Trial Protocol

##Trial design and oversight

This study was a randomized, crossover, single-center clinical trial. Patients at Shanghai Fifth People's Hospital of Fudan University were included and randomization was performed for group assignment. *The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013)*. The protocol of this study was approved by the ethics committee of Shanghai Fifth People's Hospital of Fudan University (2018)Lunshen174, and the sponsor was responsible for data collection. Signed informed consent forms were obtained from all included patients.

##Trial population

A total of 150 middle-aged women with mild to moderate OAB from Shanghai Fifth People's Hospital of Fudan University were included in this study. Patients were included if they met the following inclusion criteria: (I) married women aged 30-45 years, irrespective of fertility status; (II) urination diary could be completed for 3 days, irrespective of urge urinary incontinence status, the number of urinations ≥ 8 times within 24 hours, ≥2 times in a night, and the volume of urination <200 mL/time; (III) the overactive symptom bladder scores (OABSS) ranged from 3-11, and the score of urgency of urination ≥2; (IV) female sexual function index (FSFI) <25; (V) fixed partner; (VI) sex partners did not have male sexual dysfunction; (VII) the duration of disease >3 months; and (VIII) patients did not receive drugs within 3 months. The exclusion criteria of this study were as follows: (I) asexual experience, at lactation or menopause, pelvic floor organ prolapse, gynecological inflammation, presence of tumor, and endocrine disease; (II) stress urinary incontinence or stress urinary incontinence dominant mixed urinary incontinence; (III) urinary infection or chronic inflammation, including interstitial cystitis, bladder stones, and malignant tumors; (IV) history of transurethral and pelvic surgery; (V) patients with diabetes, glaucoma, myasthenia gravis, ulcerative colitis, severe constipation, and dyspepsia; (VI) post-voiding residual (PVR) >50 mL; (VII) patients have used M3 blockers or other OAB drugs; (VIII) patients could not adhere to Yun-type training or PFMT, and the follow-up data were unavailable.

##Randomization and study agents

Eligible patients were randomly assigned to treatment with Yun-type training or PFMT. Randomization was carried out through a central computerized system using a random number table. This study was designed as a randomized, crossover clinical trial. The intervention group was first given Yun-type training for 6 weeks, then switched to PFMT for 6 weeks after 2 weeks of elution. Patients in the control group were first treated with PFMT for 6 weeks, and changed to the use of Yun-type training for 6 weeks after 2 weeks of elution. Details regarding the Yun-type training are as follows: A 488 bi metal waist chain with a weight of 0.8+0.1 kg was worn at the waist and hip. The course included 15 minutes of crotch base warm-up. Crotch shaking, crotch twisting, crotch shaking, crotch sending, upper crotch, lower crotch, sago shaking, and other exercises were performed in the state of contract the anus and the vagina for 25 minutes (the specific time and rhythm of contract the anus and the vagina were conducted according to the command of the head coach). In the last 15 minutes, pelvic floor muscle strengthening and body relaxation exercises were performed with soothing music and with legs flexed slightly apart. Slow frequency (anus contraction and vaginal contraction lasting for 30 seconds, relaxation for 10 seconds during exhalation) and fast frequency (anus contraction and vaginal contraction lasting for 2 seconds during exhalation, relaxation for 2 seconds during exhalation) intervals were performed during inhalation 45 times per course.

##Data collection and endpoints

The outcomes were collected and analyzed in a blinded manner by investigators. The following items were collected before treatment, after 6 weeks, and after 14 weeks of interventions: OABSS, urine in daytime, nocturia, urgency, urge urinary incontinence, patient's perception of bladder condition (PPBC), urogenital distress inventory-6 (UDI-6), incontinence impact questionnaire-7 (IIQ-7), voiding volume (VV), average flow rate (Q_{ave}), maximum flow rate (Q_{max}), PVR, C-reactive protein (CRP), FSFI, sexual desire, arousal, damp, climax, pain, satisfaction, type I muscle strength, type II muscle strength, pelvic floor muscle tone, and sex partner satisfaction.

Firstly, the normality and homogeneity of variance of the collected data were assessed. Subsequently, the mean and standard deviation were applied to describe data which met the normal distribution, otherwise, the median (interquartile range) was employed. Categorical data are presented as number of events and proportion. The characteristics between the intervention and control groups were assessed by using the t test or rank sum test according to the data distribution. Then, repeated measures analysis of variance (ANOVA) was applied to analyze the changes in investigated indexes between the intervention and control groups at different observation times after applying age and BMI as covariables. All reported inspection levels were 2-sided, and a P-value of <0.05 was considered as statistically significant. The IBM Statistical Package for the Social Sciences (SPSS) software for Windows version 19.0 was applied to conduct all analyses in this study.

Article information: https://dx.doi.org/10.21037/atm-22-3357