

# A pilot trial of transcutaneous posterior tibial nerve stimulation for bladder and bowel dysfunction in older adults in residential care

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## Background

Bladder and bowel dysfunction are prevalent among older people in institutional care<sup>1</sup>. Current continence management relies on containment using absorbent pads<sup>2</sup>, which are undignified, expensive and do not treat the bladder or bowel dysfunction. Given the risk of adverse effects associated with increasing age<sup>3</sup> older people may benefit from non-pharmacological, non-invasive interventions. Transcutaneous posterior tibial nerve stimulation (TPTNS) is a technique of non-invasive peripheral electrical neuromodulation delivered using surface electrodes. It is a novel use of transcutaneous electrical stimulation for the treatment of lower urinary tract symptoms (LUTS), urinary incontinence (UI) and faecal incontinence (FI)<sup>3</sup> however no trials have included frail older people. The potential for TPTNS as first line treatment for bladder and/or bowel dysfunction in later life and an alternative to anticholinergic medication has yet to be established.

## Study aim

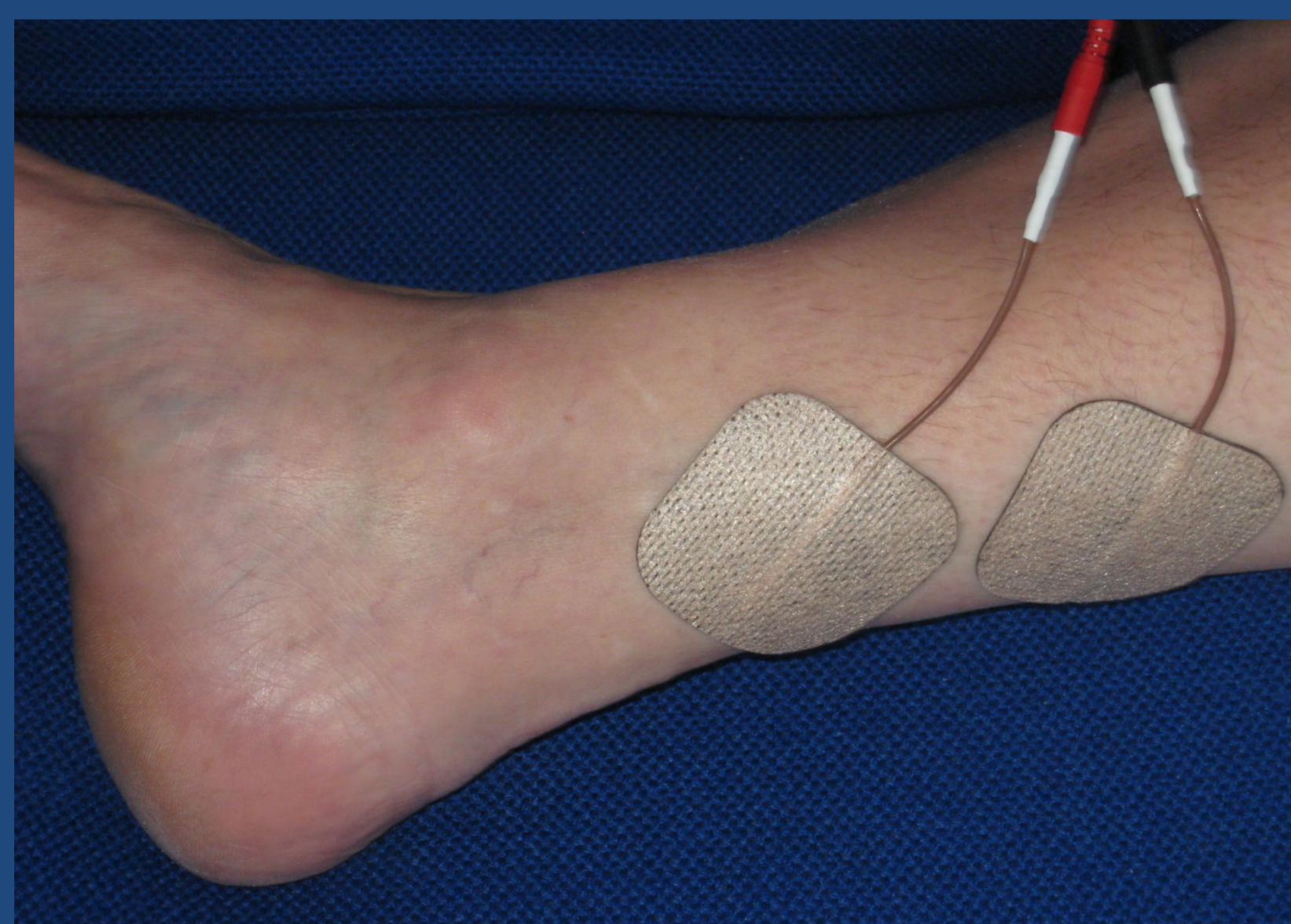
This pilot study aimed to assess the feasibility of a full-scale randomised trial of effectiveness of transcutaneous posterior tibial nerve stimulation (TPTNS) on bladder and bowel dysfunction in frail older adults in residential care.

## Design and methods

A six week pilot parallel group randomised controlled trial of TPTNS versus sham therapy was undertaken. Thirty older adults with self-reported bladder and/or bowel dysfunction were randomised, via remote computer-generated allocation, to twelve sessions of TPTNS (2 per week for 6 weeks) or sham therapy. University ethics approval was obtained.

## Intervention

TPTNS comprised 30 minute stimulation sessions delivered via two surface electrodes; negative electrode placed behind the medial malleolus, positive electrode 10cm proximal. Correct positioning was determined by noting a halux reaction. The stimulation protocol was delivered at a fixed frequency of 10 Hz, pulse width 200ms in continuous mode. Stimulation intensity determined by participant comfort level (range 10-50mA)<sup>4</sup>. Sham stimulation involved the same procedure with electrodes placed on lateral malleolus and stimulation current reduced to 2mA.



Bladder and bowel symptoms were self-reported prior to treatment and on completion of the 6 week treatment programme using the International Prostate Symptom Score (IPSS), International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-SF) and Bowel Short Form (early version of the ICIQ-Bowel). Treatment acceptability was assessed at each treatment session by directly questioning residents and care staff. Protocol fidelity was recorded. Changes in bladder and bowel symptoms (overall scores and individual symptoms) were compared between the groups.

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3. DuBeau C, Kuchel G, Johnson T, Palmer M, Wagg A Incontinence in the Frail Elderly: Report From the 4th International Consultation on Incontinence NeuroUrol.Uroynam. 29:165–178, 2010  
4. Amarenco G, Sheikh Ismael S, Even-Schneider A et al Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder *The Journal of Urology* 2003; 169: 2210-2215.

## Results

The mean age was 84.2 years (SD 10.0), 24 (80%) were female, 27 (90%) lived in residential care homes, 3 (10%) lived in sheltered accommodation. UI was the predominant dysfunction in 15 (50%), FI in 2 (7%), combined in 13 (43%). Occasional constipation was reported by 15 (50%) and constipation most or all of the time by 6 (20%). The TPTNS and sham stimulation groups were comparable at baseline with respect to age, sex and predominant bladder/bowel dysfunction.

Total IPSS score reduced in the TPTNS group by a median of 7 (IQR -8 to -3) and increased by a median of 1 (IQR -1 to 4) in the sham group, representing a significant difference between the groups (Mann-Whitney U 16.5000, Z -3.742, p < 0.001). Total ICIQ-SF scores improved by a median of 2 (IQR -6 to 0) in the TPTNS group and 0 points (IQR -3 to 3) in the sham group, representing a non-significant difference between the groups (Mann-Whitney U 65.0000, Z = -1.508, p = 0.132). Change in residual urine volumes showed a difference in the mean reduction between the groups of 55.2ml (95% CI 0.5, 110) which was significant (t = -2.215, df 11.338, p = 0.048) and indicated a greater decrease in residual urine in the TPTNS group (mean reduction 60ml, SD 80, 95%CI 6, 114) compared with the sham group (mean reduction 4.8ml, SD 23, 95% CI -9, 18).

There was a trend towards reported improvements in individual bladder and bowel symptoms in the TPTNS group (see table); differences between groups were significant for incomplete bladder emptying (X<sup>2</sup> = 8.086, df = 2, p = 0.018) and weak urinary stream (X<sup>2</sup> = 8.299, df = 2, p = 0.016). Reports of improved bowel urgency were more common in the TPTNS group compared to the sham group (27% vs 8%) however the difference was not statistically significant (X<sup>2</sup> = 2.395, df = 2, p > 0.302). Similarly 47% of the TPTNS group reported reduced faecal leakage compared with 23% of the sham group but the difference were not statistically significant (X<sup>2</sup> = 4.480, df = 2, p > 0.106). The exception to this trend was constipation which got worse in the treatment group.

TPTNS was reported to be an acceptable intervention by care home residents and care staff. No adverse effects were identified. Fidelity to the protocol was high: 28 of the 30 participants completed the full 12 session course. Two discontinued due to unrelated infection.

Type of dysfunction	Percentage of older people reporting changes in dysfunction symptoms					
	Better (%)		Same (%)		Worse (%)	
	TPTNS (n=15)	Sham (n=13)	TPTNS (n=15)	Sham (n=13)	TPTNS (n=15)	Sham (n=13)
**Incomplete bladder emptying *	8 (53%)	1 (8%)	6 (40%)	7 (54%)	1 (7%)	5 (39%)
**Frequency	11 (74%)	5 (42%)	3 (20%)	5 (42%)	1 (7%)	2 (17%)
**Urgency	11 (74%)	4 (31%)	3 (20%)	5 (39%)	1 (7%)	4 (31%)
**Nocturia	7 (47%)	3 (23%)	7 (47%)	8 (62%)	1 (7%)	2 (15%)
**Weak urinary stream *	9 (60%)	1 (8%)	4 (27%)	8 (62%)	2 (13%)	4 (31%)
**Intermittency	5 (33%)	2 (15%)	8 (53%)	6 (46%)	2 (13%)	5 (39%)
**Straining	6 (40%)	1 (8%)	6 (40%)	8 (62%)	3 (20%)	4 (31%)
***Constipation	2 (13%)	7 (54%)	9 (60%)	4 (31%)	4 (27%)	2 (15%)
***Bowel urgency	4 (27%)	1 (8%)	9 (60%)	8 (62%)	2 (13%)	4 (31%)
***Faecal leakage	7 (47%)	3 (23%)	6 (40%)	10 (77%)	2 (13%)	0 (0)

## Interpretation of results

In this group of older care home residents TPTNS was an acceptable intervention for bladder and/or bowel dysfunction. The study provides preliminary evidence of effect in reducing bladder symptoms of incomplete emptying and weak stream. Trends towards positive impact on other bladder and bowel symptoms including frequency, urgency and nocturia were found.

## Concluding message

TPTNS is safe and acceptable with evidence of potential clinical effect for both bladder and bowel dysfunction in older care home residents. The data support the feasibility of a substantive trial of TPTNS in this population.