

MANAGING FEMALE STRESS URINARY INCONTINENCE IN DEVELOPING WORLD – A RANDOMIZED CONTROL TRIAL ON EVALUATION OF SUPERVISED AND UNSUPERVISED PELVIC FLOOR MUSCLE TRAINING

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ABSTRACT

Introduction: Stress urinary incontinence is a common condition affecting women, often underreported in developing countries. Pelvic Floor Muscle Training is the first-line treatment. Supervised PFMT showing better outcomes compared to unsupervised, home-based PFMT. **Objective:** This study compares the effectiveness of both approaches in improving SUI symptoms and pelvic floor muscle strength. **Material & Methods:** A randomized controlled trial was conducted at a Tertiary care center, from June 2023 to December 2024. Sixty women with confirmed SUI were randomly assigned to supervised PFMT (Group A) or unsupervised PFMT (Group B). The primary outcome was the reduction in urinary leakage, measured by the pad test. Secondary outcomes included pelvic floor muscle strength, urinary symptoms, and patient satisfaction. **Results:** Group A showed a significant reduction in leakage, with the pad test decreasing from 22.89 grams to 3.24 grams ($p < 0.001$), compared to Group B, which reduced from 25.71 grams to 17.82 grams ($p = 0.07$). Group A also demonstrated a greater improvement in pelvic floor strength, with 66.7% reaching Oxford grades 4-5 versus 13.3% in Group B ($p = 0.023$). A significant difference in daily leak episodes was observed, with Group A reducing from 7.63 to 1.69 compared to 8.88 to 7.75 in Group B ($p < 0.001$). **Conclusion:** Supervised PFMT is more effective than unsupervised PFMT in treating SUI. However, unsupervised PFMT remains a feasible alternative in resource-limited settings when patients adhere to the regimen.

Keywords: Stress urinary incontinence, pelvic floor muscle training, urinary leakage.

ABSTRAK

Pendahuluan: Inkontinensia urin stres adalah kondisi umum yang memengaruhi wanita dan sering kali kurang dilaporkan di negara-negara berkembang. Pelatihan Otot Dasar Panggul (Pelvic Floor Muscle Training/PFMT) adalah pengobatan lini pertama. PFMT supervised menunjukkan hasil yang lebih baik dibandingkan dengan PFMT unsupervised. **Tujuan:** Studi ini membandingkan efektivitas kedua pendekatan tersebut dalam memperbaiki gejala SUI dan kekuatan otot dasar panggul. **Bahan & Cara:** Uji coba terkontrol secara acak dilakukan di pusat perawatan tersier, dari Juni 2023 hingga Desember 2024. Enam puluh wanita dengan inkontinensia urin stres (SUI) yang terkonfirmasi secara acak ditugaskan ke kelompok PFMT yang diawasi (Kelompok A) atau PFMT yang tidak diawasi (Kelompok B). Hasil utama adalah pengurangan kebocoran urin, yang diukur dengan tes Pad. Hasil sekunder meliputi kekuatan otot dasar panggul, gejala saluran kemih, dan kepuasan pasien. **Hasil:** Kelompok A menunjukkan penurunan kebocoran yang signifikan, dengan uji pembalut menurun dari 22.89 gram menjadi 3.24 gram ($p < 0.001$), dibandingkan dengan Kelompok B, yang menurun dari 25.71 gram menjadi 17.82 gram ($p = 0.07$). Kelompok A juga menunjukkan peningkatan yang lebih besar dalam kekuatan dasar panggul, dengan 66.7% mencapai tingkat Oxford 4-5 dibandingkan dengan 13.3% pada Kelompok B ($p = 0.023$). Perbedaan signifikan dalam episode kebocoran harian diamati, dengan Kelompok A menurundari 7.63 menjadi 1.69 dibandingkan dengan 8.88 menjadi 7.75 pada Kelompok B ($p < 0.001$). **Simpulan:** PFMT supervised lebih efektif dari pada PFMT unsupervised dalam mengobati SUI. Namun, PFMT unsupervised tetap menjadi alternatif yang layak di lingkungan dengan keterbatasan sumber daya jika pasien mematuhi regimen tersebut.

Kata kunci: Inkontinensia urin stres, pelvic floor muscle training, kebocoran urin.

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INTRODUCTION

Stress urinary incontinence (SUI) is a prevalent and often underreported condition, especially in developing world that significantly affects women's quality of life across all age groups. The International Continence Society (ICS) defined SUI as the involuntary leakage of urine during physical activities that increase intra-abdominal pressure, such as coughing, sneezing or exercising.¹ Research conducted across various regions of the country has estimated the prevalence of urinary incontinence to range between 20% and 30%.² In patriarchal societies like India, women's healthcare decisions are often influenced by men, despite women being the primary caregivers for their families. Despite the physical and psychological distress it causes, many women delay seeking care due to stigma, embarrassment, and lack of awareness.

The etiology of SUI involves a complex interplay of factors, including pelvic floor muscle (PFM) weakness, urethral sphincter insufficiency, childbirth trauma, aging and hormonal changes.³⁻⁴ Given the structural support these muscles provide to the urethra and bladder neck, any compromise in their function predisposes women to leakage during exertion. Among the available conservative treatment modalities, Pelvic Floor Muscle Training (PFMT) is considered the first-line therapy.⁵ PFMT improves continence by strengthening the pelvic floor musculature, enhancing neuromuscular control and promoting urethral support. Success rates of 56–75% have been reported with PFMT when patients adhere to the prescribed regimen.⁶

However, the effectiveness of PFMT largely depends on correct technique and adherence. While supervised PFMT is conducted under the guidance of trained physiotherapists, which ensures appropriate execution and motivation, it may not always be accessible due to logistical or financial constraints.⁷ Unsupervised or home-based PFMT, though more convenient, raises concerns about inconsistent adherence and improper technique, potentially limiting its benefits.⁸

OBJECTIVE

Given the socio-cultural and infrastructural challenges in resource-limited settings like India, understanding the comparative effectiveness of supervised and unsupervised PFMT is essential.⁹

This study aims to address this gap by evaluating outcomes such as symptom relief, muscle strength improvement and patient satisfaction in both settings. Through a prospective randomized design, it seeks to provide evidence-based insights that can inform treatment guidelines and make continence care more accessible and effective for women across diverse backgrounds.

MATERIAL & METHODS

This study is a prospective, randomized, controlled trial (RCT) conducted to compare the effectiveness of supervised PFMT and unsupervised home-based PFMT in the management of female SUI. It was designed to evaluate subjective and objective outcomes, including, pad test weight, reduction in frequency of urinary leakage episodes, improvement in PFM strength and patient satisfaction. The trial was conducted at a tertiary care hospital between June 2023 and December 2024 after the study was approved by the Institutional Ethics Committee (IEC/2023/1395).

Patients with urinary symptoms were assessed in the Urology OPD, where SUI was diagnosed based on a positive stress cough test and pad test (≥ 2 gram leakage).¹⁰ Patients were educated on PFM location using anatomical diagrams (Figure 1) and techniques were taught. Women aged 18 years and above with stress urinary incontinence with positive stress test and pad test (≥ 2 gram). Pregnant women, mixed incontinence with significant urgency, pelvic organ prolapse greater than stage I, neurological conditions or prior pelvic surgery. 60 participants were recruited and randomly assigned to Group A (supervised PFMT) or Group B (unsupervised PFMT). Randomization was done via sealed envelopes. Both groups were taught PFMT exercises in both the Urology and Physiotherapy departments after being allocated to their respective groups, with follow-up assessments in the Urology OPD only.

Participants in Group A underwent supervised PFMT, which involved twice-weekly 1-hour sessions for 12 weeks, under the guidance of a certified physiotherapist and rest of the week, written instructions for home-based exercise were given. Participants in Group B were given written instructions for home-based PFMT. The home exercise protocol mirrored the supervised program. Do these exercises every day in 3 positions: lying down, sitting and standing.

For each position:

1. Quick squeezes – Squeeze the muscles for 1–2 seconds, then relax for same time. Do 5 times.
2. Long holds – Squeeze and hold for 5 seconds (work up to 10 seconds), then relax for same time. Do 5 times.

This makes 1 session (upon completing exercises in all 3 positions). Do 2 exercise sessions per day - once in the morning, once in the evening. Total: 60 exercises daily.

The primary outcome measure was the objective cure of SUI, defined as a negative pad test (less than 2gram of leakage over 24 hours) after 12 weeks of treatment. The 24-hour pad test involved measuring the amount of urine leakage during a series of physical activities, including coughing, squatting and stair climbing. This objective measure was chosen to assess the treatment effect on incontinence severity.

Secondary Outcomes

- Pelvic Floor Muscle Function: Pelvic floor strength was measured using the Oxford grading system (Table 1).
- Urinary Symptoms: Daily leakage episodes in a voiding diary for 3 days.
- Patient Satisfaction: Self-assessed, where participants categorized the treatment satisfaction simply as Yes or No.

Data were analyzed using SPSS version (Version 25). Descriptive statistics were used to summarize baseline characteristics and outcome measures. Continuous variables were analyzed using

paired t-tests for within-group comparisons and independent t-tests for between-group comparisons. For non-parametric data, the Mann-Whitney U test and the Wilcoxon signed-rank test were employed. The significance level was set at $p < 0.05$. All analyses were performed according to the intention-to-treat (ITT) principle, with missing data imputed where necessary.

Sample size calculation was based on the primary outcome, the objective cure rate (negative pad test). Using data from previous studies[10], it was estimated that a minimum of (30) participants per group would be needed to detect a clinically significant difference between the two treatment groups with 80% power and a 5% significance level. This study was approved by the Ethics Committee (IEC/2023/1395) of a tertiary care hospital, and all participants provided written informed consent before enrollment. Participants were assured of the confidentiality of their data and their right to withdraw from the study at any time without penalty. The authors confirm the availability of, and access to, all original data reported in this study.

RESULTS

A total of 60 women with confirmed stress urinary incontinence were screened and randomized equally into two groups: supervised and unsupervised pelvic floor muscle training. All participants underwent baseline assessment, with detailed reasons for exclusions and losses to follow-up documented. The CONSORT diagram (Figure 1) illustrates the flow of participants through enrollment, randomization, allocation, follow-up and final analysis, ensuring transparency and rigor in reporting patient disposition throughout the study.

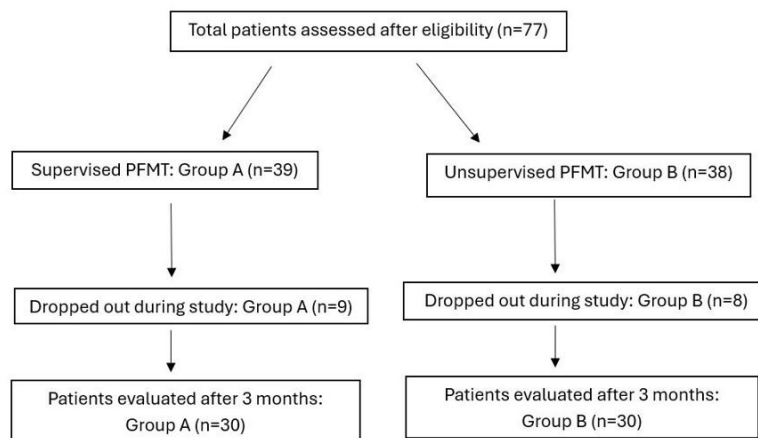


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of study participants.

Both groups were comparable at baseline in terms of demographic and clinical characteristics. There were no significant differences between the supervised (Group A) and unsupervised (Group B) groups regarding age, duration of symptoms, BMI, parity, or number of vaginal deliveries (Table 1). This comparability supports the internal validity of the subsequent outcome comparisons.

At baseline, there was no significant difference between Group A and Group B in pad test results ($p = 0.304$). After 3 months, Group A showed a significant reduction in urinary leakage (3.24 g) compared to Group B (17.82 g), with a significant between-group difference ($p < 0.001$). Within-group analysis showed a significant improvement in Group A ($p < 0.001$), but not in Group B ($p = 0.07$). Similarly, bladder diary results showed no

significant difference at baseline ($p = 0.067$). After 3 months, Group A had a marked reduction in daily leak episodes (1.69) compared to Group B (7.75), with a significant between-group difference ($p < 0.001$). Group A showed significant within-group improvement ($p < 0.001$), while Group B did not ($p = 0.61$) (Table 2).

Pelvic floor muscle strength, evaluated by the Oxford grading system, improved notably in the supervised PFMT group. At baseline, there was no significant difference in Oxford grade distribution between groups ($p = 0.871$). After three months, 66.7% of women in Group A reached grade 4 or 5 versus 13.3% in Group B ($p = 0.023$). Correspondingly, the proportion of participants with poor muscle strength (Oxford grade 1 or 2) decreased markedly in Group A compared to Group B (Table 3).

Table 1. Demographic characteristics of patients.

Variable	Group A		Group B		p value
	Mean	SD	Mean	SD	
Age	49.88	4.4	50.38	3.76	0.732
Duration of symptoms (years)	7.22	2.80	7.03	2.70	0.849
BMI	25.54	3.68	26.79	3.29	0.319
Parity	3.56	1.31	3.31	1.25	0.586
Vaginal delivery	2.25	1.06	2.19	0.98	0.864

Table 2. Pad test (grams) and Bladder diary (mean number of leak/day) analysis.

Timepoint	Parameter	Group A (Mean \pm SD)	Group B (Mean \pm SD)	Between-Group p value	Within-Group p value
Baseline	Pad Test	22.89 \pm 7.73	25.71 \pm 7.30	0.304	–
	Bladder Diary	7.63 \pm 1.67	8.88 \pm 2.03	0.067	–
3 Months	Pad Test	3.24 \pm 3.63	17.82 \pm 11.12	<0.001	A: <0.001, B:0.07
	Bladder Diary	1.69 \pm 2.06	7.75 \pm 3.02	<0.001	A: <0.001, B:0.61

Table 3. Oxford grade analyses (0-5).

Variable	Group A, n (%)	Group B, n (%)	p value
Baseline Oxford Grade (0-5)			
1	4 (13.3)	6 (20)	0.871
2	14 (46.7)	16 (53.3)	
3	10 (33.3)	7 (23.3)	
4 or 5	2 (7.6)	1 (3.3)	
Oxford Grade (0-5) after 3 months of treatment			
1	0	4 (13.3)	0.023
2	4 (13.3)	14 (46.7)	
3	6 (20)	8 (26.7)	
4 or 5	20 (66.7)	4 (13.3)	

A higher proportion of women in the supervised group expressed satisfaction with their treatment compared to the unsupervised group at the end of the intervention (Figure 2). This aligns with the trend observed in previous studies, where structured supervision enhanced motivation, adherence and patient-reported outcomes.

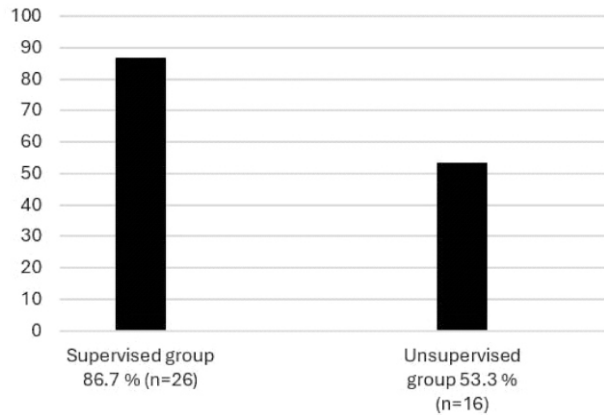


Figure 2. Patient satisfaction levels after three months of Intervention.

DISCUSSION

The primary aim of this study was to compare the efficacy of supervised versus unsupervised PFMT in the treatment of female SUI. Our results reveal significant findings that could inform clinical practices, especially regarding treatment adherence, patient outcomes and resource management. PFMT is the primary conservative treatment for SUI,¹¹ with success depending on adherence, correct execution, and follow-up.¹² Studies show supervised PFMT leads to better outcomes than unsupervised training, though its applicability to diverse populations is uncertain.¹³⁻¹⁶ Our findings support that supervised PFMT results in better outcomes than home-based training, aligning with previous research. This discussion will compare our results with existing literature and clinical implications.

This study compared supervised versus unsupervised PFMT for reducing urinary leakage. Group A (supervised PFMT) showed a significant reduction from 22.89g to 3.24g (85.9%), while Group B (unsupervised PFMT) reduced leakage by 30.7%. The difference was statistically significant ($p < 0.001$), indicating the superior efficacy of

supervised training. These findings are consistent with previous studies¹⁷⁻¹⁹ that show supervised PFMT is more effective than home-based training. Improved outcomes in Group A are attributed to better adherence, correct technique reinforcement and precise muscle contractions in a supervised setting. Bladder diary results and pelvic floor muscle strength also showed greater improvement in Group A, with 68.8% achieving Grade 4 or 5 compared to 18.8% in Group B ($p = 0.023$). These results align with previous studies²⁰⁻²² and underscore the importance of supervision in enhancing muscle strength and managing urinary incontinence.

One of the key challenges in PFMT is ensuring adherence to the prescribed exercise regimen. Non-adherence can undermine the treatment's efficacy, particularly in unsupervised settings where patients may not receive regular reinforcement or corrective feedback. However, our study found that despite the absence of direct supervision, the unsupervised group achieved comparable adherence levels to the supervised group. This is in contrast to some previous studies, which suggested that adherence to unsupervised PFMT was generally lower. The high compliance observed in the unsupervised group in this study could be attributed to initial instructions and the use of structured home exercise regimens.

Additionally, the role of patient motivation and education cannot be overlooked. Our findings support the idea that providing clear instructions and ensuring patients understand the importance of proper pelvic floor muscle contraction are crucial for achieving favorable outcomes in unsupervised PFMT. The results of this study highlight the importance of combining educational interventions with PFMT protocols to enhance patient engagement and improve adherence, particularly in settings where professional supervision is not feasible.

This study also highlights the potential of unsupervised PFMT and emphasizes that maintaining compliance and adherence to exercises is key for the effectiveness of unsupervised PFMT, especially in rural India, where healthcare access is limited. When patients consistently follow the prescribed regimen and perform exercises correctly at home, unsupervised PFMT can yield significant results, offering a viable and cost-effective alternative to supervised training.¹⁷ By enabling women to perform exercises at home, unsupervised PFMT reduces the need for frequent clinic visits, easing the burden on healthcare systems.

Despite the promising results, this study has certain limitations. The follow-up period was relatively short, and to evaluate long-term outcomes, further follow-up is required over extended periods. Also, while we evaluated urinary incontinence symptoms and muscle strength using the pad test, bladder diary and Oxford grading, future research could benefit from using more objective measures of PFM function, such as perineometry or transperineal ultrasound, to provide a more precise assessment of muscle strength.

CONCLUSION

This study provides valuable insights into the efficacy of supervised versus unsupervised PFMT for treating female stress urinary incontinence. Both treatment modalities showed improvements in patient outcomes, with supervised PFMT presenting as a more effective alternative in terms of reducing symptoms and improving PFM strength. Given the cost-effectiveness and easy accessibility of unsupervised PFMT, this approach can be implemented and integrated into clinical practice in resource-limited settings.

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