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

Joanne Booth, PhD RN
Reader, Institute for Applied Health Research
Glasgow Caledonian University
Project team

Prof Suzanne Hagen - GCU
Dr Doreen McClurg - GCU
Prof Christine Norton – Imperial College Healthcare NHS Trust
Prof Cam Donaldson - GCU
Ms Brigitte Collins – St Marks Hospital
Ms Carolyn MacInnes - NHS Greater Glasgow & Clyde
Continence in care homes

• Bladder and bowel dysfunction are prevalent among older people in institutional care
  ➢ LUTS affect >50%
  ➢ UI 30-60%
  ➢ FI >35%

• Distressing for older person and their families, associated with stigma, depression and depersonalised care – for men and women

• Current management relies on containment using pads and catheters, not treatment.

• Limited continence promoting options – prompted voiding, bladder training, caffeine reduction, fluid adjustments etc which are variable in effect and labour intensive
Key considerations for care homes

- Older people at increased risk of adverse events including:
  - adverse reactions to medicines
  - HCAI
  - falls
  - emergency admission to hospital

- Dignity and safeguarding
- Prevalence of dementia
- Costs and suppliers of continence products

Good potential to benefit from non-pharmacological, non-invasive continence related interventions.
Transcutaneous posterior tibial nerve stimulation (TPTNS)

TPTNS is a technique of non-invasive peripheral electrical neuromodulation delivered using surface electrodes.

Neuromodulation refers to any medical intervention which acts on nerves to alter the neurotransmission processes of other nerves.

TPTNS modulates the sacral nerve plexus indirectly via the posterior tibial nerve, a branch of the sciatic nerve, that originates from the same spinal segments as the nerves to the bladder and pelvic floor.

Exact mechanism of action has yet to be understood.

Used to treat overactive bladder, urinary incontinence and faecal incontinence.

Different administration route to percutaneous posterior tibial nerve stimulation (PTNS)
Percutaneous posterior tibial nerve stimulation

- Effective therapy for OAB and lower urinary tract dysfunction

- Recommended by NICE for OAB treatment, as effective in short and medium term (Oct 2010)

- No safety concerns

- Second line treatment – after conservative approaches

- Cost implications – equipment, secondary care specialists, delivery time implications
Evidence base for posterior tibial nerve stimulation

Percutaneous route:

16 studies PTNS for LUTS – 13 prospective case series, 3 RCT (n= 35, n=100, n= 225)

All studies showed significant benefit of stimulation over control – approx 50% participants respond.

60-80% success rate for refractory OAB.

Transcutaneous route:

7 prospective case series, 3 small RCTs – (n = 37, n=51, n=28) two with women with OAB, one in older women with UUI

All studies showed significant benefit of stimulation over control

48% – 68% reported cure or improvement

No studies undertaken in older adults in long-term care.

No comparison of percutaneous and transcutaneous
Research Aim

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.

Research questions:

What are the effects of a programme of TPTNS on urinary and faecal incontinence, lower urinary tract symptoms and bowel symptoms in frail older adults in residential care?

Is TPTNS a feasible first line treatment option for bladder and bowel dysfunction in older care home residents?
Method

A six week feasibility randomised, parallel group controlled trial of TPTNS versus sham stimulation.

Thirty older adults with bladder and/or bowel dysfunction were randomised to TPTNS or sham treatments.

Measures of bladder and bowel symptoms were completed at baseline and 6 weeks, after the final TPTNS session.
TPTNS intervention

- 12 stimulation sessions delivered via two surface electrodes:
  - negative electrode placed behind the medial malleolus
  - positive electrode 10cm proximal.
- Correct positioning determined by halux reaction.
- Stimulation protocol was fixed frequency of 10 Hz, pulse width 200ms in continuous mode for 30 minutes.
- Stimulation intensity determined by participant comfort level (range 10-50mA).
- Sham stimulation involved the same procedure with electrodes on lateral malleolus and stimulation current reduced to 2mA.
Outcomes

Lower urinary tract symptoms – International Prostate Symptom Score (IPSS), AUASI.

Episodes UI, severity UI – International Consultation on Incontinence Questionnaire Urinary Incontinence- short form (ICIQ – UI-SF)

Bowel urgency, leakage & constipation - ICIQ-Bowel questions

Residual urine - portable bladder scanner
Results

- 30 older adults – 15 TPTNS, 15 sham stimulation
- Mean age 84.2 years (SD 10.0)
- 80% (n=24 female)
- 90% (n=27) were resident in seven care homes (n=27), 10% lived in three different sheltered accommodation residences (n=3).

- Urinary incontinence was the predominant dysfunction in 50% (n=15)
- Faecal incontinence predominant dysfunction in 7% (n=2)
- Both bladder and bowel dysfunction were reported in 43% (n=13).
- Occasional constipation was reported by 50% (n=15) and 20% (n=6) reported constipation most or all of the time.

Groups were comparable with respect to age, sex and predominant bladder/bowel dysfunction at baseline.
LUTS

- Reduced in the TPTNS group by a median of 7 points (IQR -3 to -8)

- Increased in the sham stimulation group by a median of 1 point (IQR -1 to 3)

- Statistically significant difference between the groups (Mann-Whitney U=16.500, z= -3.742, p< 0.001).
Urinary incontinence

- Reduced by a median of 2 points (IQR 0 to -6) in the TPTNS group.

- Change of 0 points (IQR -3 to 3) in the sham group.

- Trend not statistically significant (Mann Whitney U=65,000, 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).

This was significant ($t = -2.215$, df 11.338,$p = 0.048$)

Indicated a greater decrease in residual urine in the TPTNS group (mean decrease 60ml) compared with the sham group (mean decrease 4.8ml)
# Reported symptoms changes

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

The study provides initial evidence of effect in reducing bladder symptoms overall and specifically incomplete emptying and weak stream.

Trends suggesting positive impact on other bladder symptoms including frequency, urgency and nocturia.

Trends suggesting positive impact on urinary incontinence and bowel dysfunction.

TPTNS was an acceptable intervention to care home residents and care staff.

No adverse effects were identified, TPTNS was a safe intervention.
Conclusion

TPTNS is safe and acceptable with evidence of potential clinical effect for both bladder and bowel dysfunction in frail older adults resident in care homes.

The data support the feasibility of a substantive trial of TPTNS as first line intervention in this population.
References


Schreiner L, Santos T, Knorst M. Randomised trial of transcutaneous tibial nerve stimulation to treat urge urinary incontinence in older women International Urogynecology Journal 2010; 21: 1065-1070