Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women: A short version Cochrane systematic review with meta-analysis

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Abstract

Background

Pelvic floor muscle training (PFMT) is a commonly used physical therapy for women with urinary incontinence (UI).

Objectives

To determine the effects of PFMT for women with UI in comparison to no treatment, placebo or other inactive control treatments.

Search Methods

Cochrane Incontinence Group Specialized Register, (searched 15 April 2013).

Selection Criteria

Randomized or quasi-randomized trials in women with stress, urgency or mixed UI (based on symptoms, signs, or urodynamics).

Data Collection and Analysis

At least two independent review authors carried out trial screening, selection, risk of bias assessment and data abstraction. Trials were subgrouped by UI diagnosis. The quality of evidence was assessed by adopting the (GRADE) approach.

Results

Twenty-one trials (1281 women) were included; 18 trials (1051 women) contributed data to the meta-analysis. In women with stress UI, there was high quality evidence that PFMT is associated with cure (RR 8.38; 95% CI 3.68 to 19.07) and moderate quality evidence of cure or improvement (RR 17.33; 95% CI 4.31 to 69.64). In women with any type of UI, there was also moderate quality evidence that PFMT is associated with cure (RR 5.5; 95% CI 2.87–10.52), or cure and improvement (RR 2.39; 95% CI 1.64–3.47).

Conclusions

The addition of seven new trials did not change the essential findings of the earlier version of this review. In this iteration, using the GRADE quality criteria strengthened the recommendations for PFMT and a wider range of secondary outcomes (also generally in favor of PFMT) were reported.

BACKGROUND

Pelvic floor muscle training (PFMT) consists of a programme of repeated contractions and relaxations of the pelvic floor muscles taught and supervised by a health professional.[**1**] PFMT is the most commonly used physical therapy for women with stress urinary incontinence (SUI).[**2**] It is sometimes also recommended for mixed urinary incontinence (MUI) and, less commonly in isolation, for urgency urinary incontinence (UUI).[**2**]

The biological rationale for PFMT in women with SUI is twofold. Firstly, an intentional, effective pelvic floor muscle contraction (lifting the pelvic floor muscles in a upward and forward direction) prior to and during effort or exertion clamps the urethra and increases the urethral pressure, preventing urine leakage.[**3**] Secondly, the bladder neck receives support from strong, toned pelvic floor muscles (resistant to stretching), thereby limiting its downward movement during effort and exertion, thus preventing urine leakage.[**4-6**]

PFMT could also potentially be used in the management of UUI. The biological rationale is based on Godec's observation that a detrusor muscle contraction can be inhibited by a pelvic floor muscle contraction induced by electrical stimulation.[**7**] After inhibiting the urgency to void, the woman can reach the toilet in time to avoid urine leakage.

Earlier Cochrane systematic reviews of PFMT[**8-10**] and other published systematic reviews of PFMT[**11-16**] are out-dated with the publication of new trials; all prior reviews noted the relatively few data available for analysis and considerable clinical heterogeneity in the studies.[**8-16**] There is sufficient uncertainty about the effects of PFMT, particularly the size of effect, to suggest that continuing to update earlier Cochrane reviews is warranted. Further, evidence grading standards have changed. The present review is a major update of the 2010 Cochrane systematic review by the same principal authors.

OBJECTIVES

To determine the effects of PFMT for women with urinary incontinence in comparison to no treatment, placebo or sham treatments, or other inactive control treatments.

METHODS AND SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See full version of the Cochrane systematic review.

RESULTS

Description of Studies

The search produced 704 records, from which 54 potentially relevant full-text articles were retrieved. Thirty-four reports of 21 trials met the inclusion criteria. See Figure 1.

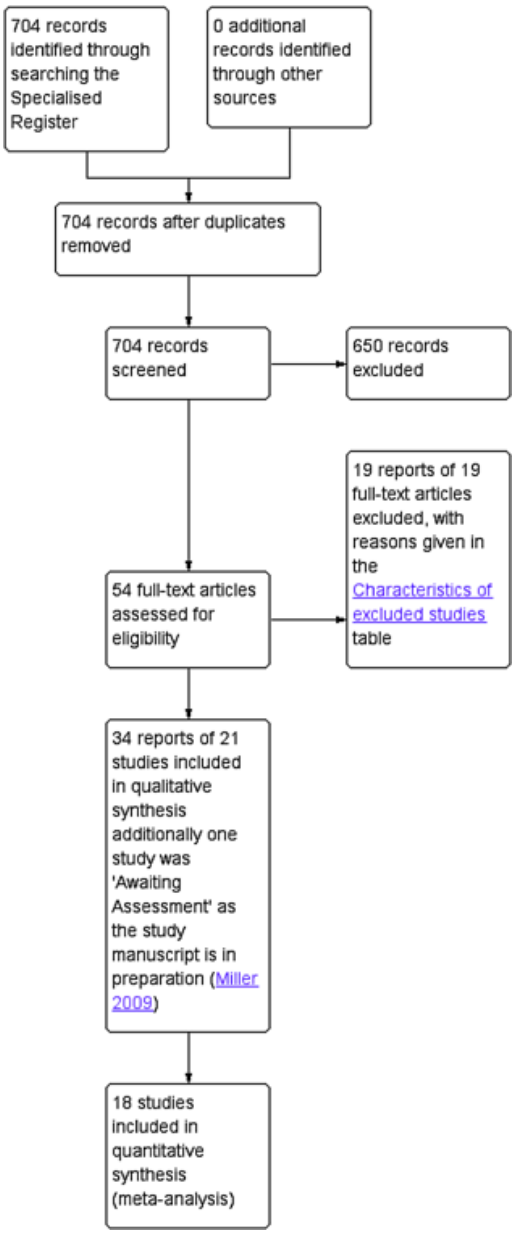


Figure 1. PRISMA Study flow diagram.

Included Studies

Twenty-one trials involving 1,281 women (665 PFMT, 616 controls) were included, 15 of which were included in the previous version of the review[**8**]; Eighteen trials (1,051 women) contributed data to the meta-analysis, but three trials contained no data usable for the pooled analysis.[**17-19**] Twelve trials contributed to the analysis of primary outcomes.[**20-31**] One trial from the previous review was excluded because it was considered to be confounded by the choice of sham.[**32**] Further details are provided in the full version of the Cochrane review.
Participants

All the women had urinary incontinence. Based on diagnosis, the subgroups used in the analysis were: SUI (15 trials),[**17, 18, 20, 22-24, 27-31, 33-35, 37**] amalgam of urinary incontinence diagnoses (six trials).[**19, 21, 25, 26, 36, 38**] No trial had participants with UUI or MUI only.
Interventions

Three trials gave no details of the PFMT programme used.[**17, 22, 35**] Of the 18 remaining trials, 13 stated that a correct voluntary PFM maximal contraction was confirmed prior to training using either vaginal, rectal or physical examination.[**18-21, 27, 29-31, 33, 34, 36-38**] Three trials reported that participants were taught a voluntary PFM maximal contraction but did not say how.[**23-25**] The individual characteristics of each exercise program (that is the number of voluntary pelvic floor muscle contractions; duration of hold; duration of rest; number of sets per day; types of contraction strength; endurance; coordination; body position; and adherence strategies) are detailed in the full Cochrane review.
Control interventions included no treatment,[**17, 18, 26, 28, 29, 31, 33-38**] placebo drug,[**21**] and sham electrical stimulation.[**22**] Inactive control treatments comprised use of an anti-incontinence device,[**20**] advice on incontinence pads,[**27**] motivational phone calls once per month,[**30**] advice on simple lifestyle alterations,[**19, 25**] general education class (cognitive function, osteoporosis and oral hygiene),[**24**] and refraining from special exercises aiming to increase muscle strength, to reduce body mass index (BMI) or to improve dietary habits.[**23**]
Outcomes

Overall there was no consistency in the choice of outcome measures by trialists. This limited the possibilities for considering together the results from individual trials. Three eligible trials did not contribute any data to the main analyses because they did not report any pre-specified outcome of interest or they did not report their outcome data in a usable way (e.g., mean without a measure of dispersion, *P* values without raw data).[**17-19**]

Primary outcome measures: Cure, and cure and improvement

Many different scales were used to measure participant reported symptomatic cure or improvement. These included Likert scales, visual analogue scales, and percent reduction in symptoms. Whatever the scale, data were included in the formal comparisons when the trialists stated the number of women who perceived they were cured or improved (as defined by the trialists) after treatment. Where more than one level of improvement was reported (e.g., much better and somewhat better), data for the greater degree of improvement was entered in the comparison. It was thought, this was more likely to capture those who had improvement that was clinically important. As some trial reports did not differentiate cure from improvement, two measures (cure only, and cure or improvement) were used so that important data were not lost. The following definitions were used by the trialists. Participant reported cure comprised:

- no urine loss or ‘dry'.[**21, 24**]
- ‘incontinence is now unproblematic'.[**20**]
- no leakage in a urinary diary.[**22, 23, 25**]
-

Participant reported cure or improvement was defined as:

- much better and somewhat better.[**26**]
- ‘75% or more perceived improvement'.[**21**]
- ‘dry' or ‘improved'.[**27**]
- ‘continent' or ‘almost continent'.[**20**]

Primary outcome measures: Symptom and condition specific quality of life measures

Seven trials used psychometrically robust questionnaires for assessment of incontinence symptoms or the impact of these symptoms on quality of life or both (e.g., B-FLUTS, KING'S HEALTH questionnaire, I-QOL).[**20, 28-31, 38**]

Risk of Bias in Included Studies

Due to brevity of reporting, it was difficult to assess the two trials that were published as conference abstracts.[**17, 35**] Seven trials had fewer than 25 women per comparison group,[**18, 22, 26, 33, 35, 36, 38**] 10 included 25–50 per group[**17, 20, 23, 24, 27-30, 34, 37**] and three had more than 50 women per group.[**19, 21, 25**] Bidmead et al. randomized participants in a 2:1 ratio, with 40 in the PFMT group and 20 as controls.[**17**] Five trials, including four recent ones, reported an a priori power calculation.[**20, 23, 25, 30, 38**] Risk of bias assessment is illustrated in Figure 2 and fully described in the complete Cochrane review.

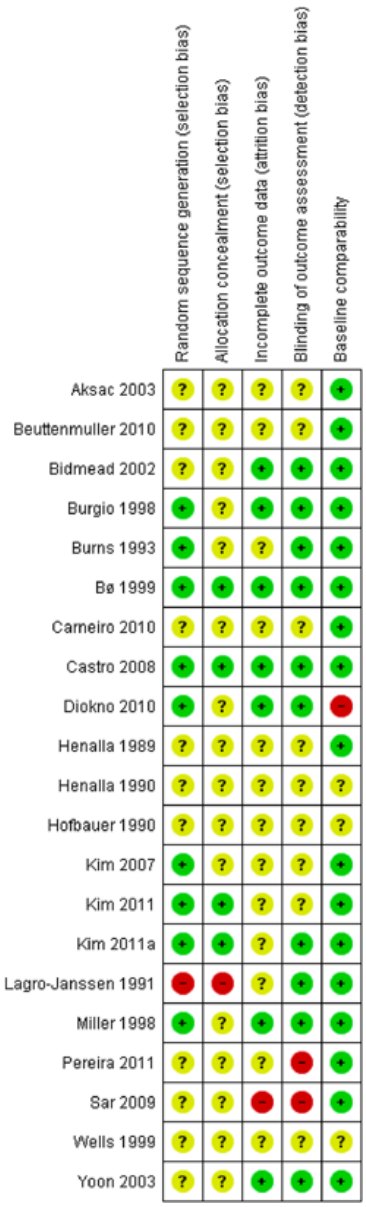


Figure 2.
Summary of risk of bias analysis.

Effects of Interventions

All primary and secondary outcomes are presented in full (including forest plots) in the complete Cochrane review.

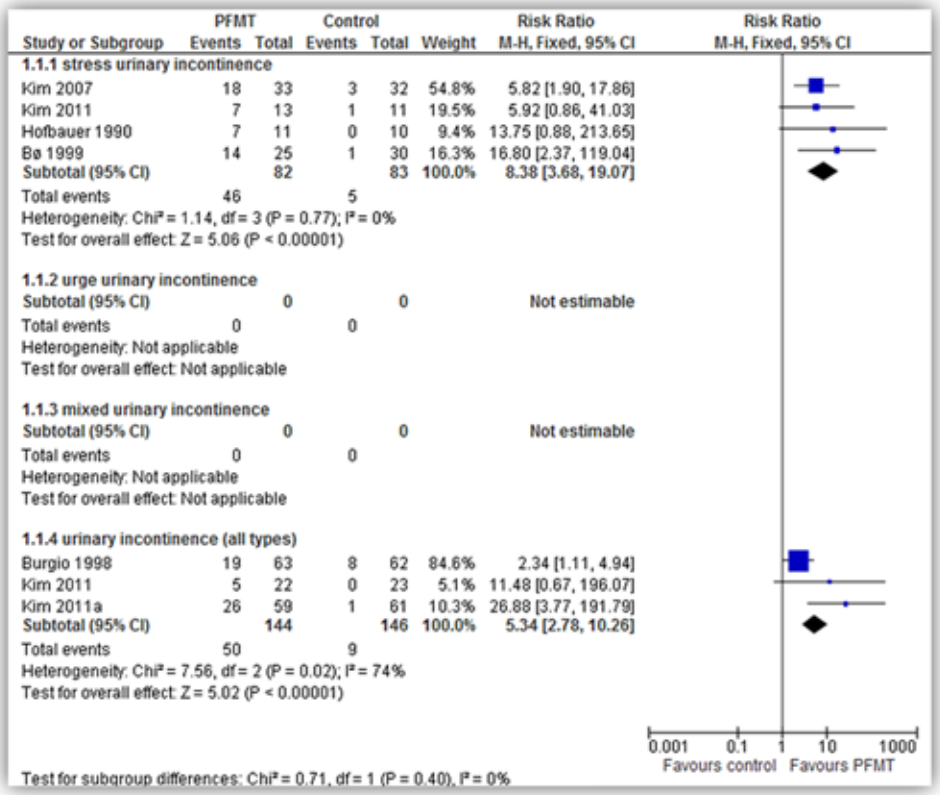
Primary Outcome Measures

Cure

Six trials reported data on cure only and the confidence intervals in all six trials were wide. All trials found that PFMT women were statistically significantly more likely to report cure (Table I).

In the four trials with women with SUI alone, PFMT women were eight times more likely to report cure than controls (46/82 (56.1%) versus 5/83 (6.0%), RR 8.38, 95% CI 3.68–19.07).[**20, 22-24**]

Table I. Forest Plot for Cure in PFMT Versus no Treatment, Placebo or Control

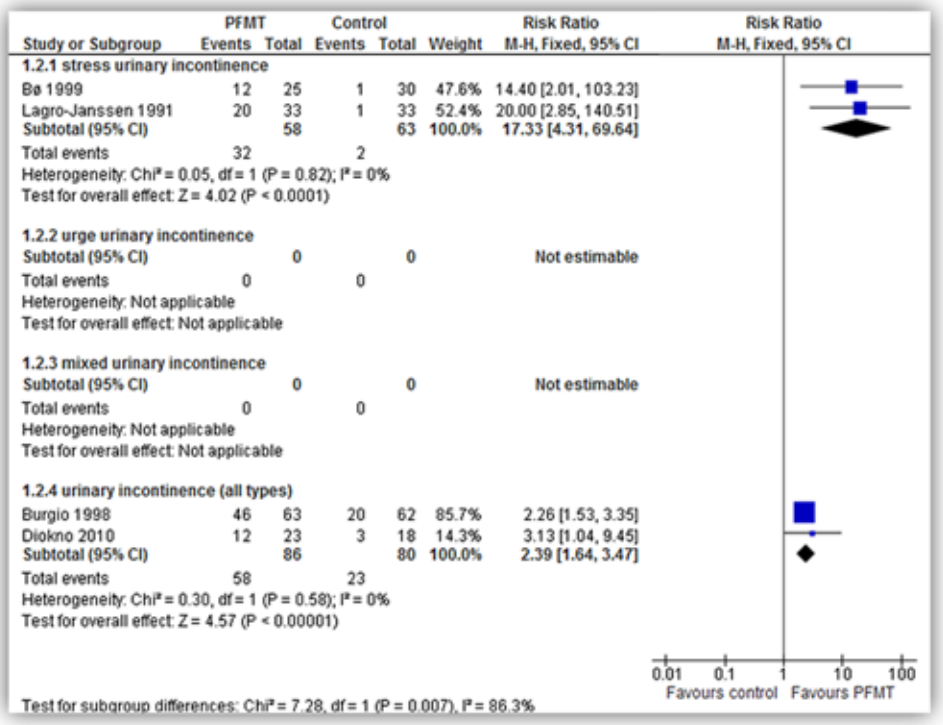


The subgroup of three trials representing an amalgam of incontinence types (including one trial that also presented data separately for SUI alone – see above)[**24**] showed individual effects favoring PFMT and a statistically significant pooled result favoring PFMT (50/144 (34.7%) versus 1/146 (0.6%), RR 5.34, 95% CI 2.78–10.26).[**21, 24, 25**] There was statistical heterogeneity and the more conservative random-effects model still favored PFMT (RR 7.50, 95% CI 1.03–54.63). Visual inspection of the forest plot suggested a smaller effect size in Burgio et al. while the effect size appeared similar in the two remaining trials.[**21**] A possible explanation of this difference in treatment effect may come from the percentage of women with urgency symptoms, which was higher in the Burgio trial than in the two others.

Cure or improvement

Four trials contributed outcome data for cure or improvement (Table II).[**20, 21, 26, 27**] Similarly, all four reported that PFMT was better than control. In two trials of SUI only,[**20, 27**] PFMT women were 17 times more likely to report cure or improvement than controls (32/58 (55.2%) versus 2/63 (3.2%), RR 17.33, 95% CI 4.31–69.64); and in two other trials (range of diagnoses),[**21, 26**] PFMT women were twice as likely to report cure or improvement than controls (58/86 (67.4%) versus 23/80 (28.7%), RR 2.39, 95% CI 1.64–3.47).

Table II. Forest Plot for Cure and Improvement in PFMT Versus no Treatment, Placebo or Control



Symptom and condition-specific quality of life

Three out of four incontinence specific quality of life domains (King's Health Questionnaire (severity), King's Health Questionnaire (physical limitation), and number of women with interference with life due to UI after treatment) were in favor of PFMT. In the fourth domain (King's Health Questionnaire [Incontinence impact]) there was statistical heterogeneity; although, the average effect for all trials favored PFMT, when a random-effects model was used, the findings did not statistically significantly support PFMT. Visual inspection of the forest plot suggested a smaller effect size in Pereira et al. while the effect size appeared similar in the two remaining trials.[**31**] Further details and forest plots are provided in the full version of the Cochrane review.

Secondary Outcome Measures

Cure at up to one year

There was limited information from two small to moderate quality trials which indicated that the benefit of PFMT seemed to persist (after treatment stopped) for up to a year in both women with SUI only (14/26 (53.8%) versus 0/25 (0%), RR 27.93, 95% CI 1.75–444.45)[**34**] and those with urinary incontinence (all types) (23/59) (38.9%) versus 1/61 (1.6%), RR 23.78, 95% CI 3.32–170.49)[**25**]. The width of the CIs means considerable imprecision in estimating longer term effect.

Patient perceived satisfaction

In trials which included women with SUI alone,[**20, 30**] PFMT women were five times more likely to be satisfied with the intervention than controls (36/51 (70.6%) versus 7/54 (12.9%), RR 5.32, 95% CI 2.63–10.74). In the one trial with women with UUI or MUI, PFMT, women were three times more likely to be satisfied with the intervention than the controls (45/58 (77.6%) versus 14/50 (28.0%), RR 2.77, 95% CI 1.74–4.41).[**21**] In contrast, women in the control groups were more likely to seek further treatment.

Number of leakage episodes in 24 hr

SUI women doing PFMT experienced one fewer leakage episodes in 24 hr compared to controls (MD −1.21, 95% CI −1.52 –−0.89).[**20, 27, 30, 37**] Similarly, those with UUI or MUI experienced about one fewer leakage episode per 24 hr compared to controls (MD −0.80, 95% CI −1.26 – −0.34).[**21**]

Short (up to one hour) pad test measured as grams of urine

Four trials reported urine loss on short pad tests in SUI women[**20, 30, 31**] and one in women with urinary incontinence (type unspecified).[**36**] Women with SUI in the PFMT groups lost significantly less urine; the comparison showed statistically significant heterogeneity but the finding still favored PFMT if a random-effects model was used (MD −13.22, 95% CI −26.36 – −0.09). Yoon[**36**] reported that PFMT women loss less urine than controls but with wide CIs that included no difference (MD −5.1, 95% CI −11.2–1.0).

Number of voids per day

Women in the incontinence (all types subgroup) reported about two and a half fewer voids per day than controls (MD −2.56, 95% CI −3.65 –−1.48).[**26, 36**]

Sexual function

One trial[**20**] in SUI women suggested that sexual function was improved by PFMT, specifically in reduction of urine leakage during intercourse (4/20 (20.0%) versus 13/25 (52.0%); RR 0.38, 95% CI 0.15–1.00).

Adherence

Of those who measured adherence, attendance at treatment sessions was generally good, and women were also motivated to practice their pelvic floor exercises during the intervention period. Long-term adherence (maintenance of home PFMT after treatment ends) was seldom reported. It was therefore not possible to assess the interaction between effect size and the adherence.

Adverse effects

Four trials specifically mentioned adverse events, and three did not report any in the PFMT group.[**20, 21, 30**] Lagro–Janssen was the only trial to report adverse events with PFMT.[**27**] and 'not wanting to be continuously bothered with the problem' (two participants).

Need for further treatment and socioeconomics

The need for further treatment such as incontinence surgery or drugs was scanty. None of the included trials reported on costs of interventions, cost effectiveness of interventions (formal economic analysis or cost utility) or resource implications.

Grading of Recommendations Assessment, Development and Evaluation (GRADE) quality of evidence

GRADE summary of findings tables were prepared separately for women with SUI at baseline (Table III) and for women with all types of urinary incontinence (SUI, UUI, MUI) (Table IV). Only 'Participant perceived cure – stress urinary incontinence' was rated as high quality evidence using the GRADE approach, and the strength of all other findings was reduced based on evidence quality.

Table III. PFMT Versus no Treatment, Placebo or Control for Urinary Incontinence in Women (SUI)

PFMT versus no treatment, placebo or control for urinary incontinence in women

*The basis for the assumed risk (e.g., the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio.

GRADE Working Group grades of evidence.

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

a Not applicable. Fewer than 10 trials.
b Random sequence generation and allocation concealment judge to be high risk in1/2 trials (Lagro–Janssen 1991).
c Random sequence generation and allocation concealment is unclear in all trials taking part in meta-analysis.
d Results are inconsistent.
e Random sequence generation and allocation concealment judge to be high risk in1 trial (Lagro–Janssen 1991).
f Random sequence generation and allocation concealment is unclear in 1/3 trials (Periera 2011).

Patient or population: women with stress urinary incontinence Intervention: PFMT versus no treatment, placebo or control

Outcomes	Illustrative comparative risks* (95% CI)	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments

PFMT versus no treatment, placebo or control for urinary incontinence in women

	Assumed risk	Corresponding risk			
	Control	PFMT versus no treatment, placebo or control			
Participant perceived cure – stress urinary incontinence	Study population		RR 8.38 (3.68–19.07)	165 (4 studies)	⊕⊕⊕⊕ higha
	60/1000	505/1000 (222/1000)			
Participant perceived cure or improvement after treatment – stress urinary incontinence	Study population		RR 17 (4.25–67.95)	121 (2 studies)	⊕⊕⊕⊖ moderatea, b
	32/1000	540/1000 (135–1000)			
Quality of life (King's Health Questionnaire/Incontinence impact after treatment) – stress urinary incontinence		The mean quality of life (King's health questionnaire/incontinence impact after treatment) – stress urinary incontinence in the intervention groups was 11.76 lower (20.83–2.69 lower)		145 (3 studies)	⊕⊖⊖⊖ very lowa, c, d
Number of leakage episodes in 24 hr – stress urinary incontinence		The mean number of leakage episodes in 24 hr – stress urinary incontinence in the intervention groups was 1.21 lower (1.52–0.89 lower)		253 (4 studies)	⊕⊕⊕⊖ moderatea, e

PFMT versus no treatment, placebo or control for urinary incontinence in women					
Short (up to one hour) pad test measured as grams of urine – stress urinary incontinence		The mean short (up to one hour) pad test measured as grams of urine – stress urinary incontinence in the intervention groups was 13.22 lower (26.36–0.09 lower)		150 (3 studies)	⊕⊕⊕⊖ moderate[a,f]
Treatment adherence – not reported	See comment	See comment	Not estimable	–	See comment
Formal economic analysis – not reported	See comment	See comment	Not estimable	–	See comment

Table IV. PFMT Versus no Treatment, Placebo or Control for Urinary Incontinence in Women (All Types)

PFMT versus no treatment, placebo or control for urinary incontinence in women
*The basis for the assumed risk (e.g., the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio. GRADE Working Group grades of evidence. High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate. a Allocation concealment is unclear in Burgio 1998 which is the biggest trial. b Not applicable. Fewer than 10 trials. c Allocation concealment is unclear in both the trials. d Allocation concealment is unclear in Burgio 1998. e Not applicable as there is only one trial. f Random sequence generation and allocation concealment judge to be unclear in 1 trial which reported this outcome. g Results are imprecise.

PFMT versus no treatment, placebo or control for urinary incontinence in women

Patient or population: women with urinary incontinence (all types) Intervention: PFMT versus no treatment, placebo or control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	PFMT versus no treatment, placebo or control				
Participant perceived cure – urinary incontinence (all types)	Study population		RR 5.5 (2.87/10.52)	301 (3 studies)	⊕⊕⊕⊖ moderate[a,b]	
	57/1000	315/1000 (165–603)				
Participant perceived cure or improvement after treatment – urinary incontinence (all types)	Study population		RR 2.35 (1.62–3.39)	166 (2 studies)	⊕⊕⊕⊖ moderate[b,c]	
	288/1000	676/1000 (466–975)				
Quality of life (King's Health Questionnaire/Incontinence impact after treatment)—urinary Incontinence (all types)—not reported	See comment	See comment	Not estimable	–	See comment	
Number of leakage episodes in 24 hr – urinary		The mean number of		125 (1	⊕⊕⊕⊖ moderate[d,]	

PFMT versus no treatment, placebo or control for urinary incontinence in women					
incontinence (all types)		leakage episodes in 24 hr – urinary incontinence (all types) in the intervention groups was 0.8 lower (1.26–0.34 lower)		study)	e
Short (up to one hour) pad test measured as grams of urine – urinary incontinence (all types)		The mean short (up to one hour) pad test measured as grams of urine – urinary incontinence (all types) in the intervention groups was 5.1 lower (11.16 lower – 0.96 higher)		25 (1 study)	⨁⨁⊖⊖ lowc, f, g
Treatment adherence – not reported	See comment	See comment	Not estimable	–	See comment
Formal economic analysis – not reported	See comment	See comment	Not estimable	–	See comment

DISCUSSION

Twenty-one trials involving 1,281 women (665 PFMT, 616 controls) were included; 18 trials (1,051 women) contributed data to the meta-analysis. The results were consistent for most of the outcomes, favoring PFMT over control. The only outcome that was consistently not different between the experimental and control conditions was generic quality of life (data not reported here – see full Cochrane review); such measures may not be sensitive enough to pick up changes

due to improvement in urinary incontinence. The main reasons for downgrading the quality of the evidence in the GRADE summary of findings table (Tables III and IV) were:

- Random sequence generation and allocation concealment was high risk or unclear in some trials;
- Results were inconsistent for the quality of life outcomes;
- Results were imprecise (heterogeneity due to variation in results, although these were generally in favor of PFMT).

Other limitations, noted in prior systematic reviews, remain. The trials were generally of small or moderate size, with insufficient detail of participant selection and a lack of clear description of the PFMT programs. There was considerable variation in interventions used, study populations, and outcome measures. There were no trials of women with UUI only or MUI only. Only short-term adherence data were reported, and were predominantly clinic/class attendance rates which may not reflect home exercise adherence. Socioeconomic data also remain scanty.

Another problem was the lack of long-term follow-up. Maintaining the effects of randomization in longer term follow-up is problematic because it is often confounded by the offer of treatment to women in the control arms; however, longer term follow-up of the whole cohort would potentially yield some useful data about duration of treatment effect after supervised treatment ends.

CONCLUSION

Implications for Practice

Based on the data available, PFMT is better than no treatment, placebo drug, or inactive control treatments for women with stress urinary incontinence or urinary incontinence (all types), but there was no information about women with UUI alone or MUI alone. Women treated with PFMT were more likely to report cure or improvement, report better quality of life, have fewer leakage episodes per day, and have less urine leakage on short office-based pad tests than controls. Women were also more satisfied with the active treatment, and according to a single moderate size trial with low risk of bias, their sexual outcomes were better. Overall, there is support for the widespread recommendation that PFMT be included in first line conservative management programmes for women with stress incontinence or in groups of women with a variety of types of incontinence. The limited nature of follow-up beyond the end of treatment in the majority of the trials means that the long-term outcomes of use of PFMT remain uncertain.

Implications for Research

Although the quality of recent trials has improved, most of the data in this review come from small to moderate sized trials of moderate methodological quality. In planning future research, trialists are encouraged to consider the following.

- The choice of primary outcomes important to women, the size of a clinically important effect, and subsequent estimation of sample size.

- Detailed reporting of PFMT exercise programmes (available as supplementary information online if necessary).
- Measuring adherence and reporting any adherence strategies used.
- The need for further treatment such as with pessaries, surgery or drugs.
- The duration of follow-up especially long term.
- The reporting of economic/cost data or formal economic analysis.

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