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Beyond the bladder: poor sleep in women with overactive bladder syndrome

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Abstract

BACKGROUND—Nocturnal bladder symptoms and sleep disruption commonly coexist in middle-aged and older women. Although sleep disruption is often attributed to nocturnal bladder symptoms in women with overactive bladder syndrome, nonbladder factors also may influence sleep in this population. Many women with overactive bladder are eager to identify nonpharmacologic strategies for both bladder symptoms and sleep disruption, given the potential adverse effects of sedative and anticholinergic bladder medications in this population.

OBJECTIVES—To provide greater insight into the complex relationship between nighttime overactive bladder symptoms and sleep disruption, and to evaluate the effects of a guided slow-paced respiration intervention on sleep outcomes in women with overactive bladder.

STUDY DESIGN—We conducted an ancillary study within a randomized trial of slow-paced respiration in women with overactive bladder symptoms. Ambulatory community-dwelling

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women who reported ≥3 episodes/day of urgency-associated voiding or incontinence were randomized to use either a portable biofeedback device (RESPeRATE; Intercure, Ltd) to practice guided slow-paced respiration exercises daily for 12 weeks (N=79) or an identical-appearing device programmed to play nonrhythmic music without guiding breathing (N=82). At baseline and after 12 weeks, bladder symptoms were assessed by voiding diary, sleep duration, and disruption were assessed by sleep diary corroborated by wrist actigraphy, and poor sleep quality was determined by a Pittsburgh Sleep Quality Index global score >5.

RESULTS—Of the 161 women randomized, 31% reported at least twice-nightly nocturia, 26% nocturnal incontinence, and 70% poor sleep quality at baseline. Of the 123 reporting any nighttime awakenings, 89% averaged 1 or more nighttime awakenings, and 83% attributed at least half of awakenings to using the bathroom. Self-reported wake time after sleep onset increased with increasing frequency of nocturnal bladder symptoms (P=.01 for linear trend). However, even among women without nocturia, average sleep quality was poor (Pittsburg Sleep Quality Index global score mean of 7.3; 95% confidence interval, 6.0–8.6). Over 12 weeks, women assigned to slow-paced respiration (N=79) experienced modest improvements in mean nocturnal voiding frequency (0.4 fewer voids/night), sleep quality (1.1 point score decrease), and sleep disruption (1.5% decreased wake time after sleep onset). However, similar improvements were detected in the music control group (N=81), without significant between-group differences.

CONCLUSIONS—Many women with overactive bladder syndrome experience disrupted sleep, but not all nocturnal awakenings are attributable to bladder symptoms, and average sleep quality tends to be poor even in women without nocturia. Findings suggest that clinicians should not assume that poor sleep in women with overactive bladder syndrome is primarily caused by nocturnal bladder symptoms. Guided slow-paced respiration was associated with modest improvements in nocturia frequency and sleep quality in this trial, but the results do not support clinician recommendation to use this technique over other behavioral relaxation techniques for improving sleep.

Keywords

insomnia; nocturia; overactive bladder; relaxation exercises; sleep; slow-paced respiration

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Overactive bladder (OAB), a syndrome defined by recurrent urges to urinate (urgency), usually with increased daytime and nighttime frequency, with or without incontinence, affects up to 20% of women,[1–3] with symptoms tending to worsen with age.[4–8] One potential consequence of OAB is sleep disruption,[2,3] with many women reporting nocturnal bladder symptoms such as urgency, voiding, or incontinence associated with waking up at night.[5,9] Among women with OAB, nocturnal bladder symptoms often are assumed to be the primary cause of poor sleep quality or interrupted sleep.

Nevertheless, many nonbladder-related factors also can influence sleep in midlife and older women, and the relationship between poor sleep and nighttime OAB symptoms may be complex or bidirectional. OAB is associated with increased levels of perceived stress and anxiety[10,11] and autonomic dysfunction[12,13] that may contribute independently to poor sleep. Sensory hyperarousal in women predisposed to insomnia may make them more

sensitive to bladder fullness and lead to more awakenings to urinate; alternatively, women may awaken for other causes, perceive an urge to urinate, and decide to use the bathroom.

In clinical studies, many women reporting improvements in nocturia with OAB treatment also report improvements in sleep.[14] However, most studies of sleep disturbance in women with OAB have relied on self-report summary questionnaires,[15] and few studies have examined whether sleep disruption among women with OAB is caused primarily by nocturnal bladder symptoms or other factors that can influence sleep in midlife and older age. To address this question, we incorporated multiple sleep measures into a randomized trial of guided slow-paced respiration in women with OAB.[16]

The Controlling Urgency through Relaxation Exercises (CURE) study[17] was a randomized trial that examined the effects of guided slow-paced respiration, hypothesized to improve perceived stress and associated autonomic dysfunction,[18,19] as a potential behavioral treatment for OAB symptoms.[12,13,20,21] Slow-paced respiration was practiced using RESPeRATE (Intercure, Ltd, Tel Aviv, Israel), a commercially available guided-breathing biofeedback device approved by the Food and Drug Administration for adjunctive treatment of hypertension, based on evidence that regular practice of slow breathing reduces high blood pressure associated with excess sympathetic cardiovascular autonomic tone.[18,19,22–28] The guided slow-paced respiration program also operates on a mobile app platform, 2breathe,[29] for use as a sleep aid, based on the hypothesized effects of reducing perceived stress and decreasing sympathetic activity, which may improve sleep.[30,31]

In this ancillary analysis of the CURE study, first we examine sleep duration, disruption, and quality in association with nocturnal bladder symptoms and examine the proportion of women's nocturnal awakenings that may be attributable to bladder symptoms vs other physical or contextual triggers. Second, because guided slow-paced respiration has the potential to address psychophysiologic mechanisms relevant to sleep[30,31] and has been recommended as a strategy to promote sleep,[34–36] we also examine the effects of this paced respiration intervention on sleep quality, duration, and disruption.

Materials and Methods

Eligibility and recruitment

Methods for the CURE trial have been published previously.[17] Participants were eligible if they documented an average of at least 3 urgency-associated voiding or incontinence episodes per day in a validated 3-day screening voiding diary[37–39] and agreed to forgo use of other standard clinical treatments for OAB during the trial. Women were excluded if they had a current urinary tract infection or hematuria, reported 3 or more urinary tract infections per year, were pregnant in the past 3 months, had chronic pulmonary conditions that might interfere with breathing exercises, or had complex urologic histories or major neurologic conditions causing urinary symptoms.[17] Women with sleep apnea or other sleep disorders were not specifically recruited or excluded. All participants provided informed consent before enrollment. The study protocol was approved by the institutional review board of the University of California San Francisco (#14–13319) and registered at ClinicalTrials.gov

(registered July 2014, initial patient enrollment: September 2014,NCT02202031, https://clinicaltrials.gov/ct2/show/NCT02202031).

Randomization and blinding

Eligible women were assigned randomly in equal ratios to slow-paced respiration or to a control arm by computer algorithm, using randomly permuted block sizes of 2, 4, and 6. Women were instructed to use their device for a minimum of 15 minutes per day for 12 weeks, consistent with recommended use of the device to manage hypertension. Participants in both arms could use the device at a time of day that was convenient to them. In the paced-respiration group, the device sensed respiratory rate using a respiration sensor belt, and headphones attached to the device emitted musical tones designed to guide the user into slowing breathing and prolonging expiration. Participants randomized to the control group were given an identical-appearing device reprogrammed to play quiet nonrhythmic music while monitoring spontaneous breathing. Unlike participants in the paced-respiration group, participants in the control group did not receive feedback with regard to their respiratory rate.

Measurements

Overactive bladder symptoms were assessed using a validated 3-day voiding diary at baseline and 12 weeks.[37–39] After receiving written and face-to-face instruction, participants recorded bedtime, awakening time, and every episode of urinary urgency, voiding in the toilet, or urine leakage and also indicated the severity of urgency associated with each episode using the validated Indevus Urgency Severity Scale.[39] Data were abstracted by trained analysts and subsequently checked by a second analyst blinded to intervention assignment. Nocturia was defined as any voiding in the toilet after the participant went to bed for the night and before getting up in the morning. Nocturnal incontinence was defined as any involuntary leakage of urine during the same time.

Sleep quality was assessed at baseline and 12 weeks using the Pittsburgh Sleep Quality Index (PSQI), a 19-item validated questionnaire[40,41] used in previous urologic studies,[9,14,15] which generates component scores for sleep quality, latency, duration, habitual efficiency, and disturbance, along with sleep medication use and daytime dysfunction. From these components, a global score of 0–21 is generated; scores >5 conventionally indicate poor overall sleep quality.[41–43]

Sleep duration and disruption were assessed using the validated Pittsburgh Sleep Diary, in which participants recorded their time in bed, time trying to fall sleep, time spent in bed before falling asleep, and number of nocturnal awakenings after first falling asleep on a nightly basis.[44–46] Participants completed sleep diaries during the same 3-day periods as voiding diaries. If awakenings were reported, participants indicated the reason from a list of common factors: bathroom use, noises, child, bed partner, discomfort, physical complaint, other, or no special reason.

Wrist actigraphy (Ambulatory Monitoring, Inc, Ardsley, NY) data were collected in a convenience subset of participants at baseline and at 12 weeks, over the same 3 nights as the Pittsburgh Sleep Diary, to confirm data on sleep duration and disruption generated from the

sleep diary. Actigraphy data (from a Mini Motionlogger Actigraph model AAM-32) were uploaded to the manufacturer's Action4 software with an autoscoring sleep analysis program based on a commonly used validated scoring algorithm.[47,48] Sleep diary and actigraphy data were abstracted then scored by analysts blinded to intervention assignment to calculate total sleep time (TST hours) as an objective measure of sleep duration and wake time after sleep onset (WASO minutes standardized for each woman as a percentage of her TST) as an objective measure of sleep disruption.

Demographic and clinical history was assessed by screening questionnaires. Study coordinators reviewed prescription and over-the-counter medication bottles. Trained coordinators also measured height and weight at baseline to calculate body mass index. Anxiety and depression symptoms were measured using the Center for Epidemiology Studies Depression Scale[49] and the Hospital and Anxiety Depression Scale[50] (Table 1).

Statistical analyses

Before analyses, it was determined that a sample of 150 women (allowing for missing data) is powered to detect between-group differences of 0.26, 0.30, and 0.28 standard deviations in WASO, TST, and PQSI, which represent small-to-moderate effects. Differences in baseline demographic and clinical characteristics between randomization arms were compared using independent samples Wilcoxon rank-sum or χ^2 tests as appropriate. Summary statistics were reported as mean and standard deviation or median and interquartile range (IQR) depending on skewedness. Changes in sleep outcomes from baseline to 12 weeks were assessed using least mean square estimates and confidence intervals derived from analysis of covariance models of change in outcomes adjusted for baseline value. *P* values were obtained using Winsorized (98–99th percentile) values for change in highly skewed variables such as PSQI sleep-onset latency minutes, WASO as a percentage of TST, and PSQI habitual sleep efficiency as a percent of time in bed. Missing sleep diary data were assumed to be missing at random, rather than assuming that participants were either treatment failures or successes.

Analyses of change in actigraphyderived TST and WASO% over 12 weeks were then performed using least squared means from repeated measures mixed models; no additional adjustments were indicated after inspection of baseline differences between groups in the subset with actigraphy data. Natural logarithm–transformed WASO% was used to accommodate skewness in WASO data. Intraclass correlation coefficients were calculated to evaluate stability and possible first-night effects due to wearing the device on the wrist.

To evaluate associations between nocturnal bladder symptoms and sleep outcomes, additional least square mean estimates of sleep quality, duration, and disruption, stratified by nocturnal bladder symptoms, were derived from separate repeated analysis of covariance mixed models using data from baseline and 12 weeks. These models were adjusted for intervention group, time (baseline and 12 weeks), interaction with time and intervention, as well as characteristics identified a priori as being likely to influence sleep outcomes (age, body mass index, menopausal status, and select medications such as benzodiazepines and non-benzo sedatives). All analyses were performed using SAS, version 9.4 (SAS Institute, Cary, NC).

Results

The CURE trial enrolled 161 women (79 to paced respiration, 82 to music control) between September 2014 and August 2017. All participants completed at least 1 sleep measure, and there was minimal loss to follow-up (Figure 1). No significant differences in mean age, baseline PSQI score, or baseline frequency of nocturnal urgency symptoms were detected between women with and without complete sleep diary data (P>.05 for all). Intervention adherence did not differ substantially between the paced respiration and music control arms over 12 weeks. On average, 95% of women were at least 80% adherent to ≥15 minutes of device use per day throughout the study, and average minutes per day of use reported at the 12-week timepoint was 16.8 in the intervention and 16.4 in the control group (P=.17).

Baseline demographic information, medication use, and frequency of nocturnal bladder symptoms are shown in Table 1. At baseline, 49% of participants averaged at least 1 moderate-to-severe urgency episode per night on their voiding diaries, 10% had at least 1 incontinence episode per night, 67% had at least 1 episode of nocturia, and 31% indicated at least 2 episodes of nocturia per night. Of the 123 participants who averaged 1 or more awakenings per night at baseline, 83% attributed more than half of awakenings to needing to use the bathroom, and 59% attributed 80% of awakenings to the same cause. Thirty percent of women reported 2 or more bathroom-related awakenings per night on average (Table 2). At baseline, the median PSQI overall sleep quality score among all participants was 7 (IQR, 5–10), with 112 (70%) experiencing clinically significant poor sleep quality as indicated by PSQI global score >5. Based on PSQI sleep diaries, median TST was 7.0 hours (IQR, 6.3–7.8), and median WASO% was 3.8% (IQR, 1.8–7.6). No significant between-group differences in baseline sleep parameters were observed.

Over 12 weeks, women in both groups reported modest improvements in nocturnal voiding frequency, PSQI global score, and sleep diary-derived WASO% (Table 3). However, no significant between-group differences or within-subject change over time in any sleep-related outcomes were observed. In the subset of women with baseline poor sleep (PSQI >5), PSQI scores improved by an average of 1.8 in the intervention and 1.6 points in the control group (Table 4); however, the absence of between-group differences persisted for all sleep outcomes.

Wrist-actigraphy data were collected from 69 women, including 28 who contributed both baseline and follow-up data. Intraclass correlation coefficients of 0.58 for TST and 0.70 for WASO% at baseline demonstrated moderate stability over 3 nights. No significant between-group differences in improvement of TST (P=.66) or WASO% (P=.12) over 12 weeks were detected by actigraphy.

In mixed-model analyses using data from the combined participant sample and from both baseline and 12 weeks, greater frequency of nocturnal voiding and incontinence episodes was associated with greater WASO% (P=.01 for linear trend, Table 5). For example, adjusted mean WASO% was 2.5% among women with no nocturia compared with 6.7% among women with 2 or more nocturia episodes per night. However, no significant associations were observed between nocturnal bladder symptom frequency and PSQI global score or

diary-based sleep duration (Table 5). In additional exploratory analyses, we re-examined nocturnal bladder symptom frequency as a continuous variable and detected additional significant associations between the number of urgency episodes and greater PSQI sleep quality score (β-coefficient=0.43, P=.04) as well as greater WASO% (β-coefficient=1.47, $P \leq .01$) (Supplemental Table 1).

Discussion/comment

Principal findings

In this sample of women with moderate-to-severe OAB symptoms, most women averaged at least 2 nocturnal awakenings per night in their diaries, and had PSQI global scores in the "poor" range (>5), despite reporting sleep duration of 6–8 hours. Greater frequency of nocturnal bladder symptoms was associated with more time awake during the night. However, women also attributed many awakenings to nonbladder factors. PSQI sleep quality scores still averaged >7 among women without nocturia, suggesting that even if nocturnal bladder symptoms were treated successfully, at least one half would continue to report poor sleep quality. Thus, our findings indicate that many women with OAB experience a phenotype of disrupted, poor sleep, but may not attribute their poor sleep to bladder symptoms.

With regard to the trial interventions, our results suggest that despite interest in paced respiration as a sleep aid, women with OAB are no more likely to experience improvements in sleep using this technique on a daily basis, compared with spending equivalent time using an alternate relaxing activity such as listening to quiet music. Although sleep duration, quality, and disruption improved modestly among women practicing slow-paced respiration, no significant between-group differences were detected in sleep outcomes measured with diary, questionnaire, or actigraphy.

Results in the context of what is known

In addition to cross-sectional studies showing associations between nocturia and poor sleep,[4,15] poor sleep was associated with development of new-onset nocturia among individuals without nocturia at baseline in 2 prospective observational studies, suggesting a bidirectional relationship.[51,52] In one urodynamics study, individuals with cystometrogram-confirmed detrusor overactivity were more likely to have detrusor contractions before awakening compared with individuals with primary insomnia or healthy controls.[53]

Regarding explanations for the lack of between-group change in sleep observed in our study, the music-listening control intervention that may have promoted relaxation, thereby modifying pathways of perceived stress and autonomic dysfunction that contribute to either bladder symptoms or poor sleep. Alternatively, previous research examining the same slow-paced respiration program has suggested that effects on sympathetic activity may be short-term rather than lasting over a 24-hour period,[23] suggesting the effects of slow-paced respiration on sleep may be diminished if not practiced directly before bedtime. Relaxation is only one of several components used in combination with nonpharmacologic treatments for chronic insomnia. Other cognitive and behavioral interventions such as sleep restriction,

stimulus control, and cognitive restructuring may be important for reducing sleep disturbance.[57]

In several small studies, patients with self-reported insomnia[58] or pulmonary arterial hypertension[59] have reported improved sleep with slow-paced respiration exercises performed before bed; however, control interventions were not included. In 2 randomized controlled trials of paced respiration for menopausal vasomotor symptoms, sleep improved more in the intervention group compared with music[60] and sleep quality improved compared with fast shallow breathing.[61] Sleep was a secondary outcome in these 2 studies, however, and differences in sleep quality were small in magnitude and PSQI scores were similar to our sample.[61]

Strengths and limitations

This research benefits from detailed, concurrent, night-by-night, assessment of bladder symptoms and sleep outcomes in an ethnically diverse, community-dwelling sample of women with OAB. A limitation of this ancillary study is that the parent trial was designed and powered to capture changes in 24-hour bladder outcomes rather than nocturnal bladder episodes specifically, and women were not required to have poor sleep quality or sleep disruption to enroll. However, we did not detect significant between-group differences in change in sleep outcomes in sensitivity analyses confined to the subset of women with poor baseline sleep quality (PSQI >5). The confidence intervals around our estimates of intervention effects exclude between-group differences greater than 30 minutes in TST or 1 point in PSQI global score, which arguably represent small-to-moderate effects, suggesting reasonable statistical power. A limitation of the PSQI global score is a lack of a validated threshold for designating respondents as having minimal clinically significant improvement, although PSQI improved 2–3 points[48,62–66] in several other studies of behavioral sleep interventions. When completing sleep diaries, participants may not have been able to provide accurate estimates of their time spent awake after going to bed; however, previous research using the Pittsburgh Sleep Diary has demonstrated strong correlations between dairy-based estimates of wake-time-after-sleep onset and actigraphy-based detection of wakeful movements.[46] In addition, it may have been difficult for participants to determine the etiology of each of their nocturnal awakenings, and we could not objectively verify whether awakenings were attributable to bladder symptoms or other causes.

Conclusion

Overall, these results highlight the complexity of sleep disturbance in women with OAB, who have high rates of poor sleep quality and sleep disruption even in the absence of nocturnal bladder symptoms. When evaluating women with OAB who experience poor sleep, clinicians may consider inquiring about factors other than nocturia or nighttime incontinence disrupting sleep.

Given the potential adverse effects of sedative medications and anticholinergic bladder medications, many women with OAB continue to seek nonpharmacologic strategies for sleep disturbance, including behavioral relaxation exercises. However, nonpharmacologic interventions for sleep, such as slow-paced respiration, should not be widely adopted

without rigorous evaluation for efficacy. Our results suggest that although women with OAB practicing slow-paced respiration may experience modest improvements in sleep, paced respiration may not offer unique benefits for sleep over other potentially relaxing practices such as listening to music.

Uncited References

32,33,54,55,56

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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AJOG at a Glance

Why was the study conducted?

This ancillary study of sleep outcomes in a randomized trial of slow-guided breathing for overactive bladder syndrome examined relationships between nocturnal overactive bladder syndrome symptoms and sleep quality.

Key findings

Women with more nocturia reported more sleep disruption, but even women without nocturia had poor sleep quality, and many nocturnal awakenings were attributed to nonbladder factors. Sleep quality and nocturia improved over 12 weeks based on sleep and bladder diaries as well as actigraphy, but slow-guided breathing was not superior to music control in improving sleep outcomes.

What does this add to what is known?

Previous studies have attributed poor sleep in women with overactive bladder syndrome largely to nocturia, but our findings highlight the potential importance of nonbladder factors in influencing sleep quality regardless of nocturia. Our findings do not support superior efficacy of paced respiration recommended elsewhere as a behavioral technique to improve sleep.

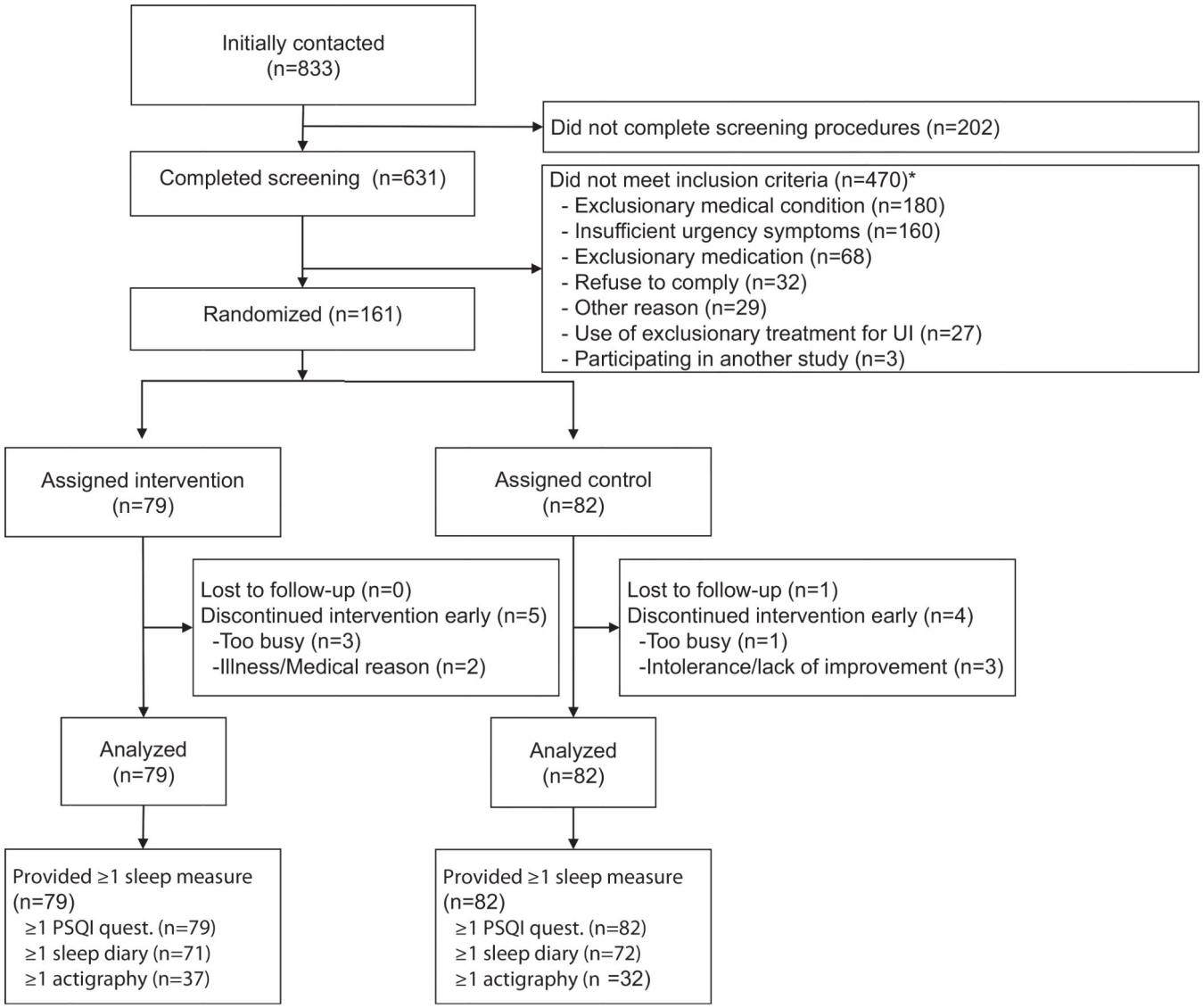

FIGURE 1: Flowchart of participant recruitment, randomization, and follow-up

*Participants could have more than 1 reason for exclusion.

PSQI, Pittsburgh Sleep Quality Index; *UI,* urinary incontinence.

Savoie et al. Beyond the bladder: poor sleep in women with overactive bladder syndrome. Am J Obstet Gynecol 2020.

TABLE 1

Baseline demographic and clinical characteristics, by intervention assignment

	All participants (N=161)	Paced respiration (N=79)	Music control (N=82)	*P* value[a]
Age, y	61.0 (±11.1)	60.4 (±11.4)	61.7 (±10.9)	.42
Race/ethnicity				
Non-Latina White	89 (55.3%)	40 (50.6%)	49 (59.8%)	.53
Non-Latina African-American	24 (14.9%)	12 (15.2%)	12 (14.6%)	
Latina White	18 (11.2%)	12 (15.2%)	6 (7.3%)	
Asian/Asian-American	14 (8.7%)	8 (10.1%)	6 (7.3%)	
Mixed	13 (8.1%)	5 (6.3%)	8 (9.8%)	
Unknown	3 (1.9%)	2 (2.5%)	1 (1.2%)	
Married	66 (41.0%)	35 (44.3%)	31 (37.8%)	.40
Gynecologic history				
Hysterectomy	25 (15.5%)	14 (17.7%)	11 (13.4%)	.45
No menses in the past year	130 (80.7%)	62 (78.5%)	68 (82.9%)	.47
Parity				
0	38 (23.6%)	19 (24.1%)	19 (23.2%)	.30
1–2	63 (39.1%)	35 (44.3%)	28 (34.1%)	
3 or more	60 (37.3%)	25 (31.6%)	35 (42.7%)	
Self-reported general health				
Excellent	47 (29.2%)	19 (24.1)	28 (34.1)	.29
Very Good	67 (41.6%)	36 (45.6%)	31 (37.8%)	
Good	40 (24.8%)	22 (27.8%)	18 (22.0%)	
Fair	7 (4.3%)	2 (2.5%)	5 (6.1%)	
Selected medical conditions[b]				
Diabetes mellitus	7 (4.3%)	2 (2.5%)	5 (6.1%)	.27
Vaginal atrophy[c]	4 (2.5%)	1 (1.3%)	3 (3.7%)	.33
Peripheral neuropathy	5 (3.1%)	2 (2.5%)	3 (3.7%)	.68
Frequency of using sleep medicine				

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	All participants (N=161)	Paced respiration (N=79)	Music control (N=82)	*P* value[a]
Not during past month	118 (73.3%)	56 (70.9%)	62 (75.6%)	.30
Less than once a week	15 (9.3%)	6 (7.6%)	9 (11.0%)	
Once or twice a week	6 (3.7%)	5 (6.3%)	1 (1.2%)	
3 or more times a week	22 (13.7%)	12 (15.2%)	10 (12.2%)	
Selected current medications				
Selective serotonin or norepinephrine reuptake inhibitor	20 (12.4%)	9 (11.4%)	11 (13.4%)	.70
Tricyclic antidepressant	7 (4.3%)	4 (5.1%)	3 (3.7%)	.66
Other antidepressant	3 (1.9%)	2 (2.5%)	1 (1.2%)	.54
Non-loop diuretic	13 (8.1%)	8 (10.1%)	5 (6.1%)	.35
Sedative-hypnotic	3 (1.9%)	1 (1.3%)	2 (2.4%)	.58
Opioid	7 (4.3%)	7 (8.9%)	0 (0.0%)	<.01
Anticholinergic or sympathomimetic	4 (2.5%)	3 (3.8%)	1 (1.2%)	.29
Thyroid medication	25 (15.5%)	13 (16.5%)	12 (14.6%)	.75
Health-related habits				
Any current smoking[c]	3 (1.9%)	0 (0.0%)	3 (3.7%)	.08
Any weekly alcohol use	78 (48.4%)	34 (43.0%)	44 (53.7%)	.18
Physical exam measures[c]				
Body mass index, kg/m^2	28.1 (±6.8)	27.8 (±5.8)	28.4 (±7.7)	.97
Nocturnal urinary symptoms[c]				
Urgency incontinence episodes/night	0.2 (±0.4)	0.2 (±0.4)	0.2 (±0.4)	.48
Urinations in the toilet/night	1.3 (±1.0)	1.3 (±1.0)	1.4 (±1.0)	.24
Pittsburgh Sleep Quality Index				
Global sleep quality score	7.3 (±3.5)	7.4 (±3.8)	7.1 (±3.2)	.62
Habitual sleep efficiency, %	86.6 (±20.8)	86.9 (±24.3)	86.3 (±16.9)	0.89
Sleep disturbances, sum	10.6 (±4.7)	10.3 (±5)	10.8 (±4.4)	0.54
Sleep latency, min	15 [10–30]	15 [10–30]	15 [5–30]	0.92
Sleep diary characteristics[c]				
Total sleep time, h	7.0 [6.2–7.8]	6.9 [6.1–7.7]	7.1 [6.4–7.8]	0.21

	All participants (N=161)	Paced respiration (N=79)	Music control (N=82)	*P* value[a]
Wake after sleep onset, %	3.8 [1.8–7.6]	3.4 [1.6–6.5]	4.8 [1.8–8.5]	0.24
Anxiety and depression symptoms[d]				
Hospital Anxiety and Depression Scale–Anxiety Subscale	6.5 (±3.9)	6.7 (±4.0)	6.2 (±3.8)	0.37
Center for Epidemiologic Studies Depression Scale	8.0 [4.0–16.0]	9.0 [4.0–20.0]	8.0 [4.0–13.0]	0.50

Data are presented as number (%), mean (± standard deviation), or median [interquartile range].

[a] *P* values were calculated using Wilcoxon rank-sum or χ^2 tests, as appropriate

[b] Based on questions in the Health History form ("Has a doctor or other healthcare providers ever told you that you had, or currently have, any of the following...")

[c] Data are missing for 2 participants for vaginal atrophy, 1 participant for current smoking, 1 participant for body mass index, 1 participant for frequency and severity of urinary symptoms at night, 25 women for total sleep time, and 27 women for wake after sleep onset

[d] Cognitive anxiety was assessed with the Hospital Anxiety and Depression Scale, which includes a 7-item Anxiety Subscale[52] for which scores range from 0 (less) to 21 (more anxiety). Depressive symptoms were assessed by the Center for Epidemiologic Studies Depression scale,[50] a 20-item measure for which scores range from 0 (less) to 60 (more depression symptoms).

TABLE 2

Number and percentage of participants reporting nocturnal awakenings at baseline, by frequency and self-reported cause of awakening

	Episodes per night (average over 3 diary days)				
	0	**0.1–0.9**	**1–1.9**	**2–2.9**	**3+**
Total awakenings for any reason	4 (2.9%)	11 (8.0%)	49 (35.5%)	43 (31.2%)	31 (22.5%)
Awakenings “to use the bathroom”	14 (10.1%)	24 (17.4%)	59 (42.8%)	32 (23.2%)	9 (6.5%)
Awakenings due to “noises, child, or bed partner”	96 (69.6%)	25 (18.1%)	11 (8.0%)	3 (2.2%)	3 (2.2%)
Awakenings due to “discomfort or a physical complaint”	97 (70.8%)	27 (19.7%)	10 (7.3%)	0 (0.0%)	3 (2.2%)
Awakenings due to “another or no special reason”	78 (56.5%)	38 (27.5%)	15 (10.9%)	6 (4.3%)	1 (0.7%)

Row percentages are shown.

TABLE 3

Change in frequency of nocturnal voiding and sleep outcomes from baseline to 12 weeks, by intervention group

	Paced respiration (N=79)		Music control (N=82)		Between-group difference	
	Change (95% CI)[a]	*P* value	Change (95% CI)[a]	*P* value	Difference (95% CI)[a]	*P* value
Nocturnal voiding episodes per night (by voiding diary)	−0.4 (−0.6 to −0.2)	<.01	−0.3 (−.4 to −0.1)	<0.1	−0.1 (−0.4 to 0.1)	.28
PSQI global score[b]	−1.1 (−1.7 to −0.6)	<.01	−1.2 (−1.7 to −0.7)	<.01	0.1 (−0.7 to 0.8)	.84
PSQI habitual sleep efficiency, %[c]	1.9 (−1.1 to 4.8)	.03	1.0 (−1.9 to 3.9)	.52	0.8 (−3.3 to 5.0)	.28
PSQI sleep disturbances sum	−2.2 (−3.1 to −1.4)	<.01	−2.8 (−3.6 to −1.9)	<.01	0.5 (−0.7 to 1.7)	.38
PSQI sleep latency, min[c]	−3.1 (−5.8 to −0.4)	<.01	−2.4 (−5.0 to 0.3)	.02	−0.8 (−4.5 to 3.0)	.66
Total sleep time in hours (by sleep diary)	0.0 (−0.3 to 0.3)	.97	0.0 (−0.3 to 0.3)	.90	0.0 (−0.4 to 0.4)	.95
Wake after sleep onset percentage (by sleep diary)[c]	−1.5 (−3.1 to 0.1)	<.01	−1.2 (−2.8 to 0.5)	<.01	−0.3 (−2.6 to 2.0)	.80

CI, confidence interval; *PSQI*, Pittsburgh Sleep Quality Index.

[a] Least square mean estimates and confidence intervals derived from analysis of covariance models. All models adjusted by baseline values

[b] PSQI score inversely related to sleep quality; improvement shown as negative change

[c] *P* values using Winsorized (98–99th percentile) values, change values using raw values.

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TABLE 4

Change in frequency of nocturnal voiding and sleep outcomes from baseline to 12 weeks, among participants with poor baseline sleep quality (defined by Pittsburgh Sleep Quality Index global score >5)

	Paced respiration (N=55)		Music control (N=57)		Between-group difference	
	Change (95% CI)[a]	*P* value	Change (95% CI)[a]	*P* value	Difference (95% CI)[a]	*P* value
Nocturnal voiding episodes per night (by voiding diary)	−0.4 (−0.6 to −0.2)	<.01	−0.2 (−0.4 to −0.0)	.05	−0.2 (−0.5 to 0.1)	.24
Pittsburgh Sleep Quality Index (PSQI) global score[b]	−1.8 (−2.5 to −1.1)	<.01	−1.6 (−2.3 to −0.93)	<.01	−0.2 (−1.1 to 0.8)	.77
PSQI habitual sleep efficiency percentage[c]	5.5 (1.6 to 9.3)	<.01	2.6 (−1.1 to 6.3)	.20	2.8 (−2.5 to 8.2)	.23
PSQI sleep disturbances sum	−2.3 (−3.4 to −1.2)	<.01	−2.9 (−4.0 to −1.9)	<.01	0.7 (−0.9 to 2.2)	.41
PSQI sleep latency, min[c]	−4.0 (−7.8 to −0.1)	<.01	−3.0 (−6.7 to 0.8)	.03	−1.0 (−6.3 to 4.3)	.62
Total sleep time in hours (by sleep diary)	0.1 (−0.3 to 0.4)	.74	0.2 (−0.2 to 0.5)	.41	−0.1 (−0.6 to 0.4)	.73
Wake after sleep onset percentage (by sleep diary)[c]	−1.9 (−4.0 to 0.2)	.01	−1.2 (−3.3 to 0.9)	.01	−0.7 (−3.6 to 2.3)	.99

CI, confidence interval; *PSQI*, Pittsburgh Sleep Quality Index.

[a] Least square mean estimates and confidence intervals derived from analysis of covariance models. All models adjusted by baseline values

[b] PSQI score inversely related to sleep quality; improvement shown as negative change

[c] *P* values using Winsorized (98–99th percentile) values, change values using raw values.

TABLE 5

Average self-reported sleep quality, duration, and disruption, by nocturnal frequency of bladder symptoms[a]

	Frequency of nocturnal voiding and incontinence episodes (regardless of association with urgency)				
	0 episodes/night	**0.01–0.99 episodes/night**	**1.00–1.99 episodes/night**	**≥2.00 episodes/night**	***P* value for trend[b]**
Pittsburgh Sleep Quality Index global sleep quality score	7.3 (6.0–8.6)	7.3 (6.0–8.6)	7.0 (5.7–8.3)	7.7 (6.5–9.0)	.46
Total sleep time in hours (by sleep diary)	6.9 (6.3–7.5)	6.7 (6.1–7.3)	7.2 (6.6–77)	7.0 (6.4–7.5)	.23
Wake after sleep-onset percentage (by sleep diary)[b]	2.5 (−0.5–5.6)	3.7 (0.6–6.9)	2.8 (−0.3–5.9)	6.7 (3.9–9.6)	.01
	Frequency of moderate-to-severe nocturnal urgency sensations (regardless of voiding or incontinence)				
	0 episodes/night	**0.01–0.99 episodes/night**	**1.00–1.99 episodes/night**	**≥2.00 episodes/night**	***P* value for trend[b]**
Pittsburgh Sleep Quality Index global sleep quality score	7.0 (5.8–8.3)	7.4 (6.2–8.7)	7.5 (6.2–8.8)	8.2 (6.8–9.7)	.11
Total sleep time in hours (by sleep diary)	6.9 (6.4–7.5)	6.8 (6.3–7.4)	7.0 (6.4–7.5)	7.1 (6.4–7.7)	.37
Wake after sleep onset percentage (by sleep diary)[b]	3.2 (0.4–6.0)	4.3 (1.4–7.2)	6.6 (3.6–9.5)	5.3 (1.8–8.8)	.06

Data are presented as least square mean estimates (95% confidence intervals) derived from separate repeated analysis of covariance mixed models, using data from both baseline and 12 weeks. All models adjusted for by intervention group, time (baseline and 12 weeks), interaction with time and intervention, age, body mass index, menopausal status, and select medications including sedative use.

[a] Adjusted least square mean estimates and confidence intervals derived from model using raw values

[b] *P* values for linear trend derived from model using logarithmically transformed sleep parameters.