REVIEW ARTICLE



Supervised versus unsupervised pelvic floor muscle training in the treatment of women with urinary incontinence- a systematic review and meta-analysis

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Abstract

Introduction and hypothesis This study synthesized the effects of supervised and unsupervised pelvic floor muscle training (PFMT) programs on outcomes relevant to women's urinary incontinence (UI).

Methods Five databases were searched from inception to December 2021 and the search was updated until June 28, 2022. Randomized and non-randomized control trials (RCTs and NRCTs) comparing supervised and unsupervised PFMT in women with UI and reported urinary symptoms, quality of life (QoL), pelvic floor muscles (PFM) function/ strength, the severity of UI, and patient satisfaction outcomes, were included. Risk of bias assessment of eligible studies was performed by two authors through Cochrane risk of bias assessment tools. The meta-analysis was conducted using a random effects model with the mean difference or standardized mean difference.

Results Six RCTs and one NRCT study were included. All RCTs were assessed as "high risk of bias" and the NRCT study was rated as "serious risk of bias" for almost all domains. The results showed that supervised PFMT is better than unsupervised for QoL and PFMs function of women with UI. There was no difference between supervised and unsupervised PFMT for urinary symptoms and improvement of the severity of UI. Results of patient satisfaction were inconclusive due to the sparse literature. However, supervised, and unsupervised PFMT with thorough education and regular reassessment showed better results than unsupervised PFMT without educating patients about correct PFMs contractions.

Conclusions Supervised and unsupervised PFMT programs, can both be effective in treating women's UI if training sessions and regular reassessments are provided.

Keywords Urinary incontinence · Pelvic floor muscle · Exercise · Training · Home exercise · Outpatient exercise

Introduction

Urinary incontinence (UI) defines as a "complaint of involuntary loss of urine" that is associated with extreme physical, psychological, and social consequences, resulting in

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impaired quality of life (QoL) [1, 2]. UI is a common condition that affects millions of people, but it is more prevalent among women [3]. Several types of UI exist, and the most common subtypes are stress, urgency, and mixed UI [4]. Stress urinary incontinence (SUI) is the most prevalent type of UI and refers to involuntary urine loss upon effort, exertion, sneezing, and coughing. Urgency UI (UUI) is defined as the complaint of involuntary leakage associated with urgency, and if both stress and urgency are present at the same time, it is called mixed UI (MUI) [5].

Physiotherapy is a well-known conservative treatment of UI. Pelvic floor muscle training (PFMT) is considered the first line of treatment of UI based on current literature [6] This is an exercise that increases pelvic floor muscles (PFMs) power, strength, and endurance. Studies reported a 56-75% success rate for PFMT [7, 8]. Hypertrophy of these



muscles followed by increasing force of contraction can provide adequate support for the urethra and anterior vaginal wall [9]. Being cost-effective and safe makes PFMT the only treatment without any restrictions [10].

Supervised PFMT programs are currently provided in physiotherapy clinics, where women attend training sessions at specified intervals and participate in either individual or group coaching sessions. Although supervised PFMT programs are effective [11], women enrolled in supervised programs may face challenges. As women need to travel to and from clinical locations, travel can become a barrier to care over time, especially for those living in rural areas. Longdistance and frequent transportation can increase financial, physical, and/or psychological stress. To overcome these challenges, unsupervised PFMT might be recommended. Evidence from a qualitative study showed that participants in unsupervised programs felt confident in self-training and felt it provided them with the ability to take charge of their symptoms [12]. Evidence of the effectiveness of interventions is necessary to prescribe these treatments. Therefore, this study aimed to review published randomized and non-randomized control trials (RCTs and NRCTs) that assessed the effects of unsupervised PFMT programs in comparison with supervised PFMT programs for managing UI symptoms, quality of life (QoL), PFMs function/strength, the severity of UI and patient's satisfaction outcomes in female adults.

Method

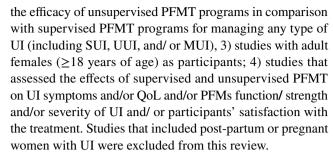
This systematic review was performed to evaluate the effectiveness of supervised and unsupervised PFMT on women with UI. The study was prepared according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [13] and the protocol was registered in the PROSPERO database (CRD42021292521).

Search strategy

The following databases were searched: MEDLINE (via PubMed), The Cochrane Library (CENTRAL), Scopus, Web of Science (WoS), and the Physiotherapy Evidence Database (PEDro). All databases were searched from inception to December 2021 and the search was updated until June 28, 2022. Finally, the reference list of all articles selected for critical appraisal and grey literature were searched for additional studies. The full search strategy of MEDLINE, Scopus, and WoS are provided in Appendix I.

Study selection

Studies were included if they met all the following criteria: 1) studies with RCT or NRCT designs; 2) studies evaluating



One reviewer conducted the database searches and removed duplicates using EndNote X9.1 software. Titles and abstracts were screened by two independent reviewers to evaluate the studies according to the inclusion criteria. The full texts of potentially entitled studies were assessed according to the inclusion criteria by two independent reviewers. Any disagreements between the two reviewers were resolved through discussion with the third reviewer.

Risk of bias assessment

To assess the potential bias that may affect the cumulative evidence, the following tools were used: The Cochrane tool for assessing the risk of bias in RCTs (RoB-2) [14], and the tool for assessing the risk of bias in NRCT studies of intervention (ROBINS-1) [15]. Two reviewers independently assessed the risk of bias in included studies. Any disagreements between the two reviewers were discussed with the third reviewer.

The RoB-2 tool evaluates five domains in RCTs: randomization process, deviations from the intended interventions, missing outcome data, measurement of the outcome, and selection of the reported results [14]. ROBINS-1 evaluates seven domains of bias: confounding bias, selection bias, measurement bias, intervention bias, missing data bias, outcome bias, and selective reporting bias [15].

RoB-2 was rated as high, low and some concerns, and ROBINS-1 was rated as low, moderate, serious, critical RoB, and "no information" when insufficient data is available to permit a judgment according to the Cochrane handbook and the technical guidance document of RoB-2 tool [16].

Data extraction

Two reviewers extracted the data independently from the eligible studies. Any disagreements were resolved by the third reviewer. The following information was extracted from the included studies: authors, publication year, sample size, details of the interventions (e.g., type, timing, and duration of treatment sessions), outcomes and measurements used, and study results.

Authors of papers were contacted to request missing or additional data. In addition, when unpublished works were retrieved in our search, an email was sent to the corresponding author(s) to determine whether the work has been subsequently published. If no response had been received from



the corresponding author(s) after three emails, the study was excluded.

Analysis

Mean difference and standardized mean difference (SMD) with 95% confidence interval were synthesized by a random effect model. Statistical analyses were performed using STATA version 14.0 (Stata Corp, College Station, TX, USA). The I^2 statistic was applied to evaluate the heterogeneity of included studies.

Results

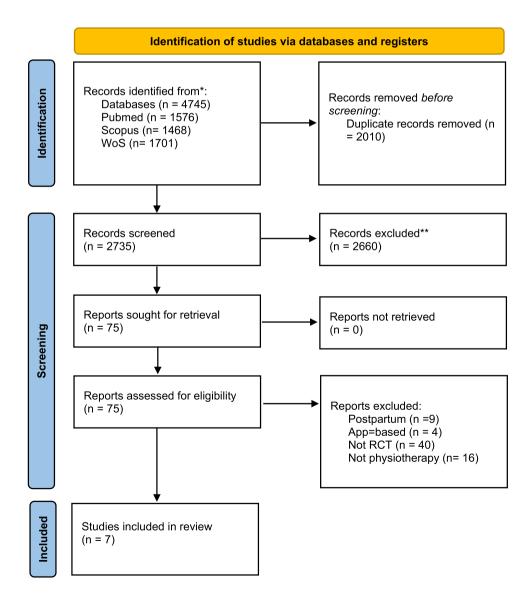
The process of study selection is summarized in Fig. 1. A total of 2735 studies were identified during the electronic and hand-search processes. After title/abstract screening, 75

studies were retrieved as full-text articles. The full-text versions of 69 studies were assessed, and six RCTs [17–22] and one NRCT [23] studies were included in this review

Risk of bias assessment

Six studies [17–22] were assessed according to the RoB-2 tool [14] and all of them were assessed as "high risk of bias" (Fig. 2) and summarised in the risk of bias graph (appendix 2). The risk of bias domain that mostly received the rating "high", was "Risk of bias in the measurement of the outcome" which was related to the awareness of outcome assessors and participants about the assignment to the intervention groups. Knowledge of assigned intervention could influence participant-reported outcomes (such as QoL) which were rated as a risk factor for biased results. Also, assessor awareness of intervention assignment may result in assessor judgment.

Fig. 1 Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram mapping the review





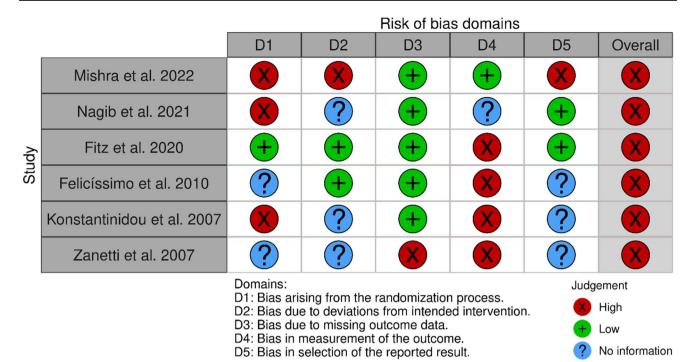


Fig. 2 risk of bias summary about each risk of bias domain for each included Randomised Controlled trial (RCT) separately

The remaining study [23] was assessed according to the ROBINS-1 tool [15], which was rated as a "serious risk of bias" (Fig. 3). The risk of bias assessment resulted in many "No information" due to the unavailability of the study protocol and inadequate reporting about confounding factors, selection of participants and deviations from intended interventions, and "serious risk of bias" ratings in almost all domains except in the domain assessing the risk of bias in the selection of the reported result which was rated as "low risk of bias".

Participants

All 7 studies [17–23] included women with SUI and in one study [22] women with UUI and MUI were also included.

Other types of UI were not assessed in the studies. The total number of participants was 312 women and the mean ages ranged between 45.61 [22] to 57.7 [17]. The sample sizes ranged from 10 [19] to 35 [17].

Components of supervised and unsupervised protocols

Treatment duration

All studies included a group with supervised sessions with the supervision of a physiotherapist [17–21, 23]. Regarding the duration of treatment, it varied from 5 weeks to one year, with a weekly frequency of 1 to 2 times and sessions of 30 [21] to 50 [20] minutes.

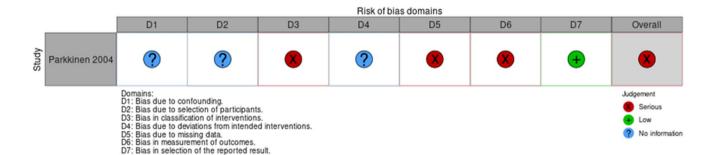


Fig. 3 risk of bias summary for the included non-randomised controlled trial



PFMT parameters

All of the PFMT parameters were the same in both supervised and unsupervised groups of each study, except for one study that received interferential and biofeedback training in each supervised session [23]. In one of the included studies, weighted vaginal balls were used in both groups [23]. Only in one study, joint warm-up exercises at the beginning and stretching exercises at the end of each session were performed [18].

Three studies reported that participants in both supervised and unsupervised groups were educated about the correct contraction of PFMs through biofeedback [23], digital palpation [21], or one supervised session at the beginning [18, 22]. Others only received exercise diaries [17, 19, 20]. Almost all studies received PFME in horizontal positions and progressed the program by changing the position to vertical and increasing the hold time of contractions [17, 18, 20, 21, 23]. Some of the included studies applied both low and high-intensity contractions in their program [18, 19, 21, 23], but others just asked participants to do the maximum contraction [19, 20]. Three included studies asked participants to do PFMs, contraction with coughing (knack maneuver) [18, 21, 23].

Reinforcement techniques

Three included studies reinforced the treatment with a monthly reassessment of PFMs through vaginal palpation performed by the physiotherapist in both supervised and unsupervised groups [17–19]. Two studies educated participants of both group, sto do a self-digital assessment [21, 23].

Outcomes

Symptom diagnosis/ screening outcomes are presented in Table 1.

QoL

Six studies measured QoL through different outcome measures including the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF; higher scores are worse) [20, 21], QoL index (higher scores are worse) [18, 19], incontinence impact questionnaire (IIQ7; higher scores are worse) [22] and Incontinence Quality of Life (I-QoL; higher scores are better – the direction of effect was inverted in the meta-analysis to allow the combination with other QoL outcome results) [17]. All but one study [18] reported significant improvement in Qol scores in both groups. Five studies were included in the meta-analysis [17, 19–22]; however, one study [18] reported the findings as median and thus was not included in the

meta-analysis. The results of the meta-analysis revealed a moderate effect in favour of the supervised group (SMD=-0.64; 95% CI: -1.25 to -0.02) with considerable heterogeneity (I^2 =75.4%) (Fig. 4).

Urinary symptoms

A total of six studies [17–21, 23] assessed the effects of supervised and unsupervised PFMT on urinary symptoms. Both supervised and unsupervised PFMT groups displayed significant improvements in urinary symptom outcomes. To evaluate treatment results based on the amount of leakages, five studies used pad test with different duration [17–20, 23]. Three studies could be included in the meta-analysis [17, 20, 23]. The overall SMD was –-0.34 (95% CI, -3.158 to 2.46) with moderate heterogeneity (I²: 44.5%), which revealed no difference between supervised and unsupervised groups for urinary symptom improvement (Fig. 5).

Among six studies that compared the effects of supervised and unsupervised PFMT on the urinary symptom, three studies were not included in the meta-analysis since the required data for meta-analysis have not been included and their measurement methods were not identical to other studies. In the study of Nagib et al. [21] results of ICIQ-SF showed improvement of urinary symptoms in both supervised and unsupervised groups after the intervention, with statistically significant better results in the supervised group. Zanetti et al. [18] showed a significant decrease in urine leakage based on urine diary in both supervised and unsupervised groups, however, the supervised group showed better results. The results of the pad test in the study of Konstantinidou et al. [19] showed improvement of the urinary symptoms specifically in the supervised group, however, the micturition diary showed statistically significant improvement in incontinence episodes per week and 24-hour frequency in both supervised and unsupervised groups.

PFMs function/ strength

Five studies assessed the effects of supervised and unsupervised PFMT on PFMs function/ strength. Of these, four studies used the Oxford scale [17, 19–21] and, one of them also used PERFECT [21]. The remaining study used electromyography [23]. For the Oxford scale, a meta-analysis was conducted on three studies providing sufficient statistical information. The pooled data showed a significant difference between the two groups in favour of supervised PFMT (SMD= 1.11; 95% CI: 0.28 to 1.93) with considerable heterogeneity (I²=74%) (Fig. 6). From two studies that were not included in the meta-analysis, one study reported no differences between supervised and unsupervised groups [23] and the results of the other study showed significantly better improvement in the supervised group [17].



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Reference	Area	Sample's number (Mean age)		Intervention description		Outcome measures	Results
		Supervised group	Supervised group Un Supervised group	Supervised Group (duration)	Un Supervised Group (duration)		
Parkinnen et al. 2004 [23] Finland 16 (47.7)	Finland	16 (47.7)	17 (45.8)	-Supervised PFMEs with biofeedback + maximal interferential ES+ vaginal ball training (once a week for a year) + -Verbal and written instructions for home exercises (twice a day, 5 days a week, for at least 4 months)	Verbal and written instructions for home exercises+ vaginal ball training (twice a day, 5 days a week, for at least 4 months)	-UISS -Pad test - Oxford scale	There were no statistically significant differences between groups in any of the outcome measures. Both groups showed significant improvement after intervention.
Zanetti et al. 2007 [18]	Brazil	23 (56)	21 (54)	Supervised perineal exercises+ stretching of hip adductors, hamstrings and paravertebral muscles (twice a week for 12 weeks, 45 min)	Performing unsupervised perineal exercises at home (same protocol with supervised group)	-urine diary -1-hour pad test -1-QOL -patient's satisfaction	The supervised group had significantly better improvement in all the measured outcomes after intervention
Konstantinidou et al. 2007 [19]	Greece	Greece 12 (47.8)	10 (47.8)	Supervised PFMT (Weekly session, 12 weeks) + written training instruction	Written instruction for home PFMT (12 weeks)	-Bladder diary - Pad test - Oxford scale -PGI-I	The supervised group had significantly better results for all measured outcomes after intervention.
Felicissimo et al 2010 [20]	Brazil	29 (51.2)	30 (48.1)	Supervised PFMT (twice a week for 8 weeks)	Performing unsupervised PFMT at home (same protocol with supervised group)	- Oxford scale -pad test - ICIQ SF -A subjective SUI cure questionnaire	No significant difference between groups for all outcomes. Both groups showed signifi- cant improvement after intervention.
Fitz et al. 2018 [17]	Brazil	34 (57.7)	35 (56)	Supervised PFMT + home exercise (three sets of ten repetitions daily during the 3 months)	Performing unsupervised PFMT at home (three sets of ten repetitions daily during the 3 months)	- Oxford scale - Bidigital examination -pad test -I-QOL -patient's satisfaction	SUI cure was significantly higher in the supervised group. There were no differences between groups in terms of satisfaction with the treatment; QOL; function of the PFMs; and number of episodes of urine leakage per week.



Table 1 (continued)

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Reference	Area	Sample's number (Mean age)	(Mean age)	Intervention description		Outcome measures	Results
		Supervised group	Supervised group Un Supervised group Supervised Group (duration)	Supervised Group (duration)	Un Supervised Group (duration)		
Nagib et al. 2021 [21]	Brazil	Brazil 20 (57)	16 (49.5)	-Supervised PFME through game therapy -Recommendations on unsupervised PFME, (twice a week for 5 weeks)	Recommendations for performing unsupervised PFME at home, (5 weeks)	-ICIQ UI-SF -PERFECT - Modified Oxford scale -Adherence	Both groups showed improvement in urinary symptoms. Relief of urinary symptoms, PFMs power and endurance were significantly better in supervised group
Mishra et al. 2022 [22]	India	27 (NA)	22 (NA)	Video based education + supervised exercise sessions (once a week for the 1 st month, twice a week for the 2 nd month and once a month for the next three months)	Video based education about continence mechanisms + strengthening exercise illustration and receiving feedback to volunteers who performed exercises in the education session	-RUIS -IIQ 7	Severity of incontinence and quality of life were different between groups at the end of treatment and supervised group showed better results.

Contractions Every Contraction Timed; PFM, Pelvic Floor Muscle; PFME, Pelvic Floor Muscle Exercise; I-QOL, Incontinence Quality of Life; QOL, Quality of Life; USS, Urinary Incontinence Severity Score; PGI-I, Patient Global Impression of Improvement; RUIS, Revised urinary incontinence scale; IIQ I, Incontinence Impact Questionnaire; III, Not Available PFMT, Pelvic Floor Muscle Training; ICIQ UI-SF, International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form; PERFECT, Power Endurance Repetitions Fast



Fig. 4 forest plot of supervised PFMT versus unsupervised: QoL outcome, pooled data from five RCTs (*n*=235)

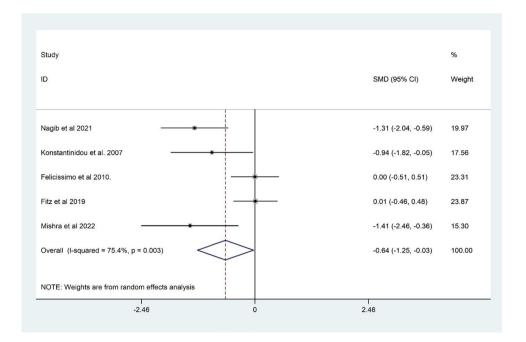
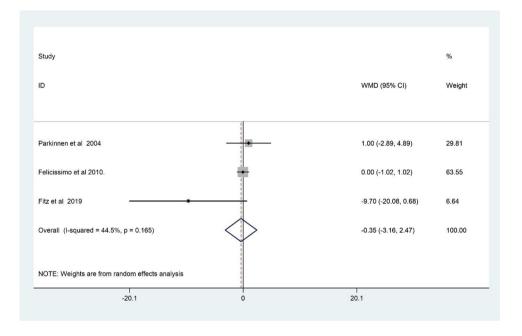


Fig. 5 forest plot of supervised PFMT versus unsupervised: urinary symptom outcome, pooled data from two RCTs and one NRCT (*n*=166)



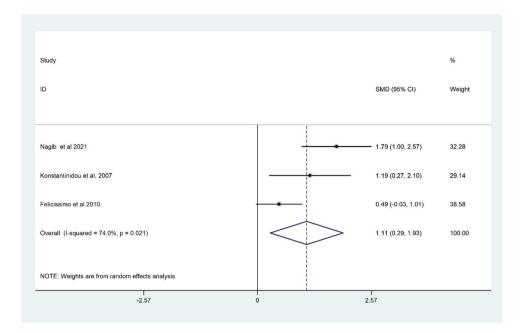
Improvement in the severity of UI

Five studies reported the improvement/ cure of the severity of UI [17, 19, 20, 22, 23] following PFMT programs. Three studies reported objective cure/ improvement [17, 20, 23] of which, one of them also reported subjective cure/ improvement [23] and two remaining studies only assessed subjective improvement [19, 22]. Fitz et al. [17] showed 61.% cure rate in the supervised group compared with 28.6% in the unsupervised group. Felicissimo et al. [20] showed objective cure/improvement in both groups based on negative pad

test in 36.6% of patients in the supervised group and 34.5% in the unsupervised group postintervention. Also, subjective cure which was measured by simple questions about the patient's feelings about their problem after the treatment showed similar improvement in both groups [20]. Konstantinidou et al. [19] showed significantly more improvement in symptoms based on Patient Global Impression of Improvement (PGI-I) in the supervised group compared with the unsupervised. In the study of Parkinnen et al. [23], the cure rate was 37.5% and 11.8% in supervised and unsupervised groups, respectively. Also, respectively, 31.3% and 47.1%



Fig. 6 forest plot of supervised PFMT versus unsupervised: PFM function/ strength outcome, pooled data from three RCTs (*n*=117)



of patients in supervised and unsupervised groups reported improvement in symptoms [23]. In the study of Mishra et al. [22], significantly more improvement was seen after 6-month-treatment in a supervised group.

Patient satisfaction

Three studies contributed data for patient satisfaction with inconclusive results [17, 18, 20]. One study showed better results in the supervised group due to not requiring further treatment compared to the unsupervised group based on subjective evaluation [18], however, the other two studies showed no differences between groups based on patient's willingness to change their treatment [17, 20].

Discussion

This study was a systematic review and meta-analysis comparing the effectiveness of the supervised versus unsupervised PFMT for the treatment of women with UI. The findings of the present systematic review and meta-analysis showed that the QoL and PFM function improved significantly in the supervised group compared to the unsupervised. There was not a significant difference in the severity of UI and the results of studies that reported patient satisfaction were inconclusive. This systematic review and meta-analysis differ from the existing Cochrane review of PFMT for UI which is limited to the comparison of PFMT to no treatment, placebo/sham, or inactive treatment [6]. Previous reviews have not compared supervised and unsupervised PFMT programs for the treatment of women with UI. This is the first systematic review and meta-analysis to compare the

outcomes of UI symptoms, QoL, PFMs function/ strength, and severity between supervised and unsupervised PFMT programs.

Based on the results of the present study, supervised PFMT was associated with a greater improvement in QoL when compared to the unsupervised PFMT group. This finding might be related to the significant improvement of PFM function/ strength in the supervised group. Increasing PFM strength and ability to maintain contraction can improve PFMs' functionality and QoL in women with UI [21, 24].

The current meta-analysis revealed no significant difference between supervised and unsupervised groups for urinary symptom improvement. However, not all the included studies produced nonsignificant results. Unsupervised PFMT programs are defined as self-administered training programs with or without education sessions [20]. Although, wide variations in implementing these programs are available. A disadvantage of unsupervised PFMT programs that probably reduces its effectiveness compared to supervised programs is the inability to perform the exercises correctly [25]. It is well known that the primary cause of treatment failure is the inaccurate performance of the exercises and lack of knowledge about the pelvic floor [26]. Interestingly, studies that reported no difference in the urinary symptoms between groups [17, 20, 23] had provided explanations about the anatomy and physiology of the lower urinary tract for the unsupervised PFMT group. Also, in these studies, inappropriate contractions were corrected and treatment adherence was motivated.

Despite all studies showing improved PFM function/ strength for both groups, the results of the meta-analysis revealed a greater impact of supervised PFMT in comparison with unsupervised programs with a strong effect size. In most of the studies that assessed the effects of supervised



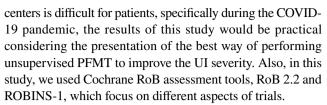
and unsupervised PFMT on PFMs function/strength, therapists who supervised the activities in the supervised group prescribed the combination of the supervised PFMT program with the program recommended for the unsupervised group [17, 19, 21]. It is possible that this strategy contributed to the positive results observed in the supervised PFMT group but not in the unsupervised PFMT group.

The results of the meta-analysis demonstrated no differences in the improvement of SUI severity among the groups, most studies had applied a pad test to evaluate the severity of UI and reported no differences between supervised and unsupervised PFMT groups [17, 20, 23]. However, not all studies were included in the meta-analysis, and the chance of objective cure of UI was four times more in the supervised PFMT group [17]. In addition, another study reported significantly better subjective results for the supervised PFMT group [22]. In most studies that found reduced UI severity, the function/ strength of the PFMs had improved with intervention in both groups [17, 20, 23]. UI severity is correlated with PFM strength [27]. When the PFMs contraction is effective, well-timed, fast, and strong, the leakage rate decreases during an increase in intra-abdominal pressure; this is facilitated by preventing urethral descent or increasing urethral pressure via either urethral clamping or mechanical compression in the pubis symphysis [9, 17, 28].

The effectiveness of supervised and unsupervised PFMT on the satisfaction of women with SUI was also assessed. Two studies [17, 20] observed no significant difference between supervised and unsupervised PFMT groups and both groups were equally satisfied with the intervention. However, one study found lower satisfaction in the unsupervised group [18]. This inconsistency observed between the studies' findings, could be due to different teaching methods implemented. Providing information regarding the lower urinary tract anatomy and physiology, correcting inappropriate contractions, and motivating and encouraging individuals for the accurate performance of PFMT have key roles in satisfaction. These factors were considered for both intervention groups in the studies of Felicíssimo et al. and Fitz et al [17, 20]. So, an online or inperson educational session at the beginning of the treatment is recommended. Also, using reinforcement techniques including regular reassessment of patients, self-assessment, and vaginal palpation, to ensure correct PFMs' contraction, is indicated.

Strengths and limitations

This study may be the first systematic review and meta-analysis that assessed the impact of supervised and unsupervised PFMT in women with UI. The findings of the study were based on a comprehensive search strategy through existing literature and presented following the PRISMA guidelines. As UI is one of the main concerns of the aging process that makes the affected person isolated, and accessibility to outpatient



However, the review has some limitations. Most studies included women with SUI, so results may not be generalizable to other types of UI and it should be noticed in future studies. Results regarding contraction types and duration of the treatments were highly heterogeneous and the RoB score of the included studies was high, particularly for the measurement of the outcome, therefore the results of this review should be implicated with caution.

Conclusion

This systematic review and meta-analysis indicated that both supervised and unsupervised PFMT has positive effects on QoL, PFMs function, urinary symptoms, and the severity of UI. Although supervised PFMT showed better results in most of the included studies compared with unsupervised PFMT, the improvement of urinary symptoms and severity of UI was almost the same between the two groups.

Implication for research

Regarding the sparse amount of research, it is required to do well-designed trials comparing supervised and unsupervised PFMT in women with UI. It is recommended to use identical and valid outcome measures to facilitate reviewing literature systematically and reach a more accurate conclusion. Also, presenting a detailed PFMT program including the number of sets and repetitions, body positions, duration of hold and rest, types of contractions, duration of each session, home exercises, warm up and cool down exercises will bring out a standardized home and outpatient PFMT program. Finally, long-term follow-up is recommended.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00192-023-05489-2.

Author's contribution in the manuscript Ghazal Kharaji: protocol development, writing manuscript, editing, interpreting the relevant literature, interpretation of data, revising the manuscript for important intellectual content

Shabnam ShahAli: protocol development, writing manuscript, editing, interpreting the relevant literature, revising the manuscript for important intellectual content

Ismail Ebrahimi-Takamjani: writing manuscript, editing

Javad Sarrafzadeh: data collection, editing Fateme Sanaei: data collection, editing

Sanaz Shanbehzadeh: data analysis, interpretation of data



Declarations

Conflicts of interest None.

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