Tibial nerve stimulation compared with sham to reduce incontinence in care home residents: ELECTRIC RCT

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Declared competing interests of authors: Lorna Aucott is a member of the National Institute for Health Research (NIHR) Public Health Research (PHR) panel and is a NIHR COVID Recovery and Learning Call Funding Committee member. Joanne Booth reports grants from the NIHR Health Technology Assessment (HTA) programme during the conduct of the study (16/111/31 – ICONS II: Identifying Continence OptioNs after Stroke randomised controlled trial). Claire Goodman reports work as a senior investigator for NIHR outside the submitted work, and membership of the Health Services and Delivery Research (HSDR) Commissioned – Board (2009–15). Doreen McClurg was a member of the HTA End of Life Care and Add-on Studies Group (2015–16). John Norrie reports grants from the University of Aberdeen and the University of Edinburgh during the conduct of the study, and declares membership of the following NIHR boards: chairperson of the Medical Research Council (MRC)/NIHR Efficacy and Mechanisms Evaluation (EME) Funding Board (2019–present), the

Cardiopulmonary Resuscitation Decision-making Committee (2016), the Health Technology Assessment (HTA) Commissioning Board (2010–16), the HTA Commissioning Sub-Board (Expression of Interest) (2016–19), the HTA Funding Boards Policy Group (2016–19), the HTA General Board (2016–19), HTA Post-Board funding teleconference (2016–19), NIHR Clinical Trials Unit Standing Advisory Committee (2018–present), the NIHR HTA and EME Editorial Board (2014–19) and the Pre-exposure Prophylaxis Impact Review Panel (2017–present).

Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

Published June 2021
DOI: 10.3310/hta25410

Scientific summary

The ELECTRIC RCT

Health Technology Assessment 2021; Vol. 25: No. 41
DOI: 10.3310/hta25410

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Urinary incontinence is prevalent in older adults living in residential and nursing care homes, especially those living with dementia. It is a distressing condition, can affect social participation, and can have a negative impact on dignity and quality of life, as well as increasing the risk of falls, fractures, sleep disturbances, depression, hygiene problems and tissue viability problems. The most common type of urinary incontinence in care home populations is 'mixed urinary incontinence', combining symptoms of overactive bladder (urgency, frequency and nocturia, with or without urgency urinary incontinence) with stress urinary incontinence, and often accompanied by additional functional urinary incontinence due to physical and mental frailty.

Options to support the management of urinary incontinence include voiding programmes, bladder training and pelvic floor muscle exercises, but none is well suited to care home environments, as these options are labour intensive, and require co-operation and engagement from residents, which may not be suitable for those with cognitive impairment. With limited evidence for interventions to promote continence in a care home context, care homes rely on absorbent pads to contain urinary leakage but they do not attempt to treat the condition.

Evidence suggests that transcutaneous posterior tibial nerve stimulation can effectively reduce urgency or mixed urinary incontinence in women and adults with neurogenic bladder dysfunction. Transcutaneous posterior tibial nerve stimulation is a simple, non-invasive intervention using a portable electrical nerve stimulator to neuromodulate the posterior tibial nerve using surface electrodes placed adjacent to the medial malleolus. Evidence suggests that it can give people improved bladder control by reducing the sensation of urgency to void and by increasing bladder capacity, thus reducing voiding frequency by increasing the time between voids and the warning time to reach a toilet. There is no requirement for recipients to actively engage with transcutaneous posterior tibial nerve stimulation intervention; therefore, it is suitable for those with cognitive impairment and stimulation at the ankle upholds the person's dignity. The ELECTRIC (ELECtric Tibial nerve stimulation to Reduce Incontinence in Care homes) trial aimed to determine if transcutaneous posterior tibial nerve stimulation can effectively reduce urinary leakage in care home residents.

Objectives

The primary objective was to determine whether or not transcutaneous posterior tibial nerve stimulation was more effective than sham stimulation at reducing the volume of urinary incontinence in care home residents at 6 weeks.

Secondary objectives were to:

- determine whether or not transcutaneous posterior tibial nerve stimulation was more effective than sham stimulation at reducing the volume of urinary incontinence at 12 and 18 weeks
- investigate mediating factors that had an impact on the effectiveness of transcutaneous posterior tibial nerve stimulation
- conduct an economic evaluation of transcutaneous posterior tibial nerve stimulation in care homes, summarising resource use and outcome data in a cost–consequences analysis
- explore experiences of care home residents, family members, and care home staff and managers regarding transcutaneous posterior tibial nerve stimulation.

Methods

The ELECTRIC trial was a multicentre, pragmatic, participant and outcome assessor-blind, randomised placebo-controlled trial to compare the effectiveness of transcutaneous posterior tibial nerve stimulation with sham stimulation in reducing the volume of urinary incontinence in care home residents. A longitudinal, mixed-methods process evaluation was conducted to investigate residents', staff's and family members' experiences of transcutaneous posterior tibial nerve stimulation, and their perceptions of intervention fidelity and acceptability, alongside an economic evaluation of transcutaneous posterior tibial nerve stimulation compared with usual continence care pathways.

Participants

Participants were recruited from care homes in Scotland and England. Residents were eligible if they had urinary incontinence at least weekly, wore absorbent pads to contain leakage and used the toilet/toilet aid to empty their bladder, with or without assistance. Exclusions included those with an indwelling urinary catheter, a symptomatic urinary tract infection, post void residual urine volume of > 300 ml, a cardiac pacemaker, epilepsy that was being treated, bilateral leg ulcers, pelvic cancer, and those who were receiving palliative care or were non-English speakers.

Residents were identified by care home staff. Where residents lacked capacity, consent was sought from a named family member, or personal or nominated consultee according to the Adults with the Incapacity (Scotland) Act 2000 [Great Britain. *Adults with Incapacity (Scotland) Act 2000*. 2000. URL: www.legislation.gov.uk/asp/2000/4/contents (accessed 4 June 2020)] and the Mental Capacity Act 2005 (England) [Great Britain. *Mental Capacity Act 2005*. 2005. URL: www.legislation.gov.uk/ukpga/2005/9 (accessed 4 June 2020)].

Randomisation

Following baseline measurements, residents were randomised (1 : 1) to the transcutaneous posterior tibial nerve stimulation group or to the sham stimulation group, using an internet-based computerised randomisation system, minimising by sex, baseline urinary incontinence severity and centre.

Intervention

Care home staff were trained to deliver and record all stimulations. Both participant groups completed 6 weeks of electrical stimulation, comprising 12 30-minute sessions delivered twice per week. In the intervention group, surface electrodes were positioned over the tibial nerve posterior to the medial malleolus. Stimulation intensity was increased to the highest comfortable level for the participant (minimum 10 mA). An implementation support facilitator worked with staff delivering the intervention to support fidelity to the stimulation programme, monitoring at three time points during the 6-week intervention period using data automatically recorded by the electrical stimulator and staff-completed diaries.

Control

For those in the sham group, surface electrodes were positioned behind the lateral malleolus to avoid the tibial nerve. Stimulation intensity, initially increased to give the participant sensations of electrical stimulation, was delivered at a subtherapeutic level of 4 mA.

Outcomes

Outcomes were collected at baseline (week 0), 6 weeks, 12 weeks and 18 weeks. The primary outcome was the volume of urine leaked over 24 hours, as determined by the weight of absorbent pads used by participants at the 6-week time point. Secondary outcomes included:

- number of absorbent pads used in 24 hours
- post void residual urine volume
- participant, family and staff Perception of Bladder Condition

- toileting skills (Minnesota Toileting Skills Questionnaire)
- quality of life (Dementia Quality of Life and Dementia Quality of Life proxy at baseline, 6 and 18 weeks)
- resource use (baseline, 6 and 18 weeks).

Participants, family members and care home staff consented to individual and focus group interviews about their experiences of the trial and transcutaneous posterior tibial nerve stimulation.

Sample size

The recruitment target was calculated as 500 residents, based on a sample size of 344 needed to detect a clinically important difference of 200 ml per 24 hours with 90% power at the two-sided 5% alpha level, including an inflated attrition estimate of 30%, to account for loss due to death, and other types of loss to follow-up.

Following 1 full year of recruitment to the ELECTRIC trial, a data cut was performed by trials unit statisticians. This involved reviewing all data collected up to the 12-month participant recruitment time point for quality and completeness. The recruitment target was reviewed in the light of lower than expected attrition of 15% and revised to a target sample of 400.

Statistical analysis

Data were analysed in accordance with the statistical analysis plan and approved prior to final data collection.

Results

Thirty-seven care homes participated, from which 408 residents were randomised: 197 to the transcutaneous posterior tibial nerve stimulation group and 209 to the sham stimulation group. Two exclusions occurred post randomisation. The two groups were comparable at baseline for age, sex, degree of physical and cognitive frailty, and dependence. A total of 85% of participants in the transcutaneous posterior tibial nerve stimulation group and 76% of participants in the sham group were unable to use the toilet independently because of mobility problems. Over 40% of participants in both groups were unable to communicate their need to use the toilet. Most (57%) had severe urinary incontinence of $\geq$ 400 ml per 24 hours and wore absorbent pads to contain leakage on a continuous basis. Good adherence to the intervention protocol was achieved: 78% of participants in the transcutaneous posterior tibial nerve stimulation group and 71% of participants in the sham group received the correct stimulation, positioned correctly, for the correct duration, on a minimum of eight occasions.

Primary outcome data were available for 85% of participants ($n = 167$ to the transcutaneous posterior tibial nerve stimulation group, and $n = 178$ to the sham stimulation group) at 6 weeks. The primary intention-to-treat analysis indicated a statistically significant, but not clinically important, mean difference between the groups of 68-ml urine leakage (95% confidence interval 0 to 136 ml; $p = 0.05$) in favour of the sham group, adjusted for baseline leakage, sex and care home site. Sensitivity analyses to assess the effects of missing data and non-compliance on the treatment effect showed similar results, supporting the primary analysis results that transcutaneous posterior tibial nerve stimulation was not superior to sham stimulation in reducing urine leakage.

No significant differences in the primary outcome were found between the groups for any of the predefined subgroup analyses for sex, severity of urinary incontinence, physical dependency, dependency in toilet use, clinical frailty, use of anticholinergic medication for urinary incontinence, or falls status.

In contrast to the between-group statistical difference at the primary outcome point for the complete-case intention-to-treat analysis, the adjusted linear time comparison models showed no statistical difference at 6 weeks (mean difference 53 ml, 95% confidence interval −22 to 128 ml; $p = 0.164$),

12-week follow-up (mean difference 70 ml, 95% confidence interval, −9 to 148 ml; $p = 0.081$) or 18-week follow-up (mean difference 21 ml, 95% confidence interval −60 to 102 ml; $p = 0.605$). Post hoc analyses to investigate the effects of functional mobility, communication ability, assistance to use the toilet, urgency urinary incontinence and care home size showed no differential effects of transcutaneous posterior tibial nerve stimulation within these additional subgroups.

Secondary outcome analyses indicated no significant differences between the groups at any time point for absorbent pad use, Perception of Bladder Condition by residents or family members, resident-rated skills for using the toilet, post void residual urine volumes or quality of life (resident or proxy). There was statistically significant improvement in staff-reported Perception of Bladder Condition at 6 weeks in favour of the intervention group; however, the difference was small and unlikely to be clinically meaningful. Staff ratings of residents' toileting skills at 6 weeks and 18 weeks were statistically significantly better in the sham group; however, the minimal differences were not considered clinically important. There were no reported serious adverse events related to transcutaneous posterior tibial nerve stimulation and no safety concerns were identified.

The economic analysis assessed costs of delivering transcutaneous posterior tibial nerve stimulation and resources used by care homes delivering care pathways for urinary incontinence. Low-reported use of primary care health-care professionals and prescribed medications for urinary incontinence, for a small number of individuals, meant that statistical power to detect between-group differences was very low. Delivery of transcutaneous posterior tibial nerve stimulation comprised a training and support package (estimated at £121.03 per staff member) and delivery of the intervention (estimated at £81.20 per participant). No between-group differences were found for the use of products related to incontinence management [average cost of £1.19 (standard deviation £1.51) per participant in 24 hours]. A total of 85% of participants needed toilet assistance routinely, requiring one or two staff to assist them five times in each 24-hour period. Use of assistive devices was reported for most participants in addition to staff time. Across the treatment groups mobility aid (≈ 40%), transfer aid (≈ 25%) and toilet aid (≈ 20%) accounted for similar proportions of special equipment required on a daily basis. The value of staff time to assist residents to the toilet (average 5 minutes per resident per visit, in the trial context) was estimated as £19.17 (standard deviation £13.22) for the transcutaneous posterior tibial nerve stimulation group and £17.30 (standard deviation £13.33) for the sham group (per resident per 24 hours). Health state utility measured using Dementia Quality of Life and Dementia Quality of Life proxy did not demonstrate statistically significant differences in improvement in health-related quality of life from baseline to the 18-week follow-up by participants, or between trial groups. Data on resource use, and outcomes for care home residents and staff were summarised together in a cost–consequences analysis balance sheet.

Qualitative interviews found that transcutaneous posterior tibial nerve stimulation was acceptable to care home residents and staff, and that it was well tolerated. Staff benefited from the ELECTRIC trial education and welcomed opportunities to learn about managing urinary incontinence in older people, and not just with the transcutaneous posterior tibial nerve stimulation and research procedures. However, despite the positivity, changes to toileting practices in response to transcutaneous posterior tibial nerve stimulation were not reported, although moves to a more person-centred approach were described. Continence care was largely provided by care assistants who did not consider urinary incontinence amenable to change in this population. There was a lack of leadership in some care homes and there was role confusion about who should be responsible for continence care.

Conclusions

The ELECTRIC trial showed that, in the care home context, with a high proportion of older residents with poor cognitive capacity and limited independent mobility, transcutaneous posterior tibial nerve stimulation was not effective in reducing urinary incontinence. The evidence suggests that there

was no beneficial effect on any continence-related outcomes or resident quality of life, despite good adherence to the intervention protocol by care home staff. The number of adverse events was very small. Transcutaneous posterior tibial nerve stimulation was acceptable as an intervention for urinary incontinence in all residents, including those with dementia, but changes to toileting practices did not accompany its use. The cost–consequence analysis suggests that there may not be an economic case for transcutaneous posterior tibial nerve stimulation. However, the positive reception to learning about urinary incontinence from the care home staff supports a case for considering education about urinary incontinence as routine in this care context.

Implications for health care

Our results suggest that care home staff can be confident that the use of transcutaneous posterior tibial nerve stimulation in care homes with a high proportion of elderly, frail residents lacking cognitive capacity, will be unlikely to confer a reduction in urinary incontinence for their residents.

Evidence from the cost–consequences analysis of the ELECTRIC trial does not suggest an economic case for transcutaneous posterior tibial nerve stimulation. However, the positive reception of urinary incontinence learning for care home staff suggests that there may a case for considering education as part of routine continuing professional development packages.

Recommendations for research

Research to investigate transcutaneous posterior tibial nerve stimulation in care home residents with overactive bladder/urgency urinary incontinence and who also have the capability to independently use the toilet would be useful to determine whether or not targeted stimulation is effective in this population.

Investigation of other approaches to treating urinary incontinence in care home residents should be considered, based on clinical assessment of the type of urinary incontinence, to target interventions at those most likely to benefit.

Research to explore the effects of in-depth training for care home staff about urinary incontinence on practice changes and how incontinence is managed, as well as continence experiences and outcomes for residents, could add greater understanding to improving continence care in the context of care homes.

The ELECTRIC trial showed that care homes engage and participate well in large research trials. Care homes should be viewed and developed further as settings for health-care research, especially as the care home context differs between NHS settings and confers unique features, which enable a more comprehensive consideration of research conduct and findings of relevance to frail older people.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN98415244 and ClinicalTrials.gov NCT03248362.

Funding

This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 25, No. 41. See the NIHR Journals Library for further project information.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.370

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 15/130/73. The contractual start date was in July 2017. The draft report began editorial review in July 2020 and was accepted for publication in January 2021. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

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