

Original Research

Effects of behavioral treatment and pelvic floor muscle training on overactive bladder syndrome: a randomized control trial

 Mayanni Magda Pereira Matias^{*} , Fátima Faní Fitz, Márcia Maria Gimenez, Letícia de Azevedo Ferreira , Maria Augusta Tezelli Bortolini , Rodrigo de Aquino Castro 

Department of Gynecology, Universidade Federal de São Paulo, São Paulo, Brazil



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ABSTRACT

Objective: To evaluate and compare the effects of behavioral treatment (BT) combined with pelvic floor muscle training (PFMT) versus BT and PFMT provided in isolation in women with overactive bladder syndrome (OAB). **Methods:** Prospective, randomised, and controlled clinical trial with concealed allocation including 110 women with OAB were randomized into three groups: BT+PFMT, BT, and PFMT. The intervention consisted of 3-month program: BT+PFMT group received an educational program with lifestyle modifications, urgency suppression techniques, bladder training, and motivation strategies, combined with PFMT; BT and PFMT groups carried out the isolated interventions described above. The primary outcome was OAB cure defined by OAB-V8 questionnaire score <8 and the absence of episodes of urgency urinary incontinence in the voiding diary. Secondary outcomes were urinary symptoms, pelvic floor muscle (PFM) function, outpatient and home adherence to the exercise sets, and subjective cure.

Results: Higher objective cure was observed in the BT+PFMT group compared with isolated PFMT and BT in both per protocol and intention-to-treat analyses. In the per protocol analysis, women receiving BT+PFMT were 5.5 times more likely to achieve objective cure than PFMT (OR 5.5; 95% CI 1.6–18.7) and 4.1 times more likely than BT (OR 4.1; 95% CI 1.3–12.8). For the intention-to-treat analysis considering losses as uncured, BT+PFMT remained more effective than PFMT alone (OR 3.4; 95% CI 1.2–9.5). All groups improved PFM function (power, endurance, fast contractions, $p < 0.001$ for all), however PFMT and PFMT+BT had better PFM function compared to BT group ($p < 0.001$ for all).

Conclusions: The combination of BT with PFMT were more effective than isolated therapies in the management of female OAB.

Introduction

Overactive bladder syndrome (OAB) is characterized by urinary urgency, with or without urge incontinence, usually accompanied by nocturia and increased urinary frequency, in the absence of urinary tract infection or other obvious pathology.¹ OAB generates a vicious cycle of anxiety and suffering related to the possible loss of urine, causing social isolation, decreased productivity, shame, frustration, and low self-esteem.² Increased urinary frequency affects around 85 % of patients, urinary urgency in 54 %, ³ UUI in 30 %;⁴ enuresis and nocturia in 55 %.⁵

Physical therapy aims to correct voiding patterns, improve the ability to suppress urgency and, thus, increase bladder capacity⁶ and decrease

the frequency and severity of UI. It involves lifestyle changes, counseling or educational programs, bladder training, techniques for suppressing urinary urgency and pelvic floor muscle (PFM) exercises to inhibit irritative bladder symptoms and muscular strength training.^{7,8} The literature presents a variety of physical therapy protocols for female UI: using bladder training,^{9–12} pelvic floor muscle training (PFMT) with biofeedback (BF)^{9,11} or without BF,^{13–15} and guided lifestyle changes¹⁴; evaluated in diverse populations presenting SUI, UUI, and MUI,^{9–13} and OAB;^{9,10,14,15} with intervention time ranging from six to 12 weeks^{9,10,12,13,15} up to two years¹¹ of follow-up.

Newman and Wein propose an approach to UI through behavioral treatment (BT)⁶ which includes an educational program that aims to

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^{*} Corresponding author at: Department of Gynaecology, Federal University of São Paulo, Brazil.

E-mail addresses: mayanni.magda@gmail.com (M.M.P. Matias), fanifitz@yahoo.com.br (F.F. Fitz), marciamariagimenez@gmail.com (M.M. Gimenez), leticia_aze@hotmail.com (L.A. Ferreira), maria.augusta@gmail.com (M.A.T. Bortolini), rodrigo.castro@uol.com.br (R.A. Castro).

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promote knowledge of voiding anatomy and physiology and the behavior of the PFM in bladder functioning, guidance on positioning and voiding habits, and identification of the main risk factors responsible for UI. Lee and Oh report that women with OAB should perform the bladder inhibition technique with phasic PFM contractions and self-distraction when they feel the strong and urgent desire to void.¹⁶ PFMT uses selective and repeated voluntary muscle contractions followed by their relaxation, which increase urethral resistance, prevent urine leakage, and inhibit detrusor contractions, being an option for OAB therapy.^{6,17,18}

While the literature is broad, physical therapy protocols usually do not add BT for OAB management, which opens a venue for therapy optimization. This study aims to verify the effects of BT techniques proposed by Newman and Wein⁶ combined with PFMT, and to compare it with BT and PFMT provided in isolation in women with OAB.

Methods

Study design

This is a single-centre prospective, randomised and controlled clinical trial. The intervention consists of three months of supervised physical therapy. Assessments were performed pre- and at the end of treatment, and included structured interviews, application of questionnaires, voiding diary, and physical and gynaecological examinations (supplementary material 1).

Research site

The study was conducted at the Urogynecology and Vaginal Surgery clinic, Department of Gynecology, Federal University of São Paulo (UNIFESP), Brazil, from April 2020 to January 2023, after approved by the local Research Ethical Board and registered at ClinicalTrials.gov NCT03331081.

Recruitment

Women candidates for the study were assessed for eligibility in two stages: (1) women with urinary symptoms were assessed by an urogynecologist who performed the clinical examination, and they were instructed to fill out the three-day urinary diary; then, they were referred to the physical therapy sector where the Overactive Bladder Questionnaire V8 (OAB-V8)¹⁹ was administered and conservative treatment was offered; (2) the physical therapist specialized in pelvic floor (PF) rehabilitation (M.M.P.M.) provided guidance on the location and function of the PFM through verbal explanations and anatomical illustrations; taught patients how to contract the PFM through bi-digital per-vaginal palpation.^{20–22} Finally, the patients able to correctly contract the PFM and with at least grade 1 muscle strength on the Oxford scale (PERFECT system)^{23,24} were invited to participate in the study and to sign an informed consent form.

Inclusion criteria

We included women over 18 years old who had: at least one episode of UI, urinary frequency ≥ 8 per day and episodes of nocturia ≥ 1 on the three-day voiding diary, OAB-V8 score ≥ 8 ¹⁹; glycated hemoglobin ≤ 5.7 %; post-void residue < 100 ml by ultrasound measurement; and PFM strength grade ≥ 1 by Oxford scale.^{23,24}

Non-inclusion and exclusion criteria

Women were excluded if they had neurological and/or chronic degenerative diseases, women with impaired cognition unable to comprehend and follow instructions and make their own decisions to participate in the study, inability to complete the voiding diary, and

when the investigators could not visually observe or feel by bidigital vaginal palpation the PF contraction. Moreover, we did not included women with cardiac pacemakers, decompensated diabetes, pregnancy, abnormal genital bleeding, and POP extending beyond the vaginal introitus, on use of anticholinergic drugs, tricyclic antidepressants or topical hormonal therapy in the six months preceding the study. Patients who were not candidate for the study were referred to an urogynecologist for care. Exclusion criteria were non-adherence to treatment programs, desire for another type of treatment, need to abandon treatment for personal reasons, and pregnancy discovered during treatment.

The participants were randomly allocated to the study groups: combined behavior therapy and pelvic floor muscle training (BT+PFMT); isolated behavior therapy (BT); and isolated pelvic floor muscle training (PFMT).

Randomization/blinding

Randomization was performed by an independent physical therapist (F.F.F.) using per block online randomization software (<http://randomization.com>).²⁵ Participants were not blinded to the treatment received. The physical therapist responsible for the treatment (M.M.P.M.) did not participate in data collection and/or statistical analysis. All investigators involved in data collection and data and/or statistical analysis were blinded to the group allocation.

Study groups

BT group

Behavior therapy group received an educational program with information about the risk factors for urinary leakage; about the PFM and bladder anatomy and function, and the interplay between the PFM and bladder functioning in the micturition control. Moreover, the patients received orientation about lifestyle modifications, instructions about urinary urgency suppression techniques, as well as bladder training (Supplementary material 2).

PFMT group

PFMT group was treated with PFM exercises performed in the outpatient clinic and at home (Supplementary material 3).

BT+PFMT group

Participants received a combined BT and PFMT intervention using the same protocols as received by the BT and PFMT groups (Supplementary material 2 and 3).

Interventions

The program consisted of 12 weeks of home and outpatient intervention. Individual outpatient sessions supervised by an experienced physical therapist every two weeks were performed, for a total of six outpatient sessions. The PFMT and BT programs lasted 20 min each; and the PFMT + BT group program lasted 40 min. Additionally, the patients were instructed to perform their exercise programs at home.

Outpatient sessions

PFMT

PFMT and BT+PFMT groups performed the exercises with supervision and feedback about the PFM contraction provided based on perineal observation; the patients were instructed to maintain the PFM contraction by verbal command.

Patients performed PFMT in six outpatient sessions under physical therapist guidance following the protocol by Bø et al.²⁰ One set consisted of 10 maximum voluntary contractions of 6 to 10 s duration progressively increased as: each contraction was held for 6 s in the 1st month, 8 s in the 2nd month, and 10 s in the 3rd month with double-time rest

between each contraction. Each set of pelvic exercises were followed by three to five fast contractions in a row progressing from three contractions in the 1st month, four contractions in the 2nd month, up to five fast contractions in the 3rd month). The protocol also included modifications in the positions which exercises were performed during the study, being in supine in the 1st month, sitting in the 2nd month, and standing position in the 3rd month (Supplementary material 3).

BT

BT group received an educational program with information about the anatomy of the muscles at the bottom of the pelvis and the function of the PFM (using illustrative figures), the bladder function (vesical filling and emptying phases), the role of the PFM for the bladder function and the mechanism by which the voluntary contraction of the PFM can postpone the urinary desire and habits (adequate urinary frequency) and the risk factors for urinary leakage.

Moreover, BT involved orientation about lifestyle modifications such as voiding positioning, eliminating bladder irritants from the diet, managing fluid intake, weight control, bowel regulation, smoking cessation, and time voiding; instructions about urgency suppression techniques as mental distraction techniques, use mental imagery and self-motivation statements, quick flicks PFM contractions, and the use of deep and slow breathing, with nasal inhalations and oral exhalations; bladder training: patients are encouraged to hold urine for 30 min beyond the initial emptying interval, with progressive increase by 15 to 30 min per week, depending on the patient's tolerance, with the goal of a voiding interval of 3.5 to 4 h; and the orientation about motivation strategies: self-adhesive labels to be placed in strategic locations at home or in the work environment, as reminder to carry out the proposed program.^{6,26,36} See bladder training protocol in the Supplementary material 2.

In each of the outpatient sessions, a new component of the bladder training protocol was addressed, any doubts about the instructions already received were clarified and patients were encouraged to follow the protocol guidelines.

Home exercises

The participants would perform their assigned program at home. PFMT and BT + PFMT groups of patients were encouraged to perform three sets of 10 repetitions daily at home following the protocol by Bø et al.,²⁰ and to record the number of sets completed per day using an exercise diary.

Primary outcome measure

Primary outcome was the OAB objective cure rate defined as a composition of clinical findings using two instruments: OAB-V8 score <8 and absence of episodes of UUI in the three-day voiding diary.

Secondary outcome measures

The instruments with the best psychometric properties (validity, reliability, and responsiveness to change) were selected for each outcome.

Urinary symptoms

Urinary symptoms were assessed using the OAB-V8¹⁹ and the three-day voiding diary.²⁷ The questionnaire includes eight questions that assess lower urinary tract symptoms (LUTS) based on the degree of discomfort reported. The score for each answer varies from 0 (not at all uncomfortable) to 5 (very uncomfortable), reaching 40 points in total, being considered positive for OAB when the score is equal to or greater than eight points.¹⁹ The quantification of LUTS and pads usage were obtained through the voiding diary records.²⁷

PFM function

PFM function was assessed by vaginal palpation and quantified according to the New PERFECT scheme. PFM strength was assessed by the Oxford Grading Scale (scores of 0–3). Endurance was expressed as the length of time, for up to 10 s, that a maximal vaginal contraction could be sustained until the muscle started to fatigue. The fast contraction variable was the number of fast maximal contractions (up to 10 s) that could be repeated.²⁴

Frequency of the outpatient sessions

Monitored by the physical therapist, attendance was expressed as the number of attended sessions out of the six sessions planned according to our protocol.

Frequency of home exercises

The number of completed exercise sets was recorded in an exercise diary²⁸ as the mean of the number of exercise sets per month performed during the 3-month therapy for both PFMT and BT+PFMT groups. The patients should perform the minimum of 1 set per day/2 or more days a week to the protocol, otherwise, they would be excluded from the study. We expected a total of 30 sets of exercises per month as 100 % adherence (excluding the outpatient sessions sets). The adherence to the techniques proposed in bladder training protocol (PFMT+BT and BT groups) were assessed by patient self-report on the occasion of the outpatient sessions.

Subjective cure

Subjective cure was measured by asking how the patient felt about their urinary symptoms after the treatment. The only two response options available were “satisfied” and “dissatisfied.” Answering “satisfied” meant that the patient did not want a different treatment. Answering “dissatisfied” indicated that the patient wanted a different treatment than the initial one.²⁷

Statistical analysis

The sample size was calculated to compare the effects of 12-week BT combined with PFMT versus BT and PFMT used in isolation on urinary symptoms assessed by OAB-V8. No previous data investigated equal protocol and outcome. Therefore, a pilot study was conducted with 10 participants in each group to estimate the effect difference and distribution of data. The mean and standard deviation of the scores of the OAB-V8 for the pilot groups were BT (8.4 ± 7.3), PFMT (7.5 ± 9.7), and PFMT+BT (6.1 ± 5.3). A standard deviation of 2.2 was estimated for a difference of 2 points in the questionnaire after the comparison among the three groups. The statistical test used was the one-way ANOVA, using a type I error of 0.05 (Bonferroni correction), a type II error of 0.2, and a study power of 80 %, 26 patients were needed in each group. We assumed losses of 0 to 25 %.

Data were organized using an electronic MS-Excel spreadsheet (MS-Office 2013 version) and the results obtained with the Statistical Package for the Social Sciences version 25.0 (IBM). Data were presented as median (25th–75th percentile) and percentage. The Likelihood ratio test was used for the variables race and education, and Chi-square test for marital status.

Objective and subjective cure rates comparison were assessed with Chi-square test and Univariate logistic regression model. Intention-to-treat (ITT) and per protocol (PP) analyses were performed for both outcomes. ITT analyses were performed considering the total randomized sample with imputation of uncured or non-satisfied when appropriate for those participants who dropped out before the study ends; and PP analyses were performed considering only participants who had completed 3 months of treatment. To compare the groups over time in relation to urinary symptoms and PFM function, the analysis of variance (ANOVA) model was used for repeated measures and with rank transformation because the variables do not present a Gaussian distribution. A value of $p < 0.05$ was considered significant.

Results

We included and randomized 110 patients. Of those, 26 women were excluded (dropout rate of 23.6 %) due to non-adherence to the therapy, other health problems or family issues. Eight-four women completed the study: BT (n = 28), PFMT (n = 30), and BT combined with PFMT (n = 26) (Fig. 1). Patients who did not complete the treatment were referred to the urogynecologist.

Baseline demographic and clinical characteristics

Baseline demographic and clinical characteristics are presented in Table 1. The groups differ only for the education variable (Table 1).

Primary outcome

Objective cure rate

The objective cure rate for OAB was higher in the BT+PFMT group compared to the isolated PFMT and BT groups in the PP analysis ($p = 0.006$), and in the ITT analysis considering those lost to follow-up as cured patients ($p = 0.004$) (Table 2). Considering the worst-case scenario in which those lost to follow-up was uncured patients, the BT+PFMT group showed better results only in relation to the PFMT group ($p = 0.044$) (Table 2), meaning that a patient who received BT combined with PFMT had 3.4 times more chance to be cured compared to a patient receiving only PFMT for OAB ($p = 0.025$).

When only the participants who completed the follow-up were analyzed (PP), one patient who received the combination of treatments had 5.5 and 4.1 times more chances of objective cure compared to a patient who received isolated PFMT ($p = 0.005$), and isolated BT ($p = 0.017$), respectively.

Secondary outcomes

Urinary symptoms – OAB-V8 questionnaire

The groups showed a reduction in questionnaire scores at the end of the treatment (time $p < 0.001$) irrespective of the group ($p = 0.235$), with similar reduction in the three groups (interaction $p = 0.050$), demonstrating the therapeutic effects of the three modalities (Table 3).

Urinary symptoms – voiding diary

The study groups showed a reduction of the daytime urinary frequency, urgency, UII, nocturia, and in the use of the pads at the end of the treatment (time $p < 0.001$ for all). The combination of therapies (PFMT+BT) showed greater reduction compared to isolated therapies regarding daytime frequency (interaction group $\times$ time, $p = 0.013$). The reduction of urgency (interaction $p = 0.287$), UII (interaction $p = 0.097$), nocturia (interaction $p = 0.775$), and the use of the pads (interaction $p = 0.461$) were similar in the three study groups (Table 4).

PFM function

There is a difference in the PF power and endurance among the groups (group: $p = 0.031$ and $p = 0.001$, respectively), with PFMT and PFMT+BT groups showing higher improvement at the end of treatment compared to BT group.

All groups presented increased power, muscular endurance, and fast contractions over time (time, $p < 0.001$ for all); however, the PFM function (power, endurance, and fast contractions) was better in the PFMT and PFMT+BT groups compared to BT group (interaction, $p < 0.001$ for all variables) (supplementary material 4).

Frequency of outpatient sessions

The frequency of attended outpatient sessions varied between five to six sessions, being no different between the groups ($p = 0.923$). In the PFMT group, 27 (90 %) patients attended six sessions; in the BT+PFMT

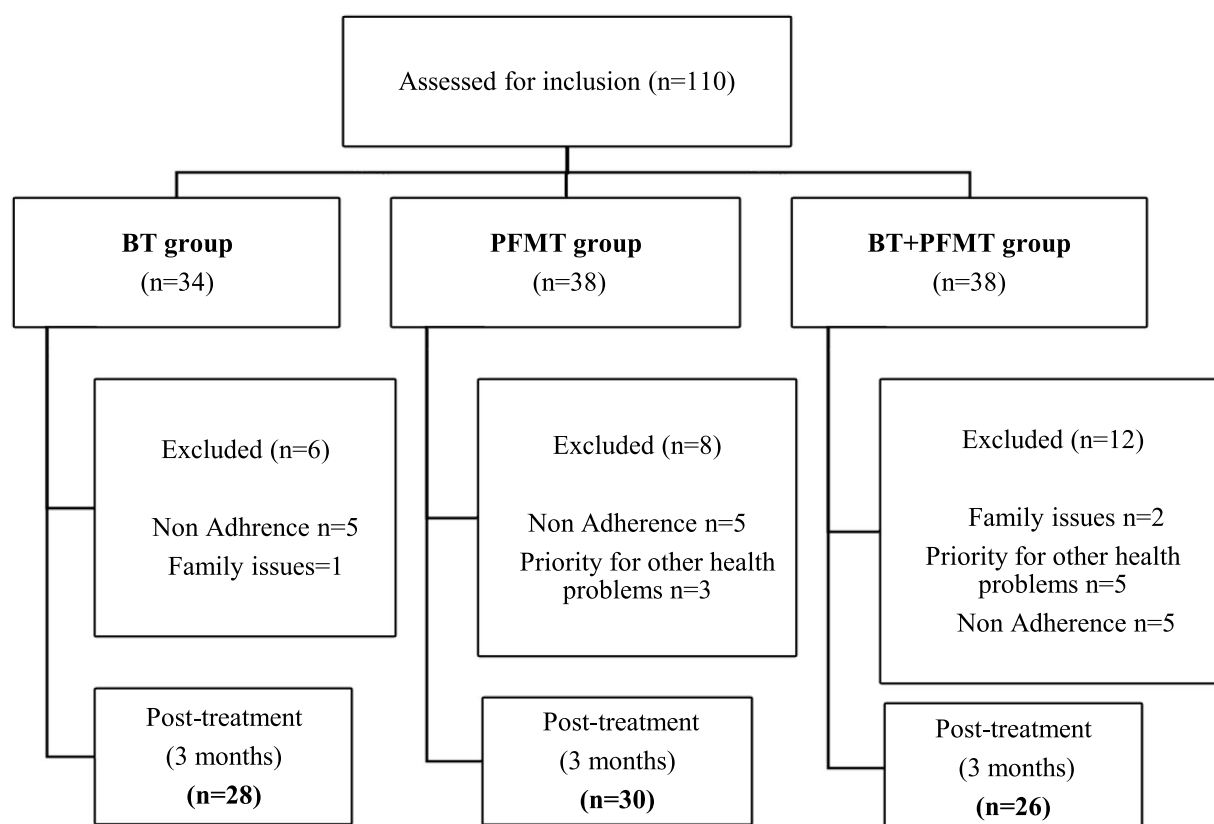


Fig. 1. Flowchart of the randomization process in the study.

Table 1

Demographic and clinical characteristics of the study groups.

Variables	BT, n = 34	BT+PFMT, n = 38	PFMT, n = 38	Total, n = 110
Age (years)	59.5 (51 - 64)	59 (49 - 66)	56 (49 - 66)	58 (49 - 65)
Race				
White	12 (35.3 %)	25 (65.8 %)	17 (44.7 %)	54 (49.1 %)
Black	6 (17.6 %)	3 (7.9 %)	5 (13.2 %)	14 (12.7 %)
Brown	16 (47.1 %)	10 (26.3 %)	16 (42.1 %)	42 (38.2 %)
Marital status				
Married	12 (35.3 %)	12 (31.6 %)	20 (52.6 %)	44 (40 %)
Divorced	3 (8.8 %)	7 (18.4 %)	9 (23.7 %)	19 (17.3 %)
Single	13 (38.2 %)	11 (28.9 %)	7 (18.4 %)	31 (28.2 %)
Widow	6 (17.6 %)	8 (21.1 %)	2 (5.3 %)	16 (14.5 %)
Education				
Incomplete elementary	17 (50 %)	6 (15.8 %)	13 (34.2 %)	36 (32.7 %)
Complete primary	4 (11.8 %)	4 (10.5 %)	3 (7.9 %)	11 (10 %)
Incomplete high school	3 (8.8 %)	3 (7.9 %)	1 (2.6 %)	7 (6.4 %)
Complete high school	7 (20.6 %)	24 (63.2 %)	11 (28.9 %)	42 (38.2 %)
Incomplete higher	1 (2.9 %)	0 (0 %)	5 (13.2 %)	6 (5.5 %)
Complete higher	2 (5.9 %)	1 (2.6 %)	5 (13.2 %)	8 (7.3 %)
Duration symptoms (months)	60 (18 - 120)	48 (24 - 90)	36 (24 - 72)	48 (24 - 96)
BMI (kg/m ²)	27.9 (25 - 31.6)	29.1 (26.5 - 30.2)	27.1 (24.2 - 31.2)	28.2 (25.1 - 31.2)
Pregnancies (N)	2.5 (2 - 4)	3 (2 - 3)	2 (1 - 4)	3 (2 - 4)
Births (N)	2 (1 - 4)	3 (2 - 3)	2 (1 - 3)	2 (1 - 3)
Menopause (age)	50 (47 - 51)	49 (46 - 49)	50 (44 - 52)	49 (45 - 51)
Voiding diary	n = 29	n = 33	n = 36	n = 98
Daytime frequency	8.6 (8.3 - 9.3)	8.6 (8.3 - 10.6)	8 (8 - 9.8)	8.6 (8 - 10)
Urinary urgency	2.3 (0.6 - 3.3)	2 (0 - 4)	2 (0.2 - 3.5)	2 (0 - 3.3)
UUI	0.6 (0.3 - 2.3)	0.6 (0.3 - 2)	1.2 (0.3 - 2.8)	0.6 (0.3 - 2.6)
Nocturia	2.3 (2 - 3.3)	2.6 (2 - 3.6)	2 (2 - 3)	2.3 (2 - 3.3)
Pads	0.6 (0 - 2)	1 (0 - 2)	0 (0 - 2.3)	1 (0 - 2)
New PERFECT scheme	n = 29	n = 32	n = 36	n = 97
Power (0-3)	1 (1 - 2)	1 (1 - 2)	1 (1 - 1)	1 (1 - 2)
Endurance (s)	3 (2 - 4)	3 (3 - 4)	3 (2 - 4)	3 (2 - 4)
Fast contractions (N)	5 (3 - 8)	5.5 (4 - 7)	6 (4.5 - 8)	5 (4 - 8)
OAB-V8 score	n = 34 24 (14 - 28)	n = 38 24 (16 - 32)	n = 38 24 (18 - 28)	n = 110 24 (16 - 29)

BMI, body mass index; BT, behavioral treatment; n, sample size; OAB-V8, Overactive Bladder Questionnaire V8; PFMT: pelvic floor muscle training; s, seconds; UUI, urgency urinary incontinence; Data were presented as median (interquartile ratios) and number (%).

group 24 (92.3 %) patients; and in the BT group 25 (89.3 %) patients.

Adherence to home exercises

The number of exercise sets performed weekly after the 1st, 2nd, and 3rd months of treatment was similar between the PFMT and BT+PFMT groups, varying between 15 and 17 sets ($p > 0.05$) (Supplementary material 5).

Subjective cure

The three groups were equally satisfied and did not desire different treatment after the interventions in all analyses carried out (Table 5).

Table 2

Comparative analyses of the OAB objective cure rates between groups.

Variable	BT	BT+PFMT	PFMT	p-value
Per protocol (n = 84)				
OAB-V8 < 8 + UUI - post-treatment = 0	7/28 (25 %)	15/26 (57.7 %)	6/30 (20 %)	0.006*
OR (CI 95 %)	0.24 (0.08; 0.7)		0.18 (0.06; 0.6)	0.009†
p-value	0.017‡		0.005‡	
Intention-to-treat ¹ as cure (n = 110)				
OAB-V8 < 8 + UUI - post-treatment = 0	13/34 (38.2 %)	27/38 (71.1 %)	14/38 (36.8 %)	0.004*
OR (CI 95 %)	0.25 (0.09; 0.6)		0.24 (0.09; 0.6)	0.005‡
p-value	0.006‡		0.003‡	
Intention-to-treat ² as uncured (n = 110)				
OAB-V8 < 8 + UUI - post-treatment = 0	7/34 (20.6 %)	15/38 (39.5 %)	6/38 (15.8 %)	0.044*
OR (CI 95 %)	0.4 (0.1; 1.1)		0.29 (0.1; 0.8)	0.051‡
p-value	0.087‡		0.025‡	

BT, behavioral treatment; PFMT, pelvic floor muscle training; N, sample size; UUI, urgency urinary incontinence; OAB-V8, Overactive Bladder Questionnaire; OR, Odds ratio; CI, confidence interval.

* Chi-square test.

† Univariate logistic regression model.

¹ Intention-to-treat analysis with the excluded patients considered cured.

² Intention-to-treat analysis with the excluded patients considered as uncured.

Table 3

Comparative analysis of the OAB-V8 questionnaire scores between groups.

OAB-V8	BT, n = 28	BT+PFMT n = 26	PFMT, n = 30
Baseline	24 (14 - 29)	24 (14 - 32)	23.5 (18 - 29)
Post-treatment	8.5 (4 - 11)	4 (3 - 10)	12 (3 - 17)
p-value*			
Group (p = 0.235)			
Time (p < 0.001)			
Interaction (Group x Time) (p = 0.050)			

BT, behavioral treatment; PFMT, pelvic floor muscle training; n: sample size; OAB-V8, Overactive Bladder V8 Questionnaire; Data were presented as median (interquartile ratios).

* ANOVA for repeated measures with rank transformation; p values statistically significant in bold.

Discussion

OAB is highly prevalent and negatively impacts women's quality of life.^{29,30} Physical therapy as the first line of treatment and the resources involve changes in behavior and lifestyle, and interventions to enhance the PFM functioning.^{6,31} Literature supports BT and PFMT combined or isolated in the OAB management.⁶ However, we observed a wide variety of intervention protocols and non-standardized methodologies among the studies, which makes it difficult to understand the benefits of these modalities. Therefore, we designed this study that includes a detailed and thorough methodological description, evaluates, and compares the effects of BT and PFMT, isolated or combined, in the management of women with OAB, accessing broad clinical outcomes: objective cure, subjective aspects, functional aspects of PFM, and treatment adherence.

A strict criterion was used to determine the objective cure rate, given by the composition of the OAB-V8 questionnaire score <8 and the absence of episodes of UUI reported in the voiding diary. Therefore, we considered cured the patient without OAB by OAB-V8 and that no longer

Table 4

Comparative analysis of urinary symptoms between groups.

Voiding diary	BT n = 28	BT+PFMT n = 26	PFMT n = 30
Daytime frequency (baseline)	8.6 (8.2 – 9.5)	8.6 (8.3 – 10.6)	8 (8 – 10)
Daytime frequency (post-treatment)	7 (6.5 – 9)	7 (6 – 8.3)	7.7 (6 – 8.3)
p-value*			
Group (p = 0.533)			
Time (p < 0.001)			
Interaction (Group x Time) (p = 0.013)			
Urgency (baseline)	2.2 (0.5 – 3.3)	2 (0 – 4)	2 (0 – 3.6)
Urgency (post-treatment)	1 (0 – 2.2)	0 (0 – 0.3)	0 (0 – 2)
p-value*			
Group (p = 0.432)			
Time (p < 0.001)			
Interaction (Group x Time) (p = 0.287)			
UUI (baseline)	0.6 (0.3 – 2.5)	0.5 (0.3 – 1.3)	1.3 (0.3 – 3)
UUI (post-treatment)	0.6 (0 – 1.8)	0 (0 – 0.3)	0 (0 – 1.3)
p-value*			
Group (p = 0.356)			
Time (p < 0.001)			
Interaction (Group x Time) (p = 0.097)			
Nocturia (baseline)	2.3 (2 – 3.3)	2.6 (2 – 3.3)	2.2 (2 – 3.3)
Nocturia (post-treatment)	1.2 (0 – 2)	1.2 (0 – 2)	1.3 (0.3 – 2)
p-value*			
Group (p = 0.755)			
Time (p < 0.001)			
Interaction (Group x Time) (p = 0.206)			
Pads (baseline)	0.5 (0 – 2.5)	1 (0 – 2)	0 (0 – 2.3)
Pads (post-treatment)	0 (0 – 1)	0 (0 – 0)	0 (0 – 1)
p-value*			
Group (p = 0.966)			
Time (p < 0.001)			
Interaction (Group x Time) (p = 0.461)			

Data obtained from the three-day voiding diary. BT, behavioral treatment; PFMT, pelvic floor muscle training; n, sample size; UUI, urgency urinary incontinence; Data were presented as median (interquartile ratios).

* ANOVA for repeated measures with rank transformation; P values statistically significant in bold.

presented UUI in her daily life. It has been recommended that for patients with UUI, the criteria for response to treatment include this symptom, and that this be measured by the change in the number of UUI episodes or the achievement of urinary continence..³²

The literature has demonstrated advantages of combining physical therapy techniques⁹ for UI management, and PFMT together with BT has been recommended to achieve better results.³³ Our results strongly support the combined BT and PFMT in the OAB management, being more effective (2 times on average) than the use of isolated therapies. Analysing only the participants who completed the 12-week follow-up (PP), a criterion that would best reproduce the differences between treatments, objective cure reached 58 % for BT + PFMT; 20 % for isolated PFMT, and 25 % for isolated BT. ITT analysis has been described as the best way to reflect a clinical scenario in practice, as it would admit problems of non-adherence to treatment and protocol deviations, providing an estimate of therapeutic effect with smaller biases. When we admit follow-up withdrawn as uncured, we indeed show better results for the combination of treatments (BT + PFMT: 40 %; PFMT: 16 %; BT: 21 %). When we admit follow-up withdrawn as a cure, we also show better results for the combination of treatments (BT+ PFMT: 71 %; PFMT: 37 %; BT: 38 %). Importantly, when PP and ITT analyses reach essentially the same conclusions, confidence in the study results

Table 5

Comparative analysis of the OAB subjective cure rates between the groups.

	BT	BT+PFMT	PFMT	p-value
Per protocol (n = 84)				
Subjective cure	19/28 (67.9 %)	21/26 (80.8 %)	23/30 (76.7 %)	0.530*
OR (95 % CI)	0.5 (0.1, 1.7)		0.78 (0.2, 2.8)	0.535 [‡]
p-value	0.283 [‡]		0.709 [‡]	
Intention-to-treat ¹ as cure (n = 110)				
Subjective cure	25/34 (73.5 %)	33/38 (86.8 %)	31/38 (81.6 %)	0.354*
OR (95 % CI)	0.42 (0.1, 1.4)		0.67 (0.1, 2.3)	0.364 [‡]
p-value	0.161 [‡]		0.531 [‡]	
Intention-to-treat ² as uncured (n = 110)				
Subjective cure	19/34 (55.9 %)	21/38 (5.3 %)	23/38 (60.5 %)	0.881*
OR (95 % CI)	1.03 (0.4, 2.6)		1.24 (0.5, 3.0)	0.881 [‡]
p-value	0.958 [‡]		0.642 [‡]	

BT, behavioral treatment; PFMT, pelvic floor muscle training; N, sample size; OR, Odds ratio; CI, confidence interval.

* Chi-square test.

[‡] Univariate logistic regression model.

¹ Intention-to-treat analysis with the excluded patients considered cured.

² Intention-to-treat analysis with the excluded patients considered uncured.

increases.³⁴

Considering urinary symptoms, our study demonstrated that the three treatments were equally effective after 3 months. These data can be partially explained by the profile of our patients, who presented non-severe LUTS. However, despite some methodological differences, other studies corroborate our findings of positive effect of BT alone or with PFMT in reducing urinary urgency, frequency, and episodes of leakage.^{11–13,15,35} A recent systematic review and meta-analysis showed inconclusive results about the BT on OAB. Only the combination of BT with intravaginal electric stimulation improves the nocturia, urinary incontinence, and quality of life. For the authors it is difficult to understand the impact of the BT on OAB symptoms due to its subjective and complex characteristics; and the heterogeneity of the studies is another factor that needs to be considered..³⁶

Subjective cure rates were measured by patient-reported satisfaction and no desire for further treatment. Assessment of treatment satisfaction can be highly useful in clinical practice. Patient-reported outcomes can confirm whether observed changes in symptoms are meaningful to the patient.³² In this context, the three treatments were equally effective regardless of the PP or ITT analysis, reinforcing the reliability of the findings. Rates were lower in the ITT groups when considering losses to follow-up as uncured (ranging from 55 %–60 %); with rates in the PP analysis being higher (ranging from 68 %–80 %). Lower cure rates in ITT analysis are expected because treatment effect estimates are generally conservative..³⁴

The literature has recommended that for better benefits of PFMT on OAB symptoms, muscle training programs should be developed according to the patient's individual muscle deficiencies.³⁷ Despite having used a non-individualized exercise program, we showed PFM function improvement with the three therapies. Not surprisingly, the groups that received protocols involving PFMT showed better muscle function when compared to the BT group. These results may be justified on the mechanisms of action of the therapies. BT aims to restore bladder function through a process of patient education, in conjunction with a timed voiding regimen that gradually increases the time interval between voids and with strategies to suppress voiding urgency, which strengthens the brain's control over bladder sensation and urethral closure.^{38–41} PFM strength training in LUTS uses selective and repeated

voluntary contractions followed by their relaxation, increasing urethral resistance, reducing, or preventing urine leakage and inhibiting detrusor contractions.^{17,18}

The benefits of short- and long-term physical therapy treatment depend on patient adherence.⁴² To our knowledge, there is no validated instrument to monitor adherence to BT than self-reported adherence to the proposed techniques and outpatient sessions attendance, which were used in the study. We used motivation strategies, suggested the use of self-adhesive labels placed in strategic locations at home or in the work environment as reminder to engage in the program and decrease potential bias inherent to a home intervention. And the supervised approach promotes greater interaction between patients and physiotherapists and attention to their problem, contributing to our high adherence rates.

The strengths of our study were the randomized controlled design, the use of supervised training by an experienced physical therapist, the use of reliable and valid outcome measures for assessing female LUTS, and the adherence rate.

Potential limitations are: (1) UI was assessed solely on the patient's history and comprehensive clinical evaluation in the context of the OAB clinical syndrome, but due to the complexity of the aspects of LUTS, complementary functional evaluation would enrich our investigation; (2) blinding was not possible due to the use of distinct therapies, however, this was counterbalanced by the blindness of the therapist and patients related to the outcome results and analyses; (3) long-term follow-up was not carried out, which is the subject of future analysis.

Conclusions

The combination of BT with PFMT was more effective than isolated therapies in the management of female OAB.

Ethics approval

The Research Ethical Committee of the Universidade Federal de São Paulo (UNIFESP) in Brazil, approved this study (2.263.747). All participants gave written informed consent before data collection began.

Declaration of competing interest

The authors declare no competing interest.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.bjpt.2025.101541](https://doi.org/10.1016/j.bjpt.2025.101541).

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