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ORIGINAL ARTICLE

Effects of two nonpharmacological treatments on the sleep quality of women with nocturia: a randomized controlled clinical trial

Daniele Furtado-Albanezi[1] · Soraia Pilon Jürgensen[1] · Mariana Arias Avila[1,2] · Grasiela Nascimento Correia[3] · Patricia Driusso[1,2]

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Abstract

Introduction and hypothesis The objective was to check the effects of two nonpharmacological treatments on the sleep quality of women with nocturia.

Methods A randomized controlled clinical trial in which 40 women with nocturia were randomized into two groups; one was subjected to tibial nerve stimulation (GTNS) and the other received pelvic floor muscle training associated with behavioral therapy (GPFMT). Both groups were followed for 12 weeks, with one session/week; evaluated by the Pittsburgh Sleep Quality Index (PSQI), King's Heath Questionnaire (KHQ), and Epworth Sleepiness Scale (ESS). The Wilcoxon test was used to compare intra-group data and the Mann–Whitney test for intergroup results. Effect size and confidence interval were calculated, and the level of significance was set at 5%.

Results Both groups showed improvements in quality of sleep, observed by the PSQI total score (GTNS from 9 ± 0.88 to 7 ± 0.94, $p = 0.002$; GPFMT from 8 ± 0.80 to 5 ± 0.94, $p < 0.001$) and the sleep/energy domain of the KHQ (GTNS from 66.66 ± 9.03 to 16.66 ± 7.20, $p = 0.002$; GPFMT from 66.66 ± 9.30 to 0.00 ± 7.26, $p = 0.001$).

Conclusions Both nonpharmacological treatments proposed (TNS or PFMT) were equally able to improve quality of sleep of women with nocturia.

Keywords Sleep disorders · Urinary tract · Electrotherapy · Nocturia · Quality of life · Pelvic floor

Introduction

Nocturia is defined as the need for the individual to wake up at night to urinate one or more times, followed and preceded by sleep [1]. The prevalence of nocturia is associated with aging [2] and affects both men and women [3]. The yearly incidence is 0.4% in adults aged less than 40 years, 2.8% for those aged 40–59 years, and 11.5% for those over 60 years [2]. It is considered a lower urinary tract symptom of multifactorial origin [3] that involves four major pathophysiological mechanisms: nocturnal polyuria, global polyuria, reduced nocturnal bladder capacity, and sleep impairments, especially when the need to urinate occurs more than twice a night, interrupting sleep and affecting quality of sleep and life [3]. It can be associated with non-restorative sleep in peri- and postmenopausal women [4]. Comorbidities that affect nocturia patients may be arthritis, asthma, bladder cancer, chronic anxiety, depression, diabetes, heart disease, hypertension, interstitial cystitis, irritable bowel disease and neurological conditions [5]. A history of hysterectomy, menopause, uterine prolapse, and bladder infection may also be associated with nocturia patients with more than two episodes per night [5].

Pharmacological treatments for nocturia can trigger side effects [6]. Thus, nonpharmacological therapy may be considered an option. Behavioral therapy [3] or pelvic floor muscle training (PFMT) are two eligible nonpharmacological therapies. PFMT can promote an inhibition of involuntary detrusor

✉ Patricia Driusso
pdriusso@ufscar.br

[1] Physical Therapy Graduate Program, Federal University of São Carlos, Rodovia Washington Luis, Km 235, São Carlos, SP 13565-905, Brazil

[2] Physical Therapy Department, Federal University of São Carlos, São Carlos, SP, Brazil

[3] Trairi Health Sciences University, Federal University of Rio Grande do Norte, Santa Cruz, RN, Brazil

contraction, improving nocturia symptoms [7]. Perineal stimulation, to inhibit the micturition reflex and consequently reduce the number of night-time awakenings to urinate, can promote the reduction of nocturnal micturition frequency and thus nocturia improvement [8]. Transcutaneous electrical tibial nerve stimulation (TNS) can also significantly improve lower urinary tract symptoms, such as urinary frequency, urgency, urinary incontinence (UI), and nocturia [9].

Despite the promising nonpharmacological treatment results for nocturia, to the best of the authors' knowledge, no studies have evaluated the effects of these approaches, PFMT and TNS, on the sleep quality of women with nocturia. Therefore, the aim of this study was to evaluate the effects of two types of nonpharmacological treatment on the sleep quality of women with nocturia. Our hypothesis was that both approaches would improve the sleep quality of women with nocturia.

Materials and methods

Study design

This was a randomized controlled clinical trial conducted at the Federal University of São Carlos in the Women's Health Research Laboratory (LAMU) between September 2013 and December 2015.

This study was approved by the institution's Ethics Committee (protocol number 379711) and registered in the Brazilian Registry of Clinical Trials under the number RBR-695TWT. All participants in the study were informed about study procedures and signed a free and informed consent form. The study was conducted according to the Declaration of Helsinki of 1975/83.

Sample size was calculated based on a previous study that compared the total Pittsburgh Sleep Quality Index (PSQI) score between people with (8.5 ± 0.4) and without nocturia (4.8 ± 0.4), according to Doo et al. [10]. Sample size was determined using G*Power Software (Düsseldorf, Germany), considering a significance level of 0.05 and a power of 0.80 to obtain an effect size of 0.8. Based on these criteria, at least 20 participants were necessary in each group. The PSQI was considered, as the aim of this study was to evaluate the effects of the proposed treatments on the sleep quality of women with nocturia.

Initially, participants filled in an evaluation form (for demographic, obstetric, and clinical data collection) and the questionnaires: the King's Health Questionnaire (KHQ), the Pittsburgh Sleep Quality Index (PSQI), and the Epworth Sleepiness Scale (ESS). Then, pelvic floor muscle (PFM) evaluation (vaginal palpation and perineometry) was performed by a physical therapist blinded to the patient's allocation. After that, patients were randomly assigned (http://www.randomization.com) to one of the two groups: GTNS (those assigned to the treatment with TNS) or GPFMT (those who underwent PFMT with behavioral therapy). Allocation was implemented by a blinded investigator who did not take part in any of the evaluation and treatment procedures. At the end of the treatment, all subjects were re-evaluated.

Screening and eligibility

All women eligible for the study were over 45 years old. Nocturia was evaluated by self-report of at least one episode of micturition every night in the previous month [1, 3]. Exclusion criteria were:

1. Uncontrolled heart disease or diabetes
2. Presence of pelvic pain or inflammation and/or urinary tract infection
3. Pregnancy
4. Cognitive deficits that prevented patients from understanding the evaluation and treatment procedures
5. Cancer
6. Chronic anxiety and depression treated with medications such as sertraline and clonazepam
7. Patients with neurogenic bladder
8. Patients on medications that could affect nightly micturition, such as antimuscarinics and antidiuretics
9. Patients with nocturnal polyuria syndrome
10. Subjective report on sleep apnea

Assessment methods

Primary outcome was considered the total score of PSQI. PSQI is a self-assessment subjective questionnaire of sleep quality comprising 19 questions, which are grouped into seven components (subjective quality of sleep, sleep latency, sleep time, total sleep efficiency, sleep disorders, hypnotic drug use; daytime dysfunction) that are scored from 0 to 3, with a total score ranging from 0 to 21. Participants with a total score from 0 to 4 are considered to have good sleep quality, 5 to 10 bad sleep quality, and those with a score above 10 are considered to have sleep disorders [11].

The KHQ is a complete register of quality of life related to UI and it consists of 21 items, presented in eight individual domains: general health perception; impact of UI; emotion; sleep/energy; social limitation; physical limitation; limitation of daily activity; personal relationships. It is also divided into two independent scales: severity measures and symptom scale (urinary frequency, nocturia, urgency, vesical hyperreflexia, stress UI, nocturnal enuresis, incontinence in sexual intercourse, urinary tract infections, and bladder pain) [12, 13]. The minimal clinically important difference for the KHQ was considered to be 5–6 points for a small change and 10–15 for a medium change [14].

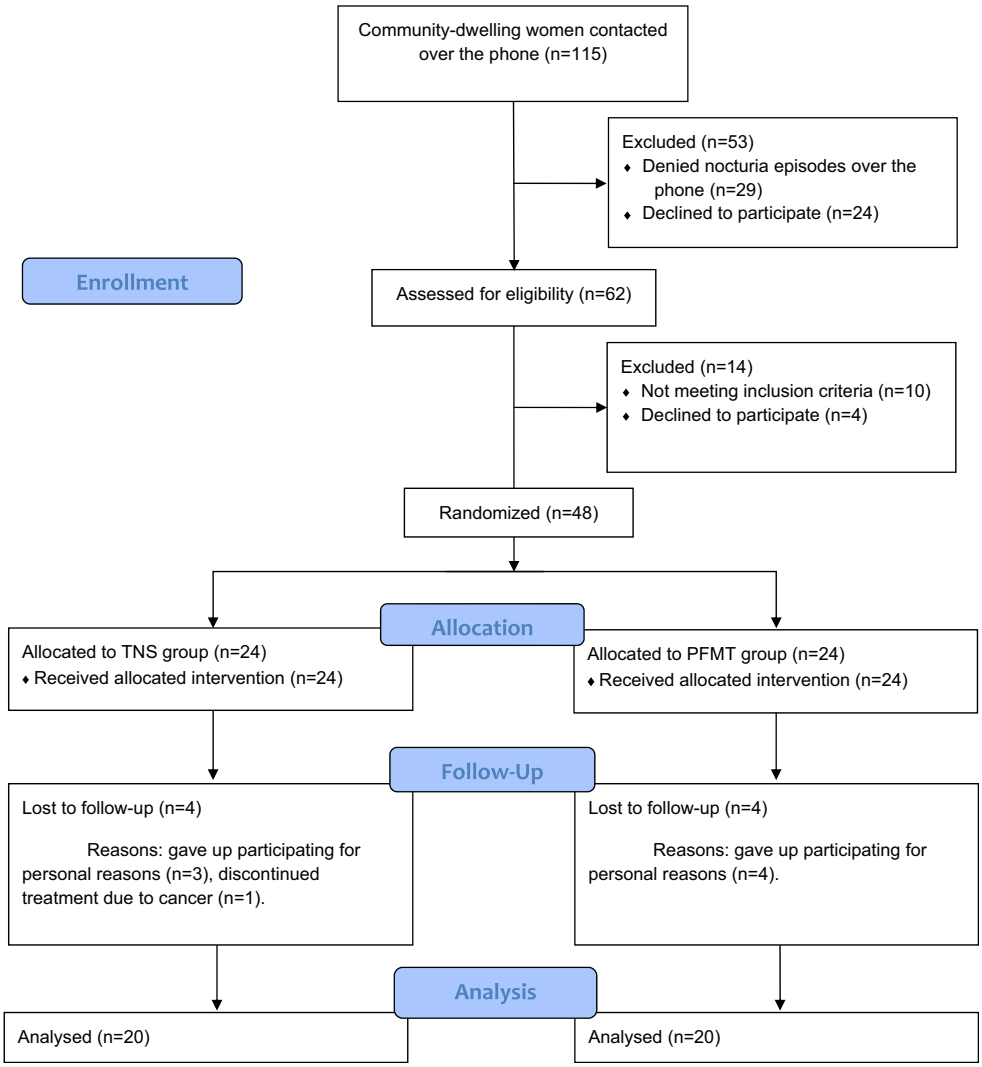

Fig. 1 Flow chart of the study

The ESS is a self-administered questionnaire that evaluates the probability of falling asleep in eight situations involving daily activities. The total score ranges from 0 to 24, with scores above 10 suggesting excessive daytime sleepiness [15, 16].

Functional PFM evaluation was performed using digital palpation. Volunteers were positioned supine with hip and knee flexion according to the protocol proposed by Laycock and Jerwood [17]. Initially, the condition of the vaginal mucosa, the presence of atrophies, sensibility, pelvic organ prolapse, and vaginal wall tonus were observed. Then, a properly trained physical therapist introduced a finger into the participant's vagina and asked her to contract the PFMs (in a "inside and up" movement) with the maximum possible force, with verbal stimuli. The classification of the degree of voluntary contraction was performed according to the Modified Oxford Scale [17].

After 5 min, participants performed PFM contraction pressure evaluation using a Peritron device (Cardio Design, Oakleigh, Victoria, Australia). This device includes a vaginal probe (28 × 55 mm) and it can evaluate pressure exerted by the PFM s from 0 to 320 H_2O cm. Participants were positioned in the supine position, with hip and knee flexion and the probe was half introduced (about 3.5 cm inside) and then the device was reset. The participant was oriented and verbally motivated to perform three 5-s PFM contractions with a 30-s interval [18], following the instruction "inside and up" with the maximum force possible. Participants were oriented to avoid the use of the abdominal, gluteal, and hip adductor muscles. The physical therapist checked if contractions were correctly performed by observing the movement of the vaginal probe and the presence of isometric contractions of the accessory muscles [19]. The average of the three valid contractions was used for data analysis.

Interventions

Both the GTNS and GPFMT groups received one 30-min treatment session per week, for 12 weeks. For TNS, a biphasic balanced sinusoidal wave pattern interferential current was

Table 1 Demographic and clinical characteristics of the study participants

	Variables		GTNS ($n = 20$)	GPFMT ($n = 20$)
Demographic data	Age (years) ± SD		58.00 ± 1.80	57.00 ± 2.43
	Body mass index (kg/m^2) ± SD		27.48 ± 1.05	25.00 ± 1.58
	Menopause (%)	Premenopausal	6 (30)	5 (25)
		Postmenopausal <5 years	4 (20)	5 (25)
		Postmenopausal >5 years	10 (50)	10 (50)
	Ethnicity (%)	White	18 (90)	19 (95)
		Black	2 (10)	1 (5)
	Education (%)	Elementary school	4 (20)	2 (10)
		High school	3 (15)	7 (35)
		Higher education	13 (65)	11 (55)
	Conjugal situation (%)	With conjugal life	12 (60)	14 (70)
		Without conjugal life	8 (40)	6 (30)
Clinical data	Avoids drinking liquids (%)	Yes	8 (40)	4 (20)
		No	12 (60)	16 (80)
	Estimated ingestion of liquids/day (%)	<1.5 L	6 (30)	6 (30)
		1.5 to 2.5 L	12 (60)	13 (65)
		> 2.5 L	2 (10)	1 (5)
	Associated urinary system symptoms (%)	Stress urinary incontinence	3 (15)	0
		Urge urinary incontinence	6 (30)	6 (30)
		Mixed urinary incontinence	7 (35)	12 (60)
		Urinary urgency	16 (80)	14 (70)
	Night-time awakenings to urinate per night (%)	Once	9 (45)	8 (40)
		Two times	5 (25)	5 (25)
		Three times or more	6 (30)	7 (35)
	Pelvic surgeries (%)	Hysterectomy	2 (10)	1 (5)
		Perineoplasty	3 (15)	3 (15)
		Cesarean	10 (50)	12 (60)
	Associated comorbidities (%)	Diabetes	0	1 (5)
		Depression	6 (30)	3 (15)
		Cardiac problems	3 (15)	5 (25)
	Pelvic floor muscles contraction pressure (cmH_2O) ± SD		43.60 ± 5.03	40.42 ± 6.12
	Pelvic floor muscles contraction force (power) ± SD		3.00 ± 0.21	3.00 ± 0.22

GTNS tibial nerve stimulation group, *GPFMT* pelvic floor muscle training group

produced by a current generator (Dualpex 961; Quark Medical Products, Brazil; ANVISA Number: 800,791–9). The bipolar mode was used, with electrodes placed over the skin with gel. At the beginning of the session, a frequency of 1 Hz was used to locate the tibial nerve. The participant performed one hallux flexion so that the motor point could be found with a greater accuracy. After the nerve location, the session began with the electrodes properly positioned at the medial edge of the left leg, one electrode about 2 cm above the medial malleolus and the other positioned in the arch of the foot [20]. During treatment, a frequency of 10 Hz was used in the continuous mode, with a pulse duration (T) of 200 μs per session [21]. The current intensity was adjusted according to the participant's sensitivity and after every 10 min any required adjustments of the current

Table 2 Number of nocturia episodes before and after treatment for both groups

Group	Number of nocturia episodes	Before (%)	After (%)
GTNS	0	0	7 (35)
	1	9 (45)	8 (40)
	2	5 (25)	5 (25)
	≥ 3	6 (30)	0
GPFMT	0	0	7 (35)
	1	8 (40)	8 (40)
	2	5 (25)	5 (25)
	≥ 3	7 (35)	0

intensity were made. No other interventions and/or education was performed on subjects from this group.

The GPFMT also received only one 30-min session per week. The physiotherapist instructed women to perform PFM contractions in different static (supine, side-lying, sitting, and standing) and dynamic (step up and down, sitting to standing, and walking) positions; in each of these positions, 8–12 maximal contractions were performed, maintained for 6 to 8 s with a 6-s rest interval between contractions. Along with exercises, behavioral therapy was performed based on vesical training with programmed urination (increase of 15 min in the urination interval per week) [22] and advice about water intake and proper diet [23]. However, women in this group were also instructed to perform PFM training exercises daily, in three sets of 8–12 maximal PFM contractions maintained for 6–8 s with a 6-s rest interval between contractions.

Statistical analysis

Data were analyzed using Statistica 7.0 software. Data normality was checked using the Shapiro–Wilk test. Data were expressed as median ± mean standard error. To compare data before and after treatment between groups, a Wilcoxon matched pairs test was used; comparison among groups was performed using the Mann–Whitney *U* test. To evaluate the clinical significance of the data, the effect sizes (ES) and confidence intervals (CI) were calculated. An ES greater than 0.8 was considered large, between 0.25 and 0.75 moderate, and less than 0.2 small [24].

Results

Forty-eight women with self-reported nocturia were evaluated and then randomly assigned to one of the two groups. Of these, 40 completed all stages of the study, totaling 20 participants in each group (Fig. 1). Demographic and clinical characteristics of each group are shown in Table 1.

Table 2 shows data regarding the change in nocturia after treatment for each group. For the GTNS, 40% of patients (n = 8) have maintained their number of awakenings after treatment, 45% (n = 9) have reduced their awakening episodes by one, 5% (n = 1) have reduced their awakening episodes by two, and 10% (n = 2) have reduced their episodes by three. For the GPMFT, 30% (n = 6) have maintained their awakening number of episodes after treatment, 45% (n = 9) have reduced their awakening episodes by one, and 25% (n = 5) have reduced their awakening episodes by two. Of those who failed, 2 of each group had three awakening episodes; 5 from the GTNS and 3 from the GPFMT presented one awakening episode.

An intragroup comparison (Table 3) has shown that, for the GTNS, there were improvements on the PSQI total score (p = 0.002, ES −2.20) and several domains of the KHQ: UI impact (p = 0.01, ES −5.33), DLA limitations (p = 0.01, ES −3.65), physical limitations (p < 0.001, ES −3.06), emotions (p = 0.04, ES −1.76), and sleep/energy (p = 0.002, ES −6.12). For the GPFMT, comparisons have revealed that there were improvements in the PSQI total score (p < 0.001, ES −3.44), ESS total score (p = 0.02, ES −1.95), and the KHQ domains of DLA limitations (p = 0.006, ES −6.19), emotions (p = 0.03, ES −1.80), and sleep/energy (p = 0.01, ES −7.99). Intergroup comparison has shown that only the UI impact domain of the KHQ (p = 0.01, ES 2.40) was better for the GPFMT (Table 3).

No collateral effects were reported by any of the volunteers who performed both treatments.

Discussion

In the present study, both proposed treatments (TNS and PFMT) resulted in a decreased number of night-time awakenings to urinate and participants' quality of sleep; hence, both treatments present a good clinical applicability and can be considered an alternative for sleep quality improvement for women with nocturia. Interestingly, both treatments presented equally good results.

Olivera et al. [25], in a systematic review, suggest that TNS, PFMT, and behavioral therapy are options for improving urgency UI, urinary volume, and quality of life. Also, the study highlights that the combination of PFMT with behavioral therapy and TNS improve nocturia, stress urinary incontinence, urge urinary incontinence, and urgency [25]. The present study was based on the combination of bladder re-education associated with the orientation of water intake and PFMT, with beneficial results to decrease the number of night-time awakenings due to the desire to urinate and increase the participant's quality of sleep. Weiss et al. [3] suggest behavioral guidelines combined with other therapies to promote nocturia improvements.

Table 3 Quality of life and sleep before and after treatment for both groups

Variables		Before	After	*p* intragroup	*p* intergroup[a]	Effect sizes intragroup[b]	Effect sizes intergroups after treatment[b]
Pittsburgh Sleep Quality Index: total score	GTNS	9.00 ± 0.88	7.00 ± 0.94	0.002*	0.50	-2.20 [−2.93 to −1.37]	2.13 [1.32 to 2.86]
	GPFMT	8.00 ± 0.80	5.00 ± 0.94	0.0005*		-3.44 [−4.33 to −2.40]	
Epworth Sleepiness Scale (total score)	GTNS	6.50 ± 1.14	6.00 ± 1.13	0.93	0.70	−0.44 [−1.06 to 0.20]	0.84 [0.18 to 1.47]
	GPFMT	7.50 ± 1.31	5.00 ± 1.25	0.02*		−1.95 [−2.66 to −1.17]	
King's Health Questionnaire by domains							
General health perception	GTNS	25.00 ± 4.66	25.00 ± 3.38	0.10	0.50	0 [−0.62 to 0.62]	0 [−0.62 to 0.62]
	GPFMT	25.00 ± 5.32	25.00 ± 4.41	0.65		0 [−0.62 to 0.62]	
UI impact	GTNS	83.33 ± 5.97	50.00 ± 6.52	0.01*	0.01*	−5.33 [−6.53 to −3.92]	2.40 [1.54 to 3.16]
	GPFMT	33.33 ± 8.17	33.33 ± 7.36	0.4		0 [−0.62 to 0.62]	
DLA limitations	GTNS	33.33 ± 7.18	8.33 ± 6.52	0.01*	0.93	−3.65 [−4.57 to −2.57]	1.24 [0.54 to 1.89]
	GPFMT	50.00 ± 9.09	0.00 ± 6.93	0.006*		−6.19 [−7.53 to −4.60]	
Physical limitations	GTNS	38.89 ± 8.21	16.66 ± 6.17	0.0005*	0.65	−3.06 [−3.90 to −2.10]	2.76 [1.84 to 3.56]
	GPFMT	16.66 ± 8.32	0.00 ± 5.92	0.07		−2.31 [−3.05 to −1.47]	
Social limitations	GTNS	5.56 ± 5.75	11.11 ± 3.24	0.12	0.47	1.19 [0.50 to 1.84]	2.32 [1.48 to 3.07]
	GPFMT	0.00 ± 5.94	0.00 ± 4.81	0.10		0 [−0.62 to 0.62]	
Personal relationships	GTNS	0.00 ± 5.94	0.00 ± 4.37	0.43	0.40	0 [−0.62 to 0.62]	0 [−0.62 to 0.62]
	GPFMT	0.00 ± 5.03	0.00 ± 3.33	0.19		0 [−0.62 to 0.62]	
Emotions	GTNS	11.11 ± 7.30	0.00 ± 5.16	0.04*	0.71	−1.76 [−2.45 to −1.00]	0 [−0.62 to 0.62]
	GPFMT	11.11 ± 7.04	0.00 ± 5.18	0.03*		−1.80 [−2.49 to −1.03]	
Sleep/energy	GTNS	66.66 ± 9.03	16.66 ± 7.20	0.002*	0.47	−6.12 [−7.45 to −4.55]	2.30 [1.47 to 3.05]
	GPFMT	66.66 ± 9.30	0.00 ± 7.26	0.001*		−7.99 [−9.66 to −6.01]	
Measurements of gravity	GTNS	33.33 ± 4.29	10.00 ± 4.18	0.01*	0.71	−5.51 [−6.73 to −4.06]	−0.78 [−1.41 to −0.13]
	GPFMT	30.00 ± 6.25	13.33 ± 4.32	0.02*		−3.10 [−3.95 to −2.13]	

UI urinary incontinence, *DLA* daily life activities

*$p<0.05$

[a] *p* intergroup after treatment

[b] Cohen d coefficient values presented as d [95% confidence interval] and refers to the comparison of after versus before and GPFMT versus GTNS

From the results of the present study, it was possible to demonstrate that TNS was effective at improving the quality of sleep by reducing the number of night-time awakenings to urinate. These data corroborate the findings about nocturia improvement of van Balken et al. [9], probably because the inhibitory effect promoted by TNS is able to increase the vesical capacity [26], and this can reduce the episodes of nocturia, because a decrease in bladder storage capacity is one of the causes of nocturia [3].

The number of episodes of nocturnal awakenings due to the urge to urinate is positively correlated with sleep disorders [27], becoming one of the most inconvenient symptoms of lower urinary tract diseases [28]. Present results have shown a decrease in both the number of nocturia episodes, seen by the total PSQI score, and the sleep/energy domain of the KHQ.

Improvement of sleep quality in the present study agrees with the findings of Brunner and Riss [29], who found that nocturia can affect the beginning and maintenance of sleep, jeopardizing its quality and duration, deregulating biological functions, and interfering in the overall quality of life [30]. Nocturia plays an important role in daytime dysfunction of women younger than 65 years old, and this fact should not be overlooked [31]; improving this condition should be one of the rehabilitation goals of women with nocturia. As such, the results of the present study present interesting possibilities in treating this symptom. In the present study, the GTNS showed improvements of daytime dysfunction observed by the PSQI and GPFMT and improvements in daytime sleepiness observed by the ESS. Thus, both groups, by presenting a decrease in episodes of nocturia, are in agreement with similar results found by Suekane et al. [30], which relates the increase in frequency of night-time awakenings to urinate with an increasing score of ESS. The reduction of the PSQI total score was more marked in the GPFMT (from 8 to 5) than in the GTNS (from 9 to 7). Several studies have stated that a total PSQI score of ≤5 suggests good sleep quality [32, 33], meaning that GPFMT patients have much improved sleep quality. Even though the domain General Health Perception from the KHQ did not show any improvements, and hence, quality of life may not have been affected, other domains such as UI impact, DLA limitation, physical limitation, emotions, sleep/energy, and measurement of gravity showed improvement after treatment for both groups.

This study has some limitations. First, sample size estimation was calculated as parametric data a priori; nonetheless, data turned out to be nonparametric, and analysis was performed accordingly. If sample size estimation had been performed as nonparametric from the beginning, 27 subjects would have been needed in each group. Thus, the small sample size makes it more difficult to make any kind of inference for bigger populations; however, we have obtained important effect sizes showing that both treatments were effective at improving quality of sleep in women with self-reported nocturia. Second, some patients ($n = 8$, 16.7%) have dropped out before treatment completion, and 7 claimed personal reasons. It is an important drop-out rate, but it is similar to the rates found by a previous study [34]. Also, the statistical reduction in KHQ scores for different domains could have been due to other related lower urinary tract symptoms, but they were not evaluated in the present study; this reduction, even though statistical, did not achieve a minimal clinically important difference. Another important question is that the present results refer to the short-term effects of the two treatments; as such, long-term effects may not be as good. Several patients ($n = 14$, 35%) did not show any improvements in nocturnal micturition episodes, and this may have been because of the inability to respond to the proposed treatment. However, 65% of the patients presented a reduction of nocturia. Future research could include larger sample sizes for each group, long-term evaluations, more subjective (such as voiding diary) and objective evaluations (such as polysomnography and urodynamic examinations), and placebo treatments to attest to the effectiveness of the treatments proposed in the present study.

Conclusion

Both nonpharmacological treatments proposed (TNS or PFMT) were equally able to improve the quality of sleep of women with nocturia. Given that both interventions are relatively easy to perform, and that a great number of patients had a positive responses, both TNS and PFMT can be considered as an alternative to improve quality of sleep of women with nocturia.

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Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflicts of interest.

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