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Effects of vaginal spheres combined with pelvic floor muscle training on sexual function, urinary incontinence, and quality of life: A pilot randomized controlled trial

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ABSTRACT

Objective: To evaluate the effects of pelvic floor muscle training (PFMT), with or without vaginal spheres (VS), on urinary incontinence severity, pelvic floor (PF) muscle strength, sexual function, and pelvic organ support in women.

Materials and Methods: This single-center, two-arm, parallel-group pilot randomized controlled trial was conducted at a tertiary hospital between October 2024 and April 2025. Women aged 18-75 years with ≥6-weeks of urinary incontinence and/or sexual dysfunction and PF muscle weakness (modified Oxford scale ≤3) were recruited. Of 40 eligible candidates, 26 (65%) were randomized via sealed opaque envelopes to receive either PFMT-only (n=14) or PFMT with VS (VS+PFMT; n=12). Both groups completed a 6-week home-based PFMT protocol; the VS+PFMT group additionally used VS daily during light physical activity. Blinded assessors evaluated PF muscle strength (modified Oxford scale), urinary symptoms (ICIQ-SF and SSI), female sexual function index (FSFI), and pelvic organ support (POP-Q). Feasibility metrics included recruitment, retention, adherence, and safety.

Results: Of 26 participants, 14 (54%) completed the intervention (7 per group). Attrition was primarily due to time constraints and exercise fatigue. Two participants in the VS+PFMT group reported mild vaginal burning. Assessment and exercise log compliance were high. Within-group analysis showed statistically significant improvements in FSFI scores (Δ=+2.53; p=0.002), ICIQ-SF scores (p=0.043), PF muscle strength (p=0.001), and POP-Q measurements (p=0.008). No significant between-group differences were observed in clinical outcomes.

Conclusion: Adjunctive use of VS with PFMT appears to be a safe, feasible, and well-tolerated intervention. Within-group improvements suggest potential therapeutic benefit in PF function and sexual health.

Keywords: Feasibility trial; Kegel balls; pelvic rehabilitation; sexual health outcomes; urinary incontinence

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INTRODUCTION

Pelvic floor dysfunction (PFD) is a multifactorial condition most often associated with pelvic floor muscle (PFM) weakness. It presents with a wide spectrum of symptoms, including urinary incontinence, vaginal laxity, and sexual dysfunction, each of which has been shown to substantially impair women's physical, psychological, and sexual well-being, ultimately leading to a marked reduction in quality of life.[1] Although pelvic floor muscle training (PFMT) is widely recognized as the first-line conservative management for PFD, its effectiveness in routine practice is frequently limited. Barriers such as poor long-term adherence, difficulties in performing correct contractions without professional supervision, and low patient engagement contribute to suboptimal outcomes, despite the strong evidence supporting PFMT in controlled research settings.[2]

To overcome these limitations, several adjunctive intravaginal devices have been introduced. Among them, vaginal cones and vaginal spheres (VS) are most commonly discussed. Their mechanisms differ: Cones rely on active muscular retention against gravity, whereas VS provide passive internal stimulation through weighted movement, theoretically enhancing proprioceptive awareness during daily activity.[3] Despite increasing availability in clinical and commercial settings, there is still a lack of high-quality randomized trials evaluating their safety, acceptability, and clinical efficacy.[4]

In light of this gap, the present pilot randomized controlled trial (RCT) was designed to assess the feasibility, tolerability, and preliminary effects of combining VS with PFMT in women with PFD. We hypothesized that adjunctive use of VS would augment PFM strength and yield additional improvements in urinary symptoms, vaginal laxity, and sexual function compared with PFMT alone.

MATERIALS AND METHODS

Trial Design

This was a single-center, parallel-group feasibility and pilot RCT with a planned 1:1 allocation ratio, conducted at a tertiary hospital between October 2024 and April 2025. The study protocol was approved by the Institutional Review Board of University of Health Sciences Türkiye, Koşuyolu High Specialization Training and Research Hospital (approval no: 2024/14/889, date: 30/07/2024). The study assessed the acceptability, safety, and preliminary effects of PFMT with or without the addition of VS in women with PFD. No major protocol modifications occurred after commencement. ClinicalTrials.gov Identifier: (NCT07048145), registered July 01, 2025.

Participants

Women aged 18-75 years with urinary incontinence and/or sexual dysfunction for ≥6-weeks and PF weakness [modified Oxford scale (MOS) ≤3] were eligible. Exclusion criteria included prior pelvic surgery, severe prolapse (POP-Q stage IV), active infection, fecal incontinence, neurological disorders, pregnancy, recent childbirth (<6-weeks), or dyspareunia due to hyperactive PF. All participants were sexually active and fluent in Turkish. Eligible patients were identified during gynecology consultations and recruited by the principal investigator (obstetrician-gynecologist). Written informed consent was obtained before randomization.

Intervention Protocol

Both groups received a structured 6-week, home-based PFMT program targeting fast- and slow-twitch fibers. Daily sessions consisted of sets of rapid and sustained contractions, progressing from 5 sets (weeks 1-3) to 10 sets (weeks 4-6). Instruction and demonstration were provided by the investigator, with visual analogies used to aid comprehension. Participants were instructed to begin PFMT in the supine position during the first week to ensure correct activation of the PFMs. As strength and coordination improved, they were encouraged to progress to sitting and, subsequently, standing positions over the 6-week period. This structured progression was applied in both groups to avoid early plateau and to accommodate participants with weak PFMs. Adherence was tracked through self-reported exercise logs. Correct performance of the contractions could not be objectively verified in the home setting, which represents a key limitation of this feasibility study.

The intervention group additionally used a medical-grade silicone vaginal sphere (90 g, 3.5 cm diameter, with internal jiggle weights). It was inserted daily for 30 minutes during weeks 1-3 and 60 minutes during weeks 4-6, worn during light physical activity such as walking or household chores. The control group completed PFMT only.

Outcomes

The primary outcomes of this study were clinical changes in sexual function, urinary incontinence severity, PFM strength, and pelvic organ support, measured using validated assessment tools. All assessments were conducted at baseline and repeated at the 6-week follow-up by the same blinded investigator. Secondary outcomes related to the feasibility of the intervention included recruitment and retention rates, adherence to the protocol, and completeness of outcome data.

Primary Outcome Measures

PFM strength was assessed using the MOS, a 6-point grading system based on digital vaginal palpation.[5] The scale ranges from 0 (no contraction) to 5 (strong contraction with firm lift and compression against resistance). Assessments were performed by the same investigator, an obstetrician-gynecologist with formal training and clinical experience in PFM assessment, in the lithotomy position.

Female sexual function was assessed using the female sexual function index (FSFI), a validated self-administered questionnaire widely used in clinical research.[6,7] The FSFI comprises 19 items grouped into six domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. Each domain is scored individually and contributes to a total score ranging from 2 to 36, with higher scores indicating better sexual function.

Urinary incontinence severity and its impact on quality of life were assessed using the international consultation on incontinence questionnaire-short form (ICIQ-SF),[8] a validated self-administered questionnaire.[9] The total score ranges from 0 to 21, with higher scores indicating greater severity. Scores are commonly categorized as mild (1-5), moderate (6-12), severe (13-18), and very severe (19-21).

The severity of urinary incontinence was further assessed using the Sandvik severity index (SSI),[10] a validated self-administered instrument.[11] The total score is calculated by multiplying the responses to these two items, resulting in a categorical classification of severity: Slight (1-2), moderate (3-6), and severe (8-9).

Pelvic organ support was assessed using the simplified pelvic organ prolapse quantification (POP-Q) system, a standardized tool that classifies prolapse based on the most distal point of vaginal descent relative to the hymen.[12] The staging ranges from 0 (no prolapse) to 4 (complete vaginal or uterine eversion.

No changes were made to the planned assessments or outcome measures after the commencement of the pilot trial.

Secondary Outcomes

Secondary outcomes included adherence (defined as completion of ≥80% of prescribed sessions via self-reported exercise logs) and qualitative feedback on tolerability and usability, obtained through brief semi-structured interviews at follow-up. Additionally, this pilot study aimed to explore key feasibility domains, including recruitment, adherence, and retention, to inform the design of a future full-scale randomized trial.

Sample Size

An initial target of 40 participants (20 per group) was pragmatically set, based on sample sizes used in similar feasibility studies on PFMT, to assess recruitment, adherence, and follow-up procedures.[13,14] Due to limited participant engagement and high dropout rates, only 14 participants (7 per group) completed the final assessments and were included in the analysis.

No interim analyses or stopping guidelines were planned or implemented, as this was a small-scale pilot trial without predefined thresholds for early termination.

Randomization

Participants were randomized in a 1:1 ratio using sealed opaque envelopes containing either "0" (PFMT) or "1" (VS+PFMT). The envelopes were prepared and shuffled by the principal investigator and numbered in advance. During enrollment, a clinic secretary uninvolved in the study implementation invited each participant to select one envelope.

Blinding of participants and providers was not possible due to the nature of the intervention. However, the principal investigator, who conducted outcome assessments at follow-up, remained blinded to group allocation to minimize bias.

The study adhered to the CONSORT 2010 guidelines and its extension for pilot and feasibility trials.[15]

Statistical Analysis

Quantitative methods were used to evaluate changes in primary clinical outcomes, including paired and independent t-tests for normally distributed data (e.g., FSFI), and non-parametric tests (Wilcoxon signed-rank, Mann-Whitney U) for skewed variables (e.g., ICIQ-SF, MOS, POP-Q). Categorical changes were analyzed using chi-square or McNemar tests where appropriate.

Secondary feasibility objectives, such as adherence and recruitment rates, were assessed using descriptive statistics. Informal qualitative feedback on intervention acceptability was obtained from participants during follow-up interviews and summarized narratively.

Analyses were conducted using SPSS version 27. All statistical tests were two-tailed, and p-values <0.05 were considered statistically significant.

RESULTS

Participant Flow

Twenty-six women were randomized to VS+PFMT (n=12) or PFMT-only (n=14). Follow-up assessments at 6-weeks were completed by 14 participants (7 from each group), resulting in a follow-up rate of 53.8% (Figure 1).

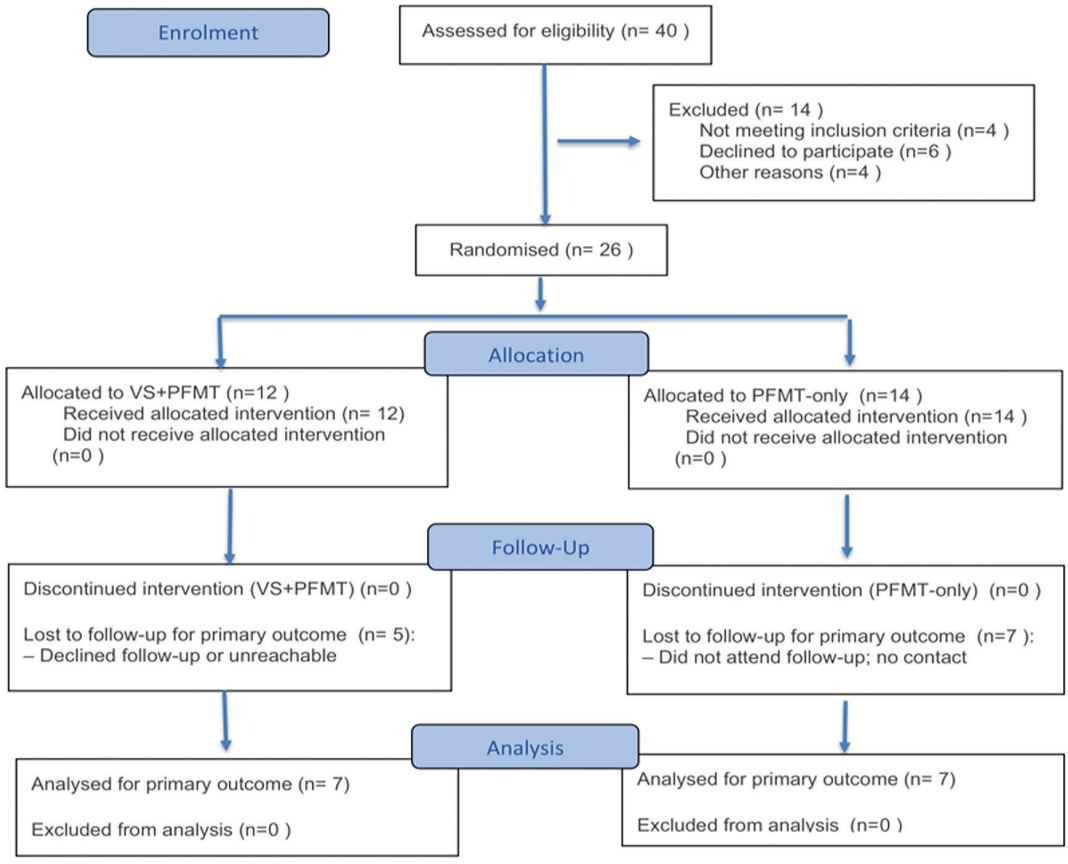

Figure 1. Flow diagram of participant progression through the feasibility and pilot randomized trial (VS+PFMT vs. PFMT-only)
Flow diagram illustrating participant progression through the feasibility and pilot randomized controlled trial comparing vaginal spheres combined with pelvic floor muscle training (VS+PFMT) versus PFMT-only. Of 40 eligible women, 26 (65%) were enrolled and randomized to either group. Fourteen participants (7 per group) completed follow-up assessments. Reasons for drop-out and discontinuation are detailed. No participants discontinued due to adverse events.
VS: vaginal spheres; PFMT: pelvic floor muscle training

Baseline Demographic and Clinical Characteristics

Baseline sociodemographic and clinical characteristics were comparable between groups. Menopausal status (16.7% vs. 7.1%, p=0.586), education level (p=0.823), income status (p=0.586), birth type (p=0.257), episiotomy history (p=0.716), and smoking status (p=0.232) showed no significant differences (Table 1).

Mean age was 41.8±8.6 years in the VS+PFMT group and 37.5±8.5 years in the PFMT-only group (p=0.214). The mean body mass index was similar across groups (27.1±4.6 vs. 27.7±4.3 kg/m², respectively). The mean number of births was 2.08±1.08 in the VS+PFMT group and 2.50±1.60 in the PFMT-only group. The mean duration of urinary incontinence prior to intervention was longer in the VS+PFMT group (72.8±105.9 months) compared to the PFMT-only group (15.4±31.6 months), although this difference did not reach statistical significance. The baseline SSI, MOS, ICIQ-SF total score, and FSFI total score were comparable between the two groups (Table 2).

Feasibility Outcomes

Recruitment

Although 40 participants were initially planned, a total of 26 women were ultimately enrolled in the study over a 6-week period. The most frequently cited reasons for declining participation included time constraints, social challenges, and the perception that the exercises were too frequent or difficult to perform. Four individuals could not be reached by phone, and eight participants who initially agreed to participate failed to attend despite two reminder calls and scheduled appointments.

Retention

Fourteen of the 26 enrolled participants (7 in the VS+PFMT group and 7 in the PFMT-only group) completed the follow-up evaluation, yielding a retention rate of 53.8%. Although this is below the commonly accepted 80% threshold for full trials, it was considered acceptable for a pilot feasibility study, especially given the nature of the intervention and the short study duration.

Table 1. Baseline characteristics of participants stratified by intervention group (VS+PFMT vs. PFMT-only)			
Variable	**VS+PFMT group (n=12)**	**PFMT-only group (n=14)**	***p*-value**
Menopause (yes)	2 (16.7)	1 (7.1)	0.586‡
Education			0.823†
- Primary school	5 (41.7)	3 (21.4)	
- Secondary school	1 (8.3)	1 (7.1)	
- High school	2 (16.7)	4 (28.6)	
- University	3 (25.0)	5 (35.7)	
- Postgraduate	1 (8.3)	1 (7.1)	
Income < expenses	2 (16.7)	1 (7.1)	0.586‡
Birth type			0.257‡
- Vaginal	7 (58.3)	8 (57.1)	
- Cesarean	3 (25.0)	1 (7.1)	
- Both	1 (8.3)	4 (28.6)	
Episiotomy (yes)	6 (50.0)	8 (57.1)	0.716†
Smoking status			0.232‡
- Non-smoker	7 (58.3)	8 (57.1)	
- <1 pack/day	3 (25.0)	6 (42.9)	
- >1 pack/day	2 (16.7)	0 (0.0)	

†: chi-square test; ‡: Fisher's exact test (used when expected cell counts were <5); data are presented as number and percentage (n, %); VS: vaginal spheres; PFMT: pelvic floor muscle training

Table 2. Baseline continuous characteristics by intervention group		
Variable	**VS+PFMT (n=12)**	**PFMT-only (n=14)**
Age (years), mean ± SD	41.8±8.6	37.5±8.5
BMI (kg/m²), mean ± SD	27.1±4.6	27.7±4.3
Number of births, mean ± SD	2.1±1.1	2.5±1.6
Duration of incontinence (months), mean ± SD	72.8±105.9	15.4±31.6
Sandvik score (pre), mean ± SD	5.5±2.9	3.2±3.3
Modified Oxford score (pre), mean ± SD	2.7±0.9	2.3±0.6
ICIQ-SF score (pre), mean ± SD	8.3±4.4	5.4±6.6
FSFI total score (pre), mean ± SD	20.4±9.4	23.1±5.3

Values are presented as mean ± standard deviation.
VS+PFMT: vaginal spheres plus pelvic floor muscle training; PFMT-only: pelvic floor muscle training alone; BMI: body mass index; FSFI: female sexual function index; ICIQ-SF: international consultation on incontinence questionnaire-short form

Acceptability

No participants discontinued the study due to dissatisfaction or discomfort with the interventions. The intervention using the VS+PFMT, which consists of two internal metal jiggle balls encased in medical-grade silicone and generates mechanical vibration through movement, was generally well tolerated (Figure 2). Only two participants reported mild transient vaginal burning, which did not require medical intervention. Overall, both the VS+PFMT and PFMT-only interventions were perceived as acceptable by the participants who completed the study.

Adherence

Self-reported adherence, tracked via exercise logs, indicated that most participants followed their assigned protocols as instructed. Although exact compliance rates varied, both groups demonstrated acceptable levels of engagement. In the VS+PFMT group, the combination of passive mechanical stimulation and scheduled PFMT may have supported motivation and adherence, despite the dual-task nature of the intervention.

Safety

No serious adverse events were reported in either group. Minor side effects were limited to two participants in the VS+PFMT group, who reported mild vaginal burning that resolved spontaneously. No participants in the PFMT-only group reported adverse effects.

Data Completeness

There were no missing data for any outcome variable, including validated instruments such as the FSFI, ICIQ-SF, SSI, and MOS grading. All data were entered manually and verified for completeness and accuracy.

Figure 2. Medical-grade silicone vaginal sphere used in the intervention
The device weighs 90 g, measures 3.5 cm in diameter, and contains internal jiggle weights to provide proprioceptive feedback and enhance pelvic floor muscle engagement

Preliminary Clinical Outcomes

Preliminary analyses were conducted to explore the potential clinical effects of the interventions. Changes in validated pelvic floor-related outcome measures, including the FSFI, the ICIQ-SF, the SSI, MOS and simplified POP-Q scores, were examined in participants who completed the follow-up assessment. Paired comparisons were used to evaluate within-group changes from baseline to post-intervention. Additionally, between-group comparisons of change scores were analyzed to assess preliminary group-level effects.

FSFI Outcomes

The mean FSFI total score (n=14, 7 for each group) significantly improved from baseline (M=24.61, SD=4.79) to post-intervention (M=27.14, SD=4.43), t(13)=-3.82, p=0.002, with a large effect size (Cohen's d=1.02). Scores showed normal distribution according to the Shapiro-Wilk test. Therefore, pre- and post-intervention values were compared using paired samples t-tests.

Among participants who completed the follow-up (n=14), significant improvements were observed in several FSFI subscales. Scores for desire (p=0.001), arousal (p=0.012), lubrication (p=0.013), and orgasm (p=0.035) increased significantly from baseline to post-intervention. No statistically significant change was observed in the satisfaction (p=0.146) and pain (p=0.620) subscales, as shown in Table 3.

Between-group comparisons showed no significant differences in total FSFI score changes (VS+PFMT: 2.40±2.66 vs. PFMT-only: 2.66±2.49; p=0.855) or in individual domains, except for pain. The PFMT-only group showed a greater improvement in pain scores (0.46±0.54 vs. -0.29±0.50; p=0.020) (Table 4).

ICIQ-SF Outcomes

A statistically significant improvement was observed in urinary incontinence symptoms following the intervention. The median ICIQ-SF score significantly decreased from baseline to post-intervention (Z=-2.02, p=0.043), based on the Wilcoxon signed-rank test.

At baseline, a significant difference was found between groups in the distribution of ICIQ-SF severity categories (p=0.018), with the PFMT-only group presenting more frequently with mild incontinence and the VS+PFMT group showing predominantly moderate symptoms. By the end of the intervention, this disparity was no longer evident (p=1.000), as both groups showed similar distributions, with the majority of participants falling into the mild incontinence category (Figure 3).

MOS Outcomes

The median score increased from baseline to post-intervention, and the change was statistically significant (Z=3.26, p=0.001) according to the Wilcoxon signed-rank test. This suggests that PFMT, with or without adjunctive intravaginal devices, was effective in enhancing pelvic floor contractility over the 6-week period.

Post-intervention comparisons of Oxford strength categories showed no statistically significant difference between the two groups. In the VS+PFMT group, 85.7% (6 out of 7) of participants were classified as having "Strong" pelvic floor strength, compared to 71.4% (5 out of 7) in the PFMT-only group (p=1.000). These findings suggest that both interventions were similarly effective in achieving high levels of PFM contractility.

POPQ Scores Outcomes

A significant reduction was observed in POP-Q scores from baseline to post-intervention (Z=-2.65, p=0.008).

Although both groups showed significant anatomical improvement in pelvic organ support based on POP-Q scores (p=0.008), the degree of change did not significantly differ between the VS+PFMT and PFMT-only groups (p=0.710).

Table 3. Pre- to post-intervention changes in FSFI domain scores among all participants (n=14)

FSFI domain	Mean difference (pre-post)	Std. deviation	Std. error mean	95% confidence interval	t	df	*p*-value
Desire	-0.64	0.60	0.16	-0.99 to -0.30	-4.02	13	0.001
Arousal	-0.64	0.82	0.22	-1.12 to -0.17	-2.92	13	0.012
Lubrication	-0.56	0.72	0.19	-0.98 to -0.14	-2.88	13	0.013
Orgasm	-0.31	0.50	0.13	-0.60 to -0.03	-2.35	13	0.035
Satisfaction	-0.29	0.69	0.18	-0.69 to 0.11	-1.55	13	0.146
Pain	-0.09	0.63	0.17	-0.45 to 0.28	-0.51	13	0.620

FSFI: female sexual function index; t: t statistic; df: degrees of freedom

Table 4. FSFI score pre-post change by intervention group

FSFI domain	VS+PFMT (mean ± SD)	PFMT-only (mean ± SD)	*p*-value
Total	2.40±2.66	2.66±2.49	0.855
Desire	0.69±0.54	0.60±0.69	0.801
Arousal	0.51±0.88	0.77±0.81	0.580
Lubrication	0.86±0.84	0.26±0.47	0.132
Orgasm	0.40±0.65	0.23±0.31	0.548
Satisfaction	0.23±0.69	0.34±0.75	0.771
Pain	-0.29±0.50	0.46±0.54	**0.020**

FSFI: female sexual function index; VS+PFMT: vaginal spheres plus pelvic floor muscle training; PFMT-only: pelvic floor muscle training alone

Harms

Two participants in the VS+PFMT group reported mild vaginal discomfort or burning sensation during the initial weeks of intervention. These symptoms resolved spontaneously and did not require medical treatment. No adverse events were reported in the PFMT-only group. In addition to minor physical complaints, some participants in the VS group expressed hesitancy related to the use of the device, indicating possible cultural or personal barriers to adherence.

DISCUSSION

This pilot randomized trial evaluated the short-term effects of PFMT, with or without adjunctive VS, in women with PFD. Significant improvements were observed in sexual function, urinary incontinence symptoms, and PFM strength across both groups, confirming the overall therapeutic value of structured PFMT. While the VS+PFMT group demonstrated greater improvements in FSFI subdomains such as lubrication and orgasm, the PFMT-only group showed comparatively greater gains in pain reduction and satisfaction. These patterns indicate that both approaches may provide domain-specific benefits, although the between-group differences did not reach statistical significance. The absence of group-level differences is likely attributable to the small sample size and limited power, rather than true clinical equivalence.

A structured PubMed search using keywords such as "PFMT," "vaginal cones," and "VS" identified more than ten RCTs on vaginal cones, but only two evaluating VS or Kegel balls. This discrepancy highlights a clear gap in the literature and underscores the novelty of our investigation, which provides feasibility data and short-term clinical outcomes for vaginal sphere use in a trial setting.

In addition to clinical outcomes, this study generated important feasibility insights. Recruitment was slower than anticipated, and retention at 6-weeks was modest, with approximately half of randomized participants completing follow-up. Despite these challenges, adherence among completers was high, and no serious adverse events occurred, suggesting that both interventions were generally acceptable and well tolerated. Collectively, these findings highlight the potential of adjunctive VS, but also emphasize the need for larger, adequately powered RCTs that can clarify clinical efficacy while addressing feasibility barriers such as recruitment and retention.

Our findings align with prior studies demonstrating that PFMT improves sexual function and urinary incontinence symptoms. A meta-analysis by Chen et al.[4] confirmed that PFMT leads to significant improvements in postpartum urinary symptoms and sexual health outcomes. Similarly, Villani et al. [3] compared PFMT alone to vaginal cone therapy and reported superior outcomes in dyspareunia and vaginal laxity among women using intravaginal devices. However, unlike Villani et al.'s[3] findings, our study did not observe statistically significant added benefit from VS use. This discrepancy may be due to differences in device type, intervention duration, or sample characteristics. While VSs may enhance muscle engagement through proprioceptive feedback,[16] their effect might require longer exposure or larger samples to become clinically evident. Our short follow-up and small sample size likely limited the ability to detect such differences.

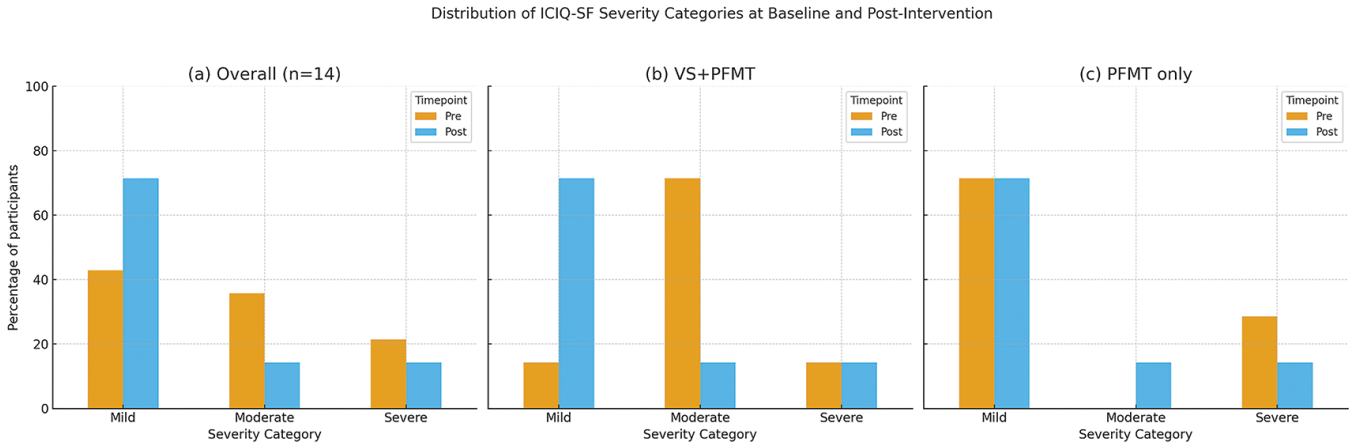

Figure 3. Distribution of ICIQ-SF severity categories at baseline and post-intervention: overall and groupwise comparison
Percentages of mild, moderate, and severe urinary incontinence are shown for (a) the overall sample (n=14), (b) the VS+PFMT group, and (c) the PFMT-only group. Bars represent the proportion of participants in each severity category at baseline (pre) and at 6-weeks (post)
ICIQ-SF: international consultation on incontinence questionnaire-short form; VS: vaginal spheres; PFMT: pelvic floor muscle training

While vaginal cones have been shown to enhance proprioceptive feedback by requiring active muscle engagement to prevent device displacement, VS lack this active resistance component. Instead, they rely on passive internal movement, which may stimulate awareness during daily activity, but their role in motor learning remains unexamined.[16] This mechanistic difference highlights the need for future studies comparing neuromuscular activation patterns and proprioceptive engagement across different device types.

In a RCT with a similar design to ours, VS were added to PFMT to improve adherence in women with urinary incontinence. However, the study found no significant improvement in adherence or treatment efficacy compared to PFMT alone.[17] The authors attributed poor adherence primarily to forgetfulness rather than a lack of perceived benefit. These findings, aligned with our own feasibility outcomes, emphasize the importance of behavioral support mechanisms, such as digital reminders and structured coaching, in future trials to enhance long-term compliance and optimize intervention effectiveness.

Similar to our findings, a recent pilot RCT by Brækken et al.[18] comparing intravaginal electrical stimulation and PFMT in women with weak PFMs found no significant difference between groups, despite observable improvements in both arms. The study concluded that a sample size of 95 participants per group would be needed to detect clinically meaningful differences.[18] This further underscores the need for adequately powered trials to evaluate the additive benefits of adjunctive therapies in pelvic floor rehabilitation.

Beyond clinical outcomes, this study provides critical feasibility insights to guide future definitive trials. Recruitment was slower than projected, and retention at 6-weeks remained suboptimal (53.8%), largely due to low motivation, time constraints, and sociocultural barriers toward pelvic floor interventions. Despite these challenges, adherence among completers was high, no serious adverse events occurred, and data completeness reached 100%, indicating good acceptability of the protocol and outcome measures.

Barriers to sustained engagement, such as competing responsibilities, travel, or lack of symptom awareness, have been previously reported as key factors limiting PFMT adherence in the general population.[19] Participants in our study expressed similar obstacles, including difficulty integrating exercises into their daily routines and underestimating the long-term benefits of PFMT. To address these issues, future trials should consider integrating mobile health applications, which offer portable, visual, and interactive platforms for structured PFMT delivery.[20] Apps may increase motivation, reduce boredom, provide real-time reminders, and offer feedback on progress, all of which can improve both adherence and retention. Additionally, culturally tailored education, remote support (e.g., WhatsApp or video follow-ups), and flexible scheduling may enhance inclusivity and engagement, particularly in populations with limited familiarity with exercise-based therapies.

Study Limitations

This study has several limitations inherent to pilot feasibility trials. First, the small sample size limited statistical power and precluded definitive conclusions regarding between-group differences. Although outcome assessors were blinded, participant blinding was not possible due to the nature of

the intervention, which may have introduced performance bias. Furthermore, the 6-week follow-up period may not fully capture long-term adherence or sustained clinical benefits. Most outcome measures were based on self-reported questionnaires, which are subject to recall and reporting bias. Additionally, we were unable to maintain consistent contact with participants who discontinued the study, which limited our ability to explore their reasons for dropout or reinforce motivation. Finally, as participants were recruited from a single tertiary care center, generalizability to broader populations may be limited.

These feasibility findings support the progression to a fully powered RCT, incorporating behavioral and digital adherence strategies to optimize implementation.

CONCLUSION

Adjunctive use of VS with PFMT appears to be a safe, feasible, and well-tolerated approach for women with PFD. Significant within-group improvements in muscle strength, urinary symptoms, sexual function, and pelvic support underscore its potential therapeutic value. These findings warrant further investigation in larger, adequately powered RCTs.

ETHICS

Ethics Committee Approval: The study protocol was approved by the Institutional Review Board of University of Health Sciences Türkiye, Koşuyolu High Specialization Training and Research Hospital (approval no: 2024/14/889, date: 30/07/2024).

Informed Consent: Written informed consent was obtained before randomization.

FOOTNOTES

Contributions

Surgical and Medical Practices: S.S.K., E.K., İ.B., Y.Ç.D., F.Ş., B.K., Concept: S.S.K., E.K., İ.B., Y.Ç.D., F.Ş., B.K., Design: S.S.K., E.K., İ.B., Y.Ç.D., F.Ş., B.K., Data Collection or Processing: S.S.K., İ.B., Y.Ç.D., F.Ş., Analysis or Interpretation: S.S.K., E.K., F.Ş., Literature Search: S.S.K., İ.B., Y.Ç.D., B.K., Writing: S.S.K., E.K., İ.B., Y.Ç.D., F.Ş., B.K.

DISCLOSURES

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