



# Home-based transcutaneous tibial nerve stimulation for overactive bladder syndrome: a randomized, controlled study

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## Abstract

**Purpose** Transcutaneous posterior tibial nerve stimulation (TPTNS) for the treatment of overactive bladder syndrome (OAB), with or without urge urinary incontinence (UII) using electrodes imbedded in the fabric of a conventional sock and an attachable battery-operated stimulation device (ZIDA<sup>®</sup>—Exodus Innovations, Sufa, Israel), was compared for effectiveness and safety to a sham procedure in a prospective, blinded, randomized, controlled trial.

**Methods** Forty patients with diagnosed with OAB were recruited from a single site. There were two groups: a treatment group (21 patients, mean age 64), which used an active ZIDA<sup>®</sup> activation device (ZIDA) and a sham control group (SCG, 19 patients, mean age 72) randomized in a 1:1 ratio. After individual fitting of the sock and face-to-face instruction in the use of the device, patients in both groups self-administered the treatment once weekly for 30 min at home for a duration of 12 weeks. Prior to randomization and in Week 12, patients completed two 3-day bladder diaries and a quality-of-life (QOL) survey. Treatment success was defined as at least a 50% reduction in urgency voids with or without incontinence or at least a 30% reduction in 24-h frequency from baseline to Week 12. The key secondary endpoint was change in QOL from baseline to Week 12.

**Results** The success rate for the primary endpoint in the ZIDA group was 80% ( $n = 16/20$ ) versus 39% ( $n = 7/18$ ) in the SCG ( $p = 0.02$ ). For QOL, the least squares mean difference in change from baseline to Week 12 between the ZIDA and sham control arms total score was  $-12.7$  (95% CI  $-20.2$  to  $-5.1$ ). No significant adverse effects were observed.

**Conclusion** TPTNS using the ZIDA home-based stimulation device offers a safe and effective treatment for patients with OAB syndrome and improves QOL.

**Trial registration** TRN: NCT04470765.

**Keywords** Urinary bladder · Overactive · Incontinence · Transcutaneous nerve stimulation · Posterior tibial nerve

## Introduction

OAB with varying degrees of mixed urinary incontinence is a common urological problem that has multiple adverse effects on QOL [1–3]. Conservative treatment options for OAB consist of behavioral techniques with or without bio-feedback [4], pelvic muscle exercises [5] or pharmacotherapy [6]. Intravesical botulinum toxin injection [7, 8] and sacral neuromodulation [9, 10] have also been shown to be effective in selected patients, but these techniques are

expensive and require medical assistance or surgical intervention. Percutaneous posterior tibial nerve stimulation (PPTNS) is a well-recognized second-line treatment for the OAB [11–13] and studies have demonstrated that TPTNS is equally effective when compared to PPTNS [14–18]. TPTNS methodology has an inherent advantage over PPTNS. It is noninvasive and can be administered in the privacy of the home. Current TPTNS technology requires the judicious placement of indiscrete conventional skin electrodes typically by a medical professional. ZIDA obviates the need for the placement of the usual skin electrodes and instead integrates them seamlessly into the fabric of a conventional sock. The electrical stimulation is achieved by simply snapping the accompanying battery-powered stimulation device to the patient's sized-to-fit sock. The device itself can be individually controlled at the time of treatment to provide

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optimum electrical stimulation. The purpose of this study was to evaluate the efficacy and safety of ZIDA for the treatment of OAB.

## Methods

The trial was conducted in the United States at a single private medical center. Patients were recruited by either referral or advertisement. A detailed discussion with the patient regarding the treatment protocol followed receipt of informed consent. All patients were older than 21 years of age and met the criteria for OAB urgency syndrome [19]. In addition, enrollment required a score of greater than 60 on the International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms Module (ICIQ-MLUTS) or International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Modules (ICIQ-FLUTS) [20]. Participants being treated with anticholinergic or beta agonist medications underwent a 2-week washout period during which medications were discontinued. Exclusion criteria included pregnancy, lactation, or a planned pregnancy during the trial, administration of intravesical injection of botulinum toxin within 36 months of study enrollment, or treatment within the previous year with other forms neuromodulation for OAB. Patients with diabetic neuropathy, Guillain–Barré syndrome, chronic inflammatory demyelinating polyneuropathy (CIDP), multiple sclerosis, a primary diagnosis of stress urinary incontinence (SUI), urinary tract infection at baseline or any other documented lower urinary tract pathology were also excluded. Other exclusions included pacemakers or implantable defibrillators, participation in another research trial involving an investigational product in the previous 12 weeks, or inflamed, infected or otherwise compromised skin in the treatment area.

### Study design

Forty eligible patients, after providing informed consent and completing two 3-day bladder diaries and a QOL short-form questionnaire (OAB-q SF) [21] were randomized to either receive an active ZIDA device or a sham control.

### Transcutaneous stimulation

Patients in the ZIDA group were provided a working ZIDA to use at home once a week for 12 weeks. Each session lasted 30 min. Patients were in weekly telephone contact with a study coordinator to verify treatment compliance. ZIDA uses a traditional textile sock with integrally embedded electrodes and electronics (Exodus Innovations Ltd., Israel). Four sizes of elastic socks (x-large, large, medium, and small) allowed

for proper positioning of the electrodes according to the sock size of the patient. The electrodes are embedded in the sock so that the top electrode will be approximately 5 cm cephalad to the medial malleolus and the second electrode over the ipsilateral calcaneus (Fig. 1). ZIDA uses one standard AAA battery and stimulation circuitry to apply an electrical current between the electrodes. The electronic-embedded sock is connected to ZIDA via metal snaps (Fig. 2). The current is in the form of a monophasic square wave. The current is user-adjustable between 0.0 and 156 mA at 20 Hz. Patients were instructed to check the positioning of the electrode-embedded sock by increasing stimulation intensity until a motor or sensory response was elicited. Not all the patients, however, experienced a physiological response and those who did not were instructed to use maximum device output and proceed with treatment. Typical responses included movement of the toes (either the big toe or the smaller toes) and/or a tingling sensation. After confirmation of proper positioning, patients were instructed to decrease the intensity of the pulse to the point of comfort. They were advised that lowering the threshold below that of a motor or sensory response during treatment did not indicate a lack of effect.

### Sham transcutaneous stimulation

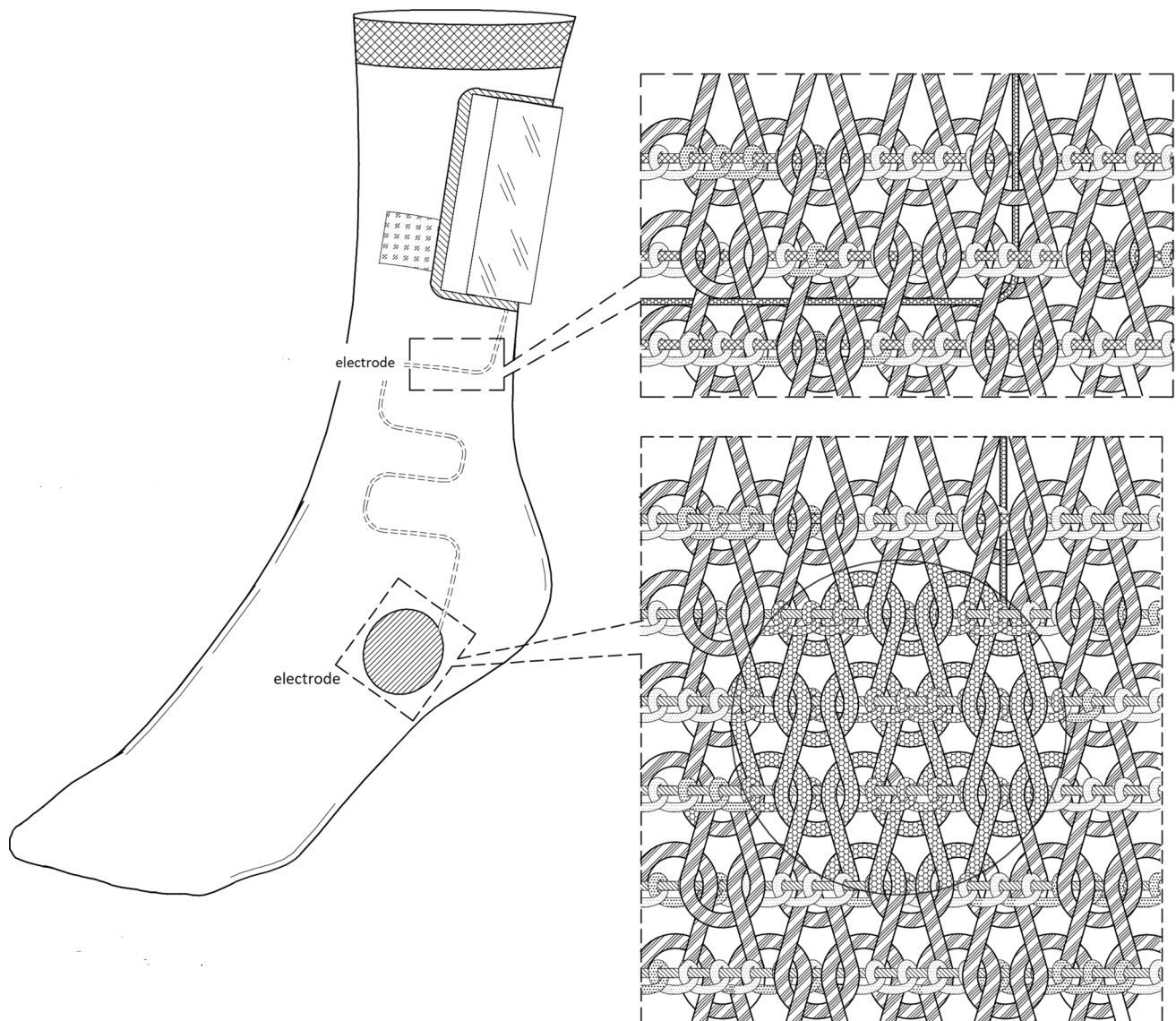
Patients in the SCG were provided with a sham device that was identical to ZIDA in appearance. When attached to the sock and switched on by the user a green operating light turned on as though to confirm that the device was operating normally. The green light automatically shut after the 30 min “treatment” similarly to ZIDA, however, in contrast to the ZIDA intervention group, no electrical stimulation was delivered. The sham group received the identical electrode-embedded sock as the ZIDA group, but the stimulating device was designed to appear to operate but did not deliver electrical stimulation. All patients including those in the sham group were also advised that lack of a motor or sensory response during treatment did not indicate a lack of effect.

### Assessment of subject blinding and subject-reported compliance

Subjects were asked what treatment they thought they received after the first week and at the end of the study. They were also asked about their compliance to the treatment protocol.

### Patient satisfaction

At the end of the study, subjects completed a questionnaire asking them to indicate their current satisfaction with ZIDA regarding its ease of use and improvement of their OAB symptoms while using ZIDA. Subjects were also asked how



**Fig. 1** Placement of electrodes/electronics integrally embedded into fabric

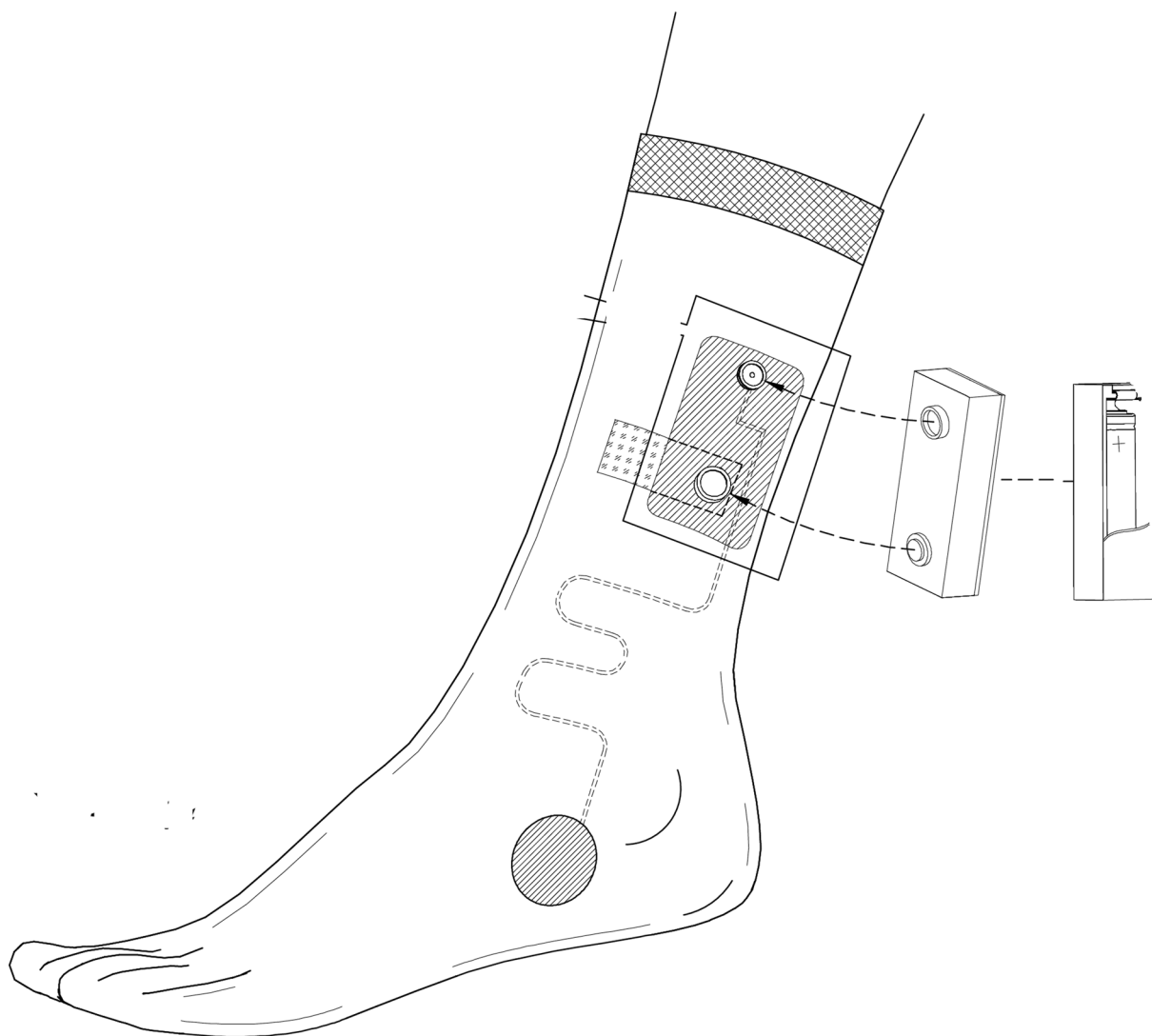
likely they were to recommend ZIDA to a family member or friend.

### Statistical evaluation

The sample size calculation was based on the clinical success rate assuming an effect size of 45%. Eighteen patients randomized to each group (total 36) were considered sufficient to demonstrate with 80% power a difference in clinical success rates between the ZIDA arm and the sham arm with a 5% two-sided significance level if the clinical success rate is 30% in the sham arm and 75% in the ZIDA arm. Accounting for a 5% drop out, the total sample size required was estimated to be 40. The randomization was 1:1 using random block sizes of 4, 6, or 8. The randomization list was

produced by a contract research organization, and a third party labeled the devices prior to distribution to the study center. The study center, principal investigator, and sponsor were blinded to the randomization assignment. After the database was locked, they were unblinded. Initially, enrollment was performed face-to-face by the principal investigator. Because of the Covid pandemic, the protocol was changed midstudy to enrollment via video conference. In addition to the written instructions for correct use of the device, each patient in each group received individual hands-on instruction in its proper use.

The primary efficacy variable, clinical treatment success, defined as at least a 50% reduction in urgency voids with or without incontinence or at least a 30% reduction in 24-h frequency voids from baseline to Week 12, was analyzed



**Fig. 2** The battery-powered device attached to the sock

using the modified intent to treat (mITT) analysis set. The mITT analysis set included all randomized subjects that started treatment and completed the Week 12 bladder diaries. Subjects completed two 3-day diaries at baseline and at Week 12. The occurrence of each void and the urgency associated with that void were recorded. The average 24-h frequency, the average number of urgency voids, and the average number of incontinence episodes over a 6-day period was calculated for each subject at baseline and at Week 12. The percent reduction from baseline to Week 12 in average 24-h frequency, average number of urgency voids per day, and average number of incontinence episodes per day were calculated for each subject. If the percent reduction in 24-h frequency was greater than or equal to 30% or the percent reduction in urgency voids was greater than or equal to 50% then the subject was considered a treatment success. A Chi-square test was used to compare the clinical treatment

success rates between the treatment arms. An overall two-sided significance level of 0.05 was used.

The secondary endpoint, QOL, was measured based on the total score from the QOL questionnaire OAB-q SF. There are 19 questions that participants score from 1 = 'none of the time' to 6 = 'all of the time'. The total score can range from 19 (best QOL) to 114 (worst QOL). Higher OAB-q SF scores indicate poorer quality of life, thus, a negative change (or decrease) from baseline indicates an improvement in quality of life. Mean changes from baseline in OAB-q SF total score were analyzed using a mixed-model for repeated measures (MMRM) approach. Restricted Maximum Likelihood estimation was used. The MMRM model included the baseline OAB-q SF total score as covariate, treatment group, time point, and treatment group-by-time point interaction as fixed effects, and subjects within treatment group as random effects. An unstructured covariance structure was used

to model the within-subject error and the Kenward–Roger approximation was used to estimate the degrees of freedom.

Exploratory endpoints of change from baseline to Week 12 in the number of urgency episodes, the number of incontinent episodes, or the 24-h frequency between the two treatment groups was examined using an analysis of covariance (ANCOVA) in the mITT population. A Chi-square test was used to compare the incontinence treatment success rates between the treatment arms.

At the end of the study, subjects in both groups completed a questionnaire asking them to indicate their current satisfaction with their respective devices from 1 = not satisfied to 10 = extremely satisfied, and for its ease of use with 1 = not easy to use 10 = extremely easy to use, and the improvement of their OAB symptoms while using the device with 1 = no improvement to 10 = extreme improvement. Subject satisfaction scores were compared between treatment groups using the Wilcoxon rank sum test. Subjects in both groups were also asked how likely they were to recommend their device to a family member or friends. The response to this question was compared between treatment groups using a Chi-square test. Two patients did not complete the trial (one patient in each group). The analysis was performed using all non-missing patients, with no imputation for missing data. An overall two-sided significance level of 0.05 was used.

## Results

The first subject signed informed consent on September 17, 2020, and started treatment on September 28, 2020. The last subject completed treatment on December 31, 2020. Allocation, randomization, and intervention results are summarized in Fig. 3. Table 1 displays the baseline demographics by treatment arm (ZIDA or SCG) for all subjects randomized.

### Primary efficacy endpoint

Table 2 displays the distribution by treatment arm of the baseline and Week 12 average 24-h frequency, average number of urgency voids per day, the average number of incontinence episodes per day, the percent reduction from baseline to Week 12 of 24-h frequency, urgency voids, and incontinence episodes. The number of treatment successes based on reduction in 24-h frequency, urgency voids and incontinence episodes are summarized at the bottom of the table. The two subjects missing Week 12 bladder diaries were not included in this analysis.

Patients in the ZIDA group had a larger overall decrease in 24-h frequency compared to patients in the SCG ( $p < 0.06$ ). 25% of patients in the ZIDA group had at least a 30% reduction in 24-h frequency compared to 0% of patients in the SCG ( $p = 0.048$ ). For urgency voids, the treatment success

rate in the ZIDA arm was 80% ( $n = 16/20$ ), significantly larger than the treatment success rate of 39% ( $n = 7/18$ ) in the SCG arm ( $p = 0.02$ ). All subjects that had at least a 30% reduction in 24-h frequency also had at least a 50% reduction in urgency voids. The incontinence success rate in the ZIDA group was 75%, significantly larger than the incontinence success rate of 33% in the SCG ( $p = 0.04$ ). Excluding subjects that had no incontinence episodes at both baseline and Week 12, the treatment incontinence success rates were 72% ( $n = 13/18$ ) in the ZIDA arm and 25% ( $n = 4/16$ ) in the sham arm ( $p = 0.02$ ). The primary endpoint of the study was met.

### Secondary efficacy endpoint

The key secondary endpoint was change in QOL from baseline to Week 12. Table 3 displays the distribution of QOL scores at baseline, Week 6 and Week 12 and the change from baseline to Week 12 stratified by treatment arm. The least squares mean difference in change from baseline to Week 12 between the ZIDA device and sham control groups for the QOL total score based on MMRM was  $-12.7$  (95% CI:  $-20.2$  to  $-5.1$ ). There was a significant improvement in QOL total score from baseline to Week 12 with ZIDA compared to SCG ( $p < 0.001$ ). Hence, the key secondary objective was met for ZIDA.

### Assessment of subject blinding and reported compliance

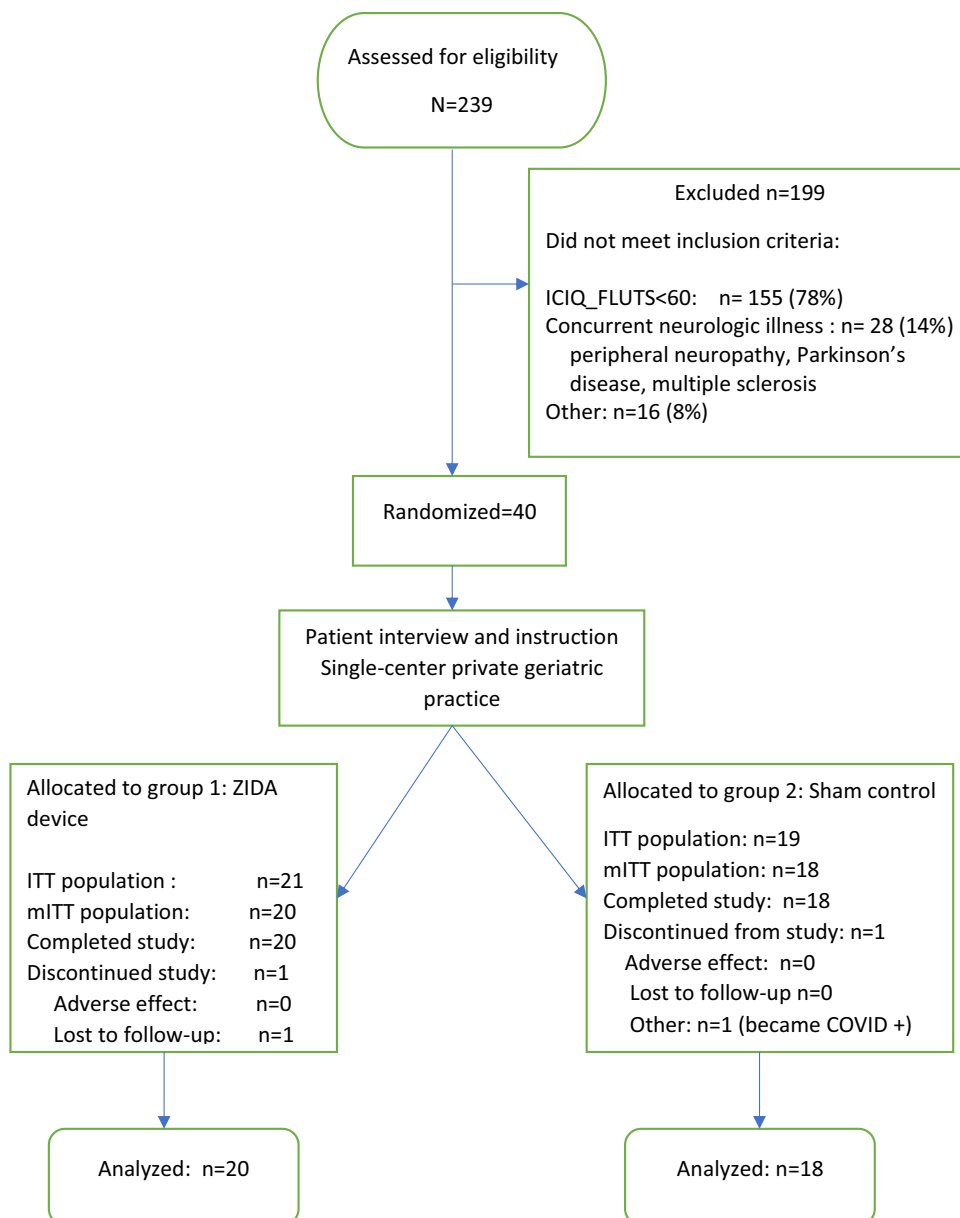
After the first treatment, about 50% of subjects in both arms thought that they were treated with ZIDA. After the last treatment, approximately 60% of subjects in both treatment arms thought that they were treated with ZIDA (Table 4). Almost half of the subjects on sham control thought after the first treatment that they were in the SCG but at the end of the study thought they were in the ZIDA group. Therefore, at both the beginning of the study and the end of the study the subjects were blinded to the treatment group. All subjects in both treatment arms reported in the results had a 100% compliance with weekly treatments.

### Subject satisfaction

The responses to the satisfaction survey are summarized by treatment group in Table 5. Subjects in the ZIDA arm reported significantly greater satisfaction with ZIDA and improvement of OAB symptoms than subjects in the SCG. All subjects in the ZIDA group reported a score of at least 6 for improvement of OAB symptoms. There was no difference in ease of use between the treatment groups.

Subjects were also asked how likely they were to recommend the ZIDA device to a family member or friend. Subjects in the ZIDA group were significantly more likely

**Fig. 3** Summary of allocation, randomization, and intervention



to definitely recommend the device compared to those in the sham control group, 79% versus 0%.

### Complications

Five adverse events were reported. One subject in the SCG reported suspected COVID-19 symptoms and general poor health and dropped out of the study at the end of Week 4. Two patients, both in the ZIDA group, developed a culture

positive urinary tract infection in weeks 3 and 4 that were felt to be nonrelated to the intervention. They were treated with antibiotics and became culture negative. Intervention was not interrupted. Two patients, both in the ZIDA arm, reported single episodes of foot pain, (Week 1 and Week 4) during or immediately after treatment. The symptoms resolved within 30 min of treatment cessation.

### Discussion

The results demonstrated significant improvement in all the measured parameters from baseline to the end of the 12-week trial period in the ZIDA group. Urgency voids



**Table 1** Demographic and baseline characteristics stratified by treatment group

Variable	Treatment arm		Total N = 40
	ZIDA device N = 21	Sham control N = 19	
<b>Gender</b>			
Female	18 (86%)	14 (74%)	32 (80%)
Male	3 (14%)	5 (26%)	8 (20%)
<b>Age (years)</b>			
Mean	64.4	72.7	68.4
Standard deviation	6.2	8.5	8.4
Median	64	73	68
Range	52, 75	58, 85	52, 85
<b>Race</b>			
White	19 (90%)	17 (89%)	36 (90%)
Hispanic	2 (10%)	2 (11%)	4 (10%)
<b>Education</b>			
High school graduate, diploma or equivalent	5 (24%)	0 (0%)	5 (13%)
Trade/technical/vocational training	0 (0%)	4 (21%)	4 (10%)
Bachelor's degree	7 (33%)	6 (32%)	13 (33%)
Master's degree	9 (43%)	7 (37%)	16 (40%)
Doctorate degree	0 (0%)	2 (11%)	2 (5%)
<b>Smoker</b>			
Yes	1 (5%)	1 (5%)	2 (5%)
No	20 (95%)	18 (95%)	38 (95%)
<b>Level of activity</b>			
Sedentary	1 (5%)	4 (21%)	5 (13%)
Lightly active	8 (38%)	7 (37%)	15 (38%)
Active	9 (43%)	7 (37%)	16 (40%)
Very active	3 (14%)	1 (5%)	4 (10%)

and incontinent episodes were significantly reduced and were translated into marked improvement in QOL. The 24-h frequency in the treatment group was also markedly reduced when compared to the SCG. The present study, however, has several limitations. Patient numbers were small, making the study prone to a type II error. In addition, the limited number of male participants while providing suggestive evidence of effectiveness requires follow-up with a larger treatment group. The design of posterior tibial nerve stimulation (PTNS) studies including a sham intervention is problematic and the response rate of patients in the sham groups of various studies have been variable. The

sham intervention in this study was similar to those in other PPTNS and TPTNS studies [12, 22] in that sham transcutaneous stimulation without simulated sensory stimulation was used in preference to providing minimal stimulation because of the concern that even limited stimulation could be sufficient to produce a neuromodulatory effect. In the SumiT trial [12], improved results were reported in 20.9% of the sham group, while in the study of Booth, et al. [23], the reported improvement of urinary incontinence in the sham group was 46%. The variability may be related in part to the subjective nature of patient responses and the fact that they are self-reported. Although validated questionnaires have been published; nevertheless, it is the patient who ultimately decides just how “urgent” was his feeling to void in relationship to the real or perceived intervention. This study was performed during the peak of the COVID pandemic when restricted mobility outside the home was the rule. It is conceivable that restricted patient movement and the nearly constant proximity to bathroom facilities while at home may have, for example, impacted the perception of urgency.

This study was powered only to identify a difference between the treatment and sham groups. A longer follow-up is required to determine the sustainability of the improvement. There is no “standard” agreed upon protocol for TPTNS treatment and protocols using twice a week treatment for 12 weeks [24] and daily treatment for three months have been reported [25]. The “30 min/week for 12 week” protocol was chosen because it was suggested as the “typical” treatment regimen in previously published PPTNS and TPTNS studies by the European Urology Association, 2018 [26]. Patient compliance with the treatment protocol was self-reported by patients. These issues should be addressed in future studies which include true oversight of treatment frequency and duration. Additional prospective studies are also required to assess the optimal frequency and duration of treatment as well as the parameters of stimulation that maximize the effect. The feasibility of using the ZIDA device for SUI was not investigated in this study since as in other TPTNS studies patients with a primary diagnosis of SUI were excluded [22, 27]. However, since other studies have suggested that electrical stimulation techniques may be an effective treatment for SUI [28, 29], additional studies using ZIDA may be warranted for this indication as well.

Placement of conventional electrodes in the anatomically correct location is critical to the success of treatment but may be difficult—especially for elderly patients. Thus,

**Table 2** Baseline and Week 12 average bladder diary by treatment group

Variable	ZIDA device N = 21*		Sham control N = 19*	
	Mean (Std)	Median (min, max)	Mean (Std)	Median (min, max)
24-h frequency				
Baseline	11.7 (3.6)	10.2 (8.2, 21.3)	11.2 (3.3)	11.3 (8, 19)
Week 12	9.9 (4.4)	8.3 (5.7, 22.7)	9.9 (2.3)	10 (6.8, 14.5)
Change from baseline to W12	- 2.0 (1.7)	- 2.1 (- 5.7, 1.3)	- 0.8 (1.8)	- 0.8 (- 4.3, 1.8)
% Reduction baseline to W12	18% (0.1)	19% (- 7%, 40%)	10% (0.1)	8% (- 20%, 28%)
Total daily urgency voids				
Baseline	5.2 (3.7)	3.8 (1, 14.2)	4.7 (2.9)	4 (1, 10.2)
Week 12	2.1 (2.3)	1.1 (0, 7.8)	3.6 (3.2)	2.8 (0.5, 11.7)
Change from baseline to W12	- 3.3 (2.7)	- 2.8 (-9.7, 1.2)	- 1.3 (3.4)	- 1.1 (- 6.3, 6.8)
% Reduction baseline to W12	62% (0.3)	71% (- 18%, 100%)	13% (0.8)	40% (- 175%, 83%)
Total daily incontinence				
Baseline episodes	1.2 (0.8)	1.3 (0, 3)	1 (0.7)	1 (0, 2.3)
Week 12	0.3 (0.3)	0.2 (0, 1)	0.6 (0.7)	0.3 (0, 2.2)
Change from baseline to W12	- 1.0 (0.7)	- 1.2 (- 2.2, 0)	- 0.4 (0.6)	- 0.2 (- 1.8, 0.3)
% Reduction baseline to W12	71% (0.3)	79% (0%, 100%)	40% (0.4)	33% (- 20%, 100%)
No incontinence week 12	7 (35%)		4 (22%)	
Treatment success (24-h frequency)	5 (25%)		0 (0%)	
Treatment success (urgency)	16 (80%)		7 (39%)	
Treatment success (incontinence)	15 (75%)		6 (33%)	

\*At Week 12, one sham control subject and one ZIDA device subject did not have bladder diary data. These subjects are excluded from Week 12 data

**Table 3** OAB-q SF total score over time stratified by treatment group

Variable	ZIDA device N = 21*		Sham control N = 19*	
	Mean (std)	Median (min, max)	Mean (std)	Median (min, max)
Baseline	74.3 (10)	73 (61, 102)	77.4 (11.1)	73 (63, 102)
Week 6	53.1 (12.7)	52 (29, 76)	66.5 (11)	65 (47, 88)
Week 12	45.6 (13.1)	46.5 (21, 68)	59.8 (14.4)	58 (33, 84)
Reduction from baseline to Week 12**	29.1 (16.5)	26 (2, 77)	17.7 (12.8)	19 (- 8, 35)

\*At Weeks 6 and 12, one sham subject did not have QOL data and at Week 12, one ZIDA device subject did not have QOL data. These subjects were omitted from the analysis

\*\*Change from baseline to Week 12 was calculated for each subject. Negative scores indicated a reduction in total QOL scores. Lower total QOL scores indicate improvement in QOL. The table presents the average reduction in QOL scores from baseline to Week 12

previous studies have required participation of medical professionals. The ZIDA sock, in addition to electronic fibers and the electrodes themselves, also incorporates elastic fibers in the knit, thus insuring a snug fit. While offering several sizes to allow for the proper placement of the electrodes; nevertheless, it might be expected that electrode placement might be less than optimal compared to electrode placement

by a trained professional. TPTNS studies previously reported used stimulating devices that delivered stimulation in the range of up to 20 mA [13]. The ZIDA device and stocking can provide up to 150 mA at 20 Hz and thus may compensate for slight deviations from the optimal placement of the electrodes.

More than 30 million people suffer from symptoms of OAB in the United States alone. Behavioral therapy may



**Table 4** Subject assessment of treatment arm stratified by actual treatment arm

Assessment of treatment arm	Actual treatment*	
	ZIDA device ( <i>N</i> = 21)	Sham control ( <i>N</i> = 19)
Subject response after first treatment		
ZIDA device	10 (48%)	9 (47%)
Sham control	11 (52%)	10 (53%)
Subject response after last treatment		
ZIDA device	13 (62%)	12 (63%)
Sham control	7 (33%)	6 (32%)
Missing	1 (5%)	1 (5%)
Both time points paired assessment		
ZIDA–ZIDA	7 (33%)	3 (16%)
ZIDA–sham	3 (14%)	5 (26%)
ZIDA–missing	0 (0%)	1 (5%)
Sham–ZIDA	6 (29%)	9 (47%)
Sham–sham	4 (19%)	1 (5%)
Sham–missing	1 (5%)	0 (0%)

\*Percentages are calculated out of the total for the actual treatment arm

be effective initially but requires high patient motivation. The exact mechanism of PTNS—transcutaneous or percutaneous and sacral nerve stimulation (SNS) is unclear but since bladder function is controlled by the nerves of the sacral plexus and since the posterior tibial nerve

(PTN) is a distal branch of the sciatic nerve it appears that retrograde stimulation of the PTN can provide effective neuromodulation of afferent pathways to the bladder. Currently, patients who do not respond to conservative or pharmacological treatments have no recourse other than invasive treatments that require administration by trained medical personnel. These treatments range in invasiveness from PPTNS and intravesical detrusor injection of onabotulinumtoxin A to SNS [9]. PPTNS, while minimally invasive, nevertheless, requires a commitment to physician's office visits. Patients are placed in the supine and a 34-gauge stainless steel needle is inserted cephalad to the medial malleolus. A stick-on electrode is placed on the same leg near the arch of the foot and the needle and electrode are connected to a low voltage stimulator. Intravesical detrusor injection and SNS are more aggressive treatment options for patients with OAB who have failed less aggressive measures. The SNS device is surgically implanted above the buttocks and a lead sends electrical impulses via the sacral nerves to the bladder. Although effective, implanted SNS is expensive and can be associated with morbidity [9]. In contrast to these treatments, ZIDA offers patients suffering from OAB, an effective treatment that can be easily applied at home, without medical assistance, and with no serious adverse effects. This study, to our knowledge, is the first to demonstrate the effectiveness of an easy-to-use, totally self-administered, TPTNS device in a homecare setting for the treatment of OAB.

**Table 5** Subject self-reported satisfaction with the ZIDA device treatment group

Question	ZIDA device ( <i>N</i> = 21)		Sham control ( <i>N</i> = 19)		<i>P</i> value
	Mean (Std)	Median (min, max)	Mean (Std)	Median (min, max)	
Current satisfaction: 1 = not satisfied to 10 = extremely satisfied	7.5 (1.9)	8 (3, 10)	4.3 (2.7)	3 (1, 9)	<0.001
Ease of use: 1 = not easy to 10 = extremely easy	7.7 (1.5)	7 (6, 10)	8.1 (1)	8 (6, 9)	0.386
Improvement of OAB symptoms: 1 = no improvement to 10 = extreme improvement	8.3 (1.1)	8 (6, 10)	5.1 (2.2)	5 (1, 8)	<0.001
Likelihood of recommending ZIDA device <i>n</i> (%) <i>p</i> < 0.001					
Definitely	15 (79%)		0 (0%)		
Likely	5 (26%)		13 (68%)		
Not likely	1 (5%)		6 (32%)		

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**Author contributions** YO: project development and manuscript preparation. RC: patient examination and data recruitment.

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## Declarations

**Conflict of interest** Y. Orlin: consultant physician, advisory board ZIDA Ltd, ZIDA device patent holder. R. Cava: financial stipend as chief investigator.

**Ethical approval** All the procedures performed in studies involving human participants were in accordance with the ethical standards of the WCG IRB (IRB00000533).

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