-1 pulse width in continuous mode and stimulation intensity (mA-1) is adjusted on a session-by-session basis according to individual resident comfort levels.

Participants will be randomised to a treatment or sham (placebo) group. Randomisation will be computer allocated on a one to one basis in random permuted blocks of size two, four or six, with stratification by gender, severity of incontinence and centre.

Those in the treatment group will receive a 12 session programme (a total of 6 hours) of tibial nerve stimulation delivered in 30 minute sessions twice weekly over a 6 week period. Those in the sham group will receive 12 sessions of low intensity, sub-clinical stimulation of the lateral sub-malleolar area, positioned specifically on the lateral aspect to avoid the tibial nerve, which runs close to the skin surface behind the medial malleolus. The stimulation parameters are identical to the TPTNS treatment other than the intensity of the current which will be set at 4mA, rather than adjusted individually as it is in the TPTNS intervention group. The current will be initially increased until the resident reports feeling some sensation following which the current will be reduced down to 4mA. All residents will be informed that they may not feel anything with this intervention and that this is quite normal.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome measure
Volume of urinary incontinence leaked over a 24 hour period, measured by subtracting dry pad weight from wet pad weight, at 6 weeks post randomisation

Secondary outcome measures
Urinary outcomes:
1. Volume of urinary incontinence leaked over a 24 hour period, measured by subtracting dry pad weight from wet pad weight, at 12 and 18 weeks post randomisation
2. Number of pads used in 24 hours at 6, 12 and 18 weeks post randomisation
3. Patient Perception of Bladder Condition (PPBC questionnaire) at 6, 12 and 18 weeks post randomisation
4. Family Carer Perception of Bladder Condition (FC-PBC questionnaire) at 6, 12 and 18 weeks

post randomisation
5. Staff Perception of Bladder Condition (S-PBC questionnaire) at 6, 12 and 18 weeks post randomisation
6. Minnesota Toileting Skills Questionnaire (MTSQ questionnaire) at 6, 12 and 18 weeks post randomisation

Quality of life outcomes:
1. Resident DEMQOL questionnaire at 6 and 18 weeks post randomisation
2. Proxy DEMQOL questionnaire at 6 and 18 weeks post randomisation

Economic outcomes:
Resource Use Questionnaire (RUQ) at 6 and 18 weeks post randomisation

Qualitative outcomes:
1. The experiences of the TPTNS intervention from the perspectives of residents, family carers and care home staff
2. Factors affecting intervention implementation in the care home context and optimisation for sustainability

Overall study start date
01/07/2017

Completion date
30/06/2020

Eligibility

Key inclusion criteria
Care home residents:
1. With self or staff reported urinary incontinence of more than once/week
2. Who use the toilet or toilet aid for bladder evacuation with or without assistance
3. Who wear absorbent pads to contain urinary incontinence

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Care Home (CH) residents with an indwelling urinary catheter
2. CH residents with symptomatic UTI
3. CH residents with PVRU volume more than 300ml
4. CH residents with a cardiac pacemaker
5. CH residents with treated epilepsy

6. CH residents with bilateral leg ulcers
7. CH residents with pelvic cancer
8. CH residents on the palliative care register
9. Non-English speakers

Date of first enrolment
01/02/2018

Date of final enrolment
20/08/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Lillyburn Care Home
United Kingdom
G66 8BY

Study participating centre
Mosswood Care Home
United Kingdom
PA3 3FA

Study participating centre
Stanely Park Care Home
United Kingdom
PA2 6HJ

Study participating centre
New Thursby Care Home
United Kingdom
FY8 2RN

Study participating centre

Priory Court Care Home
United Kingdom
FY8 1AL

Study participating centre
Other care homes to be identified in Scotland & Northern England
United Kingdom
-

Sponsor information

Organisation
Glasgow Caledonian University

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Sponsor type
University/education

Website
www.gcu.ac.uk

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Protocol available at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/1513073/#/

The trialists will publish their research in high quality journals such as the Lancet, BMJ, Age Ageing and present them at national and international conferences. A minimum of three papers are planned focusing on i) the trial results; ii) the qualitative evaluation iii) implementation of TPTNS in care home practice. The trialists will also publish their findings in practice focused journals, care home organisation journals and newsletters to target all levels of staff. These will be delivered as soon as possible following the end of the trial in 2020.

Wider dissemination will also occur via the research team members who have long established links with a wide range of key stakeholders from the Independent Care Sector, the NHS and influential clinical groups such as the International Continence Society, Association for Continence Advice, INTERDEM, British Geriatrics Society and Chartered Society of Physiotherapists. The lead for the National Continence Care Audit Pilot Evaluation (2012), Dr Danielle Harari, is a member of the research team. She also sits on the All Party Parliamentary Group for Continence and is a member of the NHS England Excellence in Continence Care group which produced national guidance on continence services. Additionally the team has two expert members of the WHO sponsored International Consultation on Incontinence.

Where possible and appropriate, the trialists will involve members of our CH Reference Group and Stakeholder & Public Involvement Group in these dissemination activities e.g. workshops and training days, conference presentations etc. An important feature of TPTNS is its simplicity and the trialists will seek to capitalise on every opportunity to publicise the potential benefits widely if study findings show it to be effective, in addition to safe and easy to use. Within a 3 year period following the end of the trial we aim to benefit care home residents by providing:
1. Evidence to support or refute the use of TPTNS to treat urinary incontinence
2. Evidence of associated costs and consequences of TPTNS implementation in the care home context
3. Understanding of support required to implement and sustain use of TPTNS to treat urinary incontinence in care homes and an implementation framework for practice change
3. A TPTNS handbook and training programme with inbuilt competency assessment to ensure staff are knowledgeable and competent to deliver TPTNS
4. A TPTNS training DVD and short video film for social media

Intention to publish date
31/12/2020

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

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/12/2019	18/12/2019	Yes	No
Results article		01/06/2021	28/06/2021	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No
Results article	Cost consequence analysis	22/11/2023	23/11/2023	Yes	No