# Percutaneous PTNS vs NAT for OAB

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<tr>
<th>Study details</th>
<th>Participants</th>
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<tr>
<td><strong>Full citation</strong></td>
<td>N = 35</td>
<td>Intervention = 12, 30-minute PTNS sessions, performed 3 times a week. Placebo = 12, 30-minute sham stimulation sessions, performed 3 times a week.</td>
<td>PTNS = 18, Placebo = 17</td>
<td><strong>Results</strong></td>
<td><strong>Limitations</strong></td>
</tr>
<tr>
<td>Finazzi-Agro, E., Petta, F., Sciobica, F., Pasqualetti, P., Musco, S., Bove, P., Percutaneous tibial nerve stimulation effects on detrusor overactivity incontinence are not due to a placebo effect: a randomized, double-blind, placebo controlled trial, Journal of Urology, 184, 2001-2006, 2010</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td><strong>Patient satisfaction with treatment</strong></td>
<td>NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials</td>
</tr>
<tr>
<td><strong>Sample size</strong></td>
<td>Interventions</td>
<td>Details</td>
<td>PTNS = 18</td>
<td><strong>Self reported rate of absolute symptom reduction per day at end point</strong></td>
<td></td>
</tr>
<tr>
<td>Ref Id</td>
<td>N = 35</td>
<td>Details</td>
<td>Placebo = 17</td>
<td>PTNS = 1.8 (1.2 – 2.2) (17) Placebo = 3.8 (3.0 – 4.5) (15)</td>
<td></td>
</tr>
<tr>
<td>Country/ies where the study was carried out</td>
<td>Interventions</td>
<td>Placebo = 17</td>
<td>PTNS = 12/17 (71%) Placebo = 0/15 (0%)</td>
<td><strong>Incontinence-specific quality of life at end point</strong></td>
<td></td>
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<tr>
<td>Italy</td>
<td>Details</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 100%</td>
<td>Scale used - Incontinence Quality of Life questionnaire (I-QOL) - Mean (range) (N)</td>
<td></td>
</tr>
<tr>
<td>Study type</td>
<td>Methods</td>
<td>PTNS = 18</td>
<td>PTNS = 100%</td>
<td>PTNS = 81.3 (73.4 – 89.2) (17) Placebo = 70.6 (62.2 – 79.1) (15)</td>
<td></td>
</tr>
<tr>
<td>Randomised controlled trial</td>
<td><strong>Methods</strong></td>
<td>Details</td>
<td>Placebo = 17</td>
<td><strong>Adverse effects of treatment</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Characteristics</strong></td>
<td>Details</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td><strong>No serious side effects were reported in either group but patients in both groups reported occasional transient</strong></td>
</tr>
<tr>
<td>Gender - Female/N (% female) PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td><strong>Level of bias: low</strong></td>
</tr>
<tr>
<td>Age (years) - Mean [SD not reported] PTNS = 44.9 years Placebo = 45.5 years</td>
<td>PTNS = 44.9 years Placebo = 45.5 years</td>
<td>PTNS = 44.9 years Placebo = 45.5 years</td>
<td>PTNS = 44.9 years Placebo = 45.5 years</td>
<td>PTNS = 44.9 years Placebo = 45.5 years</td>
<td><strong>Performance bias</strong></td>
</tr>
<tr>
<td>Incontinence episodes/3 days - Mean ± SD (N) PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td>PTNS = 4.1 ± 1.8 (18) Placebo = 4.2 ± 2.1 (17)</td>
<td><strong>Level of bias: unclear</strong></td>
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<tr>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td><strong>Attrition bias</strong></td>
</tr>
<tr>
<td>Duration of OAB - Mean ± SD</td>
<td>Interventions</td>
<td>Details</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
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<tr>
<td>Not reported</td>
<td>Interventions</td>
<td>Details</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
</tr>
<tr>
<td>Episodes of frequency/day - Mean ± SD</td>
<td>Interventions</td>
<td>Details</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
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<td>Interventions</td>
<td>Details</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
<td>PTNS = 18/18 (100%) Placebo = 17/17 (100%)</td>
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<tr>
<td>&quot;No serious side effects were reported in either group but patients in both groups reported occasional transient&quot;</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Limitations**
- NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials
- Selection bias
  - A1: appropriate randomisation - yes, "computer generated randomisation list"
  - A2: adequate concealment - unclear
  - A3: groups comparable at baseline - yes
- Performance bias
  - B1: same level of care for both groups - yes
  - B2: participants blinded - yes
  - B3: clinical staff blinded - unclear
- Attrition bias
  - C1: follow up equal for both groups - yes
  - C2: groups comparable for dropout - yes, 1/18 in PTNS and 2/17 in placebo discontinued treatment due to personal reasons
  - C3: groups comparable for missing data - yes
- Level of bias: low.
<table>
<thead>
<tr>
<th>Study details</th>
<th>Participants</th>
<th>Interventions</th>
<th>Methods</th>
<th>Outcomes and Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim of the study</strong></td>
<td>PTNS = 13.6 ± 4.0 (18) Placebo = 15.0 ± 5.7 (17) Incontinence-specific quality of life Scale used - Incontinence Quality of Life questionnaire (I-QOL) - Mean (range) PTNS = 69.6 (65.8 – 73.3) Placebo = 69.5 (65.5 – 73.5)</td>
<td>of the gastrocnemius muscle. Stimulator was briefly activated for approximately 30 seconds so the patient felt a minor electrical sensation in the skin and turned off for the rest of the treatment.</td>
<td>pain at the stimulation site* Psychological outcomes Not reported Clinical measures Not reported</td>
<td><strong>Continence status</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Study dates</strong></td>
<td>February 2007 – February 2009</td>
<td></td>
<td><strong>Power calculation</strong></td>
<td><strong>Events</strong></td>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>Source of funding</strong></td>
<td>&quot;Supported by a grant from Uroplasty, Inc&quot;.</td>
<td>With a sample size of 15 in each group this study had a power of 82.3% to yield a statistically significant result assuming that the difference in proportions was 0.45. This magnitude is reasonable according to previous published findings. A 10% dropout rate was accounted for.</td>
<td></td>
<td>Experimental</td>
<td>12</td>
</tr>
<tr>
<td><strong>Inclusion criteria</strong></td>
<td></td>
<td></td>
<td></td>
<td>Control</td>
<td>0</td>
</tr>
<tr>
<td>1] Female 2] Urge incontinence and urodynamically diagnosed detrusor overactivity incontinence 3] Unresponsive to behavioural and rehabilitation therapy or antimuscarinics 4] Able to give written, informed consent 5] 18 years or older 6] Mentally competent and able to understand all study requirements 7] Able to understand the procedures, advantages and possible side effects 8] Willing and able to complete a 3-day voiding diary and I-QoL questionnaire</td>
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<tr>
<td><strong>Intention to treat analysis</strong></td>
<td></td>
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<td></td>
<td><strong>Events</strong></td>
<td><strong>Total</strong></td>
</tr>
<tr>
<td></td>
<td>Not reported</td>
<td></td>
<td></td>
<td>Experimental</td>
<td>0</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Control</td>
<td>0</td>
</tr>
</tbody>
</table>

**D1**: follow up appropriate length - unclear, “after 12 treatments”, exact timing of outcome assessment not reported  
**D2**: outcomes defined precisely - yes  
**D3**: valid and reliable methods used to assess outcome - yes  
**D4**: investigators blind to intervention - yes "results were collected by 2 physicians and analysed by a third physician and a statistician, both of whom were blinded regarding the procedure used in any single patient”  
**D5**: investigators blinded to confounding factors - unclear  
**Level of bias**: unclear  
**Indirectness** Does the study match the review protocol in terms of: 
Population: Yes, All participants in the study had detrusor overactivity.  
Intervention: Yes  
Outcome: No. The main end point (reported here as continence status) was the number of responders. Response was defined as a 50% or greater reduction in incontinence episodes.  
Indirectness: Some  
**Other information**
<table>
<thead>
<tr>
<th>Study details</th>
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<th>Methods</th>
<th>Outcomes and Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>9] Bladder capacity 100ml or greater</td>
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<td>Participants in both groups were told that they may not have any perception of the electrical sensation due to adaptation. 1/18 in PTNS and 2/17 in placebo discontinued treatment due to personal reasons. 32/35 (91%) were assessed at end of study: PTNS = 17/18, placebo = 15/17. &quot;To verify patient blindness with respect to assigned treatment we observed that patient concordance between type of administered treatment and type of believed treatment was low (60%). This concordance was not significantly different from chance (K = 0.18, (P = 0.305)) suggesting a low ability to recognise the received treatment.&quot;</td>
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<tr>
<td>10] No signs of neurologic abnormalities at objective examination; no history of neurologic pathology</td>
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<td>11] No pharmacological treatment or pharmacological treatment unchanged for 30 days before beginning the study</td>
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<tr>
<td>Exclusion criteria</td>
<td></td>
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<tr>
<td>1] Pregnancy or intention to become pregnant during the study</td>
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<tr>
<td>2] Active urinary tract infection or recurrent urinary tract infections (more than 4 per year)</td>
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<td>3] Presence of urinary fistula, bladder or kidney stones, interstitial cystitis, cytoscopic abnormalities that could be malignant</td>
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<td>4] Diabetes mellitus</td>
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<td>5] Cardiac pacemaker or implanted defibrillator</td>
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</tbody>
</table>

**Full citation**
Peters, K.M., Carrico, D.J., Perez-Marrero, R.A., Sample size

N = 220
PTNS = 110

**Interventions**

**Details**

Intervention = 12 weekly 30-

PTNS

A 34 gauge needle

**Results**

Patient satisfaction with treatment at week 13

**Limitations**

NICE guidelines manual, Appendix D: Methodology checklist:
Study details | Participants | Interventions | Methods | Outcomes and Results | Comments |
--- | --- | --- | --- | --- | --- |
Khan, A.U., Wooldridge, L.S., Davis, G.L., Macdiarmid, S.A., Randomized trial of percutaneous tibial nerve stimulation versus sham intervention in the treatment of overactive bladder syndrome: results from the SUmiT trial, Journal of Urology, 183, 1438-1443, 2010 | Placebo = 110 | minute PTNS sessions | electrode was inserted at a 60 degree angle approximately 5cm cephalad to the medial malleolus and slightly posterior to the tibia. PTNS surface electrode was placed on the ipsilateral calcaneus as well as 2 inactive sham surface electrodes, 1 under the little toe and 1 on the top of the foot. The PTNS lead set was connected to the Urgent PC stimulator and a current level of 0.5 to 9mA at 20Hz was selected based on each subject's foot and plantar motor and sensory responses. | Scale used – 7-level global response assessment (GRA). “Responder was defined as moderately or markedly improved” PTNS = 60/110 (54.5%) Placebo = 23/110 (20.9%) Self reported rate of absolute symptom reduction at week 13 | Randomised controlled trials Selection bias A1: appropriate randomisation - yes "random block design stratified by investigational site" A2: adequate concealment - unclear A3: groups comparable at baseline - yes Level of bias: low Performance bias B1: same level of care for both groups - yes B2: participants blinded - yes B2: clinical staff blinded - unclear Level of bias: unclear Attrition bias C1: follow up equal for both groups - yes C2: groups comparable for dropout - unclear, 4/110 in PTNS and 1/110 in placebo "withdrew consent" prior to week 13 C3: groups comparable for missing data - unclear, 3/110 in PTNS and 4/110 in placebo did not contribute data to analysis due to "lost to follow-up" or "other". Level of bias: unclear Detection bias D1: follow up appropriate length - unclear, outcome measurement was performed at week 13 after 12 weeks of treatment D2: outcomes defined precisely - yes D3: valid and reliable methods used to assess outcome - yes D4: investigators blind to intervention - yes "study | Placebo = 12 weekly 30-minute sham sessions | Placebo = 60.2 (SD not reported) Incontinence episodes/day - Mean ± SD | PTNS = 62.5 (SD not reported) Placebo = 9.8 ± 10.4 (105) | PTNS = 4.6 ± 3.6 (103) Placebo = 6.1 ± 4.2 (105) | Performance bias B1: same level of care for both groups - yes B2: participants blinded - yes B2: clinical staff blinded - unclear Level of bias: unclear Attrition bias C1: follow up equal for both groups - yes C2: groups comparable for dropout - unclear, 4/110 in PTNS and 1/110 in placebo "withdrew consent" prior to week 13 C3: groups comparable for missing data - unclear, 3/110 in PTNS and 4/110 in placebo did not contribute data to analysis due to "lost to follow-up" or "other". Level of bias: unclear Detection bias D1: follow up appropriate length - unclear, outcome measurement was performed at week 13 after 12 weeks of treatment D2: outcomes defined precisely - yes D3: valid and reliable methods used to assess outcome - yes D4: investigators blind to intervention - yes "study | Placebo | Placebo = 86/110 (78.2%) PTNS = 88/110 (80.0%) | PTNS = 3.4 ± 3.5 (110) Placebo = 3.1 ± 3.5 | Placebo = 20.6 ± 20.6 (105) [higher score is better] | Performance bias B1: same level of care for both groups - yes B2: participants blinded - yes B2: clinical staff blinded - unclear Level of bias: unclear Attrition bias C1: follow up equal for both groups - yes C2: groups comparable for dropout - unclear, 4/110 in PTNS and 1/110 in placebo "withdrew consent" prior to week 13 C3: groups comparable for missing data - unclear, 3/110 in PTNS and 4/110 in placebo did not contribute data to analysis due to "lost to follow-up" or "other". Level of bias: unclear Detection bias D1: follow up appropriate length - unclear, outcome measurement was performed at week 13 after 12 weeks of treatment D2: outcomes defined precisely - yes D3: valid and reliable methods used to assess outcome - yes D4: investigators blind to intervention - yes "study | Placebo | Placebo = 86/110 (78.2%) PTNS = 88/110 (80.0%) | PTNS = 3.4 ± 3.5 (110) Placebo = 3.1 ± 3.5 | Placebo = 20.6 ± 20.6 (105) [higher score is better] | Performance bias B1: same level of care for both groups - yes B2: participants blinded - yes B2: clinical staff blinded - unclear Level of bias: unclear Attrition bias C1: follow up equal for both groups - yes C2: groups comparable for dropout - unclear, 4/110 in PTNS and 1/110 in placebo "withdrew consent" prior to week 13 C3: groups comparable for missing data - unclear, 3/110 in PTNS and 4/110 in placebo did not contribute data to analysis due to "lost to follow-up" or "other". Level of bias: unclear Detection bias D1: follow up appropriate length - unclear, outcome measurement was performed at week 13 after 12 weeks of treatment D2: outcomes defined precisely - yes D3: valid and reliable methods used to assess outcome - yes D4: investigators blind to intervention - yes "study | Study type | Randomised controlled trial | | | | Study dates | Placebo D4: investigators blind to intervention - yes "study

### Study Details

**Participants**

- Placebo: 110
- Characteristics:
  - Gender: Female/N (% female)
  - PTNS: 86/110 (78.2%)
  - Placebo: 88/110 (80.0%)
  - Age (years): Mean ± SD
  - PTNS: 62.5 (SD not reported)
  - Placebo: 60.2 (SD not reported)
  - Incontinence episodes/day: Mean ± SD
  - Placebo = 9.8 ± 10.4
  - Self reported rate of absolute symptoms
  - *Episodes of incontinence (defined as an accident associated with moderate or severe urgency):*
    - Placebo = 23/110 (20.9%)
    - PTNS = 60/110 (54.5%)
    - PTNS = 10.2 ± 11.5
    - Placebo = 62.5 (SD not reported)
  - Severity Score
  - Placebo = −29.2 ± 20.0 (102)
  - PTNS = 4.6 ± 3.6 (103)
  - Placebo = 1.9 ± 2.6 (105)
  - PTNS = 1.4 ± 2.4 (103)
  - Placebo = 20.6 ± 20.6 (105) [higher score is better]
  - PTNS = 20.6 ± 20.6 (105) [lower score is better]
  - Placebo = 60.2 (SD not reported)

**Interventions**

- Placebo = 12 weekly 30-minute sham sessions
- PTNS sessions: 60 degree angle approximately 5cm cephalad to the medial malleolus and slightly posterior to the tibia. PTNS surface electrode was placed on the ipsilateral calcaneus as well as 2 inactive sham surface electrodes, 1 under the little toe and 1 on the top of the foot. The PTNS lead set was connected to the Urgent PC stimulator and a current level of 0.5 to 9mA at 20Hz was selected based on each subject's foot and plantar motor and sensory responses.

**Methods**

- Placebo: A Streitberger placebo needle was used to stimulate the location and sensation of PTNS needle electrode insertion. An inactive PTNS surface electrode was placed on the ipsilateral calcaneus.
  - Two active TENS surface electrodes were placed, 1 under the little toe and 1 on top of the foot. Sham stimulation parameters were determined based on subject first sensory level of localised stimulation through a TENS unit.
- PTNS: Electrode was inserted at

**Outcomes and Results**

- Scale used – 7-level global response assessment (GRA). "Responder was defined as moderately or markedly improved"
  - PTNS = 60/110 (54.5%)
  - Placebo = 23/110 (20.9%)
- Self reported rate of absolute symptom reduction at week 13
  - *Episodes of incontinence (defined as an accident associated with moderate or severe urgency):*
    - Placebo = 23/110 (20.9%)
    - PTNS = 60/110 (54.5%)
    - PTNS = 10.2 ± 11.5
    - Placebo = 62.5 ± 11.5
    - *Episodes of urgency (defined as voids with moderate/severe urgency):*
      - Placebo = 23/110 (20.9%)
      - PTNS = 60/110 (54.5%)
      - PTNS = 10.2 ± 11.5
      - Placebo = 62.5 ± 11.5
      - *Data supplied by author*

**Comments**

- **Randomised controlled trials**
  - **Selection bias**
    - A1: appropriate randomisation - yes "random block design stratified by investigational site" A2: adequate concealment - unclear A3: groups comparable at baseline - yes Level of bias: low
  - **Performance bias**
    - B1: same level of care for both groups - yes B2: participants blinded - yes B2: clinical staff blinded - unclear Level of bias: unclear
  - **Attrition bias**
    - C1: follow up equal for both groups - yes C2: groups comparable for dropout - unclear, 4/110 in PTNS and 1/110 in placebo "withdrew consent" prior to week 13 C3: groups comparable for missing data - unclear, 3/110 in PTNS and 4/110 in placebo did not contribute data to analysis due to "lost to follow-up" or "other". Level of bias: unclear
  - **Detection bias**
    - D1: follow up appropriate length - unclear, outcome measurement was performed at week 13 after 12 weeks of treatment D2: outcomes defined precisely - yes D3: valid and reliable methods used to assess outcome - yes D4: investigators blind to intervention - yes "study
**Power calculation**

A sample size estimate of around 214 subjects, 107 per study arm was calculated using a 2 sided Fisher's exact binomial test based on an estimated 60% responder rate in the PTNS group and a 40% responder rate in the sham group with a 5% significance level and 80% power.

**Intention to treat analysis**

"An intent to treat analysis which counted any subject not assessed at 13 weeks as a failure was planned for the study primary end point."

**Incontinence episodes**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Experimental</strong></td>
<td>1.40</td>
<td>2.40</td>
<td>103</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>1.90</td>
<td>2.60</td>
<td>105</td>
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</table>

**Source of funding**

Supported by Uroplasty, Inc.

**Indirectness**

Does the study match the review protocol in terms of:

**Population:** Yes (although unclear whether participants were refractory to drug treatment).

**Intervention:** Yes

**Outcome:** Yes

**Indirectness:** None

**Other information**

All participants were informed that they may or may not feel a sensory stimulus effect on their lower extremities as a result of the intervention. Participants were assessed at week 13 after receiving 12 weeks of intervention sessions. 208/220 (95%) were evaluated at week 13; PTNS = 103/110, placebo = 105/110.

At week 13 the percentage of subjects who correctly identified their randomised intervention assignment was equivalent to:

 ruining diary outcome measures were blinded to the assigned treatment intervention throughout the trial."

D5: investigators blinded to confounding factors - unclear

Level of bias: unclear

...
### Study details
- Participants: Independently without difficulty
- Exclusion criteria:
  1. Pregnant or planning to become pregnant during the study duration
  2. Neurogenic bladder
  3. Botox use in bladder or pelvic floor muscles within past one year
  4. Pacemakers or implantable defibrillators
  5. Current urinary tract infection
  6. Current vaginal infection
  7. Use of interstim
  8. Use of Bion
  9. Current use of TENS in pelvic region, back or legs
  10. Previous PTNS treatment
  11. Use of investigational drug/device therapy within past 4 weeks
  12. Participation in any clinical investigation involving or impacting gynecologic, urinary or renal function within past 4 weeks

### Interventions

### Methods

### Outcomes and Results

#### Urgency episodes

<table>
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<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
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<tbody>
<tr>
<td>Experimental</td>
<td>4.60</td>
<td>3.60</td>
<td>103</td>
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<tr>
<td>Control</td>
<td>6.10</td>
<td>4.20</td>
<td>105</td>
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#### Incontinence QOL

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>-36.70</td>
<td>21.50</td>
<td>101</td>
</tr>
<tr>
<td>Control</td>
<td>-29.20</td>
<td>20.00</td>
<td>102</td>
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#### Adverse effects

<table>
<thead>
<tr>
<th></th>
<th>Events</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>6</td>
<td>110</td>
</tr>
<tr>
<td>Control</td>
<td>0</td>
<td>110</td>
</tr>
</tbody>
</table>

Comments: Between groups (52% in PTNS group, 58% in sham group), confirming the validity of the sham model.
Full citation

Ref Id
131537

Country/ies where the study was carried out
Italy

Study type
Randomised controlled trial.

Aim of the study
To evaluate long-latency somatosensory evoked potentials in patients with overactive bladder

Sample size
N = 24
PTNS = 16
Placebo = 8

Characteristics
Gender - Female/N (% female)
PTNS = 16/16 (100%)
Placebo = 8/8 (100%)
Age (years) - Mean ± SD
PTNS = 47 ± 10.5
Placebo = 42 ± 7
Incontinence episodes/day - Mean ± SD
Not reported
Detrusor overactivity - n/N (%)
Not reported
Duration of OAB (months) - Mean (range)
PTNS = 23 (6 – 48)
Placebo = 20 (6 – 52)

Interventions

Intervention = 12, 30-minute PTNS sessions, performed 3 times a week for 4 weeks
Placebo = 12, 30-minute sham stimulation sessions, performed 3 times a week for 4 weeks

Details

Intervention
A 34 gauge needle was inserted percutaneously 5cm proximal to the medial malleolus of the right and left ankle alternatively. A surface electrode was placed over the ipsilateral calcaneus. A low voltage electrical stimulator furnished a stimulation current of (0 to 10mA) with a fixed frequency of 20Hz and a pulse width of 200msec. Stimulation current was increased until flexion of the big toe or fanning of all toes. The current was set at the highest level tolerable to the patient.

Placebo
A 34 gauge needle was inserted in the medial head of the gastrocnemius muscle. Stimulator was briefly activated for approximately 30 seconds so the patient felt a minor electrical sensation in the skin and turned off for the rest of the treatment.

Power calculation

<table>
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<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Events</td>
<td>10</td>
<td>16</td>
</tr>
</tbody>
</table>

Outcomes and Results

Patient satisfaction with treatment
Not reported
Self reported rate of absolute symptom reduction per day
Not reported
Episodes of incontinence:
Not reported
Episodes of frequency:
Not reported
Continence status

Power calculation

Events
Total
10
16

Limitations
NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials
Selection bias
A1: appropriate randomisation - unclear "randomly assigned to group A (PTNS) or group B (sham PTNS)."
A2: adequate concealment - unclear
A3: groups comparable at baseline - unclear
Level of bias: unclear
Performance bias
B1: same level of care for both groups - yes
B2: participants blinded - unclear
B2: clinical staff blinded - unclear
Level of bias: unclear
Attrition bias
C1: follow up equal for both groups - yes
C2: groups comparable for missing data - yes, all participants completed treatment
C3: groups comparable for missing data - yes, all participants contributed data to analysis
Level of bias: low
Detection bias
D1: follow up appropriate length - unclear, not specified when outcome measurement performed
D2: outcomes defined precisely: yes
### Study details

- **syndrome treated by means of PTNS.**
- **Study dates**
  - Not reported
- **Source of funding**
  - Research grant: Uroplasty

### Participants

2] Presence of OAB syndrome nonresponding to conventional treatments (behavioural and rehabilitative therapy, antimuscarinics), lasting since at least 6 months. OAB syndrome was diagnosed by means of OAB-q SF part A questionnaire (score >20%).

3] Presence of at least three urgency episodes in 3 days in a 3-day bladder diary.

### Methods

With the proposed sample size, the study power to yield a statistically significant result was estimated to be of 99.3%.

**Intention to treat analysis**

Not reported

### Outcomes and Results

| Control | 0 | 8 |

### Comments

D3: valid and reliable methods used to assess outcome - unclear
D4: investigators blind to intervention - unclear
D5: investigators blinded to confounding factors - unclear
Level of bias: unclear

### Indirectness

Does the study match the review protocol in terms of:
- **Population:** Yes
- **Intervention:** No. Sessions were performed three times per week.
- **Outcome:** No. The main end point (reported here as continence status) was the number of responders. Response was defined as a 50% or greater reduction in incontinence episodes.

Indirectness: Serious

### Other information

Focus of study was "effects of neuromodulation technique on the activity of cerebral centers". Number of controls was chosen to be significantly lower than those of patients for ethical considerations. A significant reduction of OAB-q SF part A core was also noticed only in patients who underwent PTNS (from 83% to 42%, \( P = \) __\)
<table>
<thead>
<tr>
<th>Study details</th>
<th>Participants</th>
<th>Interventions</th>
<th>Methods</th>
<th>Outcomes and Results</th>
<th>Comments</th>
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