



A single-blind, randomized controlled trial to evaluate the effectiveness of transcutaneous tibial nerve stimulation (TTNS) in Overactive Bladder symptoms in women responders to percutaneous tibial nerve stimulation (PTNS)

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Abstract

Objectives To evaluate the effectiveness of transcutaneous tibial nerve stimulation (TTNS) compared to percutaneous tibial nerve stimulation (PTNS) in sustaining symptom improvement over a 6-month period in women with idiopathic Overactive Bladder (OAB) who had responded to an initial 12-week course of PTNS.

Design Randomized, active-controlled trial.

Participants Twenty-four women diagnosed with idiopathic OAB successfully treated with PTNS were included in this study.

Interventions Twelve subjects were allocated to receive monthly sessions of PTNS for six months, and twelve subjects followed a flexible home-based TTNS regime after instruction on the use of a TENS device for the same follow-up time.

Outcomes Participants were assessed at six weeks, three months and six months after completing the initial course of PTNS. Primary outcomes were changes from baseline in urinary frequency, number of episodes of urgency and number of episodes of urge urinary incontinence (UUI). Subjectively reported severity of symptoms and quality of life (QoL) were assessed using the validated OAB questionnaire (OAB-q).

Results Urinary frequency, episodes of urinary urgency and episodes of UUI did not change significantly between baseline and six months in either group. Similarly, OAB-q scores for severity of symptoms and QoL were maintained within both arms for the duration of the study. There were no statistically significant differences between the groups in any of the outcome measures at any of the study points.

Conclusion TTNS is effective in the maintenance of symptom improvement in women with OAB who had positively responded to a course of 12 weekly PTNS sessions.

The trial was registered in the Clinicaltrials.gov PRS database (Identifier: NCT02377765).

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Keywords: Urinary urgency; Urinary frequency; Detrusor overactivity; Peripheral neuromodulation; Overactive Bladder

Introduction

Overactive Bladder (OAB) is a lower urinary tract syndrome defined by the International Urogynecological Association (IUGA) and the International Continence Soci-

ety (ICS) as the presence of urinary urgency with or without urgency urinary incontinence (UUI), usually with increased daytime frequency and nocturia, in the absence of infection or other obvious pathology [1]. When OAB results in UUI, it is referred to as OAB-wet, while OAB that does not result in UUI is referred to as OAB-dry [2]. OAB is a highly prevalent condition, with 12.8% of women in the general population suffering from OAB symptoms [3]. The problem becomes increasingly prevalent and severe with age, rising to 15%

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in those over the age of 40 [4]. OAB is known to deeply affect patients' activities of daily living as well as their health-related quality of life (HRQoL) [5], with those suffering from OAB-wet reporting a greater impact on their social activities and working commitments [6]. Patients with OAB often embrace complex and concealing coping strategies, such as limiting fluid intake, avoiding travel, ensuring quick access to toilets, all of which result in severe restrictions to individual activities and social participation [7].

For those who fail to improve with conservative and pharmacological measures, alternative, more invasive techniques, such as neuromodulation or intravesical injections of onabotulinumtoxinA have emerged as a third-line option in national and international guidelines [8,9]. Currently, the two established therapeutic modalities of neuromodulation are percutaneous tibial nerve stimulation (PTNS) and sacral nerve stimulation (SNS). PTNS aims to stimulate the sacral nerve plexus (S₂–S₄ roots), where the parasympathetic innervation of the bladder originates, through the afferent fibres of the tibial nerve, a mixed nerve containing L₅–S₃ fibres [10].

A disadvantage of the use of PTNS in dealing with a chronic condition such as OAB is the need for repeated treatments after an initial 12-week course in order to avoid recurrence of symptoms [11]. Without ongoing treatment, OAB symptoms are known to significantly deteriorate within the first three to six weeks [12,13]. Three prospective cohort studies have reported on the feasibility and long-term effectiveness of continued PTNS [12,14,15]. However, this approach places great burden on patients, health professionals and health-care resources.

Transcutaneous stimulation of the tibial nerve (TTNS) has also been reported effective in improving both objective and subjective outcomes in the management of patients with idiopathic OAB symptoms [15]. TTNS has several practical advantages as it is relatively cheap, non-invasive and can be self-administered at home with surface electrodes and stimulators that are easy to operate. It is well tolerated and has no adverse side-effects [16]. However, the use of TTNS for maintenance of symptom improvement in patients who have previously responded to an initial course of PTNS has only been investigated in a small observational study [17].

The aim of this study was to evaluate the effectiveness of TTNS compared to PTNS in maintaining symptom improvement over a 6-month period in women with non-neurogenic OAB who had responded to an initial 12-week course of PTNS.

Materials and methods

Definitions and units conform to the standards jointly recommended by the IUGA and the ICS [1]. This study was a prospective, randomized active-controlled trial. Ethics approval was granted by the local independent ethics committee (NRES Committee North West – Liverpool Central. 13/NW/0826). The trial was registered in the Clinical-

trials.gov PRS database (Identifier: NCT02377765). All participants were provided with a Study Participant Information Sheet and written consent was obtained before allocation to the treatment group.

Between March 2015 and April 2016, 66 women attending the Physiotherapy Department of an acute care NHS Trust in the Northwest of England were screened for their eligibility into the study. The inclusion criteria were: females over 18 years of age; clinical diagnosis of idiopathic OAB; unresponsive to previous pharmacological treatment (antimuscarinics and/or mirabegron); positive response to an initial course of 12 weekly sessions of PTNS and agreed to participate in the trial. For the purpose of this study, positive responders were considered those subjects who had achieved a reduction in the mean number of micturitions per 24 hours of $\geq 30\%$ according to a three-day bladder diary. Exclusion criteria included women who had undergone previous surgery for stress urinary incontinence (SUI); women fitted with a pace-maker and those pregnant or planning to become pregnant. Women diagnosed with neurogenic lower urinary tract conditions, those on anticoagulant medication, as well as those unable to co-operate or fully understand the study procedures were also excluded. Concurrent use of antimuscarinic agents or mirabegron was not allowed for the duration of the study.

Twenty-four women met the above criteria and all agreed to participate in the study. They were randomised in a 1:1 ratio to a 6-month maintenance programme, receiving either one session of PTNS every four weeks or instruction on how to perform TTNS at home. Cards containing allocation to one of the treatment arms were placed in sealed, opaque, numbered envelopes, which were drawn sequentially according to a table of random numbers. The primary investigator remained blind to the group allocation for the duration of the study.

Procedures

Subjects allocated to the active control group continued to receive one 30-minute PTNS session every four weeks for six months within the Physiotherapy Department. PTNS was delivered bilaterally, as it has been described by Martin-Garcia and Trochez [18], inserting two 40 mm \times 0.20 mm (34 gauge) acupuncture needles (Classic Plus Sterile Needle, HMD Europe), three finger-breaths cranial to each medial malleolus and posterior to the medial border of the tibia. Self-adhesive electrodes were placed on the medial surface of each ipsilateral calcaneus. The stimulation was carried out with a low voltage electrostimulator (AS SUPER 4 digital, Pierenkemper GmbH, Germany), set up with a pulse duration of 200 μ seconds and a frequency of 20 Hz in continuous mode. The amplitude (0–20 mA, adjustable in steps of 0.1 mA) was increased until flexion of the first toe or fanning of all toes was seen, or tingling sensation in the sole of the foot was reported, always at the highest tolerable level. Elevation of the intensity was allowed whenever the patient described fading of the above sensation due to accommodation.

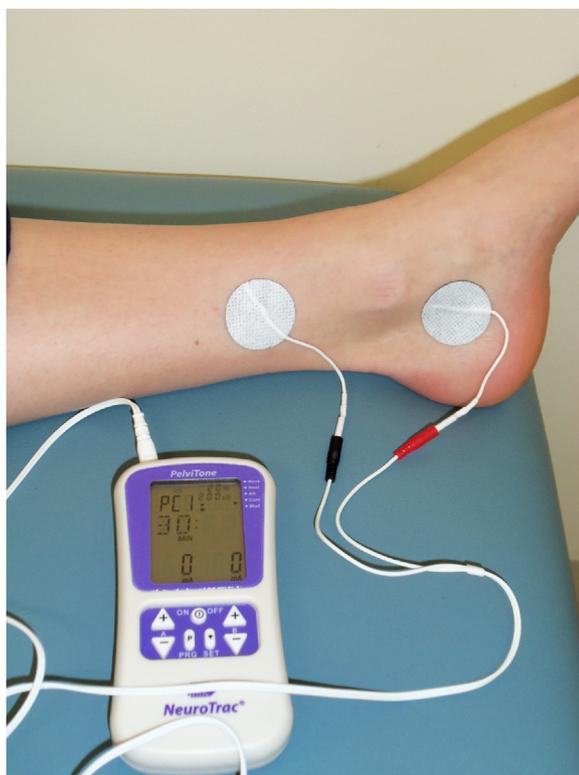


Fig. 1. Position of adhesive, surface electrodes for TTNS.

Subjects in the TTNS group were given one-to-one instruction on the administration of transcutaneous stimulation. TTNS was also applied bilaterally, using two surface, round electrodes (3 cm in diameter) on each leg, one of them placed three finger-breaths cranial to the medial malleolus and the other one on the medial surface of the ipsilateral calcaneus (Fig. 1). Electrical stimulation was delivered through a NeuroTrac Pelvitone device (Verity Medical Ltd., Hampshire, UK) using the same parameters as in the PTNS group. Participants were instructed to gradually increase the intensity until flexion of the big toe or fanning of the other toes occurred, and then to lower it slightly to avoid any motor response. They were asked to perform a minimum of three, thirty-minute sessions per week at home for a period of six months. However, they were allowed to use the stimulation more frequently (once daily maximum) if they wished to do so. Written instructions including a photograph demonstrating electrode placement were given to participants.

Data collection

Patient data were collected by the primary investigator after completing their initial twelve-week course of PTNS, which constituted the baseline of the study, and then at six weeks, three months and six months within the study period. Primary outcome measures were urinary frequency, number of episodes of urinary urgency and number of episodes of UUI obtained from a three-day bladder chart, which partici-

pants completed prior to each of the study visits. Secondary outcomes were symptom severity and Health Related Quality of Life (HRQoL) scores as measured by the OAB-q questionnaire, which participants completed during their study visits. This is a 33-item, validated, condition-specific questionnaire which has shown sound psychometric properties [19].

Statistical analysis

A sample size of eleven subjects per arm was required to achieve a level of significance of 0.05 and 80% statistical power to detect an increase in 3 micturition episodes over 24 hours, which would constitute a clinically significant deterioration in symptoms during maintenance therapy [20]. This significant worsening in OAB symptoms may occur as soon as 6 weeks after stopping PTNS treatment [13]. The authors recruited 12 participants for each group to accommodate a 10% drop-out rate. Data were analysed on an intention-to-treat basis using SPSS software (SPSS[®] version 22, SPSS, IBM Corporation, NY, USA).

Categorical data were described as absolute frequencies and percentages and were compared with the Chi-squared test. All end points were measured on a continuous scale. Those normally distributed were indicated as mean (standard deviation), while variables that were not normally distributed were described as median and interquartile range (IQR). Within groups comparisons were performed using one-way repeated measures ANOVA for normally distributed data or Friedman's test as the non-parametric alternative. *Post-hoc* analysis were undertaken only when significant differences were found. The unpaired t-test or Mann–Whitney U test were used for between-group comparisons. All results were two-sided and $P < 0.05$ indicated statistical significance.

Results

Twenty-four subjects meeting all the inclusion and exclusion criteria agreed to participate in the trial (Fig. 2). Twelve of these women were randomised to the PTNS group and twelve were randomised to the TTNS group. There were no drop-outs and data from all subjects were analysed on an intention-to-treat basis at the end of the six-month study period.

Table 1 presents demographic and baseline characteristics of participants. No significant differences between groups were found for age, BMI, parity or duration of symptoms.

Table 2 shows summary statistics for the bladder diary variables at each of the study points for both treatment groups. At baseline there were no significant differences between the groups in any of the bladder chart parameters. Friedman's test showed that within the TTNS group there was no significant change in the number of voids ($P = 0.716$) over the study period. In fact, the median (IQR) number of micturitions continued to reduce from the start of the study to six-month

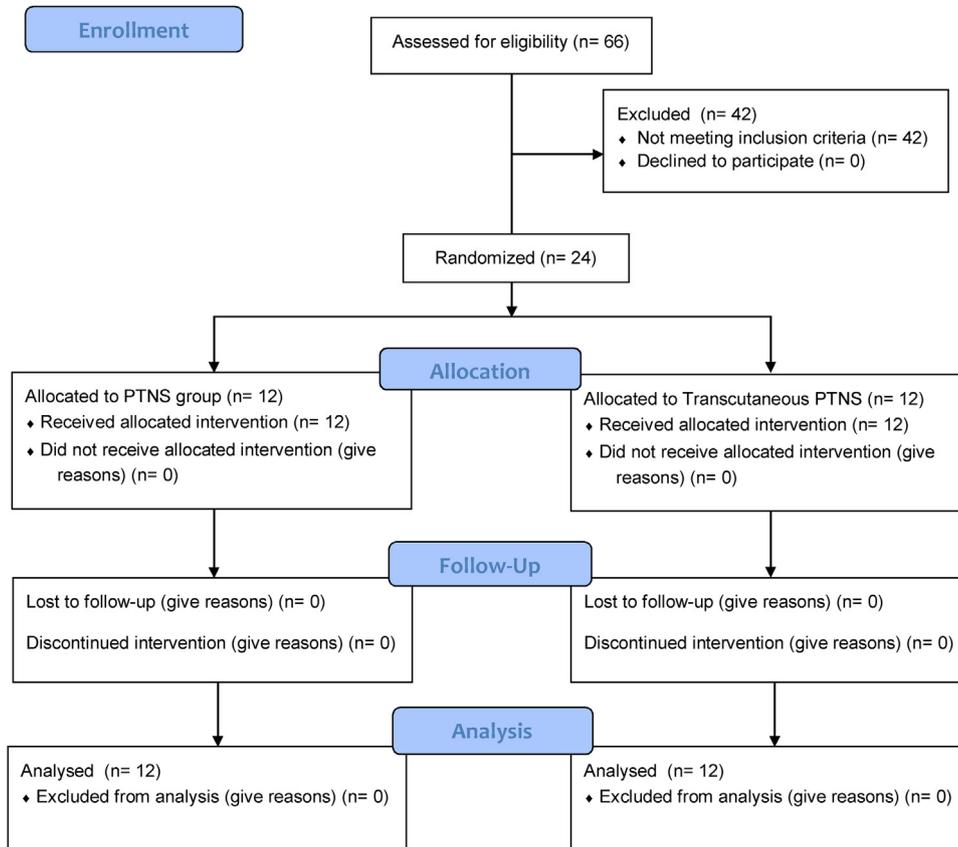


Fig. 2. CONSORT flow diagram.

follow-up: 8.5 (1.9) vs 7.7 (2.8), median of the difference -0.4 , 95% confidence interval (CI) -1.4 to 0.5 ($P=0.373$). Similarly, no significant changes were found in the number of UUI episodes in 24 hours ($P=0.900$). Interestingly, the number of episodes of urgency did vary significantly over the duration of the study ($P=0.038$). *Post-hoc* comparisons using Wilcoxon signed rank test showed a significant increase in this variable from baseline to six weeks: 1.7 (2.8) vs 3.2 (3.6), median of the difference 1.0, 95% CI 0.0 to 2.0 ($P=0.044$); and from baseline to three months: 1.7 (2.8) vs 2.5 (2.6), median of the difference 0.7, 95% CI 0.3 to 1.2 ($P=0.011$). However, no statistically significant change occurred from baseline to six months: 1.7 (2.8) vs 2.0 (1.4), median of the difference 0.3, 95% CI -0.2 to 0.7 ($P=0.325$). Effect sizes of the intervention were not calculated as the aim of the intervention was to maintain baseline outcome data, rather than achieving any clinically significant change.

Within the PTNS group, the median number of micturations in 24 hours did not change significantly over the study time points ($P=0.242$), although it did increase from 7.3 (4.7) to 8.7 (2.4) at six months (median of the difference 0.8, 95% CI -1.0 to 2.3, $P=0.208$). There was no statistically significant increase in the number of episodes of urgency or the number of UUI episodes within this group ($P=0.883$ and $P=0.655$, respectively).

The mean severity of symptoms within the TTNS group (Fig. 3) did not differ significantly amongst time points ($P=0.584$). Severity did not change significantly over time within the PTNS group either ($P=0.854$). Severity scores were also comparable between groups at six weeks, three months and six months. HRQoL scores (Fig. 4) did not change significantly during the study period within either of the groups ($P=0.948$ and $P=0.676$ for PTNS and TTNS respectively).

TTNS treatment was well tolerated and none of the participants reported any device malfunction or any adverse event with the use of the TENS unit. Within the PTNS group there were a total of three minor episodes of bleeding at the needle site in two participants and one episode of discomfort/pain over the needled area reported by one subject.

Discussion

This is the first time that TTNS has been compared to percutaneous PTNS in a randomized active-controlled trial for the maintenance of symptom improvement in women with idiopathic OAB. All bladder diary parameters at six months were comparable to those at baseline within the TTNS group.

Table 1

Subject baseline characteristics. Data are presented as mean (SD), median (IQR), or as absolute frequencies (percentage).

Baseline characteristics	PTNS <i>n</i> = 12	TPTNS <i>n</i> = 12	<i>P</i> -value
Age (years), mean (SD)	58 (10)	54 (12)	0.437
BMI (kg/m ²), mean (SD)	32 (7)	32 (7)	0.941
Number of children, mean (SD)	2.6 (1.1)	2.2 (1.3)	0.424
Duration of symptoms (months), median (IQR)	120 (249)	90 (243)	0.323
Type OAB, <i>n</i> (%)			
Mixed urinary incontinence	9 (75)	8 (67)	0.589
OAB-wet	3 (25)	3 (25)	
OAB-dry	0 (0)	1 (8)	
Hx diabetes, <i>n</i> (%)			
Yes	2 (17)	1 (8)	0.537
No	10 (83)	11 (92)	
Hx COPD, <i>n</i> (%)			
Yes	0	1 (8)	0.307
No	12 (100)	11 (92)	
Hx hypertension, <i>n</i> (%)			
Yes	4 (33)	1 (8)	0.132
No	8 (67)	11 (92)	
Constipation, <i>n</i> (%)			
Yes	1 (8)	5 (42)	0.059
No	11 (92)	7 (58)	
Smoker, <i>n</i> (%)			
Yes	1 (8)	0 (0)	0.307
No	11 (92)	12 (100)	
Hx hyperlipidemia, <i>n</i> (%)			
Yes	4 (33)	2 (17)	0.346
No	8 (67)	10 (83)	
Hx nocturnal enuresis, <i>n</i> (%)			
Yes	1 (8)	6 (50)	0.025
No	11 (92)	6 (50)	

SD, standard deviation; IQR, interquartile range.

Data are presented as mean (SD), median (IQR) or absolute frequency (%).

This is consistent with the findings by Maurelli *et al.* [17], who in a small, observational study evaluated the use of transcutaneous PTNS for maintenance therapy after an initial 12-week course of PTNS. They reported that 80% of the subjects who followed a flexible home TTNS protocol did not show an increase greater than 10% in the number of UUI episodes per 24 hours over a follow-up period of 20 months. In this study, the median number of micturitions and UUI episodes continued to decrease in the TTNS group from baseline to six-month follow-up. Moreover, no significant changes were found in subjectively reported severity of symptoms ($P=0.548$) or HRQoL scores ($P=0.513$), further supporting the efficacy of TTNS in sustaining OAB symptom improvement.

The long-term effectiveness of continued PTNS therapy has been described in three prospective observational studies [12,14,15], all of which employed a flexible approach, where treatment intervals were determined individually. As a result, the mean number of days between PTNS sessions varied sig-

Table 2

Primary outcome criteria are presented as median (IQR). Friedman's test is used for within subject analysis and Mann–Whitney U test used for between-group comparisons.

Dependent variable	PTNS (<i>n</i> = 12)	TPTNS (<i>n</i> = 12)	<i>P</i> -value ^a
Micturitions per 24 hours			
Baseline	7.3 (4.7)	8.5 (1.9)	0.551
6 weeks	8.3 (3.6)	7.7 (2.8)	0.887
3 months	8.5 (3.7)	7.5 (3.0)	0.590
6 months	8.7 (2.4)	7.7 (2.8)	0.347
<i>P</i> (Friedman's test)	0.242	0.716	
Episodes of urgency per 24 hours			
Baseline	2.0 (2.8)	1.7 (2.8)	0.977
6 weeks	0.7 (4.7)	3.2 (3.6)	0.266
3 months	1.3 (2.7)	2.5 (2.6)	0.266
6 months	0.5 (2.2)	2.0 (1.4)	0.160
<i>P</i> (Friedman's test)	0.883	0.038	
Episodes of UUI per 24 hours			
Baseline	0.0 (1.5)	0.5 (1.0)	0.514
6 weeks	0.0 (3.8)	0.5 (1.5)	0.799
3 months	0.5 (2.2)	0.2 (1.9)	0.755
6 months	0.0 (0.7)	0.2 (1.7)	0.755
<i>P</i> (Friedman's test)	0.655	0.900	

^a Mann–Whitney U-test.

nificantly (21, 28 and 61 days respectively). In line with these results, subjects within the PTNS group in this study did not experience a significant change in their urinary symptoms over the six-month follow-up period. However, our results suggest that the maintenance regimen may be standardized to one PTNS session every four weeks.

To date different TTNS regimens have been reported in the literature. A pilot randomized controlled trial (RCT) suggested that daily TTNS stimulation over a period of six weeks was more effective than twice weekly stimulation for faecal incontinence (FI) symptoms [21]. However, in the study by Maurelli *et al.* [17], 13 out of 16 patients were able to maintain the initial symptom improvement using TTNS an average of 1.6 times per week (range 1–3). In this study, participants in the TTNS group were asked to perform the stimulation a minimum of three times per week but flexibility was allowed for them to use it more frequently. Stimulation was applied bilaterally in both treatment arms. This approach is based on the hypothesis that bilateral neuromodulation may be more efficacious than the unilateral technique [18], as it activates a greater number of sensory afferent pathways. Thomas *et al.* have suggested that daily bilateral transcutaneous stimulation for six weeks was more effective than the unilateral approach for the management of FI [22]. To the best of our knowledge there are no randomized studies comparing bilateral with unilateral tibial nerve stimulation for OAB symptoms, therefore further research is required to establish whether one technique is more effective than the other.

The major strength of this study is its design as a prospective, randomized study. Also, all patients that met the inclusion and exclusion criteria accepted to participate in the study and no participants were lost to follow-up. Although

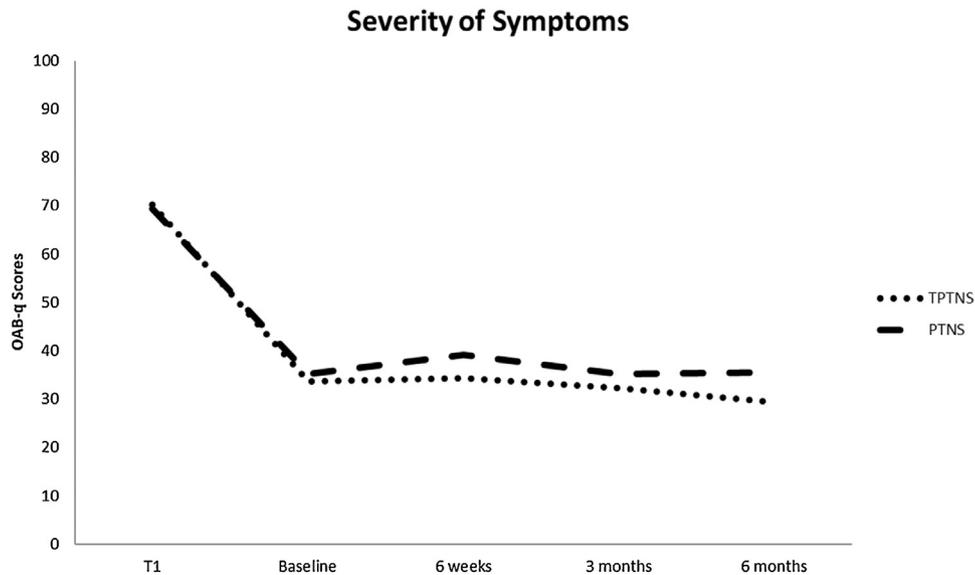


Fig. 3. OAB-q severity of symptoms scores. T₁ indicates the initiation of PTNS treatment, 12 weeks prior to enrolment in the study.



Fig. 4. OAB-q health related quality of life scores.

the sample size was determined through a statistical power calculation, the small size of the population represents the major limitation of this paper. A further limitation of the study is the lack of objective data regarding TTNS group compliance with use of the TENS unit, as the authors did not collect data on how many times participants used it. Future studies should record individual subjects' TENS usage aiming to better determine the optimum TTNS frequency for maintenance therapy. Further weaknesses include the lack of blinding of participants and therapist to the treatment assignment and the lack of a sham TTNS intervention to evaluate its placebo effect. As it is known that bladder symptoms deteriorate quickly without maintenance therapy, it was considered unethical to use a control group receiving no intervention after the initial course of PTNS. Larger studies with longer follow-up periods are required to consolidate the results observed in this study. In addition, cost-effectiveness should also be scrutinized, as the direct and indirect costs of TTNS are likely to be significantly lower than long-term PTNS therapy.

In conclusion, the results suggest that the bilateral application of TTNS may be an effective and well tolerated treatment

for the maintenance of OAB symptoms in women who benefit from an initial course of PTNS. Symptoms of subjects allocated to the four-weekly PTNS sessions also remained stable over the six-month follow-up period. However, chronic PTNS treatment requires patients to attend secondary care appointments on a regular basis, while TTNS is a non-invasive alternative that can be safely self-administered by patients or their caregivers in their own home.

Key messages

- Up until now, patients who benefit from PTNS must continue to attend hospital appointments for repeated sessions in order to keep their OAB symptoms under control.
- Our article reports that application of TTNS is an effective treatment for the maintenance of symptom improvement in OAB women who benefit from an initial course of PTNS.
- Provides new clinical information on the management of a common functional chronic condition such as OAB.

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Ethics approval: Ethics approval was granted by the local independent ethics committee (NRES Committee North West – Liverpool Central. 13/NW/0826) and the Manchester Metropolitan University (MMU) Ethics Committee (AEC).

Conflict of interest: None declared.

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