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The Effect of Home-Based Behavioural Weight Loss Combined with Pelvic Floor Muscle Training in Women Seeking Weight Loss Combined with Stress Urinary Incontinence: A Randomized Controlled Trial

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TITLE

The Effect of Home-Based Behavioural Weight Loss Combined with Pelvic Floor Muscle Training in Women Seeking Weight Loss Combined with Stress Urinary Incontinence: A Randomized Controlled Trial

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The Effect of Home-Based Behavioural Weight Loss Combined with Pelvic Floor Muscle Training in Women Seeking Weight Loss Combined with Stress Urinary Incontinence: A Randomized Controlled Trial

ABSTRACT

Introduction

Recent guidelines suggest behavioural weight loss (BWL) and pelvic floor muscle training (PFMT) as first-line treatment approaches for women with both obesity and stress urinary incontinence (SUI). However, the optimal therapeutic and management strategies for these populations remain uncertain.

Methods and analysis

This assessor-blinded parallel-group randomized controlled trial aimed to compare the efficacy of BWL alone, BWL plus conventional PFMT, and BWL plus PFMT with a biofeedback device for women who are overweight or obesity experiencing SUI or SUI-predominant mixed urinary incontinence. A total of 120 eligible women will be randomly assigned at a 1:1:1 ratio. All three groups were subjected to a 3-month self-supervision intervention after randomization and were assessed at baseline, after the 3-month intervention, 6 months after the intervention, and 12 months after the intervention. The primary outcome measure will be the self-reported severity of urinary incontinence assessed by the International Consultation on Incontinence Questionnaire-Urinary Incontinence short form. The secondary outcomes will include weight loss effectiveness, pelvic muscle strength, pelvic floor ultrasound, three-dimensional body posture, adherence to the intervention, and questionnaires for symptoms of pelvic organ prolapse, quality of life, and sexual function.

Ethics and dissemination

This study has been reviewed and given a favourable ethical opinion by the Peking Union Medical College Hospital ethics committee (K5504). All results from the study will be submitted to international journals and international conferences.

Trial registration: This trial has been registered with Clinicaltrials.gov (ChiCTR2400084015).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- A relatively large sample size and a long follow-up period enhanced the reliability of the results.
- The primary focus of our study is on women with obesity, who represent a significant population affected by urinary incontinence which has received limited attention. Moreover, a comprehensive assessment encompassing weight loss effectiveness, pelvic muscle strength, pelvic floor ultrasound, quality of life, mental health, sexual function, and three-dimensional body posture will also be conducted.
- To minimize bias, all three groups will follow the same weight loss program developed by a team of experts. For the two PFMT groups, the training protocols and frequency of supervisor contacts will be standardized, with the only difference being the use of a biofeedback device in the intervention group. Furthermore, the assessor responsible for evaluating the outcomes will be unaware of the group assignments and will maintain this blinding throughout the study period.
- A standardized approach for questionnaire completion and pelvic floor muscle training monitoring was employed, ensuring consistency in data collection.
- While assessor blinding was achieved, it was only possible for the assessors and not for participants or supervising physicians, which could introduce potential bias.

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INTRODUCTION

Overweight and obesity are growing public health problems, as projections indicate that approximately 20% of the global adult population could be affected by 2025¹. Extensive evidence supports the link between obesity and various comorbidities², such as cardiovascular disease, diabetes, and certain types of cancer. With increasing population aging, pelvic floor disorders, which are among the top five chronic diseases affecting women's health-related quality of life (HRQoL), have become increasingly pressing public health issues. Recent studies have also revealed a connection between obesity and pelvic floor disorders, particularly stress urinary incontinence (SUI)³⁻⁵. While obesity and SUI may not be life-threatening, they significantly impact the HRQoL for those affected⁶⁻⁸ and impose a considerable financial burden on healthcare systems⁹.

The first-line treatment option for women struggling with SUI or SUI-predominant mixed urinary incontinence (MUI) is pelvic floor muscle training (PFMT) for a minimum duration of three months¹⁰⁻¹¹. To enhance the effectiveness of PFMT and cater to diverse needs, various therapeutic combinations have been devised, such as biofeedback, electrical stimulation, and bladder diaries [13]. Notably, biofeedback has a well-established reputation for its efficacy¹⁰⁻¹². In addition, several randomized controlled trials (RCTs)¹³⁻¹⁶ have demonstrated the positive impact of behavioural weight loss (BWL) on reducing urinary incontinence symptoms among women with obesity. Current guidelines advocate coordinated management involving gynecologists and nutritionists in this population¹⁰⁻¹²; however, there is limited research on the optimal combined management strategy.

An RCT assessed the effects of PFMT with or without BWL in women with MUI and a body mass index (BMI) between 25 and 40 kg/m². The results revealed that BWL offered no additional benefits over PFMT¹⁷, which highlights the importance of PFMT; however, the conclusion remains to be further validated considering the limitations of

the study's sample size (n=22), the short duration of the protocol (8 weeks) and the absence of weight loss efficiency. Moreover, in real-world clinical practice, despite the significant proportion of women seeking weight loss suffering from urinary incontinence, they do not pay adequate attention to these issues and may hesitate to discuss this symptom because of its sensitive nature. While some women may experience improvements in urinary incontinence symptoms after weight loss, research on this topic is limited. Some women with noticeable symptoms might also attempt to perform PFMT on their own, but the lack of standardized procedures and inadequate supervision can greatly impede their effective resolution. There is a critical lack of public awareness and education in these populations ¹⁸, and the optimal therapeutic and management strategies for these populations remain uncertain. Additionally, limited medical resources in certain areas hinder access to appropriate healthcare services. Given that societal and healthcare structures, lifestyle modifications, and long-term interventions are essential for early recognition and prompt management, an effective self-supervision strategy is crucial for patients with both obesity and SUI. Streamlining patient convenience and reducing healthcare costs are driving the exploration of biofeedback, which may improve treatment compliance and treatment effects ^{19 20}.

Prior research ²¹ has shown that the severity of urinary incontinence symptoms often worsens with prolonged obesity, and weight management should be provided throughout a person's lifetime. However, the existing constraints on healthcare resources impede the implementation of such comprehensive guidance. The disparities in multidisciplinary team collaboration and awareness present formidable challenges to achieving optimal management of urinary incontinence among women with obesity. Therefore, there is an urgent need to increase awareness, promote research, and enhance interdisciplinary supervision in managing urinary incontinence among women with obesity. The development of an effective management strategy for BWL and PFMT tailored to this population is crucial for enhancing the quality of medical services. In

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this study, we aimed to ascertain an effective and practical home-based integrated management strategy for women with both overweight/obesity and SUI symptoms.

METHODS AND ANALYSIS

Study design

This assessor-blinded parallel-group RCT aimed to compare the efficacy of BWL alone, BWL plus conventional PFMT, and BWL plus PFMT with a biofeedback device for women who are overweight or obesity experiencing SUI or SUI-predominant MUI. Eligible patients will be randomly allocated to one of the three groups mentioned above. The participants subsequently underwent a comprehensive baseline evaluation that included the following: the provision of essential baseline clinical characteristics, including demographic details, pregnancy delivery history, lifestyle factors, etc., and the completion of validated questionnaires related to SUI symptoms and their impact. Furthermore, subjects will require objective evaluations, including pelvic floor muscle strength assessments, pelvic ultrasound scans, and three-dimensional posture assessments, which will be performed by the same assessor, who will remain blinded to the allocation status. Following randomization and baseline data collection, all participants will embark on a 3-month BWL program instructed by the same team of nutrition experts. Throughout the program, participants will need to record their dietary intake three times a week (including at least one during weekends) and complete a weekly questionnaire on physical activity levels via the International Physical Activity Questionnaire ^{22 23}. In Group I, participants will be solely involved in self-supervision BWL. In the other two groups, participants will also undergo PFMT for 3 months. During the study period, all three groups received telephone supervision every three weeks. Assessments will be conducted at baseline (pretest), 3 months (after intervention), 9 months (6 months after intervention), and 15 months (12 months after intervention) during the study period (Figure 1).

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Patient selection and recruitment

The recruitment of participants started in May 2024. Women visiting the clinical nutrition department reporting symptoms of SUI or SUI-dominated MUI will be briefed about the program. Trained physicians will screen suitable candidates who satisfy all qualifying standards and express interest in participating, and an informed consent document will then be signed by those qualified for enrolment. Theoretically, all three groups in this study will experience some degree of improvement in their condition. If any adverse events or unexpected issues arise during the study period, participants are encouraged to promptly contact the project manager.

➤ ***Inclusion criteria:***

- 1, Women with a BMI between 25 and 40 kg/cm²
- 2, Patients currently experiencing symptoms of SUI or SUI-dominated MUI
- 3, Age ≥18 years and ≤ 70 years
- 4, Agree to refrain from self-initiating new treatments during the study period

➤ ***Exclusion criteria:***

- 1, The presence of only urgency urinary incontinence
- 2, Pelvic organ prolapse greater than stage II (prolapse beyond the hymen > 1 cm)
- 3, History of pelvic floor surgery or bariatric surgery
- 4, History of pelvic or abdominal malignancy
- 5, Presence of urinary tract infection or ≥ 4 urinary tract infections within the past year
- 6, Previous PFMT under the guidance of a trained therapist lasting more than 3 months in the past 5 years

7, Delivery within the past six months, or current plans for pregnancy

8, Severe systematic diseases such as uncontrolled diabetes, hypertension, or hyperlipemia

9, Other factors that may impede participation in the trial, such as frequent business travel, mental illness, inability to voluntarily contract pelvic floor muscles, denial of sexual activity history, refusal to have a pressure measurement device placed inside the vagina, etc.

Randomization and masking

Upon the evaluation of the inclusion criteria and completion of the baseline assessments, the participants will be allocated into three groups via a computer-generated randomization tool, preserving an allocation ratio of 1:1:1. Considering the complexity of the intervention and the nature of the study, blinding of patients and physicians delivering the intervention and overseeing follow-ups is unfeasible. However, the assessors responsible for evaluating data will remain uninformed about group assignments, and participants will be instructed against disclosing their study group status to evaluating physicians.

Interventions

The training protocols for the PFMT were based on our previous research²⁴ and consisted of three sets of fast and slow contractions daily in the supine position (6 min/set, 3 repetitions). Each rep has eight max contractions (6 s) + four fast contractions (1 s), with 30 s of rest between reps. The BWL protocol used in our previous research²⁵ emphasized health education and behaviour modification. The participants followed a balanced diet with protein accounting for 30% of their daily energy, primarily whey

protein, and fat and carbohydrates accounting for 30% and 40%, respectively. They are also advised to engage in a combination of cardio- and resistance exercises.

Outcome measures

➤ **Primary outcome measure**

The primary outcome measure of SUI severity will be the validated Chinese version of the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF) ²⁶. This scale consists of four items—frequency of urine leakage (with a score range of 0 = never to 5 = always), volume of urine leakage (awarded points 0, 2, 4, and 6 for ascending volumes per occurrence), impact of urinary incontinence on daily life (scored on a scale of 0 = not at all to 10 = extremely), and types of leakage symptoms experienced during the last four weeks ²⁷. The total ICIQ-UI-SF score ranges from 0 to 21, with severity categorized as mild (0–7), moderate (8–13), or severe (14–21).

➤ **Secondary outcome measures**

Weight loss

The effect of weight loss can be assessed by measuring various indicators, such as body weight, BMI, and abdomen circumference.

Pelvic floor muscle (PFM) strength

The strength of the PFM will be quantified by employing subjective (vaginal palpation) and objective (manometry) techniques.

- ✧ ***Subjective PFM strength*** will be evaluated via digital vaginal palpation via the modified Oxford grading scale. The participants are guided to exert their maximum

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PFM contraction against the examiner's fingers within the vagina, rating their strength from 0 (no contraction) to 5 (strong contraction) ²⁸.

- ✧ **Objective PFM strength** will be measured as the maximum voluntary contraction pressure via an intravaginal manometer with a vaginal probe, 20 ml of air, and a PHENIX USB 8 NMS system. The maximum voluntary contraction pressure is obtained by deducting the vaginal resting pressure from the peak pressure achieved during maximal PFM contraction. The participants performed three trials, each 15 seconds apart, without involving abdominal, gluteal, or hip adductors. The average of these three values quantifies muscle strength, with higher pressure implying greater strength ^{29 30}.

Pelvic Floor Ultrasound

Using a Mindray Resona 8 ultrasonic diagnostic instrument, a transperineal three-dimensional volumetric probe (SD8-1U) was used. The participants were requested to empty their bladder before the examination and assume the lithotomy position. All pelvic floor ultrasound examinations for patients were performed by the same experienced physician who had undergone training and assessment, with images saved for subsequent analysis and the grouping hidden. Measurements were taken at rest and during the maximum Valsalva manoeuvre. Signal acquisition and data recording included parameters such as the detrusor thickness, bladder neck mobility, posterior bladder angle, urethral inclination angle, urethral rotation angle, and levator hiatal area.

Pelvic organ prolapse

Pelvic organ prolapse staging is determined through the utilization of the Pelvic Organ Prolapse Quantification system ³¹, which quantifies the positioning of vaginal structures relative to the hymenal ring. The subjective symptoms will be assessed with the Pelvic

Organ Prolapse Symptom Score questionnaire, which consists of seven questions examining symptom prevalence over the past month. The respondents recorded scores ranging from 0 (never) to 4 (constantly), with possible total scores ranging between 0 and 28. Higher scores signify greater symptom intensity ^{32 33}.

Three-dimensional body posture

The participants assumed a natural standing position with their hands by their sides, feet together, their toes forward, and their eyes facing forward. Depth cameras capture front and back images, followed by a full-body gait video. A smart three-dimensional posture analysis system (APHRO, EURADIS) uses depth cameras and artificial intelligence technology to assess multiple key body areas, including joint positioning, spinal curvature, and muscle distribution. The measured parameters included the thoracic kyphosis angle, lumbar lordosis angle, sacral inclination angle, shoulder tilt, leg type, lower limb (functional) length, pelvic left-right tilt, pelvic rotation, pelvic anterior-posterior tilt, and spinal sagittal axis.

Health-related quality of life

The specific HRQoL will be evaluated via the Chinese version of the Incontinence Quality of Life Instrument ³⁴. This tool consists of 22 items categorized into three subdomains: avoidance and limiting behaviour, psychosocial impacts, and social embarrassment, with each query rated on a 5-point Likert-type scale. The total score is ultimately transformed to a 0--100 scale. The participants' general HRQoL was assessed via the European Quality of Life-5 Dimensions 5-Level questionnaire ³⁵, which consists of a health description system and a visual analogue scale. The health description system covers five dimensions of health-related HRQoL: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on a scale from 1 (no problems) to 5 (extreme problems), providing a comprehensive evaluation of the participants' overall well-being. The associated visual analogue scale allows

patients to subjectively rate their health status on a scale from 0 to 100, with higher scores indicating better health status.

Sexual function

Sexual function will be assessed via the Short-form Prolapse and Incontinence Sexual Questionnaire. This instrument gauges sexual dysfunction by querying 12 queries, with scores ranging from 0 to 48. Elevated values reflect more significant sexual difficulties³⁶.

Mental health

The Hospital Anxiety and Depression Scale³⁷ is a widely used, 14-item self-report questionnaire designed to assess the level of anxiety and depression in patients being treated in nonpsychiatric hospital settings. The Hospital Anxiety and Depression Scale comprises two subscales: seven items measuring anxiety and seven items assessing depression. Each item is rated on a 0--3 scale, yielding scores ranging from 0 to 21 for both subscales. Scores of 8 or higher on either subscale indicate the presence of clinically relevant symptoms.

Overactive Bladder Symptom Score

Symptoms of OAB will be assessed by the overactive bladder symptom score³⁸ with a cumulative threshold of three or more and a subscore of at least two on item 3 regarding urgency. For severity grading, a total score of 3 to 5 indicates mild severity, scores between 6 and 11 indicate moderate severity, and a score of 12 or above signifies severe severity.

Broome Pelvic Muscle Self-Efficacy Scale

Self-efficacy will be evaluated with the Broome Pelvic Muscle Self-Efficacy Scale, which consists of 23 items covering two domains: efficacy beliefs and outcome expectations^{39 40}. In the efficacy beliefs portion, participants express their faith in PFMT practice. In the outcome expectations component, they assess their assurance of PFMT's ability to curb urine loss. Scores from this scale range from 0 to 100, with higher values indicating greater perceived self-efficacy.

Patient Global Impression of Improvement

During the 3-month intervention, participants' perceptions of urine leakage will be tracked via the Patient Global Impression of Improvement questionnaire. Physicians will conduct weekly phone calls with participants asking, "Compared with before this study, how would you rate your urinary symptoms now?" The responses are rated on a seven-point scale (1= marked improvement, 7 = marked worsening), with improvement defined as a rating of 1 (very much better) or 2 (much better)⁴¹.

Patient adherence to treatment

Patient adherence to treatment will be assessed based on subjective self-reports and the completion of relevant questionnaires. Overall adherence will be classified as follows: low adherence (fewer than 50% of the anticipated exercises), moderate adherence (between 50% and 75% of the anticipated exercises), and high adherence (75% or more of the anticipated exercises).

Sample size

The primary outcome of this study was the ICIQ-UI SF score. According to a literature review, the standard deviation of ICIQ-SF scores in obese patients with concurrent urinary incontinence ranges from 2.61 to 4.9^{17 42 43}. In this study, a standard deviation of 4 was selected for all three groups. According to the literature, the minimum

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clinically important difference in the ICIQ-SF score is 2.5 points⁴⁴. A minimum difference of 3 points was chosen in this study, and the estimated mean scores for the three groups were 15, 14, and 12, respectively¹⁷. With a bilateral alpha level of 0.05 and a power of 0.8, sample size calculation via PASS 15 software revealed that each group should include 35 participants. Considering a dropout and refusal rate of 10%, 40 participants per group were planned to be recruited, resulting in a minimum total of 120 study subjects.

Statistical analysis

The data will be analyzed with SPSS V.23.0 software. Descriptive statistics, such as the mean, standard deviation, median, and interquartile range, will be employed for continuous variables, whereas relative frequencies with percentages (n, %) will be determined for categorical variables. One-way analysis of variance was used to compare continuous variables consistent with homogeneity of variance among groups; otherwise, the Kruskal–Wallis test was used. The chi-squared test or Fisher's exact test will be used for categorical variable analysis. To examine the main and interactive effects, repeated measures analysis of variance will be employed for continuous variables following a normal distribution, denoted as the means±standard deviations. The generalized estimating equations approach, with Bonferroni correction, will be utilized for continuous variables deviating from normality, presented as medians with interquartile ranges (P₂₅, P₇₅). Significance testing will utilize a two-tailed approach, with a cut-off value of P<0.05.

Data management

As previously described in our research²⁴, the data management system for this study comprises MySQL and the Peking Union Medical College Hospital Intelligent Follow-up System databases for data storage. Data within the system is stored in a multi-tier

architecture using a local cache, Redis cache, and cloud storage. To maintain data integrity and clarity, data managers frequently review entries using both computerized and manual techniques, focusing on completeness, omissions, and ambiguous values. Publication of study data will exclude personally identifiable information such as names, images, and any other identifying details to protect participant confidentiality. This trial will be also audited by the ethics committee.

Missing data

To assess the potential bias caused by missing data, we will compare the baseline characteristics of participants who did and did not have missing values. By identifying predictive factors for missingness, we can adjust the primary outcome analysis to account for these factors if they are significantly associated with the data missing. Additionally, as part of a sensitivity analysis, we will consider using multiple imputations through chained equations to address any missing data in the primary outcome model.

Ethics and dissemination

All participants provided written informed consent, and the study was conducted in accordance with the Declaration of Helsinki. The study protocol (Version 2) and the informed consent form were approved by the Peking Union Medical College Hospital ethics committee (K5504, 2024-4-26). This trial has been registered with Clinicaltrials.gov (ChiCTR2400084015) and all participants will sign written informed consent before data collection. All results from the study will be submitted to relevant scientific journals and international conferences.

Advantage and limitation

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The key advantages of this study are that it focused on urinary incontinence symptom improvement as the primary outcome while also considering weight loss effectiveness, pelvic muscle strength, pelvic floor ultrasound, quality of life, mental health, sexual function, three-dimensional body posture, etc. Furthermore, the use of a relatively large sample size and a long follow-up period helped strengthen the reliability of the results. Throughout the study, assessor blinding was maintained to ensure fairness. Moreover, the study provided a standardized method for completing questionnaires and monitoring pelvic floor muscle contractions. However, it is important to acknowledge that while this study has several strengths, intervention blinding was only possible for assessors, not for participants or supervising physicians. Additionally, the BWL program used in this study focused primarily on a high-protein diet. Future investigations exploring various BWL approaches will contribute to more personalized treatment plans.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

Author's contributions

All the listed authors have made essential contributions to the work. The entire study will be directed by Zhijing Sun to ensure the execution and completion of the study according to the protocol. Zhijing Sun, Wei Chen and Zhao Tian conceived and designed the study protocol. Zhao Tian drafted the original manuscript. Xiuqi Wang, Linru Fu, and Tangdi Lin participated in refining the study design. All the authors have read and approved the final manuscript for publication.

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Outcomes	Baseline	After 3-month intervention	6 months after intervention	12 months after intervention
ICIQ-UI-SF	√	√	√	√
MOS	√	√		
MVCP	√	√		
POP-Q	√	√		
Pelvic Floor Ultrasound	√	√		
Three-Dimensional Body Posture	√	√		
Body weight	√	√	√	√
Abdominal circumference	√	√	√	√
I-QOL	√	√	√	√
POP-SS	√	√	√	√
OABSS	√	√	√	√
PISQ-12	√	√	√	√
EQ-5D-5 L	√	√	√	√
HADS	√	√	√	√
BPMSES	√	√	√	√
PGI-I		√	√	√

Table 1. The assessments of the participants. ICIQ-UI-SF: Incontinence Modular Questionnaire-Urinary Incontinence Short Form, MOS: Modified Oxford Scale, MVCP: Maximum Voluntary Contraction Pressure, POP-Q: Pelvic Organ Prolapse Quantification, I-QOL: Incontinence Quality of Life Instrument, PISQ-12: Short-form Prolapse Incontinence Sexual Questionnaire, POP-SS: Pelvic Organ Prolapse Symptom Score, OABSS: Overactive Bladder Symptom Score, EQ-5D-5 L: European Quality of

Life-5 Dimensions 5-Level questionnaire, HADS: Hospital Anxiety and Depression Scale, BPMSES: Broome Pelvic Muscle Self-Efficacy Scale: PGI-I: Patient Global Impression of Improvement.

Figure legends

Figure 1 Flow chart of the study. BWL: behavioural weight loss, PFMT: pelvic floor muscle training, Biof-PFMT: pelvic floor muscle training with a biofeedback device

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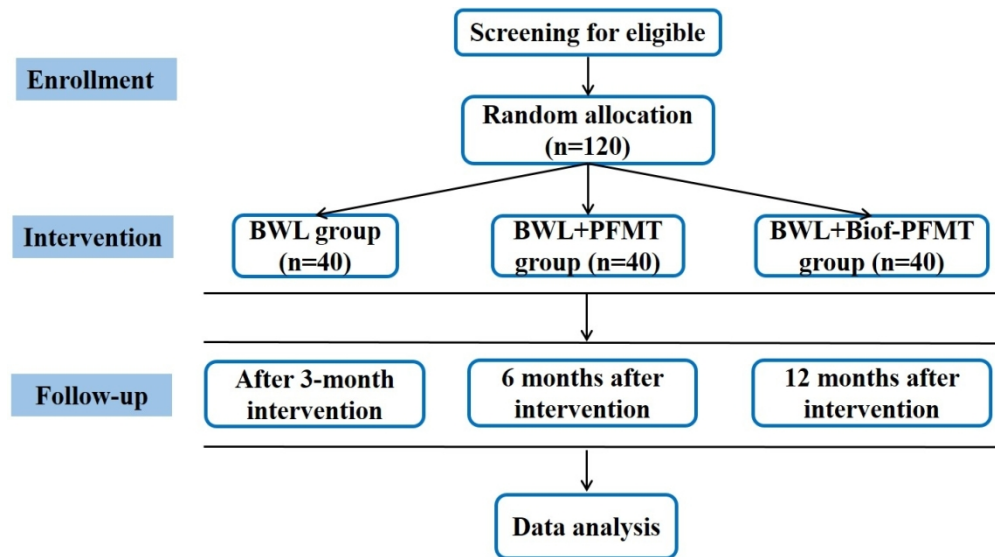


Figure 1 Flow chart of the study. BWL: behavioural weight loss, PFMT: pelvic floor muscle training, Biof-PFMT: pelvic floor muscle training with a biofeedback device

243x134mm (150 x 150 DPI)

BMJ Open

The Effect of Home-Based Behavioural Weight Loss Combined with Pelvic Floor Muscle Training in Women Seeking Weight Loss Combined with Stress Urinary Incontinence: Protocol for A Randomized Controlled Trial

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TITLE

The Effect of Home-Based Behavioural Weight Loss Combined with Pelvic Floor Muscle Training in Women Seeking Weight Loss Combined with Stress Urinary Incontinence: Protocol for A Randomized Controlled Trial

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The Effect of Home-Based Behavioural Weight Loss Combined with Pelvic Floor Muscle Training in Women Seeking Weight Loss Combined with Stress Urinary Incontinence: Protocol for A Randomized Controlled Trial

ABSTRACT

Introduction

Recent guidelines suggest behavioural weight loss (BWL) and pelvic floor muscle training (PFMT) as first-line treatment approaches for women with both obesity and stress urinary incontinence (SUI). However, the optimal therapeutic and management strategies for these populations remain uncertain.

Methods and analysis

This assessor-blinded parallel-group randomized controlled trial aims to compare the efficacy of BWL alone, BWL plus conventional PFMT, and BWL plus PFMT with a biofeedback device for women who are overweight or obesity experiencing SUI or SUI-predominant mixed urinary incontinence. A total of 120 eligible women will be randomly assigned at a 1:1:1 ratio. All the three groups will be subjected to a 3-month self-supervision intervention after randomization and will be assessed at baseline, after the 3-month intervention, 6 months after the intervention, and 12 months after the intervention. The primary outcome measure is the self-reported severity of urinary incontinence assessed by the International Consultation on Incontinence Questionnaire-Urinary Incontinence short form. The secondary outcomes include weight loss effectiveness, pelvic muscle strength, pelvic floor ultrasound, three-dimensional body posture, adherence to the intervention, and questionnaires for symptoms of pelvic organ prolapse, quality of life, and sexual function.

Ethics and dissemination

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This study has been approved by the Peking Union Medical College Hospital ethics committee (K5504). All results from the study will be submitted to international journals and international conferences.

Trial registration number: This trial has been registered with Chinese Clinical Trial Registry (ChiCTR2400084015).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- A relatively large sample size and a long follow-up period enhance the reliability of the results.
- A comprehensive assessment encompassing weight loss effectiveness, urinary incontinence symptom, pelvic muscle strength, pelvic floor ultrasound, quality of life, mental health, sexual function, and three-dimensional body posture will be conducted.
- To minimize bias, all three groups will adhere to the same expert-developed weight loss program; for the two PFMT groups, training protocols and supervisor contact frequencies will be standardized, with the sole distinction being the use of a biofeedback device. A standardized approach for questionnaire completion and pelvic floor muscle training monitoring will be employed, ensuring consistency in data collection.
- While assessor blinding will be achieved, it was only possible for the assessors and not for participants or supervising physicians, which could introduce potential bias.

INTRODUCTION

Overweight and obesity are growing public health problems, as projections indicate that approximately 20% of the global adult population could be affected by 2025¹, with some studies suggesting higher prevalence rates among women compared to men^{2,3}. Extensive evidence supports the gender-specific manifestation of obesity-associated comorbidities⁴. Notably, women with obesity demonstrate higher risks for cardiovascular complications and osteoarthritis, while men show greater predisposition to type 2 diabetes and non-alcoholic fatty liver disease⁵. With increasing population aging, pelvic floor disorders, which are among the top five chronic diseases affecting women's health-related quality of life (HRQoL), have become increasingly pressing public health issues. Recent studies have also revealed a connection between obesity and pelvic floor disorders, particularly stress urinary incontinence (SUI)⁶⁻⁸. While obesity and SUI may not be life-threatening, they significantly impact the HRQoL for those affected⁹⁻¹¹ and impose a considerable financial burden on healthcare systems¹².

The first-line treatment option for women struggling with SUI or SUI-predominant mixed urinary incontinence (MUI) is pelvic floor muscle training (PFMT) for a minimum duration of three months^{13,14}. To enhance the effectiveness of PFMT and cater to diverse needs, various therapeutic combinations have been devised, such as biofeedback, electrical stimulation, and bladder diaries [13]. Notably, biofeedback has a well-established reputation for its efficacy¹³⁻¹⁵. In addition, several randomized controlled trials (RCTs)¹⁶⁻¹⁹ have demonstrated the positive impact of behavioural weight loss (BWL) on reducing urinary incontinence symptoms among women with obesity. Current guidelines advocate coordinated management involving gynecologists and nutritionists in this population¹³⁻¹⁵; however, there is limited research on the optimal combined management strategy.

An RCT assessed the effects of PFMT with or without BWL in women with MUI and a body mass index (BMI) between 25 and 40 kg/m². The results revealed that BWL offered no additional benefits over PFMT²⁰, which highlights the importance of PFMT.

However, the conclusion remains to be further validated considering the limitations of the study's sample size (n=22), the short duration of the protocol (8 weeks) and the low weight-loss efficiency in the BWL + PFMT group, since there were no significant differences in body weight between the two groups before and after the intervention.. Moreover, in real-world clinical practice, despite the significant proportion of women seeking weight loss suffering from urinary incontinence, they do not pay adequate attention to these issues and may hesitate to discuss this symptom because of its sensitive nature. While some women may experience improvements in urinary incontinence symptoms after weight loss, research on this topic is limited. Some women with noticeable symptoms might also attempt to perform PFMT on their own, but the lack of standardized procedures and inadequate supervision can greatly impede their effective resolution. There is a critical lack of public awareness and education in these populations ²¹, and the optimal therapeutic and management strategies for these populations remain uncertain. Additionally, limited medical resources in certain areas hinder access to appropriate healthcare services. Given that societal and healthcare structures, lifestyle modifications, and long-term interventions are essential for early recognition and prompt management, an effective self-supervision strategy is crucial for patients with both obesity and SUI. Streamlining patient convenience and reducing healthcare costs are driving the exploration of biofeedback, which may improve treatment compliance and treatment effects ^{22 23}.

Prior research ²⁴ has shown that the severity of urinary incontinence symptoms often worsens with prolonged obesity, and weight management should be provided throughout a person's lifetime. However, the existing constraints on healthcare resources impede the implementation of such comprehensive guidance. The disparities in multidisciplinary team collaboration and awareness present formidable challenges to achieving optimal management of urinary incontinence among women with obesity. Therefore, there is an urgent need to increase awareness, promote research, and enhance interdisciplinary supervision in managing urinary incontinence among women with

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obesity. The development of an effective management strategy for BWL and PFMT tailored to this population is crucial for enhancing the quality of medical services. This research protocol is designed to explore an effective and practical home-based integrated management strategy for women with both overweight/obesity and SUI symptoms.

METHODS AND ANALYSIS

Study design

This assessor-blinded parallel-group RCT aims to compare the efficacy of BWL alone, BWL plus conventional PFMT, and BWL plus PFMT with a biofeedback device for women who are overweight or obesity experiencing SUI or SUI-predominant MUI. Eligible patients will be randomly allocated to one of the three groups mentioned above. The participants will undergo a comprehensive baseline evaluation that includes the following: the provision of essential baseline clinical characteristics, including demographic details, pregnancy delivery history, lifestyle factors, etc., and the completion of validated questionnaires related to SUI symptoms and their impact. Furthermore, subjects will require objective evaluations, including pelvic floor muscle strength assessments, pelvic ultrasound scans, and three-dimensional posture assessments, which will be performed by the same assessor, who will remain blinded to the allocation status. Following randomization and baseline data collection, all participants will embark on a 3-month BWL program instructed by the same team of nutrition experts. Throughout the program, participants will need to record their dietary intake three times a week (including at least one during weekends) and complete a weekly questionnaire on physical activity levels via the International Physical Activity Questionnaire^{25 26}. In BWL group, participants will be solely involved in self-supervision BWL. In the other two groups, participants will also undergo PFMT for 3 months. During the study period, all three groups will receive telephone supervision

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every three weeks. Assessments will be conducted at baseline (pretest), 3 months (after intervention), 9 months (6 months after intervention), and 15 months (12 months after intervention) during the study period (Figure 1). And the main assessment contents are shown in Table 1.

Patient selection and recruitment

The recruitment of participants in our study was initiated in May 2024, while the actual enrollment began in October 2024. Currently, nearly half of the participants have been recruited and some of them have completed the assessment after the 3-months intervention.. Women visiting the clinical nutrition department with clinically diagnosed SUI or MUI as the primary problem following the definition recognised by international guidelines ²⁷ will be informed about this program. Trained physicians will screen suitable candidates who satisfy all qualifying standards and express interest in participating, and an consent document will then be signed by those qualified for enrolment. Theoretically, all three groups in this study will experience some degree of improvement in their condition. If any adverse events or unexpected issues arise during the study period, participants are encouraged to promptly contact the project manager.

➤ ***Inclusion criteria:***

- 1, Women with a BMI ≥ 25 kg/cm²
- 2, Patients currently experiencing symptoms of SUI or SUI-dominated MUI
- 3, Age ≥18 years and ≤ 70 years
- 4, Agree to refrain from self-initiating new treatments during the study period

➤ ***Exclusion criteria:***

- 1, The presence of only urgency urinary incontinence

- 2, Pelvic organ prolapse greater than stage II (prolapse beyond the hymen > 1 cm)
- 3, Having received drug treatment for urinary incontinence or weight loss within the past month
- 4, History of pelvic floor surgery or bariatric surgery
- 5, History of pelvic or abdominal malignancy
- 6, Presence of urinary tract infection or ≥ 4 urinary tract infections within the past year
- 7, Previous PFMT under the guidance of a trained therapist lasting more than 3 months in the past 5 years
- 8, Delivery within the past six months, or current plans for pregnancy^{18 28}
- 9, Severe systematic diseases such as uncontrolled diabetes, hypertension, or hyperlipemia
- 10, Other factors that may impede participation in the trial, such as frequent business travel, mental illness, inability to voluntarily contract pelvic floor muscles, denial of sexual activity history, refusal to have a pressure measurement device placed inside the vagina, etc.

Randomization and masking

Upon the evaluation of the inclusion criteria and completion of the baseline assessments, the participants will be allocated into three groups via a computer-generated randomization tool as previous described²⁹, preserving an allocation ratio of 1:1:1. Considering the complexity of the intervention and the nature of the study, blinding of patients and physicians delivering the intervention and overseeing follow-ups is unfeasible. However, the assessors responsible for evaluating data will remain

uninformed about group assignments, and participants will be instructed against disclosing their study group status to evaluating physicians.

Interventions

The training protocols for the PFMT will be the same as our previous research ²⁹ and consist of three sets of fast and slow contractions daily in the supine position (6 min/set, 3 repetitions). Each rep has eight max contractions (6 s) + four fast contractions (1 s), with 30 s of rest between reps. The BWL protocol used in our previous research ³⁰ emphasized health education and behaviour modification. The participants will be asked to follow a balanced diet with protein accounting for 30% of their daily energy, primarily whey protein, and fat and carbohydrates accounting for 30% and 40%, respectively. They will also be advised to engage in a combination of cardio- and resistance exercises.

Outcome measures

➤ **Primary outcome measure**

The primary outcome measure of SUI severity will be the validated Chinese version of the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF) ³¹. This scale consists of four items—frequency of urine leakage (with a score range of 0 = never to 5 = always), volume of urine leakage (awarded points 0, 2, 4, and 6 for ascending volumes per occurrence), impact of urinary incontinence on daily life (scored on a scale of 0 = not at all to 10 = extremely), and types of leakage symptoms experienced during the last four weeks ³². The total ICIQ-UI-SF score ranges from 0 to 21, with severity categorized as mild (0–7), moderate (8–13), or severe (14–21).

➤ Secondary outcome measures

Weight loss

The effect of weight loss will be assessed by measuring various indicators, such as body weight, BMI, body surface area, and abdomen and hip circumference.

Pelvic floor muscle (PFM) strength

The strength of the PFM will be quantified by employing subjective (vaginal palpation) and objective (manometry) techniques.

- ✧ *Subjective PFM strength* will be evaluated via digital vaginal palpation via the modified Oxford grading scale. The participants will be guided to exert their maximum PFM contraction against the examiner's fingers within the vagina, rating their strength from 0 (no contraction) to 5 (strong contraction) ³³.
- ✧ *Objective PFM strength* will be measured as the maximum voluntary contraction pressure via an intravaginal manometer with a vaginal probe, 20 ml of air, and a PHENIX USB 8 NMS system. The maximum voluntary contraction pressure is obtained by deducting the vaginal resting pressure from the peak pressure achieved during maximal PFM contraction. The participants performed three trials, each 15 seconds apart, without involving abdominal, gluteal, or hip adductors. The average of these three values quantifies muscle strength, with higher pressure implying greater strength ^{34 35}.

Pelvic Floor Ultrasound

Using a Mindray Nuewa R9 ultrasonic diagnostic instrument, a transperineal three-dimensional volumetric probe (SD8-1U) will be used. The participants will be requested to empty their bladder before the examination and assume the lithotomy position. All pelvic floor ultrasound examinations for patients will be performed by the

same experienced physician who had undergone training and assessment, with images saved for subsequent analysis and the grouping hidden. Measurements will be taken at rest and during the maximum Valsalva manoeuvre. Signal acquisition and data recording include parameters such as the detrusor thickness, bladder neck mobility, posterior bladder angle, urethral inclination angle, urethral rotation angle, and levator hiatal area.

Pelvic organ prolapse

Pelvic organ prolapse staging is determined through the utilization of the Pelvic Organ Prolapse Quantification system³⁶, which quantifies the positioning of vaginal structures relative to the hymenal ring. The subjective symptoms will be assessed with the Pelvic Organ Prolapse Symptom Score questionnaire, which consists of seven questions examining symptom prevalence over the past month. The respondents record scores ranging from 0 (never) to 4 (constantly), with possible total scores ranging between 0 and 28. Higher scores signify greater symptom intensity^{37 38}.

Three-dimensional body posture

The participants assume a natural standing position with their hands by their sides, feet together, their toes forward, and their eyes facing forward. Depth cameras capture front and back images, followed by a full-body gait video. A smart three-dimensional posture analysis system (APHRO, EURADIS) uses depth cameras and artificial intelligence technology to assess multiple key body areas, including joint positioning, spinal curvature, and muscle distribution. The measured parameters include the thoracic kyphosis angle, lumbar lordosis angle, sacral inclination angle, shoulder tilt, leg type, lower limb (functional) length, pelvic left-right tilt, pelvic rotation, pelvic anterior-posterior tilt, and spinal sagittal axis.

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Health-related quality of life

The specific HRQoL will be evaluated via the Chinese version of the Incontinence Quality of Life Instrument ³⁹. This tool consists of 22 items categorized into three subdomains: avoidance and limiting behaviour, psychosocial impacts, and social embarrassment, with each query rated on a 5-point Likert-type scale. The total score is ultimately transformed to a 0-100 scale. The participants' general HRQoL will be assessed via the European Quality of Life-5 Dimensions 5-Level questionnaire ⁴⁰, which consists of a health description system and a visual analogue scale. The health description system covers five dimensions of health-related HRQoL: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on a scale from 1 (no problems) to 5 (extreme problems), providing a comprehensive evaluation of the participants' overall well-being. The associated visual analogue scale allows patients to subjectively rate their health status on a scale from 0 to 100, with higher scores indicating better health status.

Sexual function

Sexual function will be assessed via the Short-form Prolapse and Incontinence Sexual Questionnaire. This instrument gauges sexual dysfunction by querying 12 queries, with scores ranging from 0 to 48. Elevated values reflect more significant sexual difficulties ⁴¹.

Mental health

The Hospital Anxiety and Depression Scale ⁴² is a widely used, 14-item self-report questionnaire designed to assess the level of anxiety and depression in patients being treated in nonpsychiatric hospital settings. The Hospital Anxiety and Depression Scale comprises two subscales: seven items measuring anxiety and seven items assessing depression. Each item is rated on a 0--3 scale, yielding scores ranging from 0 to 21 for

both subscales. Scores of 8 or higher on either subscale indicate the presence of clinically relevant symptoms.

Overactive Bladder Symptom Score

Symptoms of OAB will be assessed by the overactive bladder symptom score ⁴³ with a cumulative threshold of three or more and a subscore of at least two on item 3 regarding urgency. For severity grading, a total score of 3 to 5 indicates mild severity, scores between 6 and 11 indicate moderate severity, and a score of 12 or above signifies severe severity.

Broome Pelvic Muscle Self-Efficacy Scale

Self-efficacy will be evaluated with the Broome Pelvic Muscle Self-Efficacy Scale, which consists of 23 items covering two domains: efficacy beliefs and outcome expectations ^{44 45}. In the efficacy beliefs portion, participants express their faith in PFMT practice. In the outcome expectations component, they assess their assurance of PFMT's ability to curb urine loss. Scores from this scale range from 0 to 100, with higher values indicating greater perceived self-efficacy.

Patient Global Impression of Improvement

During the 3-month intervention, participants' perceptions of urine leakage will be tracked via the Patient Global Impression of Improvement questionnaire. Physicians will conduct weekly phone calls with participants asking, "Compared with before this study, how would you rate your urinary symptoms now?" The responses are rated on a seven-point scale (1= marked improvement, 7 = marked worsening), with improvement defined as a rating of 1 (very much better) or 2 (much better) ⁴⁶.

Patient adherence to treatment

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Patient adherence to treatment will be evaluated according to subjective self-reports and the completion of relevant questionnaires.. Overall adherence will be classified as follows: low adherence (fewer than 50% of the anticipated exercises), moderate adherence (between 50% and 75% of the anticipated exercises), and high adherence (75% or more of the anticipated exercises).

Sample size

The primary outcome of this study was the ICIQ-UI SF score. According to a literature review, the standard deviation of ICIQ-SF scores in obese patients with concurrent urinary incontinence ranges from 2.61 to 4.9^{20 47 48}. In this study, a standard deviation of 4 was selected for all three groups. According to the literature, the minimum clinically important difference in the ICIQ-SF score is 2.5 points⁴⁹. A minimum difference of 3 points was chosen in this study, and the estimated mean scores for the three groups were 15, 14, and 12, respectively²⁰. With a bilateral alpha level of 0.05 and a power of 0.8, sample size calculation via PASS 15 software revealed that each group should include 35 participants. Considering a dropout and refusal rate of 10%, 40 participants per group will be planned to be recruited, resulting in a minimum total of 120 study subjects.

Statistical analysis

The data will be analyzed with SPSS V.23.0 software. Descriptive statistics, such as the mean, standard deviation, median, and interquartile range, will be employed for continuous variables, whereas relative frequencies with percentages (n, %) will be determined for categorical variables. One-way analysis of variance will be used to compare continuous variables consistent with homogeneity of variance among groups; otherwise, the Kruskal–Wallis test will be used. The chi-squared test or Fisher's exact

test will be used for categorical variable analysis. To examine the main and interactive effects, repeated measures analysis of variance will be employed for continuous variables following a normal distribution, denoted as the means $\pm$ standard deviations. The generalized estimating equations approach, with Bonferroni correction, will be utilized for continuous variables deviating from normality, presented as medians with interquartile ranges (P_{25} , P_{75}). Significance testing will utilize a two-tailed approach, with a cut-off value of $P<0.05$.

Data management

As previously described in our research ²⁹, the data management system for this study will comprise MySQL and the Peking Union Medical College Hospital Intelligent Follow-up System databases for data storage. Data within the system will be stored in a multi-tier architecture using a local cache and cloud storage. To maintain data integrity and clarity, data managers will frequently review entries using both computerized and manual techniques, focusing on completeness, omissions, and ambiguous values. Publication of study data will exclude personally identifiable information such as names, images, and any other identifying details to protect participant confidentiality. This trial will be also audited by the ethics committee.

Missing data

To assess the potential bias caused by missing data, we will compare the baseline characteristics of participants who did and did not have missing values. By identifying predictive factors for missingness, we can adjust the primary outcome analysis to account for these factors if they are significantly associated with the data missing. Additionally, as part of a sensitivity analysis, we will consider using multiple

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imputations through chained equations to address any missing data in the primary outcome model.

Ethics and dissemination

This trial has been registered with Chinese Clinical Trial Registry (<http://www.chictr.org.cn>: ChiCTR2400084015). All participants will be provided written informed consent, and the study will be conducted in accordance with the Declaration of Helsinki. The study protocol (Version 2) and the informed consent form has been approved by the Peking Union Medical College Hospital ethics committee (K5504, 2024-4-26). All results from the study will be submitted to relevant scientific journals and international conferences.

Advantage and limitation

The key advantages of this study design are that it focus on urinary incontinence symptom improvement as the primary outcome while also considering weight loss effectiveness, pelvic muscle strength, pelvic floor ultrasound, quality of life, mental health, sexual function, three-dimensional body posture, etc. Furthermore, the use of a relatively large sample size and a long follow-up period will strengthen the reliability of the results. Throughout the study, assessor blinding will be maintained to ensure fairness. Moreover, the study provide a standardized method for completing questionnaires and monitoring pelvic floor muscle contractions. However, it is important to acknowledge that this study also has several limitations. Firstly, intervention blinding will only be possible for assessors, not for participants or supervising physicians. Additionally, the BWL program used in this study focus primarily on a high-protein diet. Future investigations exploring various BWL approaches will contribute to more personalized treatment plans.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

Author’s contributions

All the listed authors have made essential contributions to the work. Guarantor is Zhijing Sun and the entire study will be directed by Zhijing Sun to ensure the execution and completion of the study according to the protocol. Zhijing Sun, Wei Chen and Zhao Tian conceived and designed the study protocol. Zhao Tian drafted the original manuscript. Xiuqi Wang, Linru Fu, and Tangdi Lin participated in refining the study design. All the authors have read and approved the final manuscript for publication.

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Outcomes	Baseline	After 3-month intervention	6 months after intervention	12 months after intervention
ICIQ-UI-SF	√	√	√	√
MOS	√	√		
MVCP	√	√		
POP-Q	√	√		
Pelvic Floor Ultrasound	√	√		
Three-Dimensional Body Posture	√	√		

Body weight	✓	✓	✓	✓
Abdominal circumference	✓	✓	✓	✓
I-QOL	✓	✓	✓	✓
POP-SS	✓	✓	✓	✓
OABSS	✓	✓	✓	✓
PISQ-12	✓	✓	✓	✓
EQ-5D-5 L	✓	✓	✓	✓
HADS	✓	✓	✓	✓
BPMSES	✓	✓	✓	✓
PGI-I		✓	✓	✓

Table 1. The assessments of the participants. ICIQ-UI-SF: Incontinence Modular Questionnaire-Urinary Incontinence Short Form, MOS: Modified Oxford Scale, MVCP: Maximum Voluntary Contraction Pressure, POP-Q: Pelvic Organ Prolapse Quantification, I-QOL: Incontinence Quality of Life Instrument, PISQ-12: Short-form Prolapse Incontinence Sexual Questionnaire, POP-SS: Pelvic Organ Prolapse Symptom Score, OABSS: Overactive Bladder Symptom Score, EQ-5D-5 L: European Quality of Life-5 Dimensions 5-Level questionnaire, HADS: Hospital Anxiety and Depression Scale, BPMSES: Broome Pelvic Muscle Self-Efficacy Scale: PGI-I: Patient Global Impression of Improvement.

Figure legends

Figure 1 Flow chart of the study. BWL: behavioural weight loss, PFMT: pelvic floor muscle training, Biof-PFMT: pelvic floor muscle training with a biofeedback device

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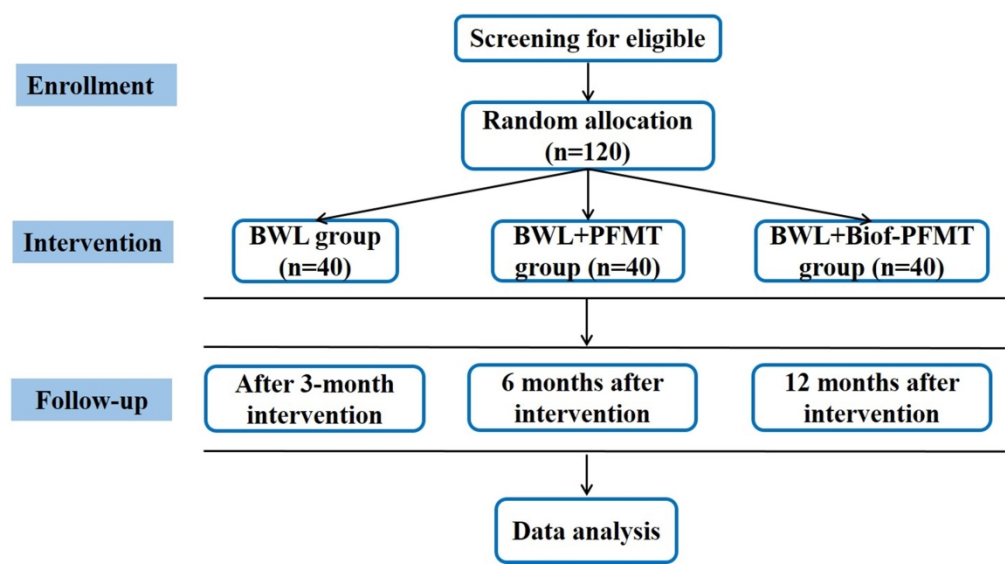


Figure 1 Flow chart of the study. BWL: behavioural weight loss, PFMT: pelvic floor muscle training, Biof-PFMT: pelvic floor muscle training with a biofeedback device

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BMJ Open

The Effect of Home-Based Behavioural Weight Loss Combined with Pelvic Floor Muscle Training in Women Seeking Weight Loss Combined with Stress Urinary Incontinence: Protocol for A Randomized Controlled Trial

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TITLE

The Effect of Home-Based Behavioural Weight Loss Combined with Pelvic Floor Muscle Training in Women Seeking Weight Loss Combined with Stress Urinary Incontinence: Protocol for A Randomized Controlled Trial

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The Effect of Home-Based Behavioural Weight Loss Combined with Pelvic Floor Muscle Training in Women Seeking Weight Loss Combined with Stress Urinary Incontinence: Protocol for A Randomized Controlled Trial

ABSTRACT

Introduction

Recent guidelines suggest behavioural weight loss (BWL) and pelvic floor muscle training (PFMT) as first-line treatment approaches for women with both obesity and stress urinary incontinence (SUI). However, the optimal therapeutic and management strategies for these populations remain uncertain.

Methods and analysis

This assessor-blinded parallel-group randomized controlled trial aims to compare the efficacy of BWL alone, BWL plus conventional PFMT, and BWL plus PFMT with a biofeedback device for women who are overweight or obesity experiencing SUI or SUI-predominant mixed urinary incontinence. A total of 120 eligible women will be randomly assigned at a 1:1:1 ratio. All the three groups will be subjected to a 3-month self-supervision intervention after randomization and will be assessed at baseline, after the 3-month intervention, 6 months after the intervention, and 12 months after the intervention. The primary outcome measure is the self-reported severity of urinary incontinence assessed by the International Consultation on Incontinence Questionnaire-Urinary Incontinence short form. The secondary outcomes include weight loss effectiveness, pelvic muscle strength, pelvic floor ultrasound, three-dimensional body posture, adherence to the intervention, and questionnaires for symptoms of pelvic organ prolapse, quality of life, and sexual function.

Ethics and dissemination

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This study has been approved by the Peking Union Medical College Hospital ethics committee (K5504). All results from the study will be submitted to international journals and international conferences.

Trial registration number: This trial has been registered with Chinese Clinical Trial Registry (ChiCTR2400084015).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- A relatively large sample size and a long follow-up period enhance the reliability of the results.
- A comprehensive assessment encompassing weight loss effectiveness, urinary incontinence symptom, pelvic muscle strength, pelvic floor ultrasound, quality of life, mental health, sexual function, and three-dimensional body posture will be conducted.
- To minimize bias, all three groups will adhere to the same expert-developed weight loss program; for the two PFMT groups, training protocols and supervisor contact frequencies will be standardized, with the sole distinction being the use of a biofeedback device. A standardized approach for questionnaire completion and pelvic floor muscle training monitoring will be employed, ensuring consistency in data collection.
- While assessor blinding will be achieved, it was only possible for the assessors and not for participants or supervising physicians, which could introduce potential bias.

INTRODUCTION

Overweight and obesity are growing public health problems, as projections indicate that approximately 20% of the global adult population could be affected by 2025¹, with some studies suggesting higher prevalence rates among women compared to men^{2,3}. Extensive evidence supports the gender-specific manifestation of obesity-associated comorbidities⁴. Notably, women with obesity demonstrate higher risks for cardiovascular complications and osteoarthritis, while men show greater predisposition to type 2 diabetes and non-alcoholic fatty liver disease⁵. With increasing population aging, pelvic floor disorders, which are among the top five chronic diseases affecting women's health-related quality of life (HRQoL), have become increasingly pressing public health issues. Recent studies have also revealed a connection between obesity and pelvic floor disorders, particularly stress urinary incontinence (SUI)⁶⁻⁸. While obesity and SUI may not be life-threatening, they significantly impact the HRQoL for those affected⁹⁻¹¹ and impose a considerable financial burden on healthcare systems¹².

The first-line treatment option for women struggling with SUI or SUI-predominant mixed urinary incontinence (MUI) is pelvic floor muscle training (PFMT) for a minimum duration of three months^{13,14}. To enhance the effectiveness of PFMT and cater to diverse needs, various therapeutic combinations have been devised, such as biofeedback, electrical stimulation, and bladder diaries [13]. Notably, biofeedback has a well-established reputation for its efficacy¹³⁻¹⁵. In addition, several randomized controlled trials (RCTs)¹⁶⁻¹⁹ have demonstrated the positive impact of behavioural weight loss (BWL) on reducing urinary incontinence symptoms among women with obesity. Current guidelines advocate coordinated management involving gynecologists and nutritionists in this population¹³⁻¹⁵; however, there is limited research on the optimal combined management strategy.

An RCT assessed the effects of PFMT with or without BWL in women with MUI and a body mass index (BMI) between 25 and 40 kg/m². The results revealed that BWL offered no additional benefits over PFMT²⁰, which highlights the importance of PFMT.

However, the conclusion remains to be further validated considering the limitations of the study's sample size (n=22), the short duration of the protocol (8 weeks) and the low weight-loss efficiency in the BWL + PFMT group, since there were no significant differences in body weight between the two groups before and after the intervention.. Moreover, in real-world clinical practice, despite the significant proportion of women seeking weight loss suffering from urinary incontinence, they do not pay adequate attention to these issues and may hesitate to discuss this symptom because of its sensitive nature. While some women may experience improvements in urinary incontinence symptoms after weight loss, research on this topic is limited. Some women with noticeable symptoms might also attempt to perform PFMT on their own, but the lack of standardized procedures and inadequate supervision can greatly impede their effective resolution. There is a critical lack of public awareness and education in these populations ²¹, and the optimal therapeutic and management strategies for these populations remain uncertain. Additionally, limited medical resources in certain areas hinder access to appropriate healthcare services. Given that societal and healthcare structures, lifestyle modifications, and long-term interventions are essential for early recognition and prompt management, an effective self-supervision strategy is crucial for patients with both obesity and SUI. Streamlining patient convenience and reducing healthcare costs are driving the exploration of biofeedback, which may improve treatment compliance and treatment effects ^{22 23}.

Prior research ²⁴ has shown that the severity of urinary incontinence symptoms often worsens with prolonged obesity, and weight management should be provided throughout a person's lifetime. However, the existing constraints on healthcare resources impede the implementation of such comprehensive guidance. The disparities in multidisciplinary team collaboration and awareness present formidable challenges to achieving optimal management of urinary incontinence among women with obesity. Therefore, there is an urgent need to increase awareness, promote research, and enhance interdisciplinary supervision in managing urinary incontinence among women with

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obesity. The development of an effective management strategy for BWL and PFMT tailored to this population is crucial for enhancing the quality of medical services. This research protocol is designed to explore an effective and practical home-based integrated management strategy for women with both overweight/obesity and SUI symptoms.

METHODS AND ANALYSIS

Study design

This assessor-blinded parallel-group RCT aims to compare the efficacy of BWL alone, BWL plus conventional PFMT, and BWL plus PFMT with a biofeedback device for women who are overweight or obesity experiencing SUI or SUI-predominant MUI. Eligible patients will be randomly allocated to one of the three groups mentioned above. The participants will undergo a comprehensive baseline evaluation that includes the following: the provision of essential baseline clinical characteristics, including demographic details, pregnancy delivery history, lifestyle factors, etc., and the completion of validated questionnaires related to SUI symptoms and their impact. Furthermore, subjects will require objective evaluations, including pelvic floor muscle strength assessments, pelvic ultrasound scans, and three-dimensional posture assessments, which will be performed by the same assessor, who will remain blinded to the allocation status. Following randomization and baseline data collection, all participants will embark on a 3-month BWL program instructed by the same team of nutrition experts. Throughout the program, participants will need to record their dietary intake three times a week (including at least one during weekends) and complete a weekly questionnaire on physical activity levels via the International Physical Activity Questionnaire^{25 26}. In BWL group, participants will be solely involved in self-supervision BWL. In the other two groups, participants will also undergo PFMT for 3 months. During the study period, all three groups will receive telephone supervision

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every three weeks. Assessments will be conducted at baseline, after the 3-month intervention, 6 months after intervention, and 12 months after intervention (Figure 1). The primary assessment contents for each phase are detailed in Table 1.

Patient selection and recruitment

The enrolment of participants in our study began in October 2024. Currently, nearly half of the participants have been recruited and some of them have completed the assessment after the 3-months intervention.. Women visiting the clinical nutrition department with clinically diagnosed SUI or MUI as the primary problem following the definition recognised by international guidelines ²⁷ will be informed about this program. Trained physicians will screen suitable candidates who satisfy all qualifying standards and express interest in participating, and a consent document (Supplementary material) will then be signed by those qualified for enrolment. Theoretically, all three groups in this study will experience some degree of improvement in their condition. If any adverse events or unexpected issues arise during the study period, participants are encouraged to promptly contact the project manager.

➤ ***Inclusion criteria:***

- 1, Women with a BMI ≥ 25 kg/cm²
- 2, Patients currently experiencing symptoms of SUI or SUI-dominated MUI
- 3, Age ≥18 years and ≤ 70 years
- 4, Agree to refrain from self-initiating new treatments during the study period

➤ ***Exclusion criteria:***

- 1, The presence of only urgency urinary incontinence
- 2, Pelvic organ prolapse greater than stage II (prolapse beyond the hymen > 1 cm)

- 3, Having received drug treatment for urinary incontinence or weight loss within the past month
- 4, History of pelvic floor surgery or bariatric surgery
- 5, History of pelvic or abdominal malignancy
- 6, Presence of urinary tract infection or ≥ 4 urinary tract infections within the past year
- 7, Previous PFMT under the guidance of a trained therapist lasting more than 3 months in the past 5 years
- 8, Delivery within the past six months, or current plans for pregnancy^{18 28}
- 9, Severe systematic diseases such as uncontrolled diabetes, hypertension, or hyperlipemia
- 10, Other factors that may impede participation in the trial, such as frequent business travel, mental illness, inability to voluntarily contract pelvic floor muscles, denial of sexual activity history, refusal to have a pressure measurement device placed inside the vagina, etc.

Randomization and masking

Upon the evaluation of the inclusion criteria and completion of the baseline assessments, the participants will be allocated into three groups via a computer-generated randomization tool as previous described²⁹, preserving an allocation ratio of 1:1:1. Considering the complexity of the intervention and the nature of the study, blinding of patients and physicians delivering the intervention and overseeing follow-ups is unfeasible. However, the assessors responsible for evaluating data will remain uninformed about group assignments, and participants will be instructed against disclosing their study group status to evaluating physicians.

Interventions

The training protocols for the PFMT will be the same as our previous research ²⁹ and consist of three sets of fast and slow contractions daily in the supine position (6 min/set, 3 repetitions). Each rep has eight max contractions (6 s) + four fast contractions (1 s), with 30 s of rest between reps. The BWL protocol used in our previous research ³⁰ emphasized health education and behaviour modification. The participants will be asked to follow a balanced diet with protein accounting for 30% of their daily energy, primarily whey protein, and fat and carbohydrates accounting for 30% and 40%, respectively. They will also be advised to engage in a combination of cardio- and resistance exercises.

Outcome measures

➤ **Primary outcome measure**

The primary outcome measure of SUI severity will be the validated Chinese version of the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF) ³¹. This scale consists of four items—frequency of urine leakage (with a score range of 0 = never to 5 = always), volume of urine leakage (awarded points 0, 2, 4, and 6 for ascending volumes per occurrence), impact of urinary incontinence on daily life (scored on a scale of 0 = not at all to 10 = extremely), and types of leakage symptoms experienced during the last four weeks ³². The total ICIQ-UI-SF score ranges from 0 to 21, with severity categorized as mild (0–7), moderate (8–13), or severe (14–21).

➤ **Secondary outcome measures**

Weight loss

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The effect of weight loss will be assessed by measuring various indicators, such as body weight, BMI, body surface area, and abdomen and hip circumference.

Pelvic floor muscle (PFM) strength

The strength of the PFM will be quantified by employing subjective (vaginal palpation) and objective (manometry) techniques.

- ✧ ***Subjective PFM strength*** will be evaluated via digital vaginal palpation via the modified Oxford grading scale. The participants will be guided to exert their maximum PFM contraction against the examiner's fingers within the vagina, rating their strength from 0 (no contraction) to 5 (strong contraction) ³³.
- ✧ ***Objective PFM strength*** will be measured as the maximum voluntary contraction pressure via an intravaginal manometer with a vaginal probe, 20 ml of air, and a PHENIX USB 8 NMS system. The maximum voluntary contraction pressure is obtained by deducting the vaginal resting pressure from the peak pressure achieved during maximal PFM contraction. The participants performed three trials, each 15 seconds apart, without involving abdominal, gluteal, or hip adductors. The average of these three values quantifies muscle strength, with higher pressure implying greater strength ^{34 35}.

Pelvic Floor Ultrasound

Using a Mindray Nuewa R9 ultrasonic diagnostic instrument, a transperineal three-dimensional volumetric probe (SD8-1U) will be used. The participants will be requested to empty their bladder before the examination and assume the lithotomy position. All pelvic floor ultrasound examinations for patients will be performed by the same experienced physician who had undergone training and assessment, with images saved for subsequent analysis and the grouping hidden. Measurements will be taken at

rest and during the maximum Valsalva manoeuvre. Signal acquisition and data recording include parameters such as the detrusor thickness, bladder neck mobility, posterior bladder angle, urethral inclination angle, urethral rotation angle, and levator hiatal area.

Pelvic organ prolapse

Pelvic organ prolapse staging is determined through the utilization of the Pelvic Organ Prolapse Quantification system³⁶, which quantifies the positioning of vaginal structures relative to the hymenal ring. The subjective symptoms will be assessed with the Pelvic Organ Prolapse Symptom Score questionnaire, which consists of seven questions examining symptom prevalence over the past month. The POP-SS comprises seven items, each scored on a 5-point Likert scale (0 = never, 1 = occasionally, 2 = sometimes, 3 = most of the time, 4 = all of the time). A total score (range: 0–28) is calculated by summing responses to the seven symptom items. Additionally, participants indicate which symptom causes them the greatest bother^{37 38}.

Three-dimensional body posture

The participants assume a natural standing position with their hands by their sides, feet together, their toes forward, and their eyes facing forward. Depth cameras capture front and back images, followed by a full-body gait video. A smart three-dimensional posture analysis system (APHRO, EURADIS) uses depth cameras and artificial intelligence technology to assess multiple key body areas, including joint positioning, spinal curvature, and muscle distribution. The measured parameters include the thoracic kyphosis angle, lumbar lordosis angle, sacral inclination angle, shoulder tilt, leg type, lower limb (functional) length, pelvic left-right tilt, pelvic rotation, pelvic anterior-posterior tilt, and spinal sagittal axis.

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Health-related quality of life

The specific HRQoL will be evaluated via the Chinese version of the Incontinence Quality of Life Instrument ³⁹. This tool consists of 22 items categorized into three subdomains: avoidance and limiting behaviour, psychosocial impacts, and social embarrassment, with each query rated on a 5-point Likert-type scale. The total score is ultimately transformed to a 0-100 scale. The participants' general HRQoL will be assessed via the European Quality of Life-5 Dimensions 5-Level questionnaire ⁴⁰, which consists of a health description system and a visual analogue scale. The health description system covers five dimensions of health-related HRQoL: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on a scale from 1 (no problems) to 5 (extreme problems), providing a comprehensive evaluation of the participants' overall well-being. The associated visual analogue scale allows patients to subjectively rate their health status on a scale from 0 to 100, with higher scores indicating better health status.

Sexual function

Sexual function will be assessed via the Short-form Prolapse and Incontinence Sexual Questionnaire. This instrument gauges sexual dysfunction by querying 12 queries, with scores ranging from 0 to 48. Elevated values reflect more significant sexual difficulties ⁴¹.

Mental health

The Hospital Anxiety and Depression Scale ⁴² is a widely used, 14-item self-report questionnaire designed to assess the level of anxiety and depression in patients being treated in nonpsychiatric hospital settings. The Hospital Anxiety and Depression Scale comprises two subscales: seven items measuring anxiety and seven items assessing depression. Each item is rated on a 0--3 scale, yielding scores ranging from 0 to 21 for

both subscales. Scores of 8 or higher on either subscale indicate the presence of clinically relevant symptoms.

Overactive Bladder Symptom Score

Symptoms of OAB will be assessed by the overactive bladder symptom score ⁴³ with a cumulative threshold of three or more and a subscore of at least two on item 3 regarding urgency. For severity grading, a total score of 3 to 5 indicates mild severity, scores between 6 and 11 indicate moderate severity, and a score of 12 or above signifies severe severity.

Broome Pelvic Muscle Self-Efficacy Scale

Self-efficacy will be evaluated with the Broome Pelvic Muscle Self-Efficacy Scale, which consists of 23 items covering two domains: efficacy beliefs and outcome expectations ^{44 45}. In the efficacy beliefs portion, participants express their faith in PFMT practice. In the outcome expectations component, they assess their assurance of PFMT's ability to curb urine loss. Scores from this scale range from 0 to 100, with higher values indicating greater perceived self-efficacy.

Patient Global Impression of Improvement

During the 3-month intervention, participants' perceptions of urine leakage will be tracked via the Patient Global Impression of Improvement questionnaire. Physicians will conduct weekly phone calls with participants asking, "Compared with before this study, how would you rate your urinary symptoms now?" The responses are rated on a seven-point scale (1= marked improvement, 7 = marked worsening), with improvement defined as a rating of 1 (very much better) or 2 (much better) ⁴⁶.

Patient adherence to treatment

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Patient adherence to treatment will be evaluated according to subjective self-reports and the completion of relevant questionnaires.. Overall adherence will be classified as follows: low adherence (fewer than 50% of the anticipated exercises), moderate adherence (between 50% and 75% of the anticipated exercises), and high adherence (75% or more of the anticipated exercises). To enhance compliance, a strict informed consent process will be implemented to ensure that participants fully understand the study requirements during the recruitment phase. Besides, we adopt a single-center design in the current study and have a dedicated person in charge of regular supervision to facilitate closer patient monitoring and streamlined communication.

Sample size

The primary outcome of this study was the ICIQ-UI SF score. According to a literature review, the standard deviation of ICIQ-SF scores in obese patients with concurrent urinary incontinence ranges from 2.61 to 4.9^{20 47 48}. In this study, a standard deviation of 4 was selected for all three groups. According to the literature, the minimum clinically important difference in the ICIQ-SF score is 2.5 points⁴⁹. A minimum difference of 3 points was chosen in this study, and the estimated mean scores for the three groups were 15, 14, and 12, respectively²⁰. With a bilateral alpha level of 0.05 and a power of 0.8, sample size calculation via PASS 15 software revealed that each group should include 35 participants. Considering a dropout and refusal rate of 10%, 40 participants per group will be planned to be recruited, resulting in a minimum total of 120 study subjects.

Statistical analysis

The data will be analyzed with SPSS V.23.0 software. Descriptive statistics, such as the mean, standard deviation, median, and interquartile range, will be employed for

continuous variables, whereas relative frequencies with percentages (n, %) will be determined for categorical variables. One-way analysis of variance will be used to compare continuous variables consistent with homogeneity of variance among groups; otherwise, the Kruskal–Wallis test will be used. The chi-squared test or Fisher's exact test will be used for categorical variable analysis. To examine the main and interactive effects, repeated measures analysis of variance will be employed for continuous variables following a normal distribution, denoted as the means $\pm$ standard deviations. The generalized estimating equations approach, with Bonferroni correction, will be utilized for continuous variables deviating from normality, presented as medians with interquartile ranges (P₂₅, P₇₅). Significance testing will utilize a two-tailed approach, with a cut-off value of P<0.05.

Data management

As previously described in our research ²⁹, the data management system for this study will comprise MySQL and the Peking Union Medical College Hospital Intelligent Follow-up System databases for data storage. Data within the system will be stored in a multi-tier architecture using a local cache and cloud storage. To maintain data integrity and clarity, data managers will frequently review entries using both computerized and manual techniques, focusing on completeness, omissions, and ambiguous values. Publication of study data will exclude personally identifiable information such as names, images, and any other identifying details to protect participant confidentiality. This trial will be also audited by the ethics committee.

Missing data

To assess the potential bias caused by missing data, we will compare the baseline characteristics of participants who did and did not have missing values. By identifying

predictive factors for missingness, we can adjust the primary outcome analysis to account for these factors if they are significantly associated with the data missing. Additionally, as part of a sensitivity analysis, we will consider using multiple imputations through chained equations to address any missing data in the primary outcome model.

Ethics and dissemination

This trial has been registered with Chinese Clinical Trial Registry (<http://www.chictr.org.cn>: ChiCTR2400084015). All participants will be provided written informed consent, and the study will be conducted in accordance with the Declaration of Helsinki. The study protocol (Version 2) and the informed consent form has been approved by the Peking Union Medical College Hospital ethics committee (K5504, 2024-4-26). All results from the study will be submitted to relevant scientific journals and international conferences.

Advantage and limitation

The key advantages of this study design are that it focus on urinary incontinence symptom improvement as the primary outcome while also considering weight loss effectiveness, pelvic muscle strength, pelvic floor ultrasound, quality of life, mental health, sexual function, three-dimensional body posture, etc. Furthermore, the use of a relatively large sample size and a long follow-up period will strengthen the reliability of the results. Throughout the study, assessor blinding will be maintained to ensure fairness. Moreover, the study provide a standardized method for completing questionnaires and monitoring pelvic floor muscle contractions. However, it is important to acknowledge that this study also has several limitations. Firstly, intervention blinding will only be possible for assessors, not for participants or supervising physicians. Additionally, the BWL program used in this study focus

primarily on a high-protein diet. Future investigations exploring various BWL approaches will contribute to more personalized treatment plans.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

Author’s contributions

All the listed authors have made essential contributions to the work. Guarantor is Zhijing Sun and the entire study will be directed by Zhijing Sun to ensure the execution and completion of the study according to the protocol. Zhijing Sun, Wei Chen and Zhao Tian conceived and designed the study protocol. Zhao Tian drafted the original manuscript. Xiuqi Wang, Linru Fu, and Tangdi Lin participated in refining the study design. All the authors have read and approved the final manuscript for publication.

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Outcomes	Baseline	After 3-month intervention	6 months after intervention	12 months after intervention
ICIQ-UI-SF	√	√	√	√
MOS	√	√		
MVCP	√	√		
POP-Q	√	√		
Pelvic Floor Ultrasound	√	√		

Three-Dimensional Body Posture	✓	✓		
Body weight	✓	✓	✓	✓
Abdominal circumference	✓	✓	✓	✓
I-QOL	✓	✓	✓	✓
POP-SS	✓	✓	✓	✓
OABSS	✓	✓	✓	✓
PISQ-12	✓	✓	✓	✓
EQ-5D-5 L	✓	✓	✓	✓
HADS	✓	✓	✓	✓
BPMSES	✓	✓	✓	✓
PGI-I		✓	✓	✓

Table 1. The assessments of the participants. ICIQ-UI-SF: Incontinence Modular Questionnaire-Urinary Incontinence Short Form, MOS: Modified Oxford Scale, MVCP: Maximum Voluntary Contraction Pressure, POP-Q: Pelvic Organ Prolapse Quantification, I-QOL: Incontinence Quality of Life Instrument, PISQ-12: Short-form Prolapse Incontinence Sexual Questionnaire, POP-SS: Pelvic Organ Prolapse Symptom Score, OABSS: Overactive Bladder Symptom Score, EQ-5D-5 L: European Quality of Life-5 Dimensions 5-Level questionnaire, HADS: Hospital Anxiety and Depression Scale, BPMSES: Broome Pelvic Muscle Self-Efficacy Scale: PGI-I: Patient Global Impression of Improvement.

Figure legends

Figure 1 Flow chart of the study. BWL: behavioural weight loss, PFMT: pelvic floor muscle training, Biof-PFMT: pelvic floor muscle training with a biofeedback device

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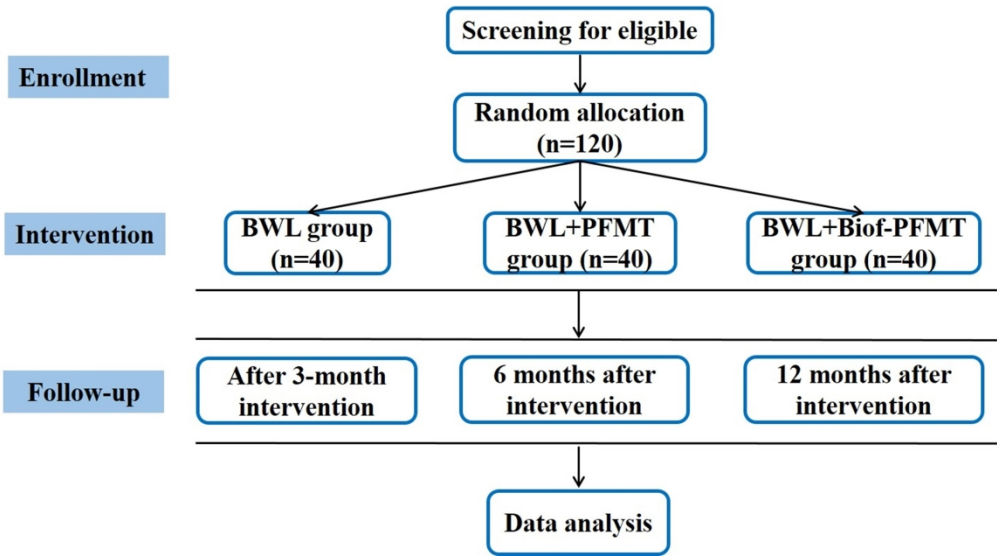


Figure 1 Flow chart of the study. BWL: behavioural weight loss, PFMT: pelvic floor muscle training, Biof-PFMT: pelvic floor muscle training with a biofeedback device

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