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Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women (Review)

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[Intervention Review]

Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women

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ABSTRACT

Background

Pelvic floor muscle training is the most commonly used physical therapy treatment for women with stress urinary incontinence (SUI). It is sometimes also recommended for mixed and, less commonly, urgency urinary incontinence.

Objectives

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

Search methods

We searched the Cochrane Incontinence Group Specialised Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL) (1999 onwards), MEDLINE (1966 onwards) and MEDLINE In-Process (2001 onwards), and handsearched journals and conference proceedings (searched 15 April 2013) and the reference lists of relevant articles.

Selection criteria

Randomised or quasi-randomised trials in women with stress, urgency or mixed urinary incontinence (based on symptoms, signs, or urodynamics). One arm of the trial included pelvic floor muscle training (PFMT). Another arm was a no treatment, placebo, sham, or other inactive control treatment arm.

Data collection and analysis

Trials were independently assessed by two review authors for eligibility and methodological quality. Data were extracted then cross-checked. Disagreements were resolved by discussion. Data were processed as described in the *Cochrane Handbook for Systematic Reviews of Interventions*. Trials were subgrouped by diagnosis of urinary incontinence. Formal meta-analysis was undertaken when appropriate.

Main results

Twenty-one trials involving 1281 women (665 PFMT, 616 controls) met the inclusion criteria; 18 trials (1051 women) contributed data to the forest plots. The trials were generally small to moderate sized, and many were at moderate risk of bias, based on the trial reports. There was considerable variation in the interventions used, study populations, and outcome measures. There were no studies of women with mixed or urgency urinary incontinence alone.

Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women (Review)

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Women with SUI who were in the PFMT groups were 8 times more likely than the controls to report that they were cured (46/82 (56.1%) versus 5/83 (6.0%), RR 8.38, 95% CI 3.68 to 19.07) and 17 times more likely to report cure or improvement (32/58 (55%) versus 2/63 (3.2%), RR 17.33, 95% CI 4.31 to 69.64). In trials in women with any type of urinary incontinence, PFMT groups were also more likely to report cure, or more cure and improvement than the women in the control groups, although the effect size was reduced. Women with either SUI or any type of urinary incontinence were also more satisfied with the active treatment, while women in the control groups were more likely to seek further treatment. Women treated with PFMT leaked urine less often, lost smaller amounts on the short office-based pad test, and emptied their bladders less often during the day. Their sexual outcomes were also better. Two trials (one small and one moderate size) reported some evidence of the benefit persisting for up to a year after treatment. Of the few adverse effects reported, none were serious.

The findings of the review were largely supported by the summary of findings tables, but most of the evidence was down-graded to moderate on methodological grounds. The exception was 'Participant perceived cure' in women with SUI, which was rated as high quality.

Authors' conclusions

The review provides support for the widespread recommendation that PFMT be included in first-line conservative management programmes for women with stress and any type of urinary incontinence. Long-term effectiveness of PFMT needs to be further researched.

PLAIN LANGUAGE SUMMARY

Pelvic floor muscle training versus no treatment for urinary incontinence in women

Stress incontinence is the involuntary leakage of urine with a physical activity such as coughing or sneezing. Urgency leakage occurs with a strong need to urinate, but the person cannot make it to the toilet in time. A combination of stress and urgency leakage is called mixed incontinence.

The review of trials found that pelvic floor muscle training (muscle-clenching exercises) helps women cure and improve stress urinary incontinence in particular, and all types of incontinence.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. 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

Patient or population: patients with urinary incontinence in women

Settings:

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 - stress urinary incontinence	Study population		RR 8.38 (3.68 to 19.07)	165 (4 studies)	⊕⊕⊕⊕ high ¹	
	60 per 1000	505 per 1000 (222 to 1000)				
	Moderate					
	62 per 1000	520 per 1000 (228 to 1000)				
Participant perceived cure or improvement after treatment - stress urinary incontinence	Study population		RR 17 (4.25 to 67.95)	121 (2 studies)	⊕⊕⊕⊖ moderate ^{1,2}	
	32 per 1000	540 per 1000 (135 to 1000)				
	Moderate					
	32 per 1000	544 per 1000 (136 to 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			145 (3 studies)	⊕⊖⊖⊖ very low ^{1,3,4}	

		(20.83 to 2.69 lower)		
Number of leakage episodes in 24 hours - stress urinary incontinence		The mean number of leakage episodes in 24 hours - stress urinary incontinence in the intervention groups was 1.21 lower (1.52 to 0.89 lower)	253 (4 studies)	⊕⊕⊕⊖ moderate ^{1,5}
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 to 0.09 lower)	150 (3 studies)	⊕⊕⊕⊖ moderate ^{1,6}
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

*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.

¹ Not applicable. Fewer than 10 trials.

² Random sequence generation and allocation concealment judge to be high risk in 1/2 trials (Lagro-Janssen 1991).

³ Random sequence generation and allocation concealment is unclear in all trials taking part in meta-analysis.

⁴ Results are inconsistent.

⁵ Random sequence generation and allocation concealment judge to be high risk in 1 trial (Lagro-Janssen 1991).

⁶ Random sequence generation and allocation concealment is unclear in 1/3 trials (Periera 2011).

Summary of findings 2. 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

Patient or population: patients with urinary incontinence in women

Settings:
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 to 10.52)	301 (3 studies)	⊕⊕⊕⊖ moderate ^{1,2}	
	57 per 1000	315 per 1000 (165 to 603)				
	Moderate					
	16 per 1000	88 per 1000 (46 to 168)				
Participant perceived cure or improvement after treatment - urinary incontinence (all types)	Study population		RR 2.35 (1.62 to 3.39)	166 (2 studies)	⊕⊕⊕⊖ moderate ^{2,3}	
	288 per 1000	676 per 1000 (466 to 975)				
	Moderate					
	245 per 1000	576 per 1000 (397 to 831)				
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 hours - urinary incontinence (all types)		The mean number of leakage episodes in 24 hours - urinary incontinence (all types) in the intervention groups was 0.8 lower (1.26 to 0.34 lower)		125 (1 study)	⊕⊕⊕⊖ moderate ^{2,4,5}	
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 mea-		25 (1 study)	⊕⊕⊕⊖ low ^{2,5,6,7}	

		asured as grams of urine - urinary incontinence (all types) in the intervention groups was 5.1 lower (11.16 lower to 0.96 higher)		
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

*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.

¹ Allocation concealment is unclear in Burgio 1998 which is the biggest trial.

² Not applicable. Fewer than 10 trials.

³ Allocation concealment is unclear in both the trials.

⁴ Allocation concealment is unclear in Burgio1998.

⁵ Not applicable as there is only one trial.

⁶ Random sequence generation and allocation concealment judge to be unclear in 1 trial which reported this outcome.

⁷ Results are imprecise.

BACKGROUND

Description of the condition

Urinary incontinence

Urinary incontinence is a common problem amongst adults living in the community. It is more frequent in women, increasing with age, and is particularly common amongst those in residential care (Hunnskaar 2002). Estimates of prevalence are influenced by the definition of incontinence, the sample population, and the format of questions about incontinence. In addition, figures are unlikely to reflect the true scope of the problem because embarrassment and other factors may lead to under-reporting. Estimates of prevalence of urinary incontinence in women vary between 25% to 45% in most studies (Milsom 2013a). Data from the widely cited EPICONT study of urinary incontinence in women (27,936 Norwegian women) suggest a gradual increase in prevalence with age to an early peak prevalence around midlife (50 to 54 years) which coincides with menopause, followed by a slight decline or stabilisation until about 70 years of age when the prevalence begins to rise steadily (Hannestad 2000). Pregnancy, labour and vaginal delivery (versus caesarean section) are significant risk factors for later urinary incontinence, but the strength of this association diminishes substantially with age (Milsom 2013a).

Isolated stress urinary incontinence (SUI) accounts for half of all urinary incontinence (UI), with most studies reporting 10% to 39% prevalence. With few exceptions, mixed urinary incontinence (MUI) is found to be next most common, with most studies reporting 7.5% to 25% prevalence. Isolated urgency urinary incontinence (UUI) is uncommon, with 1% to 7% prevalence (Milsom 2013b). The type of urine leakage is classified according to what is reported by the woman (symptoms), what is observed by the clinician (signs), and on the basis of urodynamic studies. The definitions of the different types of urinary incontinence given below are those of the International Continence Society (Haylen 2010).

Not only is urinary incontinence a serious medical condition in that it can lead to perineal rash, pressure ulcers and urinary tract infections (Resnick 1989), it is also an undeniable social problem, creating embarrassment and negative self-perception (Hunnskaar 1991; Johnson 1998). UI has been found to reduce both social interactions and physical activities (Resnick 1989) and is associated with poor self-rated health (Johnson 1998), impaired emotional and psychological well-being (Johnson 1998) and impaired sexual relationships (Temml 2001). Women with urinary incontinence often find themselves, in the medium or long term, isolated and relatively inactive (Fantl 1996). Moreover, urinary incontinence in older women doubles the risk of admission to a nursing home, independent of age or the presence of co-morbid conditions (Hunnskaar 1991).

Stress urinary incontinence (SUI)

If a woman reports involuntary urine leakage with physical exertion (symptom) or a clinician observes urine leakage at the same time as the exertion (sign) this is called stress urinary incontinence (SUI). When urodynamic studies demonstrate involuntary loss of urine during increased intra-abdominal pressure, but the leakage is not accompanied by a contraction of the detrusor muscle (bladder smooth muscle), this is called urodynamic stress incontinence (USI) (Haylen 2010). SUI is likely to be due to anatomical defects in the structures that support the bladder and urethra, resulting in

suboptimal positioning of these structures at rest or on exertion, or dysfunction of the neuromuscular components that help control the urethral sphincter or urethral pressure. As a result, the bladder outlet (urethra) is not closed off properly during exertion and this results in leakage.

Urgency urinary incontinence (UUI)

The symptom of urgency urinary incontinence (UUI) is present when a woman reports involuntary leakage associated with or immediately preceded by a sudden compelling need to void (that is urgency). The sign of UUI is identified by the observation of involuntary urine leakage from the urethra synchronous with the sensation of a sudden, compelling desire to void that is difficult to defer. UUI usually results from an involuntary increase in bladder pressure due to contraction of the detrusor muscle. If there is a known neurological cause for the detrusor muscle dysfunction this is called neurogenic detrusor overactivity, but if the cause is not known the condition is called idiopathic detrusor overactivity.

Mixed urinary incontinence (MUI)

Many women have symptoms or signs of both stress and urgency urinary incontinence, and urodynamic studies sometimes reveal that urine leakage results from a combination of USI and detrusor overactivity. When women have symptoms and/or signs of both SUI and UUI this is called mixed urinary incontinence (MUI).

Description of the intervention

Treatment of urinary incontinence

A wide range of treatments have been used in the management of urinary incontinence, including conservative interventions (such as physical therapies, lifestyle interventions, behavioural training, and anti-incontinence devices), pharmaceutical interventions and surgery. This review will focus on one of the physical therapies, specifically pelvic floor muscle training.

Pelvic floor muscle training (PFMT)

Pelvic floor muscle training (PFMT) has been part of exercise programs in Chinese Taoism for over 6000 years (Chang 1984). It first entered modern medicine in 1936; a paper by Margaret Morris describing tensing and relaxing of the pelvic floor muscles introduced the use of PFMT as a preventative and treatment option for urinary and faecal incontinence to the British physiotherapy profession (Morris 1936). However, PFMT as a treatment for SUI did not become widespread until after the mid-1900s when the American gynaecologist Arnold Kegel reported on the successful treatment of 64 cases of female SUI using pelvic floor muscle exercises with a pressure biofeedback perineometer (Kegel 1948).

How the intervention might work

Biological rationale for PFMT for SUI and MUI

The biological rationale is two-fold. Firstly, an intentional, effective pelvic floor muscle contraction (lifting the pelvic floor muscles in a cranial and forward direction) prior to and during effort or exertion clamps the urethra and increases the urethral pressure, preventing urine leakage (DeLancey 1988a). Ultrasonography and magnetic resonance imaging (MRI) studies have demonstrated the cranial and forward movement of the pelvic floor muscles during active contraction and the resulting impact on the urethral position, which supports this rationale (Bø 2001; Thompson 2003). Miller

et al (1998) named this counter-balancing pelvic floor muscle contraction prior to a cough as the 'knack' and assessed its effectiveness in a randomised controlled trial (RCT) (Miller 1998); they demonstrated that a voluntary pelvic floor muscle contraction before or during coughing can reduce leakage after only one week of training. Other published research, employing the term 'pelvic floor muscle functional training', recommends pre-contracting the pelvic floor muscles not only during a cough but for any daily task that results in increased intra-abdominal pressure (Carrière 2006). Thus, research suggests that the timing of a pelvic floor muscle contraction might be an important factor in the maintenance of urinary continence.

However, the optimal strength required to clamp the urethra and prevent urine leakage has not yet been determined. In healthy continent women, activation of the pelvic floor muscles before or during physical exertion seems to be an automatic response that does not require conscious effort (Bø 1994; Deindl 1993; Peschers 2001). There is some evidence that this pelvic floor muscle 'reflex' contraction is a feed-forward loop and might precede a bladder pressure rise by 200 to 240 msec (Constantinou 1982; Thind 1990). For incontinent women, learning to rapidly perform a strong, well-timed pelvic floor muscle contraction may actively prevent urethral descent during an intra-abdominal rise in pressure (Bø 1995).

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 (Bø 2004; DeLancey 1988b; Peschers 2001). Bø has suggested that intensive strength training may build up the structural support of the pelvis by permanently elevating the levator plate to a higher position inside the pelvis and by enhancing the hypertrophy and stiffness of its connective tissues (Bø 2004). In line with and supporting this hypothesis, differences in the anatomical position of the pelvic floor muscles have been demonstrated between continent and incontinent women (Hoyte 2001; Peschers 1997; Pontbriand-Drolet 2012). Additionally, dynamometric studies have shown that women with SUI or MUI demonstrate less pelvic floor muscle tone, maximal strength, rapidity of contraction and endurance as compared to continent women (Morin 2004; Pontbriand-Drolet 2012; Verelst 2004).

Further, in an uncontrolled MRI reconstruction study, a significant reduction in the internal surface area of the levator ani was observed after PFMT suggesting an increase in passive stiffness of the levator ani, which is indicative of the state of pelvic floor muscle tone (Dumoulin 2007). Griffin (1994), using a pressure probe inside the vagina, also showed a significant difference in individuals' pelvic floor muscle resting pressure three to four weeks after starting PFMT and increased resting pressure after PFMT was completed (Griffin 1994). Furthermore, Balmforth 2004 reported increased urethral stability at rest and during effort following 14 weeks of supervised PFMT and behavioural modifications.

Thus, there is a growing body of evidence to support the rationale that PFMT improves pelvic floor muscle tone and that it may facilitate more effective automatic motor unit firing of the PFM, preventing pelvic floor muscle descent during increased intra-abdominal pressure, which in turn prevents urine leakage (Bø 2007). Given the above biological rationale, the objective of PFMT for SUI is usually to improve the timing (of contraction), strength, endurance and stiffness of the pelvic floor muscles.

Biological rationale for PFMT for UUI

PFMT can also 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 (Godec 1975). Further, de Groat (1997) demonstrated that during urine storage there is an increased pudendal nerve outflow response to the external urethral sphincter increasing intraurethral pressure and representing what he termed a 'guarding reflex' for continence (de Groat 1997; de Groat 2001).

Additionally, Morrison 1995 demonstrated that Barrington's micturition centre excitatory loop switches on when bladder pressures are between five to 25 mmHg, while the inhibitory loop is predominantly active above 25 mmHg. Inhibition involves an automatic (unconscious) increase in tone for both the pelvic floor muscle and the urethral striated muscle. Thus, voluntary pelvic floor muscle contractions may be used to control UUI. After inhibiting the urgency to void and the detrusor contraction, the woman can reach the toilet in time to avoid urine leakage. However, the number, duration, intensity and timing of the pelvic floor muscle contraction required to inhibit a detrusor muscle contraction is not known.

Types of PFMT programmes

There is not an absolute dividing line that differentiates strength from endurance-type exercise programmes; it is common for both strength and fatigue resistance to improve in response to an exercise programme, although one may be affected more than another. Characteristic features of strength training include low numbers of repetitions with high loads; where ways to increase load include increasing the amount of voluntary effort with each contraction and performing exercise with and then against gravity. Endurance training is characterised by high numbers of repetitions or prolonged contractions with low to moderate loads. Behavioural training to improve coordination and urge suppression usually involves the repeated use of a voluntary pelvic floor muscle contraction (VPFMC) in response to a specific situation, for example VPFMC prior to cough, and VPFMC with the sensation of urgency.

Why it is important to do this review

Many women are referred for PFMT on the basis of symptoms or clinical signs of stress, urgency, or mixed urinary incontinence. There is currently no consensus about the need for urodynamic investigations before PFMT (Clement 2013; Lucas 2012), but a single randomised controlled trial indicated that there was no statistically significant difference in the conservative treatment outcome if the referral was made on the basis of symptom diagnosis or urodynamics (Ramsay 1995). The sensitivity and specificity of urodynamic diagnosis seems variable depending on the expertise of the investigator, the scope of testing, and the dysfunction being investigated. For these reasons diagnoses based on symptoms, signs and urodynamic investigations were all included in this review.

Earlier Cochrane reviews of PFMT (Dumoulin 2010; Hay-Smith 2002b; Hay-Smith 2006) and other previously published systematic reviews of PFMT (Berghmans 1998; Berghmans 2000; Bø 1996; de Kruif 1996; Fedorkow 1993; Wilson 1999) are outdated; new trials have been published. Although these reviews have identified a number of PFMT trials there were few data and considerable clinical heterogeneity in the studies. 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.

The present review is a major update of [Dumoulin 2010](#). This review investigates whether PFMT is an effective treatment in the management of female urinary (stress, urgency and mixed) incontinence compared to no treatment, placebo, sham or control treatments. Other reviews address whether:

(a) one type of PFMT is better than another ([Hay-Smith 2011](#)), or whether feedback or biofeedback has a role to play ([Herderschee 2011](#));

(b) PFMT is better than other treatments (for example other physical therapies, medication and surgery) (Protocol by [Lins 2013](#)); and

(c) if the addition of PFMT to other therapies adds benefit ([Ayeleke 2013](#)).

A separate review considers the role of PFMT in the treatment and prevention of urinary and faecal incontinence related to childbirth ([Boyle 2012](#)).

OBJECTIVES

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

METHODS

Criteria for considering studies for this review

Types of studies

The review included only randomised controlled trials and quasi-randomised trials (for example using allocation by alternation). Other forms of controlled clinical trials were excluded.

Types of participants

All women with urinary incontinence and diagnosed as having stress, urgency or mixed urinary incontinence on the basis of symptoms, signs or urodynamic evaluation, as defined by the trialists. Trials that recruited men and women were eligible for inclusion providing demographic and outcome data were reported separately for women.

Trials of women with urinary incontinence whose symptoms might be due to significant factors outside the urinary tract were excluded, for example neurological disorders, cognitive impairment, lack of independent mobility and cancer or radiotherapy. Studies investigating nocturnal enuresis in women were also excluded.

Studies that specifically recruited antenatal or postnatal women (childbearing women) were excluded. Given the physiological changes of the pregnancy and postpartum period it is possible that the effect of PFMT might differ in this group. PFMT for the prevention and management of urinary incontinence in antenatal and postnatal women is addressed in another Cochrane review ([Boyle 2012](#)).

Types of interventions

One arm of all eligible trials included the use of a PFMT program to ameliorate symptoms of existing urine leakage. Thus, studies of PFMT for primary or secondary prevention of urinary incontinence were excluded. Another arm of the trial was a no-treatment arm, a placebo treatment arm, a sham treatment arm (for example sham electrical stimulation) or an inactive control treatment arm (for example advice on use of pads).

PFMT was defined as a programme of repeated voluntary pelvic floor muscle contractions taught and supervised by a healthcare professional. All types of PFMT programmes were considered, including using variations in the purpose and timing of PFMT (for example PFMT for strengthening, PFMT for urge suppression), different ways of teaching PFMT, types of contractions (fast or sustained) and number of contractions.

Trials in which PFMT was combined with a single episode of biofeedback (for the purposes of teaching a pelvic floor muscle contraction) or advice on strategies for symptoms of urgency or frequency (but without a scheduled voiding regime characteristic of bladder training) were eligible for inclusion. Trials in which PFMT was combined with another conservative therapy (for example bladder training, biofeedback, vaginal cones or electrical stimulation) or drug therapy (for example an anticholinergic) were excluded.

Types of outcome measures

A subcommittee (Outcome Research in Women) of the Standardisation Committee of the International Continence Society suggested that research investigating the effect of therapeutic interventions for women with urinary incontinence consider five outcome categories: the woman's observations (symptoms), quantification of symptoms (for example urine loss), the clinician's observations (anatomical and functional), quality of life, and socioeconomic measures ([Lose 1998](#)). One or more outcomes of interest from each domain were chosen for the review.

The authors of the review also considered the International Classification of Function, Disability, and Health (ICF), a World Health Organization (WHO) initiative describing a conceptual framework for understanding health and the consequences of health conditions ([WHO 2002](#)), when choosing the primary outcomes of interest for the review. The framework describes the inter-relationships between a woman's impairment of body functions and structures (for example pelvic floor muscle dysfunction), limitations in activity (for example avoids running because of leakage), and restricted participation (for example decides not to go hiking with family because of leakage). Thus, the choice of condition specific quality of life as one of the primary outcome measures reflects the importance the authors place on the effects incontinence has on women's activities and participation, while a measure of impairment (for example of pelvic floor muscle function) was of secondary importance.

Primary outcomes

The primary outcomes of interest were the following.

A. Patient reported measures

1. Symptomatic cure of urinary incontinence at the end of treatment (reported by the woman and not the clinician)

2. Symptomatic cure or improvement of urinary incontinence at the end of treatment (reported by the woman and not the clinician)
3. Symptom and condition specific health measures (specific instruments designed to assess incontinence (e.g. King's Health Questionnaire (Kelleher 1997), Incontinence Quality of Life (I-QOL) (Donovan 2005), Bristol Female Lower Urinary Tract Symptoms (B-FLUTS) questionnaire (Jackson 1996))

Secondary outcomes

B. Patient reported measures

- Longer-term symptomatic cure and improvement after stopping treatment (six months to one year after end of treatment; > one year after end of treatment)
- Satisfaction
- Need for further treatment (e.g. surgery, drugs, PFMT)

C. Patient reported quantification of symptoms

- Number of leakage episodes (per 24 h)
- Number of micturitions during the day (frequency)
- Number of micturitions during the night (nocturia)

D. Clinicians' measures

- Pad and paper towel testing short (up to one hour) or long (24 hours) urine loss (grams of urine lost)
- Number cured or improved based on pad weights in short office-based pad test

E. Quality of life (not condition specific)

- General health status measures e.g. Short Form-36 (Ware 1993)
- Psychosocial outcome measures (e.g. Hopkins Symptoms Checklist for psychological distress (SCL-90-R) (Derogatis 1974), Hospital Anxiety and Depression Scale (HADS) (Zigmond 1983))
- Sexual function or problems (e.g. leakage during intercourse, impact on sexual function)

F. Adverse effects

- Adverse effects (e.g. discomfort, soreness, pain, bleeding)

G. Socioeconomic measures

- Costs of interventions
- Cost-effectiveness of interventions (formal economic analysis, cost utility)
- Resource implications

H. Measures of likely moderator variables

Measures of pelvic floor muscle function

- a. digital evaluation,
- b. pelvic floor muscle dynamometry,
- c. pelvic floor muscle electromyography,
- d. vaginal squeeze pressure,
- e. perineal ultrasound.

Measure of adherence:

- a. number of study participants attending or completing treatment sessions,
- b. number of study participants performing PFMT or adherence to home and clinic-based PFMT,
- c. number of contractions completed per session, day or week.

I. Other outcomes

- Non-prespecified outcomes judged important when performing the review

Quality of evidence (GRADE)

Quality of evidence was assessed by adopting the GRADE approach (Guyatt 2011a; Guyatt 2011b; Guyatt 2013a; Guyatt 2013b). The following factors were considered for assessing the quality of evidence:

1. limitations in the study design;
2. inconsistency of results;
3. indirectness of evidence;
4. imprecision;
5. publication bias.

The GRADE working group strongly recommends including up to seven main outcomes in a systematic review (Guyatt 2011a; Guyatt 2011b). In this systematic review the following critical outcomes were selected for assessing the quality of evidence with the GRADE approach:

- 1) symptomatic cure of urinary incontinence (reported by the woman and not the clinician);
- 2) symptoms of cure or improvement of urinary incontinence (reported by the woman and not the clinician);
- 3) symptom and condition specific quality of life assessment (e.g. Incontinence Impact Questionnaire, King's Health Questionnaire);
- 4) number of urinary leakage episodes;
- 5) pad and paper towel testing short (up to one hour) or long (24 hours) urine loss (grams of urine lost);
- 6) treatment adherence;
- 7) formal economic analysis (for example cost-effectiveness, cost utility).

Search methods for identification of studies

This review drew on the search strategy developed by the Cochrane Incontinence Group. There were no language or other restrictions imposed on any of the searches described below.

Electronic searches

Relevant trials were identified from the Cochrane Incontinence Group Specialised Trials Register. For more details of the search methods used to build the Specialised Register please see the Group's [module](#) in *The Cochrane Library*. The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL) (1999 onwards), MEDLINE (1966 onwards), and

MEDLINE In-Process (2001 onwards), and handsearching of journals and conference proceedings. Most of the trials in the Cochrane Incontinence Group Specialised Register are also contained in CENTRAL. The date of the last search was 15 April 2013.

The terms used to search the Incontinence Group Specialised Register are given below:

```
(({{DESIGN.CCT*}} OR {{DESIGN.RCT*}}) AND ({{INTVENT.PHYS.PFMT*}} OR {{INTVENT.PHYS.BIOFEED*}}) AND {{TOPIC.URINE.INCON*}}
```

(All searches were of the keyword field of [Reference Manager 2012](#)).

Searching other resources

In addition, relevant conference abstracts identified from the Incontinence Group Specialised Register search were cross-referenced to determine if a full-length report had been published. Known trialists and other experts in the field have been contacted to ask for possible relevant trials, published or unpublished.

Additional trials have been sought from the reference lists of included trials.

Data collection and analysis

Selection of studies

Only randomised and quasi-randomised controlled trials of PFMT for the treatment of UI were included. Two review authors (CD together with student GMS and JHS) independently screened the list of titles and abstracts generated by our search. Full-text articles of potentially relevant studies were retrieved. We also included trials for which only abstracts were available. Two review authors (CD with GMS or JHS) independently assessed the full-text articles or abstracts for eligibility. We contacted study investigators as required. Any differences of opinion were resolved by discussion or involvement of a third party. Studies formally considered for the review but excluded were listed with the reasons given for their exclusion. The selection process is documented with a PRISMA flow chart ([Figure 1](#)).

Figure 1. PRISMA study flow diagram.

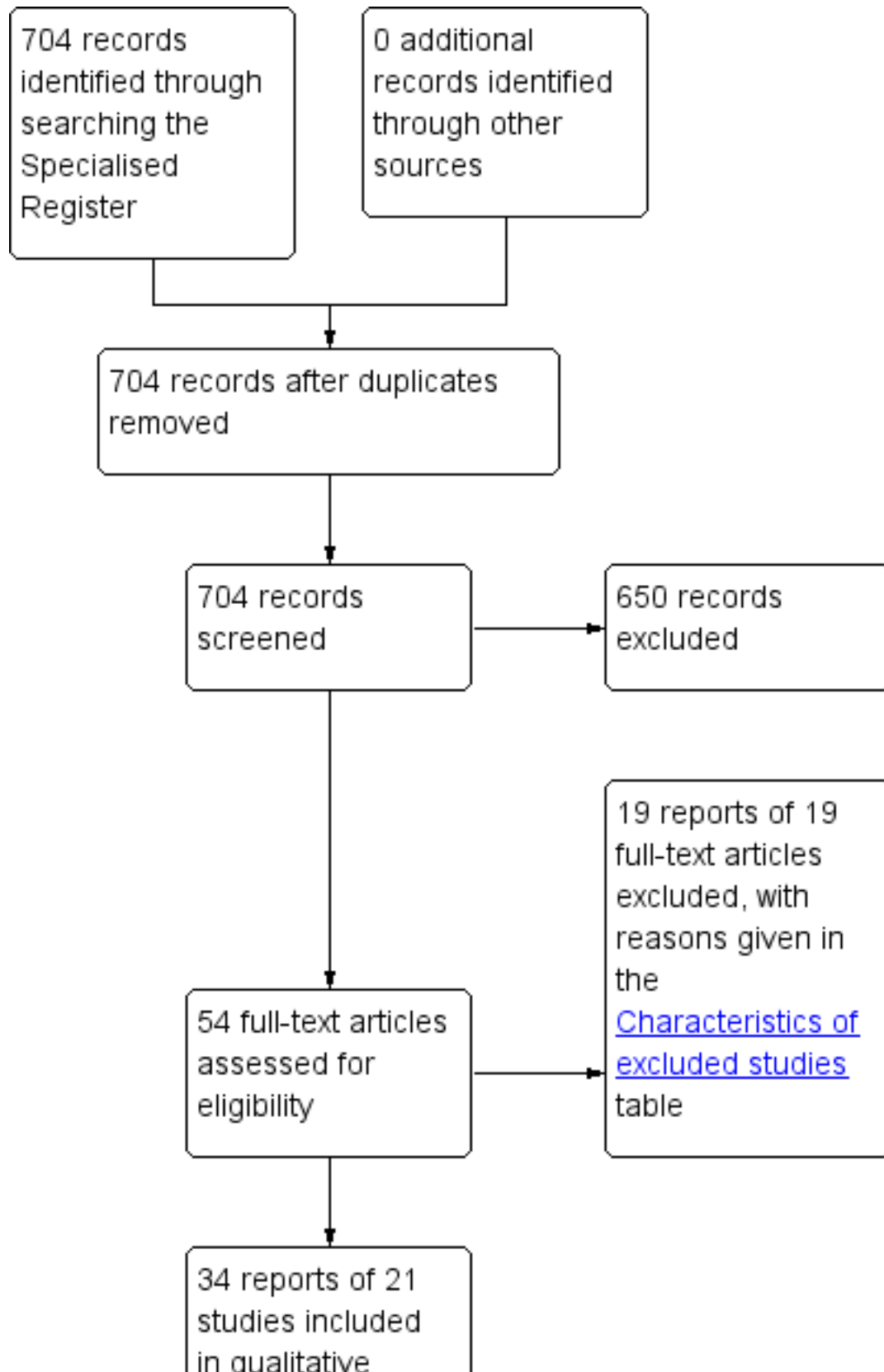
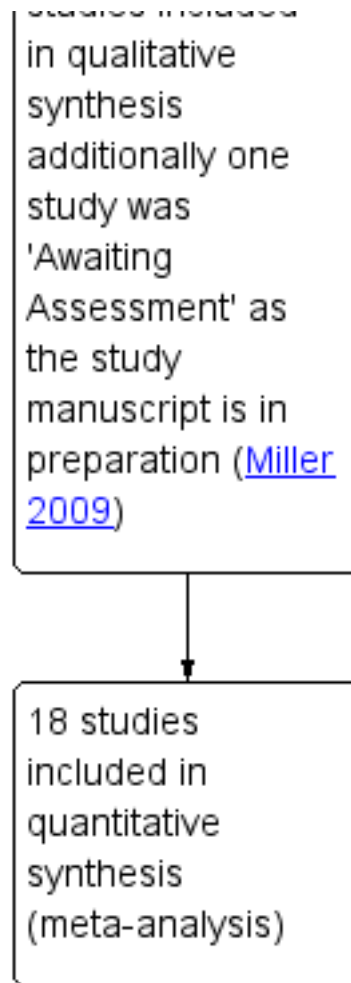


Figure 1. (Continued)



Data extraction and management

Data extraction was undertaken independently by two review authors (CD with GMS and JHS) and cross-checked. Any differences of opinion related to the data extraction were resolved by discussion. Where study data were possibly collected but not reported, or data were reported in a form that could not be used in the formal comparisons, further clarification was sought from the trialists. In addition, where the reported data were clearly incomplete (that is data from abstracts for ongoing trials) the trialists were contacted for data from the completed trial. When found, these data were added to the extraction sheet. For data entry, performed by CD, Review Manager software (RevMan 5.1) was used. All included trial data were processed as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Data entry was cross-checked by JHS. Any differences of opinion related to the data extraction were resolved by discussion. For categorical outcomes we related the numbers reporting an outcome to the numbers at risk in each group to derive a risk ratio. For continuous variables we used means and standard deviations to derive mean differences. We had planned to undertake formal meta-analysis, where appropriate.

Assessment of risk of bias in included studies

The risk of bias in the included trials was assessed using the Cochrane risk of bias assessment tool (Higgins 2011). This includes the following.

- Random sequence generation (selection bias).
- Allocation concealment (selection bias).
- Blinding (performance bias) (because it was not possible to blind the participants or the care givers this element was not assessed).
- Blinding of outcome assessment (detection bias).
- Selective reporting (reporting bias) (because no trial protocols were available this element was not assessed).
- Incomplete outcome data (attrition bias).
- Baseline comparability of the randomised groups.

Two review authors (CD with GMS or JHS) independently assessed these domains. Any differences of opinion were resolved by consensus.

Measures of treatment effect

Analyses were based on available data from all included trials relevant to the comparisons and outcomes of interest. For

trials with multiple publications, only the most up-to-date or complete data for each outcome were included. Meta-analysis was undertaken where data were available from more than one study assessing the same outcome. A fixed-effect model was used for calculations of pooled estimates and their 95% confidence intervals.

For categorical outcomes we related the numbers reporting an outcome to the numbers at risk in each group to calculate a risk ratio (RR) with 95% confidence interval (CI). For continuous variables we used means and standard deviations to calculate a mean difference (MD) with 95% CI. For positive outcomes such as cure, we altered the labelling of the forest plots. If data to calculate RRs or MDs were not given, we utilised the most detailed numerical data available to calculate the actual numbers or means and standard deviations (for example test statistics, P values).

Unit of analysis issues

The primary analysis was per woman randomised.

Dealing with missing data

The data were analysed on an intention-to-treat basis, as far as possible, meaning that all participants must be analysed in the groups to which they were randomised. If this was not the case, we considered whether the trial should be excluded.

Data were reported as given in the trials, except if there was evidence of differential loss to follow-up from the randomised groups. In that case, the use of imputation of missing data was considered.

If trials reported sufficient detail to calculate mean differences but not enough information to calculate the associated standard deviation (SD), the outcome was assumed to have a standard deviation (SD) equal to the highest SD from other trials within the same analysis.

Attempts were made to obtain missing data from the original trialists.

Assessment of heterogeneity

Trials were only combined if they were thought to be clinically similar. Heterogeneity between trials was assessed by visual inspection of plots of the data, the Chi² test for heterogeneity and the I² statistic (Higgins 2003; Higgins 2011). We defined the thresholds for interpretation of the I² statistic according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Assessment of reporting biases

In view of the difficulty of detecting and correcting for publication bias and other reporting biases, the authors aimed to minimise their potential impact by ensuring a comprehensive search for eligible studies and by being alert for duplication of data.

Data synthesis

Trials were combined if the interventions and populations were similar, based on clinical criteria. To combine trial data, a meta-analysis was conducted and a fixed-effect model approach to the analysis was used unless there was evidence of heterogeneity across trials.

Subgroup analysis and investigation of heterogeneity

Analysis within subgroups was used to address the effect of the type of incontinence on outcome. Because the rationale for PFMT is different for the two main types of urinary incontinence (stress and urgency) it is plausible to expect a difference in the outcome of PFMT on the basis of the type of incontinence. It is commonly believed that PFMT is most effective for women with SUI and that it may be effective, in combination with behavioural interventions, for women with MUI. In the past, PFMT has rarely been the first-choice treatment for women with UUI alone (Moore 2013).

The four pre-specified diagnostic subgroups were trials that recruited women with:

1. stress urinary incontinence (SUI) alone (symptoms, signs, urodynamic stress incontinence (USI));
2. urgency urinary incontinence (UUI) alone (symptoms, signs, idiopathic detrusor overactivity incontinence);
3. mixed urinary incontinence (MUI) (symptoms or signs of both SUI and UUI, or idiopathic detrusor overactivity incontinence with USI);
4. a range of diagnoses of urinary incontinence (women could have SUI, UUI or MUI, but data were not reported separately according to these subgroups).

If heterogeneity between trials was sufficiently large, an investigation to identify its causes would be conducted. The investigation of heterogeneity addressed the populations and interventions in the individual trials. The investigation could also include subgroup analyses, meta-regression and sensitivity analyses. If heterogeneity remained after appropriate investigation, and possible removal of outlying trials, a random-effects model could be used in the meta analysis.

Sensitivity analysis

The effects of including or excluding trials at high risk of bias were investigated by means of sensitivity analyses.

RESULTS

Description of studies

Results of the search

The literature search produced 704 records which were screened, from which 54 potentially relevant full-text articles were retrieved. There were 34 reports of 21 trials that met the inclusion criteria and 19 reports of 19 studies were excluded with reasons given in the [Characteristics of excluded studies](#) table. Additionally, one study (Miller 2009) was not fully assessable as the manuscript was still in preparation and this study is in [Studies awaiting classification](#). The flow of literature through the assessment process is shown in the PRISMA flowchart (Figure 1).

Included and excluded trials

Of the 21 included trials, three trials contained no data usable in forest plots ((Bidmead 2002; Miller 1998; Wells 1999) and 18 contributed to forest plots. Twelve trials contributed to the analysis of primary outcomes:

1. cure (Bø 1999; Burgio 1998; Hofbauer 1990; Kim 2007; Kim 2011; Kim 2011a);

2. cure or improvement (Bø 1999; Burgio 1998; Diokno 2010; Lagro-Janssen 1991);
3. symptom or condition specific health measures (Beuttenmuller 2010; Bø 1999; Carneiro 2010; Castro 2008; Pereira 2011).

Fourteen trials had more than two treatment arms (Aksac 2003; Beuttenmuller 2010; Bidmead 2002; Bø 1999; Burgio 1998; Burns 1993; Castro 2008; Diokno 2010; Henalla 1989; Henalla 1990; Hofbauer 1990; Kim 2011; Pereira 2011; Yoon 1999). Only descriptions and data relating to the PFMT and control arms were given in this review. Of the 21 included trials, 15 were included in the previous version of the review (Dumoulin 2010). One trial from the previous review was excluded (van Leeuwen 2004), as reported earlier, because it was considered to be confounded by the choice of sham PFMT.

Included studies

More details of the trials are given in the 'Characteristics of included studies' table.

Design

All included trials were randomised controlled trials except one (Lagro-Janssen 1991), which was considered to be quasi-randomised.

Sample sizes

Sample size ranged from a total of 15 to 143 participants per study.

Setting

The settings were single centres (14 trials) in Turkey, Brazil, USA, UK, Germany, Japan or Korea, or multiple centres (two trials) in Norway and the Netherlands. In two other trials, participants came from either a multiple counties register in the USA or a single resident register in Tokyo, Japan.

Participants

All the women had urinary incontinence. Nine trials diagnosed the type of urinary incontinence based on symptoms or signs, or both; the symptomatic diagnoses were:

- urinary incontinence (Diokno 2010; Kim 2011; Kim 2011a; Sar 2009; Yoon 2003), and
- SUI (Beuttenmuller 2010; Kim 2007; Miller 1998; Pereira 2011).

The other 12 trials reported urodynamic diagnoses:

- eight of these included women with USI only (Aksac 2003; Bidmead 2002; Bø 1999; Castro 2008; Carneiro 2010; Henalla 1989; Henalla 1990; Hofbauer 1990);
- Wells and co-workers included women with SUI or MUI (Wells 1999);
- Lagro-Janssen and co-workers included women with SUI, UUI, or MUI although a subset of data was available for women with USI only (Lagro-Janssen 1991);
- Burns et al included women with USI with or without detrusor overactivity incontinence, but the proportion with mixed symptoms was small (9%) (Burns 1993);
- Burgio et al included women with detrusor overactivity incontinence with or without USI, and about half had MUI (51%) (Burgio 1998).

Based on diagnosis, the incontinence subgroups used in the analysis were:

- SUI, 15 trials (Aksac 2003; Beuttenmuller 2010; Bidmead 2002; Bø 1999; Burns 1993; Carneiro 2010; Castro 2008; Henalla 1989; Henalla 1990; Hofbauer 1990; Kim 2007; Kim 2011; Lagro-Janssen 1991; Miller 1998; Pereira 2011);
- Urinary incontinence, range of diagnoses, six trials (Burgio 1998; Diokno 2010; Kim 2011a; Sar 2009; Wells 1999; Yoon 2003);

No trial had participants with UUI or MUI only.

Lagro-Janssen and colleagues recruited women with SUI, UUI or MUI, and those with urgency or mixed urinary incontinence were offered bladder training. However, data from women with SUI (who received PFMT only) were reported separately, so this trial was eligible for the review (Lagro-Janssen 1991).

Other characteristics

In nine trials leakage frequency was one of the inclusion criteria, being:

- more than once a month (Kim 2007; Kim 2011; Pereira 2011);
- twice or more per month (Lagro-Janssen 1991);
- once or more per week (Kim 2011a);
- twice or more per week (Burgio 1998);
- three times or more per week (Burns 1993; Castro 2008); or
- one to five leakage episodes per day (Miller 1998).

Three trials used amount of leakage from a pad test:

- more than 1 g during a 30 minute test (Yoon 2003);
- more than 2 g during a 60 minute pad test (Sar 2009); or
- more than 4 g on a short clinic-based pad test, with standardised bladder volume (Bø 1999).

Aside from diagnosis and some measure of leakage severity, no other inclusion criteria were reported consistently, although nine trials restricted participation based on age. These trials recruited women aged:

- 20 to 65 years (Lagro-Janssen 1991);
- 35 to 50 years (Carneiro 2010);
- 35 to 55 years (Yoon 2003);
- 55 years and older (Burgio 1998; Burns 1993);
- 60 years or more (Miller 1998);
- 70 years and older (Kim 2007; Kim 2011; Kim 2011a).

Common exclusion criteria were untreated urinary tract infection, post-void residual greater than a specified amount, neurological disorders, and cognitive impairments.

Interventions

The individual characteristics of the active interventions and control interventions are detailed in the PFMT protocol table that can be found in the [Characteristics of included studies](#) table and are summarised in [Appendix 1](#).

Active intervention: pelvic floor muscle training (PFMT)

Three trials gave no details of the PFMT programme used (Bidmead 2002; Henalla 1990; Hofbauer 1990). Of the 18 remaining trials, 13 stated that a correct VPFMC was confirmed prior to training using either vaginal, rectal or physical examination (Aksac 2003; Bø 1999; Burgio 1998; Burns 1993; Carneiro 2010; Castro 2008; Henalla 1989; Lagro-Janssen 1991; Miller 1998; Pereira 2011; Sar 2009; Wells 1999; Yoon 2003). Three trials (Kim 2007; Kim 2011; Kim 2011a) reported that participants were taught to do a VPFMC but did not say how they were taught.

PFMT was taught by specialist nurses in 10 trials, physiotherapists in 10 trials, and in one it was by a family doctor.

Based on the descriptions of training, two trials had PFMT programmes that clearly or predominantly targeted co-ordination (Miller 1998) or strength training (Bø 1999). Miller and colleagues described a short (one week) programme to improve co-ordination between a VPFMC and a rise in intra-abdominal pressure. Bø et al recommended a programme that comprised 8 to 12 high intensity (close to maximal) VPFMC, with 6 to 8 second hold and three to four fast contractions added at the end of each hold, 6 second rest between contractions, three times per day. Exercises were done in different body positions that included lying, kneeling, sitting and standing, all with legs apart (Bø 1999).

It was more difficult to characterise or categorise the other PFMT programmes because they were either a mixed (for example strength and endurance) programme or had not described a key training parameter (for example amount of voluntary effort per contraction). The individual characteristics of each exercise program (that is the number of voluntary pelvic floor muscle contractions; duration of holding time; duration of rest time; number of sets per day; types of contraction strength; endurance; co-ordination; body position; and adherence strategies) are detailed in Appendix 1.

Of interest, many of the recent trials described a mixed program of short or short and rapid contractions of 1 to 3 sec and long sustained contractions of 6 to 10 sec (Diokno 2010; Kim 2011; Kim 2011a; Sar 2009) in addition to contraction prior to and during a cough (Castro 2008; Diokno 2010; Sar 2009) and in different body positions (Beuttenmuller 2010; Carneiro 2010; Kim 2007; Kim 2011; Kim 2011a; Pereira 2011; Sar 2009).

Control interventions

Control interventions included:

- no treatment (Aksac 2003; Beuttenmuller 2010; Bidmead 2002; Burns 1993; Carneiro 2010; Diokno 2010; Henalla 1989; Henalla 1990; Miller 1998; Pereira 2011; Sar 2009; Yoon 2003);
- placebo drug (Burgio 1998);
- sham electrical stimulation (Hofbauer 1990);
- other inactive control treatments that comprised:

- use of an anti-incontinence device (Bø 1999),
- advice on incontinence pads (Lagro-Janssen 1991),
- motivational phone calls once per month (Castro 2008),
- advice on simple lifestyle alterations (Kim 2011a; Wells 1999),
- general education class (cognitive function, osteoporosis, and oral hygiene) (Kim 2011);
- refraining from special exercises aiming to increase muscle strength, walking speed, to reduce body mass index (BMI) or to improve dietary habits (Kim 2007).

More details are available in the [Characteristics of included studies](#) table.

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. It was disappointing that 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 (for example mean without a measure of dispersion, P values without raw data) (Bidmead 2002; Miller 1998; Wells 1999).

As the length of intervention and timing of post-intervention assessment varied, no attempt was made to report outcomes at a particular time point. Post-intervention outcomes were used as it was assumed that the trialists would choose to complete treatment and measure outcomes when maximum benefit was likely to have been gained. Data from after treatment stopped or any longer-term follow-up are reported as secondary outcomes.

Primary outcomes - participant-reported measures

Measurement of symptomatic cure or symptomatic cure or improvement of urinary incontinence:

Many different scales were used to measure a participant's response to treatment, including Likert scales, visual analogue scales, and per cent 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 (for example 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.

- Participant perceived cure defined as no urine loss or 'dry' (Burgio 1998; Kim 2011).
- Participant perceived cure as 'incontinence is now unproblematic' (Bø 1999).
- Cure was also reported by women as no leakage in a urinary diary (Hofbauer 1990; Kim 2007; Kim 2011a).
- Participant perceived cure and improvement defined as much better and somewhat better (Diokno 2010).
- Participant perceived cure and improvement defined as '75% or more perceived improvement' (Burgio 1998).

- Participant perceived cure and improvement defined as 'dry' or 'improved' (Lagro-Janssen 1991).
- Participant perceived cure and improvement defined as 'continent' or 'almost continent' (Bø 1999).

Measurement of symptoms and condition-specific health measure (specific instruments designed to assess incontinence)

Seven trials used psychometrically robust questionnaires for assessment of incontinence symptoms or the impact of these symptoms on quality of life, or both.

B-FLUTS

Bø and colleagues (Bø 1999) used the Bristol Female Lower Urinary Tract Symptoms Questionnaire (B-FLUTS), which has established validity, reliability and responsiveness to change for evaluation of urinary incontinence symptoms in women (Donovan 2005). Only two parts of the questionnaire were reported, the lifestyle and sex life questions, therefore they are not presented in the forest plot but rather Appendix 2. The data were reported as frequencies rather than mean scores.

KING'S HEALTH questionnaire

Beuttenmuller and colleagues (Beuttenmuller 2010), Carneiro and colleagues (Carneiro 2010) and Pereira and colleagues (Pereira 2011) used the King's Heath questionnaire, which has established validity, reliability and responsiveness to change or evaluation of urinary incontinence symptoms in women (Kelleher 1997; Margolis 2011).

I-QOL

Castro and colleagues (Castro 2008) and Sar and colleagues (Sar 2009) used the urinary incontinence specific quality of life instrument (I-QOL), which has established validity, reliability and responsiveness to change or evaluation of incontinence symptoms in women (Bushnell 2005; Wagner 1996). Castro and colleagues reported the total score after treatment (Castro 2008) while Sar and colleagues only reported change from baseline (Sar 2009).

The Social Activity Index

Bo and colleagues (Bø 1999) reported a symptom score that addressed activity limitation (difficulty with certain activities and functions) in nine social situations (The Social Activity Index). This index has established reproducibility in women with SUI (Bo 1994).

Severity index for urinary incontinence

Diokno and colleagues (Diokno 2010) reported a urinary severity index score (the Sandvik Severity Index for Urinary Incontinence). This index has been validated in women with urinary incontinence (Sandvik 2000).

Urine leakage score

Kim and colleagues (Kim 2011a) reported a urine leakage score calculated based on a self reported one week urinary diary. No information was given on the psychometric properties of this instrument.

Urinary incontinence score

Yoon and colleagues (Yoon 1999) reported on a urinary incontinence score calculated from a 5 point Likert type scale regarding severity of leakage with 18 pre-specified activities

associated with urine loss. No information was given on the psychometric properties of this instrument.

Secondary outcomes - participant-reported measures

Longer-term symptomatic cure and improvement after stopping treatment (six months to one year after end of treatment; > one year after end of treatment)

Most of the trials evaluated cure or cure and improvement immediately after the treatment period. Only two trials (Henalla 1989; Kim 2011a) evaluated cure in the intermediate term: nine months and seven months after treatment respectively.

No trials evaluated cure or improvement one year or more after the end of treatment.

Satisfaction and need for further treatment

Three trials reported on patient perceived satisfaction following the intervention (Bø 1999; Burgio 1998; Castro 2008) and two reported on the number of women needing further treatment (Bø 1999; Burgio 1998).

Participant-reported quantification of symptoms

Number of leakage episodes

Seven of the trials used diaries to collect data on leakage episodes, for:

- two days (Yoon 2003);
- three days (Bø 1999; Sar 2009);
- four days (Wells 1999);
- seven days (Castro 2008; Lagro-Janssen 1991); or
- 14 days (Burgio 1998; Burns 1993).

Yoon and colleagues collected but did not report these data directly; rather, leakage per 48 h was reported as an incontinence score (Yoon 2003). Sar reported mean change from baseline (Sar 2009), and Wells reported means without a measure of dispersion (Wells 1999). To enable comparison between trials the data were presented as number of leakage episodes in 24 hours.

Number of micturitions during the day (frequency) or during the night (nocturia)

Further, two trials reported on frequency of voids per day and per night (Diokno 2010; Yoon 2003).

Clinician's measures

Pad and paper towel testing in a short test (up to one hour) or long test (24 hours) (grams of urine lost) and number cured or improved based on pad weights in short office-based pad test

Eight trials reported data on pad and paper towel tests:

- eight trials used office-based short pad tests (Aksac 2003; Bidmead 2002; Bø 1999; Castro 2008; Henalla 1989; Henalla 1990; Pereira 2011; Yoon 2003);
- in addition to the short pad test, Bø used a 24 hour home-based pad test (Bø 1999);
- one used a paper towel test (Miller 1998); and
- one further trial reported only a 24 hour pad test (Diokno 2010).

Aside from differences in the type of test, trialists also presented their data differently. Data were usually categorised (such as cured, improved, not improved) or reported as a mean with standard deviation. The former data were used to report the number of women with objective cure or improvement of incontinence, while the latter were reported as grams of urine lost.

Quality of life (not condition-specific)

General health status measures

Two trials reported non-condition specific quality of life (QOL) data (Bø 1999; Burgio 1998). Burgio and colleagues (Burgio 1998) used the Hopkins Symptom Checklist for psychological distress with 90 items and a total score (Global Severity Index) (Derogatis 1983). Bo and colleagues (Bø 1999) used the Norwegian Quality of Life Scale to assess general health and QOL prior to and after the intervention (Wahl 1998).

Measures of sexual function

One trial reported the effect of PFMT on urinary incontinence during intercourse and in terms of interference with sexual satisfaction (Bø 1999).

Adverse effects

Four trials reported on adverse effects (Bø 1999; Burgio 1998; Castro 2008; Lagro-Janssen 1991).

Socioeconomic measures

No trials reported on costs of interventions, cost-effectiveness of interventions (formal economic analysis, cost utility) or resource implications.

Measure of likely moderator variables

Measurement of pelvic floor muscle function

- Five trials used perineometry to measure vaginal squeeze pressure (Aksac 2003; Beuttenmuller 2010; Bø 1999; Pereira 2011; Yoon 2003)
- Three trials used vaginal electromyography (Burns 1993; Carneiro 2010; Wells 1999)
- Eight trials used digital palpation (Aksac 2003; Beuttenmuller 2010; Carneiro 2010; Castro 2008; Diokno 2010; Miller 1998; Pereira 2011; Wells 1999)
- One trial used perineal ultrasound (Carneiro 2010)

Measurement of adherence

Six trials attempted to measure adherence to home PFMT using either exercise or training diaries (Bidmead 2002; Bø 1999; Kim 2007; Kim 2011a; Wells 1999) or self-reported adherence (Lagro-Janssen 1991). Three trials attempted to measure attendance at exercise sessions (Burns 1993; Castro 2008; Kim 2007).

Excluded studies

Full details of the studies are given in the 'Characteristics of included studies' table.

Risk of bias in included studies

Figure 2 and Figure 3 summarize the results of the risk of bias analysis.

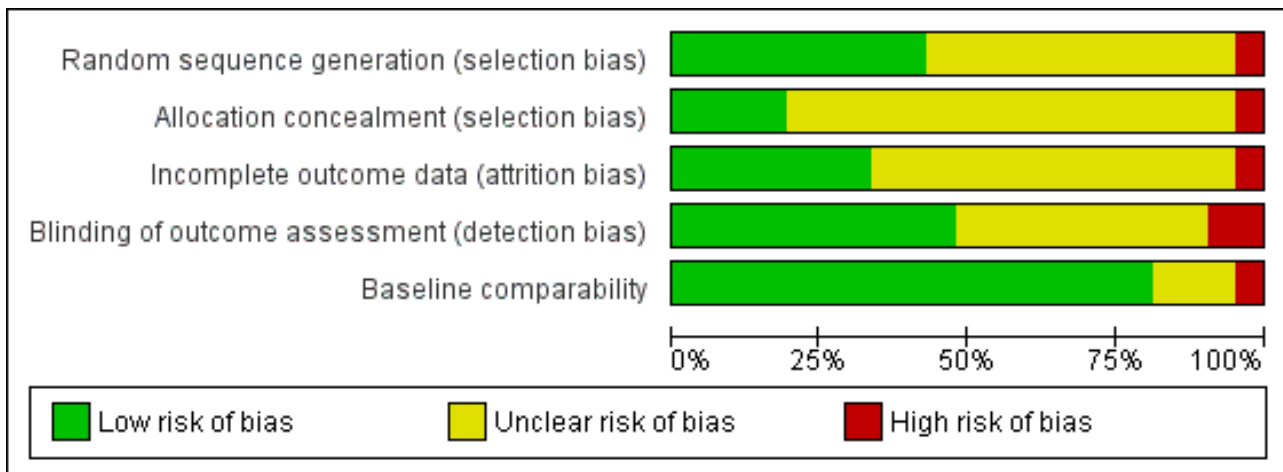
Figure 2.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Incomplete outcome data (attrition bias)	Blinding of outcome assessment (detection bias)	Baseline comparability
Aksac 2003	?	?	?	?	+
Beuttenmuller 2010	?	?	?	?	+
Bidmead 2002	?	?	+	+	+
Burgio 1998	+	?	+	+	+
Burns 1993	+	?	?	+	+
Bø 1999	+	+	+	+	+
Carneiro 2010	?	?	?	?	+
Castro 2008	+	+	+	+	+
Diokno 2010	+	?	+	+	-
Henalla 1989	?	?	?	?	+
Henalla 1990	?	?	?	?	?

Figure 2. (Continued)

Henalla 1990	?	?	?	?	?
Hofbauer 1990	?	?	?	?	?
Kim 2007	+	?	?	?	+
Kim 2011	+	+	?	?	+
Kim 2011a	+	+	?	+	+
Lagro-Janssen 1991	-	-	?	+	+
Miller 1998	+	?	+	+	+
Pereira 2011	?	?	?	-	+
Sar 2009	?	?	-	-	+
Wells 1999	?	?	?	?	?
Yoon 2003	?	?	+	+	+

Figure 3.



Due to brevity of reporting it was difficult to assess the two trials that were published as conference abstracts (Bidmead 2002; Henalla 1990). Seven of the trials were small, with fewer than 25 women per comparison group (Aksac 2003; Diokno 2010; Henalla 1990; Hofbauer 1990; Miller 1998; Sar 2009; Yoon 2003); 10 were of moderate size with around 25 to 50 per group (Beuttenmuller 2010; Bø 1999; Burns 1993; Carneiro 2010; Castro 2008; Henalla 1989; Kim 2007; Kim 2011; Lagro-Janssen 1991); and the other three allocated

more than 50 women per group (Burgio 1998; Kim 2011a; Wells 1999). Bidmead et al randomised participants in a 2:1 ratio, with 40 in the PFMT group and 20 as controls (Bidmead 2002). There were no large or very large trials. Five trials, including four recent ones, reported an a priori power calculation (Bø 1999; Castro 2008; Kim 2007; Kim 2011a; Sar 2009).

Allocation

Random sequence generation

A genuine random sequence was generated in nine trials (for example computer generation of random numbers, block size) (Bø 1999; Burgio 1998; Burns 1993; Castro 2008; Diokno 2010; Kim 2007; Kim 2011; Kim 2011a; Miller 1998). Eleven trials stated only that women were allocated at random, with no further description (Aksac 2003; Beuttenmuller 2010; Bidmead 2002; Carneiro 2010; Henalla 1989; Henalla 1990; Hofbauer 1990; Pereira 2011; Sar 2009; Wells 1999; Yoon 2003). The abstract of one study stated that women were randomly allocated to comparison groups, but the methods section of the same paper reported that women were "consecutively assigned" (Lagro-Janssen 1991); it therefore appears this was a quasi-randomised trial rather than a randomised trial.

Allocation concealment

Four trials reported allocation concealment adequately (Bø 1999; Castro 2008; Kim 2011, Kim 2011a). For the remaining 16 trials (Aksac 2003; Beuttenmuller 2010; Bidmead 2002; Burgio 1998; Burns 1993; Carneiro 2010; Diokno 2010; Henalla 1989; Henalla 1990; Hofbauer 1990; Kim 2007; Miller 1998; Pereira 2011; Sar 2009; Wells 1999; Yoon 2003) there was not sufficient information, therefore it was not clear if allocation was adequately concealed. One trial (Lagro-Janssen 1991) had inadequate allocation concealment (alternate allocation) which was considered to be quasi-randomised.

Blinding

Blinding of intervention from participants and care providers (performance bias)

Given the nature of PFMT it is difficult, and often impossible, to blind the treatment provider and participants during treatment. We therefore did not report this criterion separately as all the trials were unable to blind the participants or care providers.

Blinding of outcome assessment (detection bias)

Ten trials reported using blinded outcome assessors (Bidmead 2002; Bø 1999; Burgio 1998; Burns 1993; Castro 2008; Diokno 2010; Kim 2011a; Lagro-Janssen 1991; Miller 1998; Yoon 2003).

In nine trials, the authors did not report sufficient information to conclude that the outcome assessment was blinded (Aksac 2003; Beuttenmuller 2010; Carneiro 2010; Henalla 1989; Henalla 1990; Hofbauer 1990; Kim 2007; Kim 2011; Wells 1999).

The two last trials reported that the outcome assessors were not blinded to treatment assignment (Pereira 2011; Sar 2009).

Incomplete outcome data

There were no dropouts or losses to follow-up in one trial (Miller 1998). In six trials it appeared there were no dropouts, but this was not clearly stated in the trial reports (Aksac 2003; Beuttenmuller 2010; Carneiro 2010; Henalla 1989; Henalla 1990; Hofbauer 1990). Fourteen trials reported attrition, dropouts or losses to follow-up. In these 14 trials the proportion was:

- less than 10% in five (Burns 1993, Kim 2007; Kim 2011; Kim 2011a; Lagro-Janssen 1991);

- between 11% and 15% in six (Bø 1999; Burgio 1998; Castro 2008; Diokno 2010; Pereira 2011; Yoon 2003); and
- more than 20% in two (Bidmead 2002; Sar 2009) to nearly 50% in another (Wells 1999).

The proportion of withdrawals or losses to follow-up was higher in the control group in two trials (Burgio 1998; Sar 2009), with no clear differences in the other trials. In one trial (Burgio 1998) the cause of the differential dropout was not thought to be significantly related to the intervention, but in the other (Sar 2009) there was differential dropout from the groups: 5/22 women were excluded from the control group analysis as they received other treatment for their incontinence and this was not reflected in the analysis of the remaining 17.

Selective reporting

It was unclear if there was selective reporting of the outcomes in all 21 trials because the protocols were not available for most studies. We therefore did not report this criterion separately.

Other potential sources of bias

Baseline comparability

Seventeen trials were comparable at baseline for all important outcomes and demographic characteristics that might predict outcomes such as symptom severity or duration (Aksac 2003; Beuttenmuller 2010; Bidmead 2002; Burgio 1998; Burns 1993; Bø 1999; Carneiro 2010; Castro 2008; Henalla 1989; Kim 2007; Kim 2011; Kim 2011a; Lagro-Janssen 1991; Miller 1998; Pereira 2011; Sar 2009; Yoon 2003). Three trials did not give enough information to assess baseline comparability between groups (Henalla 1990; Hofbauer 1990; Wells 1999). Finally, one trial (Diokno 2010) reported a statistically significant difference between the PFMT and control groups for age, with the PFMT group being older than the control group (Diokno 2010).

Analysis by intention to treat, attrition and dropout

Full intention-to-treat analysis requires that all participants are analysed in the group to which they were randomly assigned whether they adhered to treatment or not, crossed over to other treatments, or withdrew (Ferguson 2002). However, for the purpose of this review we have accepted the results as presented in the reports for those participants who provided outcome data at any time point, unless there was evidence of differential dropout from the groups. This was only the case in one trial (Sar 2009) but we were unable to adjust the data.

It was not clear if any other included study met the above criteria for intention to treat, but two stated that the primary analysis was by intention to treat (Bidmead 2002; Burgio 1998) and another stated that intention-to-treat analysis (Bø 1999) did not alter the findings of the primary analysis. We have assumed that in the absence of information to the contrary, all the trials analysed the participants in their assigned groups, with the exception of Sar 2009 as noted above.

In six trials, outcome data were reported for all the randomised participants (that is there appeared to be no dropouts) (Aksac 2003; Carneiro 2010; Henalla 1989; Henalla 1990; Hofbauer 1990; Miller 1998).

In four trials, data were reported only for those participants who reached outcome time points, but there was no evidence of differential dropout from the groups (Diokno 2010; Kim 2011; Kim 2011a; Pereira 2011).

In one trial, there was not enough information to inform an opinion on intention-to-treat analysis because the numbers at the outcome time points were not provided (Beuttenmuller 2010).

Effects of interventions

See: [Summary of findings for the main comparison PFMT versus no treatment, placebo or control for urinary incontinence in women \(SUI\)](#); [Summary of findings 2 PFMT versus no treatment, placebo or control for urinary incontinence in women \(all types\)](#)

Twenty-one randomised or quasi-randomised trials compared PFMT (665 women) with no treatment, placebo, sham or other non-active control treatments (616 women). Three trials did not contribute any data suitable for meta-analysis (Bidmead 2002; Miller 1998; Wells 1999). In the 18 trials contributing data, the two comparison groups comprised 541 and 510 women respectively.

Readers should note that when referring to the graphs (forest plots) for six of the outcomes (participant perceived cure, participant perceived cure or improvement, number of women with interference with life due to urinary incontinence, number cured, number cured or improved on short pad test (objective) and patient perceived satisfaction) the right hand side of the plot favours PFMT. For the remaining outcomes the left hand side of the plot favours PFMT. This decision was made in order to keep interpretation of the forest plots clinically intuitive.

When a study did measure one of the outcomes but the data could not be included in the analysis for some reason, this was noted and the consistency with the usable data is briefly discussed. Data in 'Other data' tables are only briefly discussed to give an indication of whether the findings were broadly consistent or not.

Primary outcome measures

Participant reported measures

Symptomatic cure or improvement

Six trials reported data from women on cure only. The confidence intervals in all six trials were wide. All trials found that PFMT women were statistically significantly more likely to report they were cured (Analysis 1.1). In the four trials which included women with SUI alone, PFMT women were eight times more likely to report cure than controls (Bø 1999; Hofbauer 1990; Kim 2007; Kim 2011) (46/82 (56.1%) versus 5/83 (6.0%), RR 8.38, 95% CI 3.68 to 19.07, Analysis 1.1.1).

The three trials which included women with any incontinence showed a statistically significant result favouring PFMT (RR 5.34, 95% CI 2.78 to 10.26, Analysis 1.1.4) (Burgio 1998; Kim 2011; Kim 2011a). There was statistical heterogeneity although there was agreement in the direction of effect in all three individually, favouring PFMT. However, the finding still favoured PFMT even if a random-effects model was used (RR 7.50, 95% CI 1.03 to 54.63). Visual inspection of the forest plot suggested a smaller effect size in Burgio 1998 while the effect size appeared similar in the two remaining trials. 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.

Four trials contributed outcome data for cure or improvement (Bø 1999; Burgio 1998; Diokno 2010; Lagro-Janssen 1991). Similarly, all four reported that PFMT was better than the control interventions. In trials which included women with SUI alone (Bø 1999; Lagro-Janssen 1991), PFMT women were 17 times more likely to report cure or improvement than controls (32/58 (55%) versus 2/63 (3.2%), RR 17.33, 95% CI 4.31 to 69.64, Analysis 1.2.1); and in trials which included women with all types of urinary incontinence (Burgio 1998; Diokno 2010), PFMT women were twice as likely to report cure or improvement than controls (58/86 versus 23/80, RR 2.39, 95% CI 1.64 to 3.47, Analysis 1.2.4).

One further trial reported information on cure or improvement (Wells 1999) but the data were not suitable for meta-analysis (mean without measure of dispersion).

Symptom and condition specific health measures

Three out of four different measures of quality of life specific to the effect of urinary incontinence were in favour of PFMT (Analysis 1.3; Analysis 1.5; Analysis 1.6) in women with urinary incontinence (SUI and all types) (Analysis 1.7). In the fourth measure (King's Health Questionnaire, incontinence impact after treatment) (Analysis 1.4), there was statistical heterogeneity and although all trials were on the same side of the forest plot when a random-effects model was used, the findings did not statistically support PFMT. Visual inspection of the forest plot suggested a smaller effect size in Pereira 2011 while the effect size appeared similar in the two remaining trials. A possible explanation of this difference in treatment effect may come from the intensity of the PFMT program, which was higher in the Pereira trial than in the two others.

Further, favouring PFMT was not evident in the three trials that reported the King's Health Questionnaire general health score in SUI women (Beuttenmuller 2010; Carneiro 2010; Pereira 2011) (Analysis 1.8) but this may be because measures of general health are less sensitive to changes in continence.

Three trials (Bø 1999; Diokno 2010; Kim 2011a) reported other measures of symptoms and their effect on incontinence-specific quality of life outcomes. These are given in detail in Appendix 2.

Secondary outcome measures

Patient reported measures

Longer-term cure and improvement after stopping treatment

There was limited information from two small to moderate quality trials (Henalla 1989; Kim 2011a) which indicated that the benefit of PFMT seemed to persist (after treatment stopped) for up to a year in both women with urinary incontinence (all types) (23/59 (38.9%) versus 1/61 (1.6%), RR 23.78, 95% CI 3.32 to 170.49) (Kim 2011a) and SUI women only (14/26 (53.8%) versus 0/25 (0%), RR 27.93, 95% CI 1.75 to 444.45) (Analysis 1.9; Analysis 1.10). The CIs in both trials were wide and hence these results need further confirmation.

Satisfaction

Three trials measured participant satisfaction with treatment for SUI (Bø 1999; Castro 2008) or for women with urinary incontinence (all types) (Burgio 1998) (Analysis 1.11). In trials which included women with SUI alone (Bø 1999; Castro 2008), 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 to 10.74, [Analysis 1.11.1](#)). There was statistical heterogeneity but the findings still favoured PFMT if a random-effects model was used (RR 5.54, 95% CI 1.15 to 25.63).

In the one trial with women with all types of urinary incontinence, PFMT women were three times more likely to be satisfied with the intervention than the controls (45/58 (77.6%) versus 14/50 (28%), RR 2.77, 95% CI 1.74 to 4.41, [Analysis 1.11.4](#)).

Need for further treatment

Two trials reported that more women needed further treatment in the control groups; one trial in women with SUI ([Bø 1999](#)) (RR 0.17, 95% CI 0.07 to 0.42) and one in women with urinary incontinence of all types ([Burgio 1998](#)) (RR 0.19, 95% CI 0.10 to 0.36, [Analysis 1.12](#)).

Patient reported quantification of symptoms

Number of leakage episodes in 24 hours

While all five trials with data showed statistically significant results favouring PFMT, visual inspection of the forest plot suggested the effect size might be greater in the trial by Lagro-Jansen and colleagues, while the effect sizes appeared similar in the four remaining trials. It was not clear why the data from Lagro-Janssen ([Lagro-Janssen 1991](#)) and co-workers might be different from the two other trials in women with SUI, or the trials overall. A possible explanation of the overestimate of treatment effect might be an inadequate concealment of the randomisation process (alternation). The point estimates in the other four trials were similar, and all were statistically significant. SUI women doing PFMT experienced about one leakage episode less per 24 hours compared to controls (RR -1.21, 95% CI -1.52 to -0.89). As there was statistical heterogeneity, a random-effects model was used but the finding still favoured PFMT (RR -1.45, 95% CI -2.38 to -0.52).

Similarly, those with urinary incontinence of any type (detrusor overactivity with or without USI, [Burgio 1998](#)) experienced about one less leakage episode per 24 hours compared to controls (RR -0.80, 95% CI -1.26 to -0.34, [Analysis 1.13](#)).

Number of voids per day (frequency) and per night (nocturia)

Two trials in women with urinary incontinence (all types) reported data on frequency ([Diokno 2010](#); [Yoon 2003](#)). PFMT women reported about two and a half fewer voids per day than controls (MD -2.56, 95% CI -3.65 to -1.48, [Analysis 1.14](#)). However, there was no statistically significant difference in the number of night-time voids between the PFMT and control groups although the CI was wide ([Diokno 2010](#); [Yoon 2003](#)) ([Analysis 1.15](#)).

Two trials ([Bø 1999](#); [Yoon 2003](#)) reported leakage episodes through a leakage index rather than the number of leakages. These are reported in detail in [Appendix 3](#).

Clinicians' measures

Pad and paper towel tests (up to one hour or 24 hour)

Up to one hour: four trials reported urine loss on pad tests in SUI women ([Bø 1999](#); [Castro 2008](#); [Pereira 2011](#)) and one in women with urinary incontinence (all types) ([Yoon 2003](#)). Women with SUI in the PFMT groups lost significantly less urine on the one hour pad tests. There was statistical heterogeneity but the finding still favoured

PFMT if a random-effects model was used (RR -13.22, 95% CI -26.36 to -0.09). Yoon ([Yoon 2003](#)) in women with unspecified urinary incontinence reported that PFMT women had about 5 g less urine loss than controls but with wide CIs that included no difference (MD -5.1, 95% CI -11.3 to 1.1, [Analysis 1.16](#)).

Test over 24 hours: one trial reported urine loss on a 24 h pad test with SUI women ([Bø 1999](#)) and one trial with women with urinary incontinence (all types) ([Diokno 2010](#)). There was no difference between PFMT and control on the 24 hour test for SUI women ([Bø 1999](#)) or in all types of urinary incontinence ([Diokno 2010](#)) ([Analysis 1.17](#)).

Number cured or improved based on pad weights in short office-based pad test (objectively diagnosed urinary incontinence)

When urine leakage was objectively assessed based on the number of women who had dry pads (short pad test) SUI women were more likely to be cured in the PFMT arms (number cured 38/71 (53.5%) versus 4/64 (6.3%) in the control group, RR 7.5, 95% CI 2.89 to 19.47, [Analysis 1.18.1](#)) and similarly for cure or improvement (41/54 (75.9%) versus 2/42 (4.8%), RR 8.22, 95% CI 3.17 to 21.28, [Analysis 1.19.1](#)).

Four trials ([Aksac 2003](#); [Bidmead 2002](#); [Diokno 2010](#); [Miller 1998](#)) reported pad or paper towel tests in other ways or reported data where the mean difference was not estimable. These data are given in detail in [Appendix 4](#). The data were generally in agreement with the findings above.

Quality of life (not condition specific)

General health status measures

Validated measures were used to assess generic quality of life ([Bø 1999](#)) and psychological distress ([Burgio 1998](#)). Neither study found any statistically significant difference between PFMT and control groups in either SUI women or women with urinary incontinence (all types) ([Appendix 5](#)).

Effect of urinary incontinence (UI) on sexual function

One trial ([Bø 1999](#)) in SUI women suggested that sexual function was improved by PFMT, in general effect on sex life ([Analysis 1.20](#)) and in terms of reduction of urine leakage during intercourse ([Analysis 1.21](#)).

Adverse effects

Four trials specifically mentioned adverse events, and three did not report any in the PFMT group ([Bø 1999](#); [Burgio 1998](#); [Castro 2008](#)). Lagro-Janssen ([Lagro-Janssen 1991](#)) was the only trial to report adverse events with PFMT. These were: pain (one participant), uncomfortable feeling during exercise (three participants) and 'not wanting to be continuously bothered with the problem' (two participants).

Socioeconomic measures

None of the included trials reported a formal economic analysis, nor any economic data.

Measures of likely moderator variables

Measures of pelvic floor muscle (PFM) function

Eleven trials ([Aksac 2003](#); [Beuttenmuller 2010](#); [Bø 1999](#); [Burns 1993](#); [Carneiro 2010](#); [Castro 2008](#); [Diokno 2010](#); [Miller 1998](#); [Pereira 2011](#);

Wells 1999; Yoon 2003) reported measures of pelvic floor muscle function.

- One trial (Carneiro 2010) used perineal ultrasound to measure morphological changes in pelvic floor muscles after treatment.
- Five trials (Aksac 2003; Beuttenmuller 2010; Bø 1999; Pereira 2011; Yoon 2003) used vaginal squeeze pressure to measure functional changes in pelvic floor muscles.
- Eight trials (Aksac 2003; Beuttenmuller 2010; Carneiro 2010; Castro 2008; Diokno 2010; Miller 1998; Pereira 2011; Wells 1999) used vaginal digital assessment to measure functional changes in pelvic floor muscles.
- Finally three trials (Burns 1993; Carneiro 2010; Wells 1999) used electromyography (EMG) measures of pelvic floor muscle function.

Of the 11 trials, two did not report the data in such a way that it was possible to calculate the mean difference in vaginal squeeze pressure, EMG activity, or digital palpation score (Aksac 2003; Wells 1999). Overall, there were no consistent patterns in measures of pelvic floor muscle function. Details are given in Appendix 6.

Measures of adherence

From diaries

Bø (Bø 1999) and co-workers reported the highest rate of adherence to PFMT (95%) using exercise and training diaries. Bidmead 2002 found that 75% of women allocated to PFMT had excellent (daily) or good (training more than three times a week) adherence to exercise on using exercise and training diaries. Women in the study by Lagro-Janssen 1991 rated their adherence as excellent or good (62%), reasonable (20%), or poor or none (18%). Kim (Kim 2007) reported adherence to home PFMT only in the follow-up period (after the intervention to the follow-up assessment) using exercise and training diaries with 30% of women doing their pelvic floor muscle exercises every day; two to three times per week in 45.5%, and once or less per week in 24.2% (Kim 2007). In their 2011 trial, the same research group (Kim 2011a) reported adherence using exercise and training diaries for home PFMT in the follow-up period, again with 35.7% of women doing their pelvic floor muscle exercises every day, two to three times per week in 42.9%, and once or less per week in 21.4% (Kim 2011a). Wells reported a greater exercise frequency in the treatment group at the beginning of the trial although no raw data were available to support this finding (Wells 1999).

From attendance at appointments

Three trials attempted to measure attendance at exercise sessions (Burns 1993; Castro 2008; Kim 2007). Two trials reported very good to excellent attendance rates at clinic appointments (70%, Kim 2007; 92%, Castro 2008) and the third (Burns 1993) did not present any data.

Methods to increase adherence

Five trials used adherence strategies to encourage participants to do their PFMT exercises. Sar and colleagues (Sar 2009) used a telephone call to encourage participants and answer questions. Diokno and colleagues (Diokno 2010) used as reinforcement a two to four week follow-up which consisted of vaginal examination, measurement of pelvic floor muscle strength, and a test measuring participants' ability to perform correctly the verbally instructed exercise program. Burns (Burns 1993) used weekly and three and

six month telephone reminders for treatment appointments and weekly exercise reminder cards were mailed between visits (Burns 1993). Bo and colleagues (Bø 1999) used audiotape with verbal guidance for home training (Bø 1999). Kim and colleagues (Kim 2007) used a pamphlet illustrating the pelvic floor muscles and strengthening exercises (Kim 2007).

GRADE quality of evidence

Summary of findings tables were prepared separately for women with SUI at baseline (Summary of findings for the main comparison) and for women with all types of urinary incontinence (SUI, UUI, MUI) (Summary of findings 2). The findings of the review were supported in the tables, but in all cases except one the quality of the evidence was downgraded. The exception was 'Participant perceived cure - stress urinary incontinence' in women with SUI, which was rated as high quality. This suggested that SUI was eight times more likely to be cured in this subgroup (RR 8.38, 95% CI 3.68 to 19.07, Analysis 1.1.1), which is a much higher estimate of success than suggested in the other subgroups or other outcomes. However, it has a very wide CI and was derived from two small and two moderate size trials.

DISCUSSION

This review is the first in a series of reviews of PFMT for urinary incontinence (UI) in women, and it should be viewed in that context. This review considers whether PFMT is better than no treatment, placebo, sham, or non-active control treatments. Other reviews consider whether:

- (a) one type of PFMT is better than another (Hay-Smith 2011), or whether feedback or biofeedback has a role to play (Herderschee 2011);
- (b) PFMT is better than other treatments (for example other physical therapies, medication, and surgery (Lins 2013); and
- (c) if the addition of PFMT to other therapies adds benefit (Ayeleke 2013).

A separate review considers the role of PFMT in the treatment and prevention of urinary and faecal incontinence related to childbirth (Boyle 2012).

Summary of main results

Is PFMT better than no treatment, placebo or control treatments?

Of the 21 trials that addressed this question, 18 reported data suitable for analysis for the outcomes of interest.

For cure or cure and improvement, in the four trials that included women with SUI alone there was clear information that women undergoing PFMT were eight times more likely to have their incontinence cured (46/82 (56.1%) were cured in the PFMT group versus 5/83 (6.0%) in the untreated groups, RR 8.38, 95% CI 3.68 to 19.07, Analysis 1.1.1); and similarly in two trials, women having PFMT were 17 times more likely to have their incontinence cured or improved (32/58 (55%) versus 2/63 (3.2%), RR 17.33, 95% CI 4.31 to 69.64, Analysis 1.2.1).

In the three trials including women with all types of urinary incontinence, all reported that the PFMT was better than the control intervention for cure, although because of statistical heterogeneity

a random-effects model was used for this subgroup (RR 8.33, 95% CI 1.06 to 65.48, [Analysis 1.1.4](#)). Visual inspection of the forest plot suggested a smaller effect size in one trial, [Burgio 1998](#) (RR 2.34, 95% CI 1.11 to 4.94), where the urgency component of urinary incontinence was more prevalent than in the two other trials (RR 16.74, 95% CI 0.97 to 288.47 ([Kim 2011](#)) and RR 26.88, 95% CI 3.77 to 191.79 ([Kim 2011a](#))). Additionally, two trials contributed outcome data for cure and improvement in women with all types of urinary incontinence and PFMT women were twice as likely to report cure or improvement as the control group women (58/86 versus 23/80, RR 2.39, 95% CI 1.64 to 3.47, [Analysis 1.2.4](#)).

Where reported, quality of life due to incontinence was also improved by the active PFMT intervention both in women with SUI and women with all types of urinary incontinence. Women were also more satisfied with the active treatment, while women in the control groups were more likely to seek further treatment. PFMT women leaked urine less often, lost smaller amounts on short office-based pad tests, emptied their bladders less often during the day, and their sexual outcomes were better. Adverse events were rare and in the one trial that did report any they were minor. However, there was no shift in generic quality of life measures, perhaps because measures of general health are less sensitive to changes in continence status.

The improvement in pelvic floor muscle function as the mechanism by which urinary incontinence improved was supported by many trials. Attendance at treatment sessions was generally good, and women were also motivated to practice their pelvic floor exercises during the intervention period. However, the information about persistence of benefit in the long term was only presented in two trials, and the need for further treatment such as incontinence surgery or drugs was scanty. Finally, no trial reported formal economic analysis.

The findings of the review were largely supported in the summary of findings tables, but most of the evidence was downgraded to moderate on methodological grounds ([Summary of findings for the main comparison](#); [Summary of findings 2](#)).

Overall completeness and applicability of evidence

Types of incontinence in participants

Although we pre-specified four clinical subgroups for baseline type of urinary incontinence (SUI, UUI, MUI, urinary incontinence of all types) in the analysis, we only obtained data contributing to the forest plot from two of them (SUI, urinary incontinence of all types). No trials investigated the effect of PFMT versus control in two subgroups, women with urgency urinary incontinence (UUI) only or with mixed (SUI and UUI) incontinence only.

Further, participants were selected for the trials solely on the basis of the type of incontinence, diagnosed according to signs, symptoms or urodynamics. Theoretically, women with rupture of ligaments or fascia, partial or complete avulsion of the PFM, or even severe peripheral nerve damage may have responded differently to PFMT than women without such major anatomical defects, which may affect the estimate of treatment effect. Use of new imaging techniques may improve the researcher's ability to give a more specific diagnosis and use a more homogenous sample of participants, or present their data according to women who did and did not have such defects ([Dumoulin 2011](#)).

Variation in interventions

There was large variation in the PFMT programmes, as reported in Table 1. Further, the exercise regimen in both the clinic-based and home PFMT programmes was often incompletely reported ([Appendix 1](#)). It was difficult to make judgements about the similarities and differences between the training programmes, and hence their potential relative effectiveness. Including trials with a suboptimal exercise 'dose' could adversely affect the estimate of differences in treatment effect. Although assessment of the interactions between the quality of the exercise programmes and their effects has been recommended ([Herbert 2005](#)), it was not possible to explore this aspect in this review. Nevertheless, the more recent trials reported PFMT exercise regimens that were more in line with the literature on skeletal muscle training theory and pelvic floor muscle dysfunction.

Outcomes

Some important secondary outcomes were either missing or were rarely reported. Medium-term follow-up (less than one year) was reported only in two trials, both of which favoured the active PFMT but with very wide confidence intervals ([Analysis 1.9](#); [Analysis 1.10](#)). There was no report of long-term follow-up after one year. Arguably, the need for further treatment (for example the use of another conservative intervention, pessary, surgery or a drug) would provide a robust and objective measure of the ultimate success of treatment: unfortunately this was not reported in any of the trials.

Treatment adherence (for example performance of pelvic floor muscles exercise) was reported only in the short term (during the intervention) and in some trials not in the control groups, so it could not be compared between the groups. It was, therefore, not possible to assess the interactions between the effect size and the adherence to treatment.

Quality of the evidence

Trial quality and reporting

Twenty-one small to moderate trials (n = 1281) contributed data to the review for the SUI and all urinary incontinence subgroups; none contributed to the UUI only and MUI only population subgroups.

The major limitations in reporting of the included trials were the absence of details on participant selection and the lack of a clear description of the PFMT programs. Another problem was the absence of long-term follow-up.

The results were consistent for most of the outcomes, favouring PFMT over control. The only outcome that was consistently not different between the experimental and control conditions was generic quality of life; but these measures may not be sensitive enough to pick up changes due to improvement in urinary incontinence.

GRADE summary of findings

The main reasons for downgrading the quality of the evidence in the GRADE summary of findings tables 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 favour of PFMT).

Potential biases in the review process

Of the 21 included trials, four were at high risk of bias:

- [Lagro-Janssen 1991](#) for its lack of genuine randomisation and inadequate allocation concealment;
- [Pereira 2011](#) for its lack of blinding of outcome assessment;
- [Sar 2009](#) for its management of attrition; and
- [Diokno 2010](#) for its differences in baseline comparability (especially with regard to age, those in the treatment group were older).

Because of the nature of the intervention, which is a complex interaction between the therapist and the patient, it was not possible to blind either party and therefore we did not score the trials on this element of risk of bias as they would all be at high risk. It was also not possible to assess incomplete outcome data because none of the trials had published protocols. It was clear that most trials could not, and did not intend to, report long-term follow-up because, most often, the untreated groups received treatment after the end of the trial.

Agreements and disagreements with other studies or reviews

The findings of this update of our Cochrane review are consistent with the previous version of this Cochrane review ([Dumoulin 2010](#)) and an HTA Monograph which investigated all conservative methods of managing SUI ([Imamura 2010](#)).

The scope of this review did not include comparisons of different PFMT regimens. Other Cochrane reviews to consider are:

- different approaches to PFMT ([Hay-Smith 2011](#));
- biofeedback ([Herderschee 2011](#));
- cones ([Herbison 2002](#));
- PFMT in antenatal and postnatal women ([Boyle 2012](#)).

Two relevant related Cochrane reviews are:

- Pelvic floor muscle training added to another active treatment versus the same active treatment alone for urinary incontinence in women ([Ayeleke 2013](#));
- Pelvic floor muscle training versus other treatments for urinary incontinence in women ([Lins 2013](#)).

Considerations for future research

The outcomes of incontinence research would be much more useful if trialists selected a primary outcome measure that mattered to women, chose secondary measures to cover a range of important domains, and opted for standardised tools with established validity, reliability and responsiveness to measure outcomes. One domain that requires particular attention in future is socioeconomic, as it has been poorly addressed to date. Two trials included in the review asked women if they wanted further treatment or were satisfied with the treatment outcome, or both. Questions such as these have potential merit, but asking women if they are cured or better with treatment may not differentiate those who are better and do not want any further intervention from

those who are better but not sufficiently so to be satisfied with the treatment outcome. There is also scope for the use of validated questionnaires that evaluate the bother or distress associated with symptoms (for example the Urogenital Distress Inventory).

Duration of follow-up beyond the end of supervised treatment needs attention. As the aim of treatment is long-term continence, it would be appropriate if the outcome was measured at least one year after the end of treatment. As PFMT generally precedes other more invasive treatment options, such as surgery, the proportion of women satisfied with the outcome of PFMT (and for how long they remain so) would provide essential information for women, clinicians and service planners.

The reporting of methods and data could be much improved. Some included trials collected data for outcomes of interest but did not report it in a useful manner (for example point estimates without a measure of dispersion). It was also difficult to assess one of the primary ways to minimise risk of bias, allocation concealment, because the methods of randomisation were usually poorly described. Trialists are referred to the CONSORT and revised CONSORT statements for appropriate standards of trial reporting ([Begg 1996](#); [Boutron 2008](#); [Moher 2001](#)).

In essence, there is a need for at least one large, pragmatic, well-conducted and explicitly reported trial comparing PFMT with control to investigate the longer-term (more than one year), clinical effectiveness and cost-effectiveness of PFMT. An important primary outcome measure should be added to cure and improvement of incontinence: the need to use extra interventions (such as pessaries, drugs or surgery) after the end of the PFMT intervention.

Such a trial could recruit separate groups of women with symptoms of stress, urgency, or mixed urinary incontinence based on clinical history and physical examination; and with a sample size based on a clinically important difference in self reported urinary incontinence and condition specific quality of life outcomes, and sufficient for subgroup analysis on the basis of type of urinary incontinence. Stratification or minimisation procedures could be used to ensure an even distribution of women with different types of urinary incontinence across both arms of the trial.

One arm of the study would comprise a supervised PFMT programme based on sound exercise science with confirmation of a correct voluntary pelvic floor muscle contraction, and incorporate appropriate supervision and adherence measures to promote maintenance of knowledge acquisition, behaviour skills and motivation ([Dumoulin 2011](#)). The choice of programme would have to be set against the resource implications of intensively supervised individual programmes and the opportunity cost this represents. Careful clinical judgement is needed about what sort of programme could actually be applied in everyday practice and in different countries with their different healthcare delivery systems. The other arm of the trial would be a control treatment, for example an explanation of the anatomy and physiology of the bladder and pelvic floor, or advice on good bladder and lifestyle habits, with the same explanation and advice given in both arms. Such a trial would require substantial funding and multiple recruitment centres. A formal economic analysis, and process evaluation (for example to check intervention fidelity), would also be an important part of such a trial.

AUTHORS' CONCLUSIONS

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 urgency urinary incontinence alone or mixed urinary incontinence. 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 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. At this time, it is not known whether PFMT is cost-effective in the long term, hence the need for a pragmatic, well-conducted and explicitly reported trial comparing PFMT with control to investigate the longer-term clinical effectiveness and cost-effectiveness of PFMT.

Implications for research

Although the quality of recent trials has improved (choice of outcome, duration of follow-up, reporting method and data), 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 (urinary outcomes and quality of life), the size of a clinically important effect, and subsequent estimation of sample size.
- Choice and reporting of PFMT exercise programmes, including details of number of VPFMC per set, duration of hold, duration

of rest, number of sets per day, body position, types of contractions, and other recommended exercises (see [Appendix 1](#)).

- The reporting on adherence to outcome and adherence strategies including practice of pelvic floor muscle exercises in both the intervention and control groups.
- The need for further treatment such as with pessaries, surgery or drugs.
- The choice and reporting of secondary outcome measures, e.g. sexual function,
- The duration of follow-up especially long-term.
- The reporting of formal economic analysis (for example cost-effectiveness, cost utility).
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- The duration of follow-up especially long-term.
- The reporting of formal economic analysis (for example cost-effectiveness, cost utility).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Aksac 2003

Methods	3 arm RCT, parallel design Not clear if adequate allocation concealment Not clear if blinded outcome assessment
Participants	50 women with urodynamic SUI No further inclusion or exclusion criteria stated Median age, years: PFMT 52.5 (SD7.9), control 54.7 (SD7.8) Single centre, Turkey
Interventions	1. PFMT (n=20). Use of digital palpation to teach VPFMC with abdominal and buttock muscle relaxation. Weekly clinic visits for 8 weeks. Details of PFMT programme in Data Table 01.03 2. Control (n=10). No PFMT 3. PFMT with biofeedback (n=20)
Outcomes	Primary outcome: not stated Other outcomes: pad test cure (weight gain of 1g or less), pad test improvement (50% or greater reduction in pad weight), vaginal squeeze pressure, digital palpation score, incontinence frequency (four point ordinal scale), Social Activity Index On a four-point ordinal scale (1=urine loss once a day to 4=urine loss once a month), the median (standard deviation) score in the PFMT group was 3.5 (0.5) and in controls it was 2.4 (0.9)
Notes	Post-treatment evaluation at 8 weeks, no longer-term follow-up Dropouts: not stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"patient was requested to choose a closed letter upon her first admission, and she was enrolled to a group in accordance with the number written in the letter" 'no mention of sealed, opaque, consecutively numbered'
Allocation concealment (selection bias)	Unclear risk	"patient was requested to choose a closed letter upon her first admission, and she was enrolled to a group in accordance with the number written in the letter"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information about study completion or (n) in the results or tables
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if blinded outcome assessment
Baseline comparability	Low risk	Baseline comparable for age, weight, parity, abortions, maximum birth weight, UI type

Beuttenmuller 2010

Methods	3 arm RCT
Participants	<p>75 female patient with SUI</p> <p>Method of diagnosis: not reported 'women with a diagnosis of SUI'</p> <p>Inclusion: not reported</p> <p>Exclusion: not reported</p> <p>Mean age (SD): Group PFMT: 49.96 (5.26); Group Control : 44.82 (4.88)</p> <p>Single Center: the rehabilitation unit of PF disorders in Fortaleza-Ceara</p>
Interventions	<p>Group A (n = 25): PFMT intervention</p> <p>Taught by: physiotherapist</p> <p>Correct VPFMC confirmed? not reported but assessed by the evaluator prior to treatment</p> <p>Number VPFMC per set: 8</p> <p>Number sets per day: not reported</p> <p>Duration of hold: 5 sec</p> <p>Duration of rest: not reported</p> <p>Type(s) of contraction, e.g. submaximal, maximal ?: long and short contraction with the participant in supine lying position with knee bent, sitting in the chair or on the gym ball, on all fours, standing</p> <p>Duration of programme: 20 minutes (in groups of 4) twice weekly for 6 weeks except during menstrual periods or due to other complications</p> <p>Number and type of contact with health professional(s): twice/ weekly</p> <p>Measure of adherence? Not reported</p> <p>Reported level of adherence: Not reported</p> <p>Other information:</p> <p>Kinesitherapy was accomplished through standing or sitting exercises using a Swiss ball of varying size, according to the height and weight of the patient. Proprioceptive exercises such as hopping on a ball, moves to raise the pelvis (anteversion, retroversion, lateralisation and circumduction) were used. Additionally exercises were used to contract the PFM to the original position, working the two fiber types I and II by performing contract-relax perineal exercises and hold-relax training, respectively, up to 6 sec</p> <p>Group B (n =25): Control intervention</p> <p>'no physical therapy at that time.'</p>
Outcomes	KHQ, PFM 1finger intravaginal evaluation using the Oxford scale, intra-vaginal pressure perineometry
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'randomly divided in 3 groups'

Beuttenmuller 2010 (Continued)

Allocation concealment (selection bias)	Unclear risk	Not clear if allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear if there was attrition
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if outcome assessment blinded
Baseline comparability	Low risk	Groups comparable at baseline for age and BMI

Bidmead 2002

Methods	4 arm RCT, parallel design (after treatment period control patients crossed over into group 3) Not clear if adequate random allocation concealment Blinded outcome assessment Primary analysis by intention to treat	
Participants	Women with urodynamic SUI (number recruited not clear, 170 or 173?) Inclusion: new diagnosis of SUI or no treatment for SUI in previous 6 months Exclusion: not further criteria reported Mean age, years: PFMT 46.2 (SD 8.5), control 47.5 (SD 11.5) Single centre, UK	
Interventions	<ol style="list-style-type: none"> 1. PFMT (n=40). Conventional PFMT supervised by physiotherapist. Individually tailored lifestyle advice. Five clinic visits in 14 weeks (weeks 1, 3, 6, 10 and 14) 2. Control (n=20). No treatment for 14 weeks. Thereafter crossed over into group 3 3. PFMT with electrical stimulation (n=?) 4. PFMT with sham electrical stimulation (n=42) 	
Outcomes	Primary outcome measure: not stated Other outcome measures: pad test, King's Health Questionnaire	
Notes	Post-treatment evaluation at 14 weeks, no longer-term follow-up Dropouts: 10/40 PFMT, 7/20 control, 15/? PFMT + electrical stimulation, 12/42 PFMT + sham stimulation	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomised"
Allocation concealment (selection bias)	Unclear risk	Not clear if adequate random allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar in each of the four groups at around 25%
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded outcome assessment

Bidmead 2002 (Continued)

Baseline comparability	Low risk	Groups comparable at baseline for age, severity, severity of GSI on urodynamics
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Burgio 1998

Methods	3 arm RCT, parallel design Stratified by type (UUI, MUI) and severity of incontinence (number of leakage episodes) Not clear if adequate allocation concealment Blinded outcome assessment Primary analysis by intention-to-treat
Participants	197 women, with DO with or without urodynamic SUI Inclusion: community dwelling women aged 55 years or more, 2 or more urge accidents per week, urge incontinence predominant pattern Exclusion: continual leakage, uterine prolapse past introitus, unstable angina, decompensated heart failure, history of malignant arrhythmias, impaired mental status (MMSE<20) Mean age, years: PFMT 67.3 (SD 7.6), control 67.6 (SD 7.6) Mean duration symptoms, years: 9.4 (10.8), control 12.7 (15.9) More than 10 leakage episodes per week: PFMT 52%, control 54% Diagnosis: 96 UUI only (49%), 101 MUI (51%) Single centre, USA
Interventions	1. PFMT (n=65). Use of anorectal biofeedback to teach VPFMC with abdominal muscle relaxation. Response to urge (pause, sit, relax, repeated VPFMC to suppress urge). Use of bladder-sphincter biofeedback at third visit for those with <50% reduction in leakage episodes to teach VPFMC against increasing fluid volume and urge. Fortnightly clinic visit with nurse practitioner, 8 weeks. Details of PFMT programme in Data Table 01.03 2. Controls (n=65). Placebo drug, three times a day, for 8 weeks. Capsule contained 500 mg riboflavin phosphate marker. Fortnightly clinic visit with nurse practitioner 3. Drug (n=67)
Outcomes	Primary outcome: change in leakage frequency (2 week urinary diary) Secondary outcomes: Hopkins Symptom checklist for psychological distress, self report (worse to much better), satisfaction with progress (not at all to completely), perceived improvement (none or 0% to dry or 100%), willingness to continue PFMT, desire for other treatment, leakage episodes (2 week urinary diary), cystometry (for 105/197)
Notes	Post-treatment evaluation at 10 weeks, no longer-term follow-up Dropouts: 4/65 PFMT, 12/65 control, 12/67 drug ITTA: for primary outcome, most recent urinary diary data carried forward

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"within each stratum, randomization was performed with computer-generated random numbers using a block size of 6 to avoid inequity in group size"
Allocation concealment (selection bias)	Unclear risk	"within each stratum, randomization was performed with computer-generated random numbers using a block size of 6 to avoid inequity in group size"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition rate per group and reasons given: not thought to be due to intervention except for one participant in the placebo drug groups

Burgio 1998 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded outcome assessment
Baseline comparability	Low risk	"Before treatment the groups were comparable on all key parameters except that subject in behavioral treatment had more children, were less likely to have a high school education and more likely to have a rectocele"

Burns 1993

Methods	3 arm RCT, parallel design Not clear if adequate allocation concealment Blinded outcome assessment
Participants	135 women, with urodynamic SUI with or without DO Inclusion: women with SUI or MUI, 55 years or older, minimum of 3 leakage episodes per week, demonstrates leakage with stress manoeuvres during physical examination, MMSE>23, absence of glycosuria or pyuria, post void residual <50 ml, maximum uroflow >15 ml/s. Exclusion: no additional criteria reported Mean age, years: PFMT 63 (SD 6), control 63 (5) Mean leakage episodes 24 hours: PFMT 2.6 (SD 2.1), control 2.6 (2.6) Diagnosis: 123 urodynamic SUI (91%), 12 (9%) Single centre, USA
Interventions	1. PFMT (n=43, after dropouts). Booklet explaining anatomy, PFMT, and completion of exercise and urinary diaries. Videotape describing exercise protocol. Weekly exercise reminder cards mailed between visits. Weekly clinic visits with nurse, 8 weeks. Details of PFMT programme in Data Table 01.03 2. Control (n=40, after dropouts). No treatment 3. PFMT with weekly clinic biofeedback (n=40, after dropouts)
Outcomes	Primary outcome: leakage episodes (2-week urinary diary) Secondary outcomes: incontinence severity (based on number of leakage episodes from diary), pelvic floor muscle EMG, cystometry
Notes	Post-treatment evaluation at 8 weeks, with longer term follow up at 12 weeks and 6 months Dropouts: 10/135 and 2/135 excluded from analysis (no urinary diary); group not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"randomized blocking was employed to balance the number of subjects in each group"
Allocation concealment (selection bias)	Unclear risk	Not clear if adequate allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	10/135 dropped out or withdrawn, 2 did not have bladder diary data so excluded from analysis
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded outcome assessment
Baseline comparability	Low risk	Table 1 socio-demographic comparable

Bø 1999

Methods	<p>4 arm RCT, parallel design</p> <p>Stratified by severity of leakage on pad test</p> <p>Adequate allocation concealment</p> <p>Blinded outcome assessment</p> <p>Secondary analysis by intention to treat</p> <p>A priori power calculation</p>
Participants	<p>122 women, with urodynamic SUI</p> <p>Inclusion: women with a history of SUI, waiting for surgery or recruited through advertising, >4g leakage on pad test with standardised bladder volume</p> <p>Exclusion: other types of incontinence, DO on urodynamics, residual urine >50 ml, maximum uroflow < 15 ml/s, previous surgery for urodynamic SUI, neurological or psychiatric disease, ongoing urinary tract infection, other disease that could interfere with participation, use of concomitant treatments during trial, inability to understand instructions given in Norwegian</p> <p>Mean age, years: PFMT 49.6 (SD 10.0), control 51.7 (SD 8.8)</p> <p>Mean duration symptoms, years: PFMT 10.2 (SD 7.7), control 9.9 (SD 7.8)</p> <p>Mean leakage episodes 24 hours: PFMT 0.9 (SD 0.6), control 1.0 (SD 1.0)</p> <p>Diagnosis: 122 urodynamic SUI (100%)</p> <p>5 centres, Norway</p>
Interventions	<p>1. PFMT (n=29). Explanation of anatomy, physiology, and continence mechanism by physiotherapist. Audiotape of home training programme. Weekly 45 minute exercise class with PFMT in a variety of body positions, and back, abdominal, buttock and thigh muscle exercises. Monthly clinic visit with physiotherapist, 6 months. Details of PFMT programme in Data Table 01.03</p> <p>2. Controls (n=32). Explanation of anatomy, physiology, and continence mechanism. Correct VPFMC confirmed by palpation. No clinic visits. Offered instruction in use of the Continence Guard (14 accepted)</p> <p>3. Electrical stimulation (n=32)</p> <p>4. Vaginal cones (n=29)</p>
Outcomes	<p>Primary outcomes: 60 second pad test with standardised bladder volume, self-report (very problematic to unproblematic)</p> <p>Secondary outcomes: Norwegian Quality of Life Scale, Bristol Female Lower Urinary Tract Symptoms Questionnaire, Leakage Index, Social Activity Index, leakage episodes (3 day urinary diary), 24 hour pad test, vaginal squeeze pressure</p>
Notes	<p>Post-treatment evaluation at 6 months, no longer-term follow-up</p> <p>Dropouts: 4/29 PFMT, 2/32 controls, 7/32 electrical stimulation, 2/29 vaginal cones</p> <p>ITTA: baseline values used for losses to follow up</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer generated random number"
Allocation concealment (selection bias)	Low risk	Publication states "random". Contact with author confirms random number generation, and sealed opaque envelopes
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>Attrition details:</p> <p>3 could not complete the study (asthma, change of work, death in the family), 2 were excluded because they used other treatment during the trial. Dropout: 2 from PFMT (8%) (motivation, travel time) and 0 from control group (0%)</p>

Bø 1999 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	"physicians evaluating the effect of the treatment were also blind to allocation of treatment"
Baseline comparability	Low risk	Table 1

Carneiro 2010

Methods	2 arm RCT
Participants	<p>50 women aged 30-55 with SUI</p> <p>Method of diagnosis: urodynamic</p> <p>Inclusion: women referred by urologists and gynaecologists with urodynamic diagnosis of SUI due to bladder neck hypermobility or pressure drop under stress (PDS) of 90 cm H₂O or higher</p> <p>Exclusion: SUI due to intrinsic insufficiency (PDS) less than 60 cm H₂O), prior surgical correction of SUI and genital prolapse of any grade in physical examination</p> <p>Mean age (SD): Group PFMT: 49.24 (7.37); Group Control : 45.25 (6.60)</p> <p>Single Center: Cafisio physical therapy clinic</p>
Interventions	<p>Group A (n = 25): Experimental group</p> <p>Taught by: physical therapist</p> <p>Correct VPFMC confirmed? Yes and maximum voluntary contraction was verified by initial assessment, individually for each women</p> <p>Number VPFMC per set: 8-12 repetitions of 5 perineal exercises</p> <p>Number sets per day: once</p> <p>Duration of hold: 6-10</p> <p>Duration of rest: not mentioned</p> <p>Type(s) of contraction, e.g. submaximal, maximal?: not reported</p> <p>Duration of programme: 30 minutes, twice weekly for 8 consecutive weeks</p> <p>Number and type of contact with health professional(s): twice/ weekly</p> <p>Measure of adherence? Not reported</p> <p>Reported level of adherence: Not reported</p> <p>Other information:</p> <ul style="list-style-type: none"> - Verbal information about the PFM function, visualisation of PF component with anatomical figures - 5 minutes of proprioception sitting on a 75-cm diameter therapeutic ball. During that time, participant were asked to make lateral movements of the pelvis, pelvic anteversion movements, short jumps, and figure of 8 movement with the pelvis <p>Group B (n = 25): Control group</p> <p>'The control group carried out no activity during the 8 weeks, as they were on the waiting list'</p>

Carneiro 2010 (Continued)

Outcomes Ultrasound examination, surface EMG with an intra-vaginal probe, PFM bi-digital muscle strength test, KHQ

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Using a simple random sampling'
Allocation concealment (selection bias)	Unclear risk	Not clear if adequate allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if outcome assessment blinded
Baseline comparability	Low risk	'Groups comparable for age, vaginal delivery, caesarian delivery and time with UI' 'Time with UI was almost significantly different between the two group with the Group A having had UI for a longer time'

Castro 2008

Methods	4 arm RCT, parallel design Adequate allocation concealment Blinded outcome assessment A priori power calculation
Participants	118 women, with urodynamic SUI without DO Inclusion: women with urodynamic stress urinary incontinence, no detrusor overactivity, a positive cough test, more than 3 g leakage measured on pad test with standardize bladder volume (200ml); average of 3 episodes of UI per week Exclusion: Chronic degenerative disease that would affect muscular or nerve tissues, advanced genital prolapse, pregnancy, active or recurrent UTI, vulvovaginitis, atrophic vaginitis, continence surgery within a year, subjects with pacemaker, Valsalva leak point pressure less than 60 mmH ₂ O in sitting with 250 ml in bladder or UCP less than 20 cmH ₂ O in sitting position at maximal cystometric capacity Mean age, years: PFMT 56.2 (SD 12.5), Control 52.6 (11.2) Leakage episodes in 7 days: PFMT 10.3 (SD 10.1), Control 10.5 (7.0). Mean BMI: PFMT 25.9 (SD 5.0), Control 26.9 (SD 5.1) Single centre?, Sao Paulo, Brazil
Interventions	1. PFMT (n=26): Three 45 minute exercises classes per week (including PFMT) for 6 months with supervision by physiotherapist 2. Control (n=24): No visit with therapist but motivational phone calls once per month
Outcomes	Primary outcomes: Objective cure of stress incontinence based on a negative pad test with a standardized bladder volume (<2g in weight)

Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women (Review)

Castro 2008 (Continued)

Secondary outcomes: I-QoL, voiding diary (number of leakage in 7 days), PFM digital evaluation using oxford scale, urodynamics evaluation, subjective cure "satisfied" or "dissatisfied"

Notes Post-treatment evaluation at 6 months, no longer-term follow-up
 Dropouts and withdrawal: 3/26 PFMT, 5/24 controls

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers
Allocation concealment (selection bias)	Low risk	"Once enrolled by a physician investigator, subjects were assigned to four distinct groups: pelvic floor exercises, electrical stimulation, vaginal cones, or untreated controls. The division of the four groups was undertaken by using computer-generated random numbers prepared by the Biostatistics Center of the Federal University of São Paulo"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Drop out (PFM =2, 2 lack of clinical improvement) (Control = 2, 2lack of improvement) excluded (PFM =1 pregnancy) (Control =3 change in city)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded outcome assessment
Baseline comparability	Low risk	"there were no significant difference between the groups in any of demographics, clinical characteristics or outcome measurements" table 1

Diokno 2010

Methods	2 arm RCT
Participants	<p>45 adult incontinent ambulatory females</p> <p>Method of diagnosis: symptoms of incontinence on the Medical Epidemiological and Social aspects of Aging questionnaire (MESA)</p> <p>Inclusion: MESA score showing incontinence. 'Previously failed anti-incontinence surgery was not considered exclusion.'</p> <p>Exclusion: 'Currently under treatment for UI, history of bladder cancer, stroke, multiple sclerosis, Parkinson's, epilepsy, spinal cord tumour or trauma, pregnancy, MESA of 72% or higher for urge score or MESA of 70% or higher for stress score, in addition to urge percentage higher than stress percentage (to eliminate those with total incontinence and those with urge predominant symptoms, respectively)</p> <p>Mean age (SD): Group PFMT: 60.6 (14.4) Group Control: 52.2 (12.6)</p> <p>Setting: Four Michigan Counties</p>
Interventions	<p>Group A (n = 23): PFMT intervention</p> <p>Taught by: urology nurse</p> <p>Correct VPFMC confirmed? Yes vaginal examination to test for PFM strength were performed by two nurses</p>

Diokno 2010 (Continued)

Number VPFMC per set: 25 contractions in lying and other positions (5 short contractions (quick squeezes) and 20 long contractions (hold up to 6 seconds) +knack when needed (sneezing)

Number sets per day: twice per day

Duration of rest: not reported

Type(s) of contraction, e.g. submaximal, maximal?: maximal

Duration of programme: 1 teaching session, 1 follow-up session and daily exercises with an audiotape of PFMT

Number and type of contact with health professional(s): Once after 2-4 weeks with vaginal exam if needed and written test on new knowledge acquired

Measure of adherence? Not reported

Reported level of adherence: Not reported

Other important information:

Bladder training tips if needed: Progressive voiding schedule based on patient's diary done before attending the class, interval increased by 15-30 minutes, use pelvic muscle contraction and distraction to inhibit detrusor. Goal: voiding interval of 3.5 to 4 hours while awake

This was not applicable if they already have the 3-5-4 hour interval at baseline

'2-h power point presentation lecture in groups by two trained urology nurses. Paper handouts were distributed'

Group B (n = 18): Control intervention

No information given on behavioral intervention at any time

Outcomes	'Improvement, as measured by reduction of severity level on a 3 point scale (severe to moderate or mild and moderate to mild), or 'no-improvement' for those who stayed the same or worsened, voiding frequency/intervoid interval, continence status with pad testing (g), cough test leak diameter (in cm), stress test (percentage positive) and PFM strength with digital score (pressure, displacement, duration)
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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'randomisation was performed in groups of five using the SAS system'
Allocation concealment (selection bias)	Unclear risk	Adequate allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Total attrition: One could not contract and did not get randomised, so 44/45 participated to randomisation Group A: 0/23 (0%) Group B: 3/21 (14%) reason: had incomplete data
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Vaginal examinations to test PFM strength and collection of bladder diary and 24h pad test were performed by two nurses other than the lecturers

Diokno 2010 (Continued)

Baseline comparability	High risk	'The only demographic statistically significant difference between the two groups was in age.' Those in the treatment group were older
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Henalla 1989

Methods	4 arm RCT, parallel design Not clear if adequate random allocation concealment Not clear if blinded outcome assessment
Participants	100 women with urodynamic SUI Exclusion: fistula, more than one surgical procedure for incontinence, major degree of prolapse, absolute contraindication to oestrogens Single centre, UK.
Interventions	A PFMT (n=26). Correct VPFMC taught by physiotherapist. Weekly clinic visit for 12 weeks. Details of PFMT programme in Data Table 01.03 B Control (n=25). No treatment C Electrical stimulation (n=25) D Drug (n=24). Oestrogen
Outcomes	Primary outcome measure: not stated Other outcome measures: pad test cure (negative following positive result), pad test improvement (50% or greater reduction in pad weight), cystometry Cured or improved at 3 months: A 17/26, B 0/25, C 8/25, D 3/24 Cured or improved at 9 months: A 14/26, B 0/25, C 7/25 D 0/24
Notes	Post-treatment evaluation at 12 weeks, with longer-term follow-up at 9 months (questionnaire) Dropouts: none at 12 weeks?

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"were allocated at random"
Allocation concealment (selection bias)	Unclear risk	Not clear if adequate random allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information about attrition
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if blinded outcome assessment
Baseline comparability	Low risk	"the groups were comparable regarding age weight and parity"

Henalla 1990

Methods	3 arm RCT, parallel design
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Henalla 1990 (Continued)

Not clear if adequate random allocation concealment
 Not clear if blinded outcome assessment

Participants	26 women with urodynamic SUI Inclusion: postmenopausal Exclusion: no further criteria stated Mean age, years: 54 (range 49-64) Single centre, UK
Interventions	1. PFMT (n=8). No detail given 2. Control (n=7). No treatment 3. Drug (n=11). Oestrogen
Outcomes	Primary outcome: not stated Other outcome measures: pad test cure or improved (not defined), vaginal pH, vaginal cytology, anal EMG
Notes	Post-treatment evaluation at 6 weeks, no longer-term follow-up Dropouts: none?

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomized"
Allocation concealment (selection bias)	Unclear risk	Not clear if adequate random allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information about attrition
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if blinded outcome assessment
Baseline comparability	Unclear risk	Not clear groups comparable at baseline

Hofbauer 1990

Methods	4 arm RCT, parallel design Not clear if adequate random allocation concealment Not clear if blinded outcome assessment
Participants	43 women with urodynamic SUI Exclusion: urge incontinence Mean age, years: 57.5 (SD 12) Grade 3 incontinence: 4 PFMT, 2 control
Interventions	1. PFMT (n=11). Exercise programme including PFMT, abdominal and hip adductor exercise, twice a week for 20 minutes with therapist, and daily home programme 2. Control (n=10) Sham electrical stimulation 3. PFMT + electrical stimulation (n=11) 4. Electrical stimulation (n=11)

Hofbauer 1990 (Continued)

Outcomes	Primary outcome: not stated Other outcome measures: incontinence scale (? symptom scale, not defined), leakage episodes (urinary diary), cystometry
Notes	Not clear when post-treatment evaluation performed. Further follow-up at 6 months Dropouts: none?

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomised"
Allocation concealment (selection bias)	Unclear risk	Translated from German, "random"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information about attrition
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if blinded outcome assessment.
Baseline comparability	Unclear risk	Not clear groups comparable at baseline

Kim 2007

Methods	2 arm RCT, crossover design Stratification: level of physical fitness and leakage episode Not clear if adequate random allocation concealment Not clear if blinded outcome assessment A priori power calculation Single urban centre, Japan
Participants	70 women with SUI symptoms Inclusion: Urine leakage more than once per month, UI associated with exertion Exclusion: Urge or mixed UI symptoms, No leakage or not enough Mean age, years: PFMT 76.6 (SD 5.0), control 76.6 (8.3) Frequency score of urine leakage: PFMT 3.4 (SD 1.3), control 3.0 (1.3)
Interventions	1. PFMT (n=35): 60 minute exercise class twice a week for 12 weeks and 30 minutes home exercises twice a week 2. Control (n = 35): Live normal life and refrain from exercises aiming to increase muscle strength, walking speed, to reduce BMI, or to improve dietary habits for 12 weeks
Outcomes	Primary outcomes: ICIQ, frequency of UI leakage (worse to cured) at 3 and at 12 months Secondary outcomes: BMI, grip strength, walking speed, hip adductor strength

Kim 2007 (Continued)

On a six-point leakage scale of cure (0 = no urine leakage, 1 = less than once per month, 2 = 1 to 3 per month, 3 = 1 to 2 per week, 4 = every two days and 5 = every day), the post-treatment score was significantly better for PFMT group than for the control group with a mean (standard deviation) score post-treatment in the PFMT group of 1.5 (1.8) compared to controls 2.4 (1.4) (MD -0.9, 95% CI -1.7 to -0.1)

Notes Post treatment evaluation at 3 months, with longer-term follow up at 12 months
 Dropouts: 2/35y: PFMT, 3/35 Control

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer generated random number"
Allocation concealment (selection bias)	Unclear risk	Unclear - what did they actually say, e.g. "random"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"5 participants (2 = PFMT and 3 = control group) where not able to complete study because of hospitalisation = 1, asthma =1, knee pain =1, or fracture = 2." no information about who is in what group?
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if blinded outcome assessment.
Baseline comparability	Low risk	Table 1

Kim 2011

Methods	4 arm RCT
Participants	<p>147 community-dwelling women aged 70 years and older with SUI, MUI or UUI</p> <p>Method of diagnosis: symptoms</p> <p>Inclusion: Urine leakage more than once per month, suffering from stress, urge and mixed UI according to symptoms, being 70 and older.</p> <p>Exclusion: Unclear type of UI, having urine leakage less than once per month, impaired cognition (MMSE lower than 24), unstable cardiac conditions such as ventricular dysrhythmias, pulmonary edema or other musculoskeletal conditions</p> <p>Mean age (SD): Group PFMT intervention: 76.7 (3.6) Group Control intervention: 75.8 (3.6)</p> <p>Setting: Basic Resident Register of 5935 women aged 70 years years and older that resided in the Itabashi ward of Tokyo as of 1 April 2006</p>
Interventions	<p>Group A (n = 37): PFMT intervention</p> <p>Taught by: clinician giving the PFM and fitness protocol</p> <p>Correct VPFMC confirmed? not reported</p> <p>Number VPFMC per set: 10 fast and 10 sustained contractions</p> <p>Number sets per day: 3</p>

Kim 2011 (Continued)

Duration of hold: 3 seconds for fast contractions, 6 to 8 seconds for sustained contractions

Duration of rest: 5 seconds for fast contractions and 10 seconds for sustained contractions

Type(s) of contraction, e.g. submaximal, maximal: PFM contraction without excessively straining the abdomen, performed in lying, sitting, standing position with legs apart

Duration of programme: 60 minutes, twice weekly for 12 weeks in groups

Number and type of contact with health professional(s): twice/ weekly for 12 weeks

Measure of adherence? 'The subjects were asked to document the time and sets of exercises performed at home each day.'

Reported level of adherence: recording sheet. not reported

Other information:

- The participants were informed that straining the abdomen increases abdominal pressure and exerts pressure on the PFM. The subjects were trained to exert force only on the PFM without excessively straining the abdomen

- Warm-up and stretching 10 to 15 min including shoulder rotation, waist rotation and others , PFMT (as above) in addition to fitness: strength training of the thigh and abdominal muscles performed between PFMT, weight bearing exercises, ball exercises and others

-Home exercises two to 3 sets of (PFM +13 exercises) at least 3 times a week (duration approximately 30 minutes)

Group B (n = 36): Control intervention

General education class once per month for 3 months where participants were educated on cognitive function, osteoporosis and oral hygiene

Outcomes	Subjective cure (interview), Complete cessation of urine loss episode was defined as cured, functional fitness, change in frequency of urine loss episodes (5 point scale), ICIQ
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Notes	
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'computer-generated random numbers'
Allocation concealment (selection bias)	Low risk	'The investigators were blind to the allocation of interventions.'
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Group A: PFMT intervention = 2/37 (5%) Group B: Control intervention = 2/36 (6%) reasons for not completing the study in all 4 cases not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if blinded outcome assessment

Kim 2011 (Continued)

Baseline comparability	Low risk	Groups comparable at baseline for anthropometric values, physical fitness, measures and interview survey
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Kim 2011a

Methods	2 arm RCT
Participants	<p>127 community dwelling women aged 70 and older with SUI, MUI or UUI</p> <p>Method of diagnosis: symptoms</p> <p>Inclusion: Urine leakage more than once per week, suffering from stress, urge and mixed UI according to symptoms, being 70 years old or more, completing a 1-week urinary diary</p> <p>Exclusion: Unclear type of UI, having urine leakage less than once per week, not completing the 1 week bladder diary, Impaired cognition (MMSE lower than 24), unstable cardiac conditions such as ventricular dysrhythmias, pulmonary oedema, or other musculoskeletal conditions</p> <p>Mean age (SD): Group PFMT intervention: 76.1 (4.3) Group Control intervention: 75.7 (4.4)</p> <p>Setting: Urban community-based study</p>
Interventions	<p>Group A (n = 63): PFMT intervention</p> <p>Taught by: clinician giving the PFM and fitness protocol</p> <p>Correct VPFMC confirmed? not reported</p> <p>Number VPFMC per set: 10 fast and 10 sustained contractions</p> <p>Number sets per day: 3</p> <p>Duration of hold: 3 seconds for fast contractions, 6 to 8 seconds for sustained contractions</p> <p>Duration of rest: 5 seconds for fast contractions and 10 seconds for sustained contractions</p> <p>Type(s) of contraction, e.g. submaximal, maximal: PFM contraction without excessively straining the abdomen, performed in lying, sitting, standing position with legs apart</p> <p>Duration of programme: 60 minutes, twice weekly for 12 weeks in groups</p> <p>Number and type of contact with health professional(s): twice/weekly for 12 weeks</p> <p>Measure of adherence? 'The subjects were asked to document the time and sets of exercises performed at home each day.'</p> <p>Reported level of adherence: Recording sheet. Attendance rate to PFMT intervention, home exercise frequency</p> <p>Other important information:</p> <p>-Warm-up and stretching 10 to 15 min, PFMT (as above) in addition to fitness: strength training of the thigh and abdominal muscles performed between PFMT, back, legs, trunk and use of an exercise ball</p> <p>-Home exercises two to 3 sets of (PFM +13 exercises) at least 3 times a week (duration approximately 30 minutes)</p> <p>Group B (n = 64): Control intervention</p>

Kim 2011a (Continued)

General education class once per month for 3 months where participants were educated on cognitive function, osteoporosis and oral hygiene

Outcomes

ICIQ frequency of UI leakage (scale 0 -5) at 3 months and 7 months

Subjective cure (leakage disappeared) at 3 and 7 months according to bladder diary, BMI, waist line, grip strength, walking speed, hip adductor strength

Cure of UI at 3 months: A 26/59, B 1/61

Cure of UI at 7 months: A 23/59, B 1/61

Notes
Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'computer-generated random number'
Allocation concealment (selection bias)	Low risk	'the randomisation procedure was blinded'
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Total: 7/127 (6%) Group A: PFMT intervention = 4/63 (6%) hip fracture (n = 1), moving (n=1), knee pain (n=1), spouse care (n=1) Group B: Control intervention = 3/64 (5%) death (n=1) hospitalisation (n=1), decreased motivation (n=1)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'the investigators that evaluated the effects of the exercise treatment were blind to the allocation of interventions'
Baseline comparability	Low risk	'Most of the baseline characteristics were similar between the groups'. All those presented in table 1 were similar between groups

Lagro-Janssen 1991
Methods

2 arm RCT, parallel design
 Stratified by type and severity of incontinence
 Inadequate allocation concealment
 Blinded outcome assessment

Participants

110 women, with urodynamic SUI with or without DO
 Inclusion: women between 20 and 65 years of age reporting 2 or more leakage episodes per month
 Exclusion: previous incontinence surgery, neurological causes of incontinence, urinary tract infection, temporary cause of incontinence
 Mean age, years: PFMT 46.1 (SD 10.1), controls 44.6 (SD 8.2)
 Symptoms for more than 5 years: PFMT 55%, control 33%
 Mean leakage episodes 24 hours: PFMT 2.5 (SD 2.0), control 3.3 (SD 2.2)
 Diagnosis: 66 urodynamic SUI (60%), 20 MUI (18%), 18 UUI (16%), 6 other (6%). NB: only data from urodynamic SUI women are included in the review, because women with other diagnoses also had bladder training
 13 general practices, the Netherlands

Lagro-Janssen 1991 (Continued)

Interventions	1. PFMT (n=54, but 33 with urodynamic SUI only). Advice about incontinence pads from practice assistant. Information on PFM function and how to contract by family doctor. PFMT for 12 weeks. Details of PFMT programme in Data Table 01.03 2. Control (n=56, but 33 with urodynamic SUI only). Advice about incontinence pads only. Offered treatment after 12 weeks
Outcomes	Primary outcome: not stated Other outcomes: incontinence severity (12 point score), subjective assessment, health locus of control questionnaire, general health questionnaire, leakage episodes (7 day diary), self-reported treatment adherence
Notes	Post-treatment evaluation at 12 weeks, with longer term follow up at 6 months, 12 months and 5 years Dropouts: 1/54 PFMT, 3/56 control.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Consecutively (ie: quasi-random because of alternation)
Allocation concealment (selection bias)	High risk	"the patient were assigned consecutively to the treatment or control groups which were stratified on the basis of the severity of their incontinence" Inadequate allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No dropout reported before 6 months (or end of study first phase which is of interest for us)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded outcome assesment
Baseline comparability	Low risk	table 1 "no significant difference were found"

Miller 1998

Methods	2 arm RCT, parallel design (after one month controls cross over into treatment group) Not clear if adequate allocation concealment Blinded outcome assessment
Participants	27 women with symptoms and signs of SUI Inclusion: community dwelling women, mild to moderate SUI (at least one and up to 5 leaks per day), 60 years or more, direct visualisation of urine loss on cough with 100ml or more voided after stress test Exclusion: systemic neuromuscular disease, previous bladder surgery, active urinary tract infection, delayed leakage after cough, more than moderate leakage with cough, inability to do a VPFMC, prolapse below hymenal ring Mean age, years: 68.4 (SD 5.5) Mean number leakage episodes per day: 1.4 (SD 1.4) Single centre, USA
Interventions	1. PFMT (n=13). Education on basic physiology and function of pelvic floor muscles, digital palpation to teach VPFMC. Taught 'The Knack', i.e. VPFMC prior to hard cough maintained throughout cough until abdominal wall relaxed. Practice at home for one week 2. Control (n=14). No treatment for one week, then cross over to treatment group at one month

Miller 1998 (Continued)

Outcomes Primary outcome measure: Paper towel test
 Secondary outcome measures: digital palpation

A paper towel test was reported as mean wet area and SD on either a moderate or a deep cough. PFMT women reported about 20 cm² less of wet area than controls on a medium cough (MD -20.8, 95% CI -46.5 to 4.9) and 21 cm less of wet area than controls on a deep cough (MD -21.4, 95% CI -50 to 7.2). However, in both cases, the wide confidence intervals included no difference.

Notes Post-treatment evaluation: one week, no longer-term follow-up
 Dropouts: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"randomly assigned in blocks of two"
Allocation concealment (selection bias)	Unclear risk	"randomly assigned in blocks of two"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Evaluation, only one week after and report on all participants
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinding of outcome assessment
Baseline comparability	Low risk	Groups comparable at baseline

Pereira 2011

Methods 3 arm parallel RCT

Participants 49 women over 18 years of age

Method of diagnosis: SUI symptoms

Inclusion: complain of urinary leakage on stress (two standard questions about stress and urgency UI used to determine patient eligibility: During the past month, have you involuntary got wet while performing some kind of physical exertion, coughing, lifting, sneezing or laughing? For urgency, the question was During the past month, have you experienced such a strong urge to urinate that it was impossible to get to the toilet on time? Those answering yes to the stress question only and who had not undergone physical therapy for UI before were included

Exclusion: With symptoms of urgency urinary incontinence and mixed urinary incontinence, latex allergies, vaginal or urinary infections, pelvic organ prolapse greater than grade II on Baden-Walker classification system, cognitive or neurological disorder, uncontrolled hypertension and inability to carry out the evaluation or treatment

Mean age (SD): Group PFMT intervention: 60.20 (8.16); Individual PFMT intervention: 60.6 (12.63); Control intervention: 61.53 (10.11)

A single centre study: Laboratory for assessment and intervention on Women's health, Federal university of Sao Carlos, Brazil

Interventions Group A (n = 17): Group PFMT intervention

Pereira 2011 (Continued)

Taught by: Physical therapist

Correct VPFMC confirmed? Yes with vaginal palpation

Number VPFMC per set: not clear, 100 in total on average in intervention sessions

Number sets per day: not mentioned

Duration of hold during intervention sessions: (mean time of the group was considered as the time of sustained contraction). The time of sustained contraction was increased by 1 s per week up to 10 s

Duration of rest during intervention sessions: double the duration of hold

Type(s) of contraction, e.g. submaximal, maximal: *'100 contractions were performed on average, composed of phasic contractions held for 3 sec with 6 sec rest and tonic contractions of 5-10 s followed by 10-20 sec rest. To minimize the muscle fatigue, the resting time was rigidly observed in all sessions and the time of sustained contraction was slowly increased. PFMT was carried out in supine, sitting and standing positions. The degree of difficulty progressed according to the positions adopted, the number of repetitions, and the time of sustained contraction.'*

Group B (n = 17): Individual PFMT intervention:

Taught by: physical therapist

Correct VPFMC confirmed? Yes with vaginal palpation

Number VPFMC per set: not clear, 100 in total on average in intervention sessions

Number sets per day: not mentioned

Duration of hold: 3-10 seconds during intervention sessions. The time of sustained contraction was increased by 1 s per week up to 10 s

Duration of rest: 6-20 seconds in intervention sessions

Type(s) of contraction, e.g. submaximal, maximal: *"100 contractions were performed on average, composed of phasic contractions held for 3 sec with 6 sec rest and tonic contractions of 5-10 s followed by 10-20 sec rest. To minimize the muscle fatigue, the resting time was rigidly observed in all sessions and the time of sustained contraction was slowly increased. PFMT was carried out in supine, sitting and standing positions. The degree of difficulty progressed according to the positions adopted, the number of repetitions, and the time of sustained contraction."*

Other important information on the group and individual interventions:

Duration of programme: two 1h weekly sessions in clinic for 6 weeks

Number and type of contact with health professional(s): 12 group or individual sessions twice/ weekly for 1h for a total of 6 weeks

Measure of adherence? No

Explanation about anatomy of the PFM and continence mechanism

Group C (n = 15): Control intervention: did not received any treatment during the corresponding treatment time

Outcomes

1hour pad test, KHQ, PFM pressure perineometry, PFM digital evaluation of strength, subjective satisfaction with tx (The only two response options available were 'satisfied' and 'dissatisfied'. Answering 'satisfied' indicated that the patient did not want a different treatment. Answering 'dissatisfied' indicated that the patient wanted a different treatment from the initial one), adverse effects

Notes

Risk of bias

Pereira 2011 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"participants blindly drew one of the 49 preprinted cards in opaque sealed envelopes from a box" no mention of successively numbered
Allocation concealment (selection bias)	Unclear risk	"participants blindly drew one of the 49 preprinted cards in opaque sealed envelopes from a box"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Total: 4/34 (8%) Group intervention= 2/17 (12%)* Individual intervention = 2/17 (12%)* control intervention = 0/15 0% * reasons: health problem or family (information not given per treatment group)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Evaluator was not blinded
Baseline comparability	Low risk	Group similar at baseline for demographics and clinic characteristics

Sar 2009

Methods	2 arm parallel RCT
Participants	41 Women Diagnosis of urinary incontinence: signs (2g. of urine on a 1h pad test) Inclusion: women with stress or mixed signs on surgical waiting list between 2005-2007, MMSE score: 25 and more Exclusion: UTI, previous surgery of UI, neurological disease, diabetes mellitus, comorbid conditions likely to interfere with tx, UI medication, inability to understand Turkish language Mean age: PFMT group =41.82 (8.65); Control group = 44.64 (6.90) Two centres: Outpatient urology clinics attached to a country hospital and a university hospital in Izmir, Turkey
Interventions	Group A (n = 19): PFMT Taught by: nurse Correct VPFMC confirmed? Yes using vaginal palpation Number VPFMC per set: 30 contractions per set Number sets per day: 3 Duration of hold: 1 to 10 seconds Duration of rest: same as contraction time Type(s) of contraction, e.g. submaximal, maximal: quick flicks (1-2 sec contractions), sustained progressive (5-10 seconds) contractions + knack

Sar 2009 (Continued)

Duration of programme: 6 weeks

Position: supine, sitting and standing

Measure of adherence? weekly telephone call to encourage exercises practice and answer questions

Reported level of adherence: not reported

Other important information on the intervention: taught about the anatomy of the pelvic floor, lower urinary tract anatomy and continence mechanism. Information was summarised in an illustrated hand-book

Group B (n = 22): control

not contacted

Outcomes

 Sar reported all outcomes as change scores and SD which we could not use in our forest plot. All outcomes significantly favoured PFMT versus control ($P < 0.01$)

I-QOL: PFMT A 23.19 (11.43) 17, versus control B 5.74 (6.26) 17

Bladder diary (change in leakage/3 days): PFMT A -3.23 (2.19) 17 versus control B 0.82 (2.81) 17

1h pad test (change in gms from baseline): PFMT A -5.11 (7.29) 17 versus control B 8.88 (12.52) 17

PFM strength: mean and maximum as pressure using intra-vaginal perineometry: PFMT A 9.47 (6.53) 17 versus control B -2.23 (4.43) 17 and PFMT 11.23 (7.60) 17 versus control B -3.70 (4.71) 17 respectively

Notes
Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'randomly assigned to an intervention or control group' 'stratified based on PFM strength, frequency of UI episodes and severity of UI on a 1h pad test'
Allocation concealment (selection bias)	Unclear risk	Not clear if allocation concealment
Incomplete outcome data (attrition bias) All outcomes	High risk	Total 7/41 (17%) Group A = 2 (11%) drop out: non adherence to treatment regimen Group B = 5 (23%) Excluded: used other treatment during the trial
Blinding of outcome assessment (detection bias) All outcomes	High risk	'this trial was not blinded'
Baseline comparability	Low risk	No significant differences at baseline for age, body mass index, parity, cystocele, rectocele duration of symptoms, menopause status, PFM strength, episode of leakage, 1h pad tests, I-QOL scores

Wells 1999

Methods 4 arm RCT, parallel design
 Not clear if adequate allocation concealment

Wells 1999 (Continued)

	Outcome assessment not blind No intention to treat analysis
Participants	286 community living women, with symptoms of stress or mixed urinary incontinence Inclusion: aged over 21, self described as having uncontrolled urine loss and-or excessive day toileting frequency, independent in self care, able to speak and ear a conversation in English adequately over the phone, negative urinalysis, able to contract the PFM as demonstrated on physical examination, able to read, understand and agree to the diagnostic consent form Exclusion: diagnosis of degenerative neurological disorder, pregnancy, high risk of infection following urologic instrumentation Mean age, years: 56 (SD 12.76) Single centre, USA
Interventions	1. PFMT (n =71): Initial training and active pelvic floor muscle exercises then monthly visits for observation, coaching and encouragement 2. Control (n = 72): directed one week a month to keep a daily record of fluid intake, toileting and urine leakage and discern a pattern and make simple life style alterations if possible. Received diary by mail monthly
Outcomes	Pelvic floor muscle strength, urethral pressure and wetting No details given on primary and secondary outcomes
Notes	Post-treatment evaluation at 5 months, no longer term follow-up Dropouts: 30/71 PFMT, 35/72 Controls

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Subjects were randomly assigned
Allocation concealment (selection bias)	Unclear risk	Not clear if adequate allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear if incomplete outcome data
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessment not blind
Baseline comparability	Unclear risk	Not clear if groups were comparable at baseline

Yoon 2003

Methods	3 arm RCT, parallel design Not clear if adequate allocation concealment Blinded outcome assessment
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Yoon 2003 (Continued)

Participants	50 women with urinary incontinence Inclusion: urine loss >1g on 30 minute pad test, 14 voids or more in 48 hours Exclusion: women under 35 and over 55 years of age, urinary tract infection, previous surgery for urinary incontinence, hormonal or other drug therapy for incontinence Mean voids per day: PFMT 15.1 (SD 1.6), control 16.3 (1.8) Diagnosis: urinary incontinence (100%) Single centre, Korea
Interventions	1. PFMT (n=15). 20 minutes weekly session of EMG biofeedback with nurse, 8 weeks. Details of PFMT programme in Data Table 01.03 2. Control (n=14). No treatment or clinic contact
Outcomes	Primary outcome: not stated Other outcomes: urinary incontinence score (severity based on leakage with 18 activities), leakage episodes and frequency (2 day diary), 30 minute pad test, vaginal squeeze pressure
Notes	Post-treatment evaluation at 8 weeks, with no longer-term follow-up Dropouts: 2/15 PFMT, 2/21 Bladder training, 2/14 controls

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Using random number
Allocation concealment (selection bias)	Unclear risk	"assigned randomly to the control and treatment groups by using random numbers". Not clear if adequate allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Two women from the PFM group and 2 women from control withdrew due to family problem
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded outcome assessment
Baseline comparability	Low risk	"no baseline difference"

DO=detrusor overactivity, EMG=electromyography, ITTA=intention-to-treat analysis, MMSE=mini mental state examination, MUI=mixed urinary incontinence, PFMT=pelvic floor muscle training, SD=standard deviation, SUI=stress urinary incontinence, RCT=randomised controlled trial, USI=urodynamic stress urinary incontinence, UUI=urge urinary incontinence, VPFMC=voluntary pelvic floor muscle contraction.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Abdulaziz 2012	2 arm RCT comparing biofeedback assisted PFMT to a control group. Considered to be a comparison of PFMT + biofeedback to control
Albers-Heitner 2008	Qualitative study, not a RCT
Bernier 2008	Electrical stimulation, biofeedback + PFMT used in the treatment arm of the RCT
Bernier 2008a	Electrical stimulation, biofeedback + PFMT used in the treatment arm of the RCT

Study	Reason for exclusion
Beuttenmuller 2011	3 arm RCT comparing PFMT, PFMT + Estim and control. No UI outcome
Burgio 2002	3 arm RCT comparing PFMT + biofeedback, PFMT, and self help booklet (including advice on PFMT). Considered to be a comparison of different approaches to PFMT
Chang 2011	3 arm RCT comparing acupressure, sham acupressure and usual care. No PFMT group
Felicissimo 2010	2 arm RCT comparing two PFMT interventions: intensive supervised and unsupervised PFMT
Ferreira 2011	2 arm RCT comparing two PFMT interventions: home based and supervised PFMT
Ferreira 2011a	Intervention: PFM educational group intervention not PFMT
Ghoniem 2005	PFMT versus sham PFMT comparison was considered to be confounded by the choice of sham PFMT
Goode 2003	3 arm RCT comparing PFMT + electrical stimulation, PFMT, and self help booklet (including advice on PFMT). Considered to be a comparison of different approaches to PFMT
Hazewinkel 2009	2 arm preventive and therapeutic RCT comparing PFMT to control in women in early stage of cervical cancer with and without pelvic floor symptoms. Data of those with UI not presented separately
Kumari 2008	2 arm RCT comparing PFMT + bladder training to the absence of treatment
Ramsay 1990	PFMT versus sham PFMT comparison was considered to be confounded by the choice of sham PFMT
Rutledge 2012	2 arm RCT comparing PFMT/behavioural therapy to usual care. Considered to be a comparison of a combined PFMT with bladder training intervention to control, not just PFMT alone
van Leeuwen 2004	4 arm RCT comparing duloxetine alone, duloxetine + imitation PFMT, PFMT + placebo and PFMT alone. Imitation PFMT and PFMT is considered to be a comparison of different approaches to PFMT
Yang 2012	2 arm RCT comparing PFMT + biofeedback and control in gynaecology cancer survivors not specific to UI 'women who scored above 2 on of at least one of the bowel, bladder or sexual function questionnaires were selected
Yoon 1999	3 arm, probably quasi-randomised trial, comparing PFMT, electrical stimulation, and control (not defined), for women with urodynamic SUI. This abstract contains no data; P values only

PFMT=pelvic floor muscle training, RCT=randomised controlled trial, SUI=stress urinary incontinence, USI=urodynamic stress urinary incontinence,

Characteristics of studies awaiting assessment *[ordered by study ID]*

Miller 2009

Methods	RCT
Participants	Women with UI
Interventions	Knack instruction as provided by a video versus a video on food pyramid instruction

Miller 2009 (Continued)

Outcomes	Incontinence episode on a diary, leakage volume on quantified stress test, self reported improvement
Notes	No usable data in abstract; manuscript in preparation

DATA AND ANALYSES
Comparison 1. PFMT versus no treatment, placebo or control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participant perceived cure	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 stress urinary incontinence	4	165	Risk Ratio (M-H, Fixed, 95% CI)	8.38 [3.68, 19.07]
1.2 urge urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 mixed urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.4 urinary incontinence (all types)	3	290	Risk Ratio (M-H, Fixed, 95% CI)	5.34 [2.78, 10.26]
2 Participant perceived cure or improvement after treatment	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 stress urinary incontinence	2	121	Risk Ratio (M-H, Fixed, 95% CI)	17.33 [4.31, 69.64]
2.2 urge urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.3 mixed urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.4 urinary incontinence (all types)	2	166	Risk Ratio (M-H, Fixed, 95% CI)	2.39 [1.64, 3.47]
3 Quality of life (King's Health Questionnaire/Severity measure after treatment)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Stress Urinary incontinence	3	145	Mean Difference (IV, Fixed, 95% CI)	-13.14 [-21.10, -5.18]
3.2 Urge urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.3 Mixed urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.4 Urinary Incontinence (all types)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Quality of life (King's Health Questionnaire/Incontinence impact after treatment)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 Stress Urinary incontinence	3	145	Mean Difference (IV, Fixed, 95% CI)	-11.76 [-20.83, -2.69]
4.2 Urge urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.3 Mixed urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.4 Urinary Incontinence (all types)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Quality of life (King's Health Questionnaire/Physical limitation)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
5.1 Stress Urinary incontinence	3	145	Mean Difference (IV, Fixed, 95% CI)	-11.89 [-20.55, -3.23]
5.2 Urge urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.3 Mixed urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.4 Urinary Incontinence (all types)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Number of women with interference with life due to UI	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
6.1 stress urinary incontinence	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.2 urge urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.3 mixed urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.4 urinary incontinence (all types)	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 I-QOL	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.1 Stress urinary incontinence	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.2 Urge urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

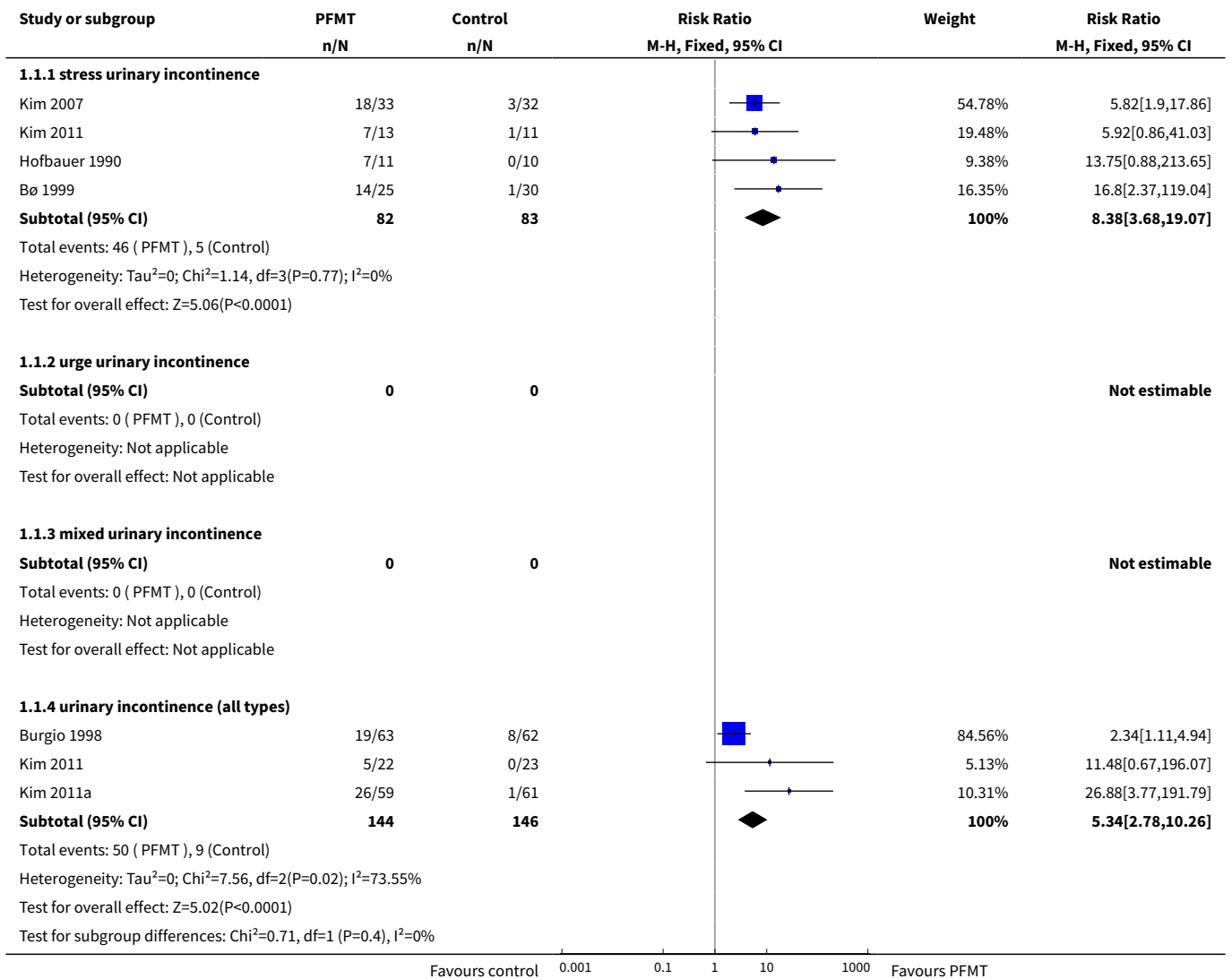
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.3 Mixed urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.4 Urinary incontinence (all types)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Quality of life (King's Health Questionnaire/General health score)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
8.1 Stress Urinary incontinence	3	145	Mean Difference (IV, Fixed, 95% CI)	1.81 [-3.40, 7.03]
8.2 Urge urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.3 Mixed urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.4 Urinary Incontinence (all types)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Cure at up to one year	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
9.1 stress urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.2 urge urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.3 mixed urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.4 urinary incontinence (all types)	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Cure or improvement at up to one year	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
10.1 stress urinary incontinence	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.2 urge urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.3 mixed urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.4 urinary incontinence (all types)	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Patient perceived satisfaction	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
11.1 stress urinary incontinence	2	105	Risk Ratio (M-H, Fixed, 95% CI)	5.32 [2.63, 10.74]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.2 urge urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.3 mixed urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.4 urinary incontinence (all types)	1	108	Risk Ratio (M-H, Fixed, 95% CI)	2.77 [1.74, 4.41]
12 Number of women needing further treatment	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
12.1 stress urinary incontinence	1	55	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.07, 0.42]
12.2 urge urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
12.3 mixed urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
12.4 urinary incontinence (all types)	1	106	Risk Ratio (M-H, Fixed, 95% CI)	0.19 [0.10, 0.36]
13 Number of leakage episodes in 24 hours	5		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
13.1 stress urinary incontinence	4	253	Mean Difference (IV, Fixed, 95% CI)	-1.21 [-1.52, -0.89]
13.2 urge urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
13.3 mixed urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
13.4 urinary incontinence (all types)	1	125	Mean Difference (IV, Fixed, 95% CI)	-0.80 [-1.26, -0.34]
14 Number of voids per day (frequency)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
14.1 stress urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14.2 urge urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14.3 mixed urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14.4 urinary incontinence (all types)	2	66	Mean Difference (IV, Fixed, 95% CI)	-2.56 [-3.65, -1.48]

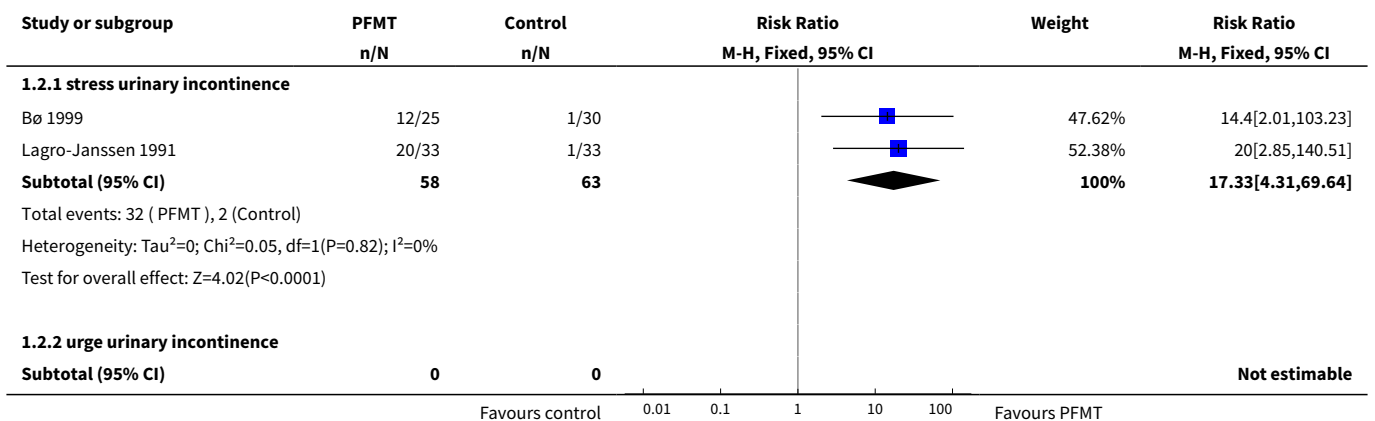
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
15 Number of voids per night (nocturia)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
15.1 stress urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15.2 urge urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15.3 mixed urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15.4 urinary incontinence (all types)	2	66	Mean Difference (IV, Fixed, 95% CI)	0.04 [-0.40, 0.48]
16 Short (up to one hour) pad test measured as grams of urine	4		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
16.1 Stress urinary incontinence	3	150	Mean Difference (IV, Fixed, 95% CI)	-4.36 [-6.77, -1.96]
16.2 Urge urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.3 mixed urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.4 urinary incontinence (all types)	1	25	Mean Difference (IV, Fixed, 95% CI)	-5.10 [-11.16, 0.96]
17 24 hour pad test (grams)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
17.1 Stress urinary incontinence	1	55	Mean Difference (IV, Fixed, 95% CI)	-27.5 [-61.24, 6.24]
17.2 Urge urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
17.3 Mixed urinary incontinence	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
17.4 Urinary incontinence (all types)	1	41	Mean Difference (IV, Fixed, 95% CI)	-1.20 [-15.24, 12.84]
18 Number cured on short pad test (objective) after treatment	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
18.1 stress urinary incontinence	3	135	Risk Ratio (M-H, Fixed, 95% CI)	7.50 [2.89, 19.47]
18.2 urge urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

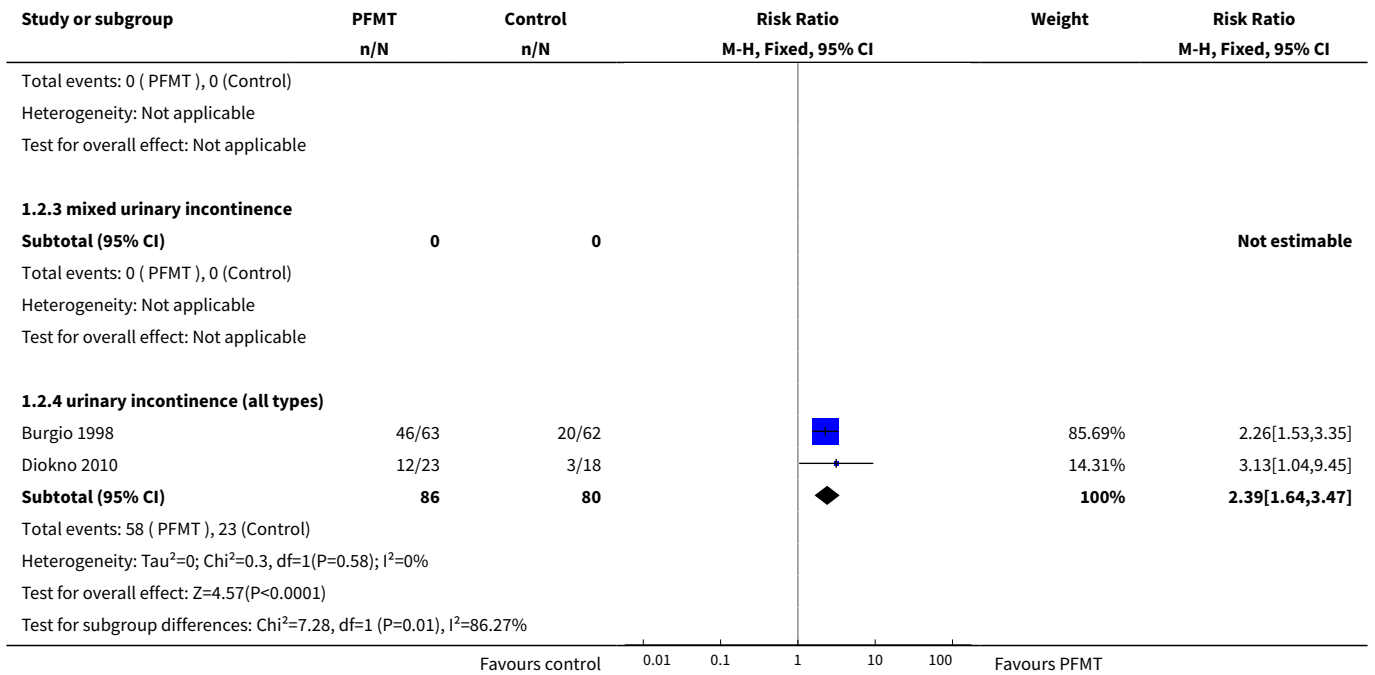
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
18.3 mixed urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
18.4 urinary incontinence (all types)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19 Number cured or improved on short pad test (objective) after treatment	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
19.1 stress urinary incontinence	3	96	Risk Ratio (M-H, Fixed, 95% CI)	8.22 [3.17, 21.28]
19.2 urge urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19.3 mixed urinary incontinence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19.4 urinary incontinence (all types)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
20 Number of women with sex life spoilt by UI	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
20.1 stress urinary incontinence	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.2 urge urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.3 mixed urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.4 urinary incontinence (all types)	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21 Number of women with UI during intercourse	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
21.1 stress urinary incontinence	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21.2 urge urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21.3 mixed urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21.4 urinary incontinence (all types)	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 1 Participant perceived cure.

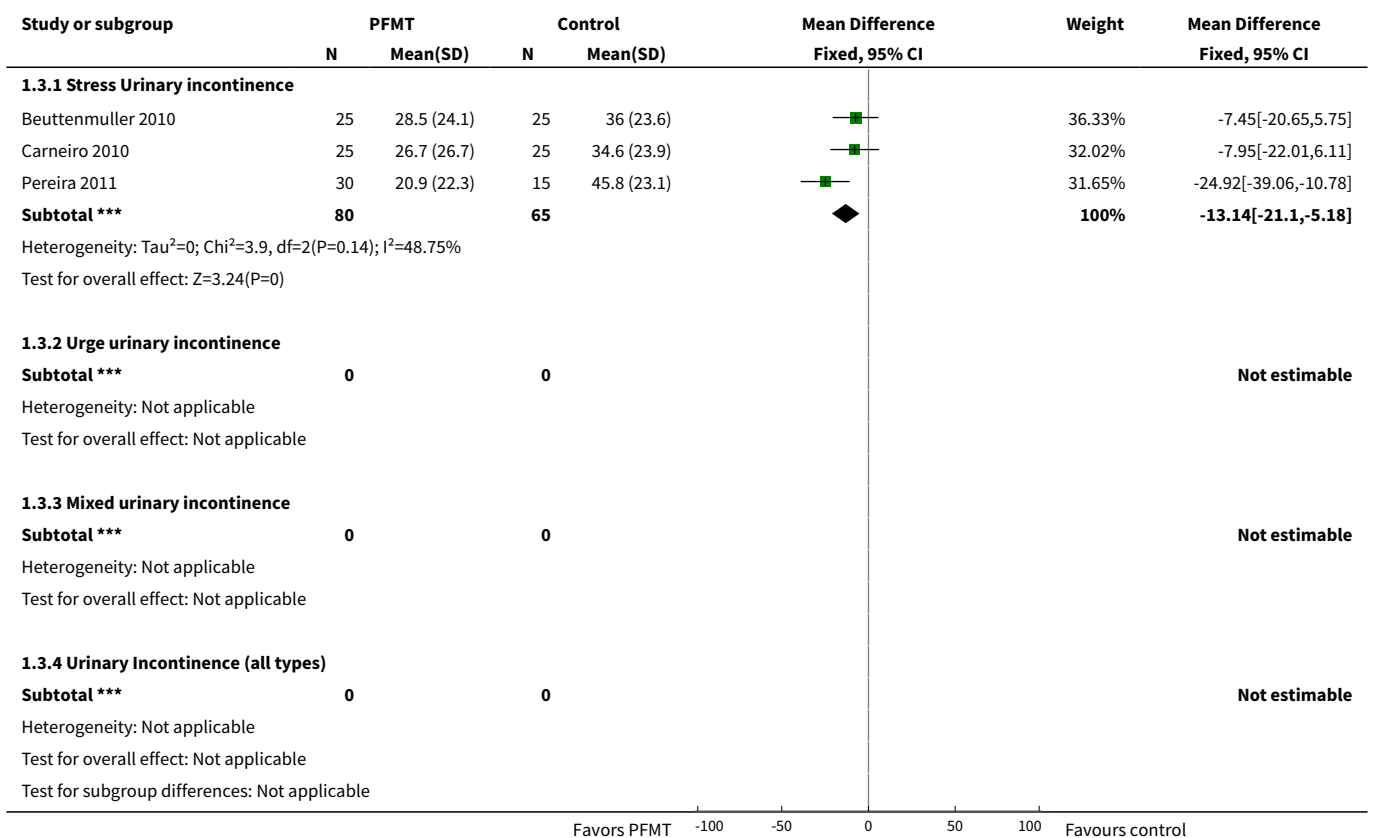


Analysis 1.2. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 2 Participant perceived cure or improvement after treatment.

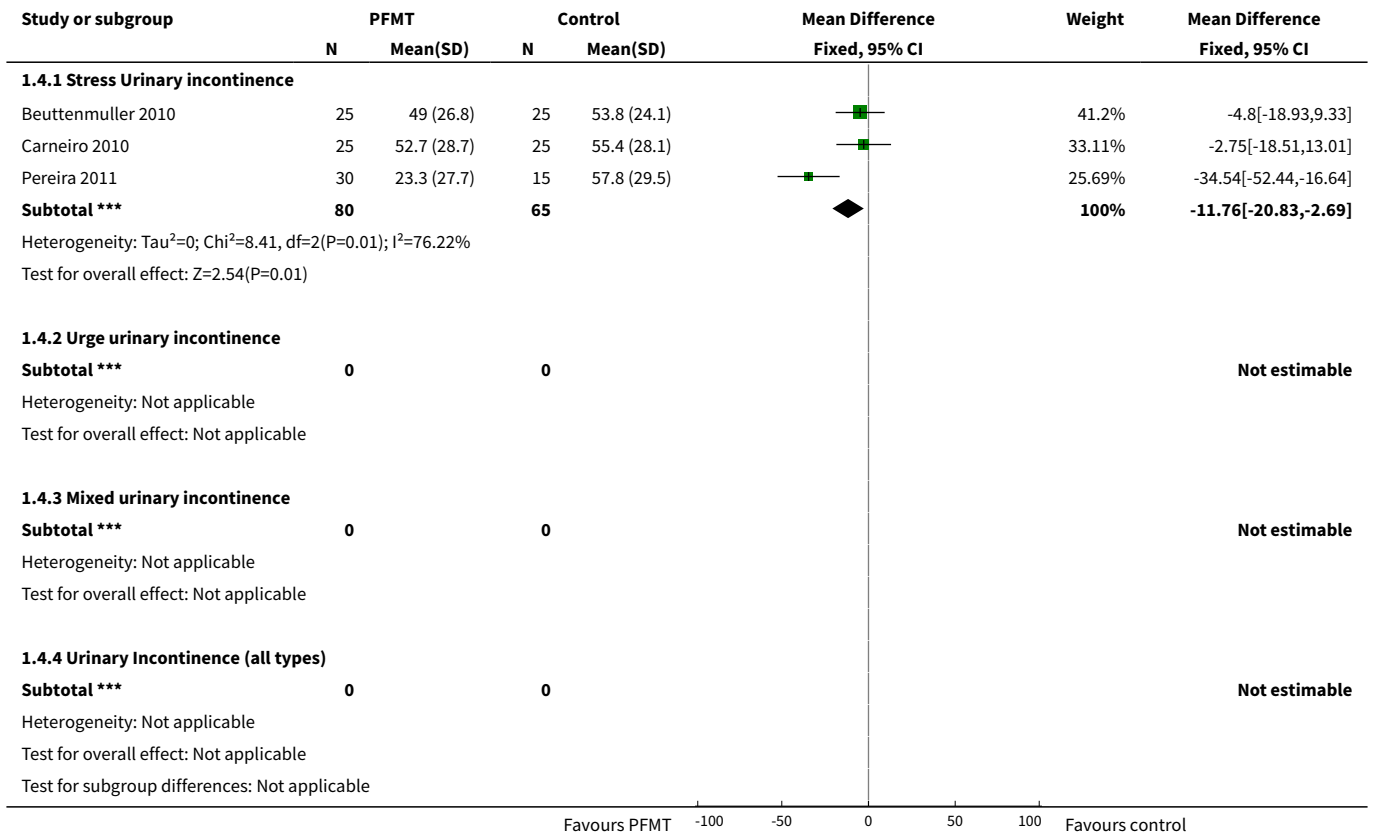




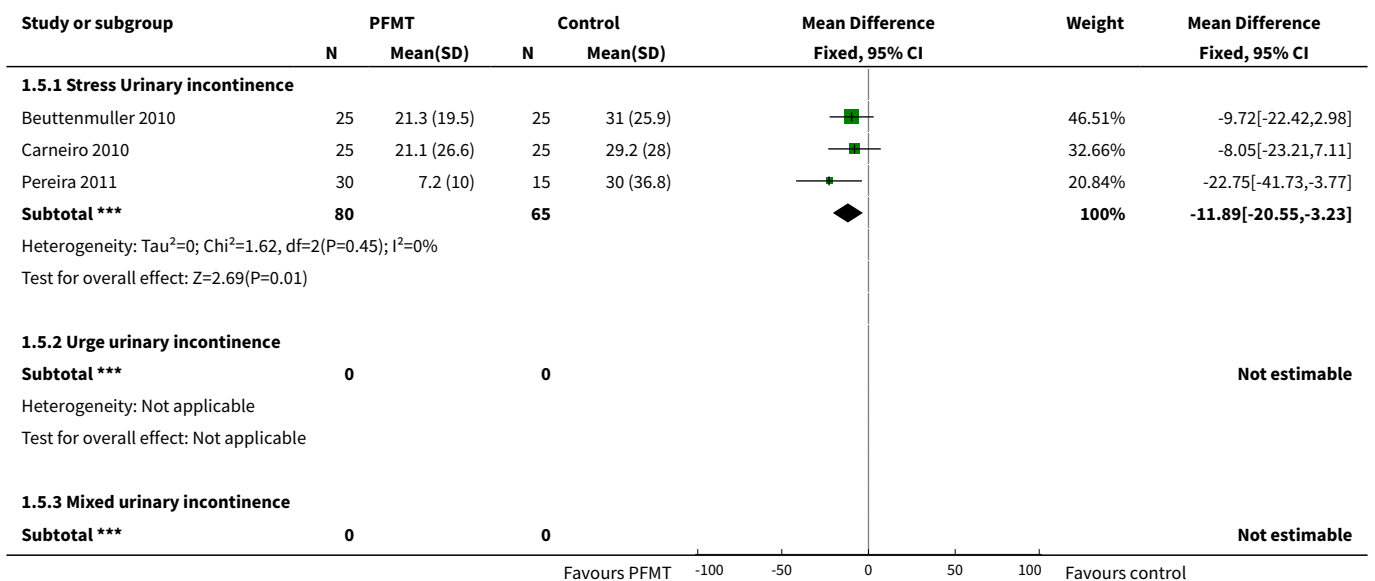
Analysis 1.3. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 3 Quality of life (King's Health Questionnaire/Severity measure after treatment).

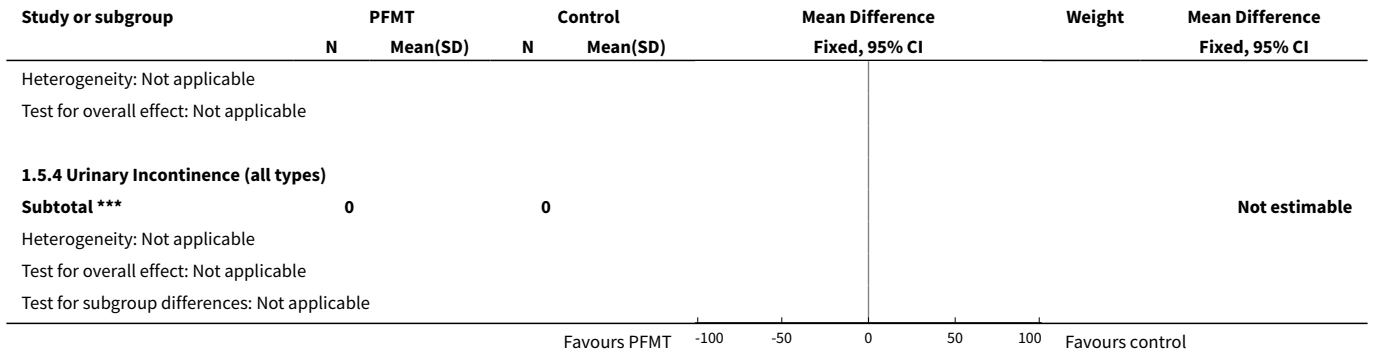


Analysis 1.4. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 4 Quality of life (King's Health Questionnaire/Incontinence impact after treatment).

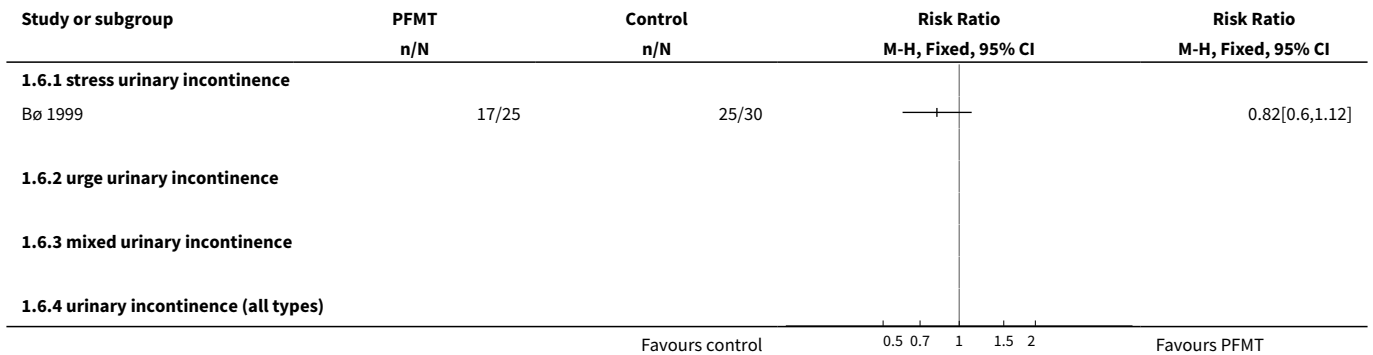


Analysis 1.5. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 5 Quality of life (King's Health Questionnaire/Physical limitation).

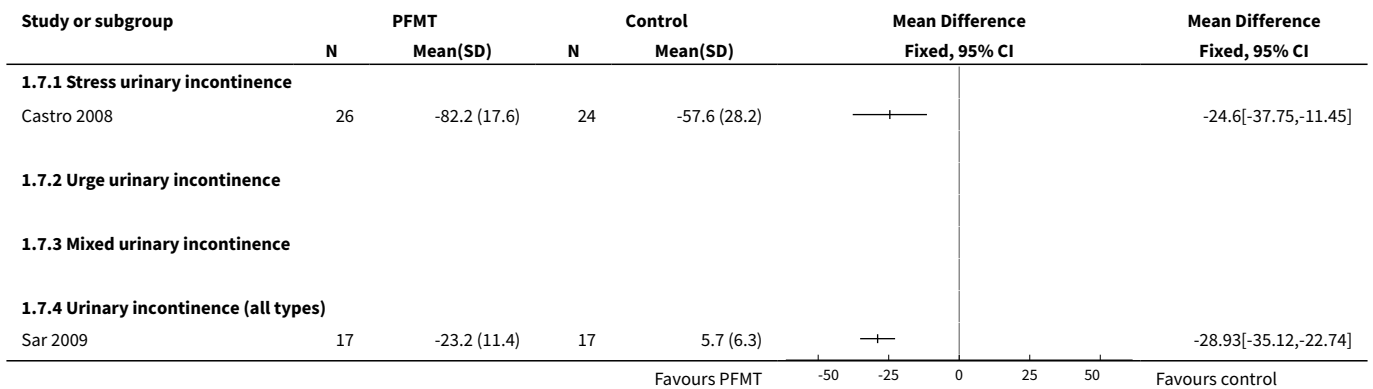




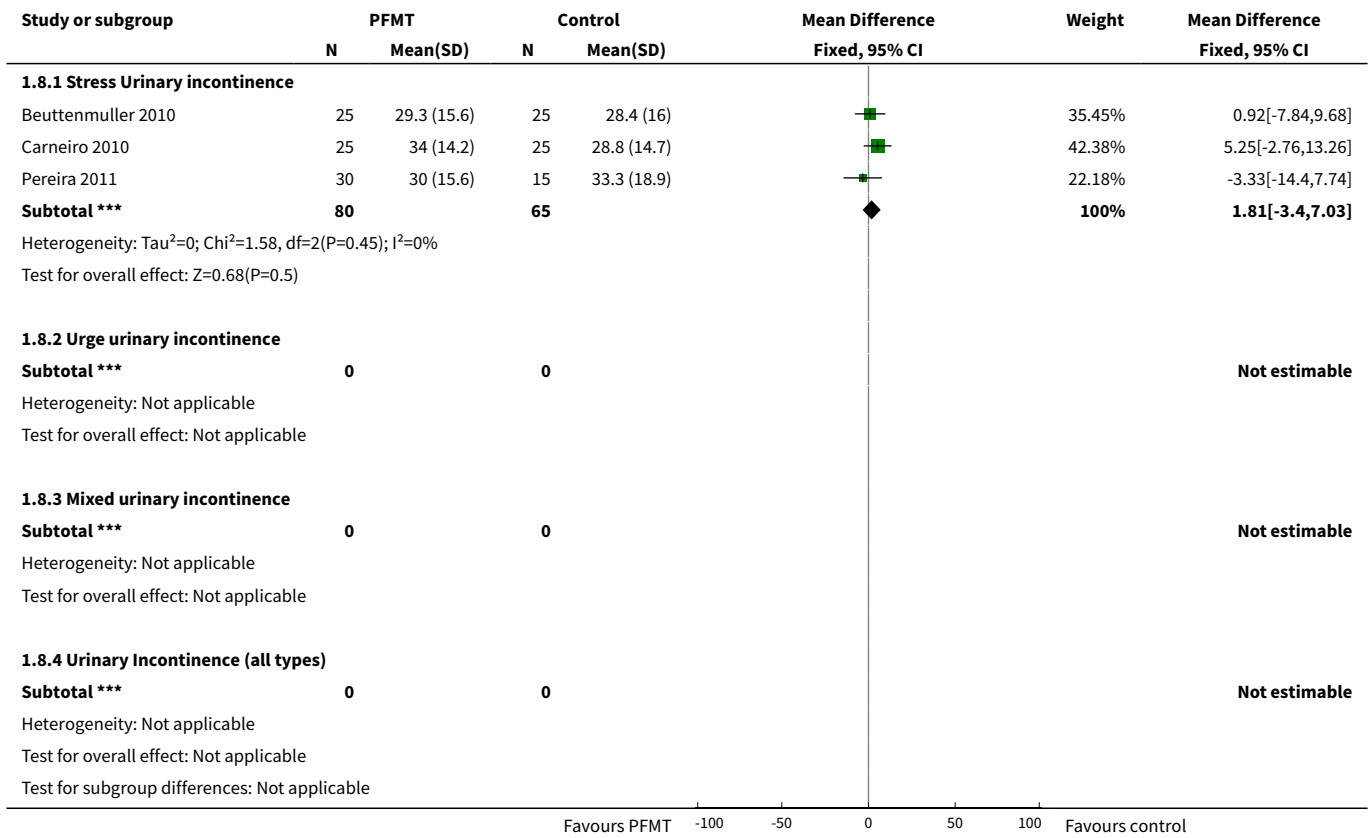
Analysis 1.6. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 6 Number of women with interference with life due to UI.



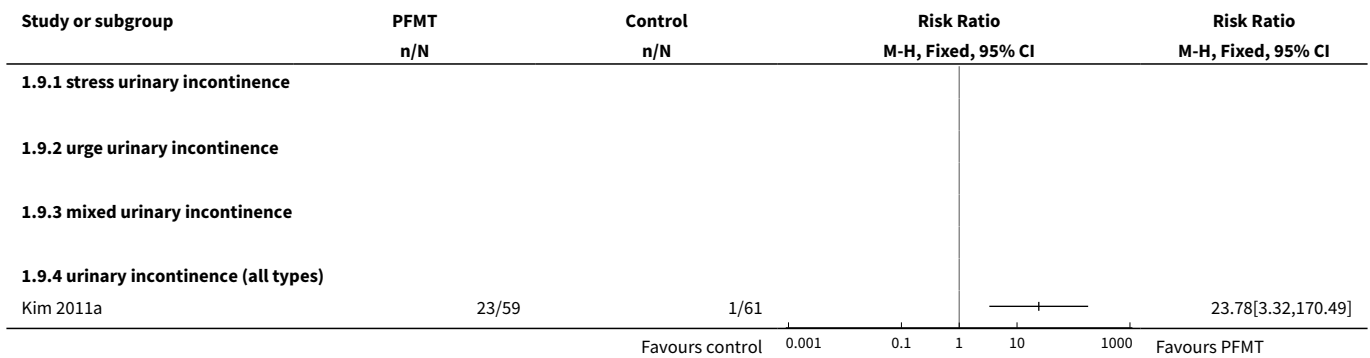
Analysis 1.7. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 7 I-QOL.



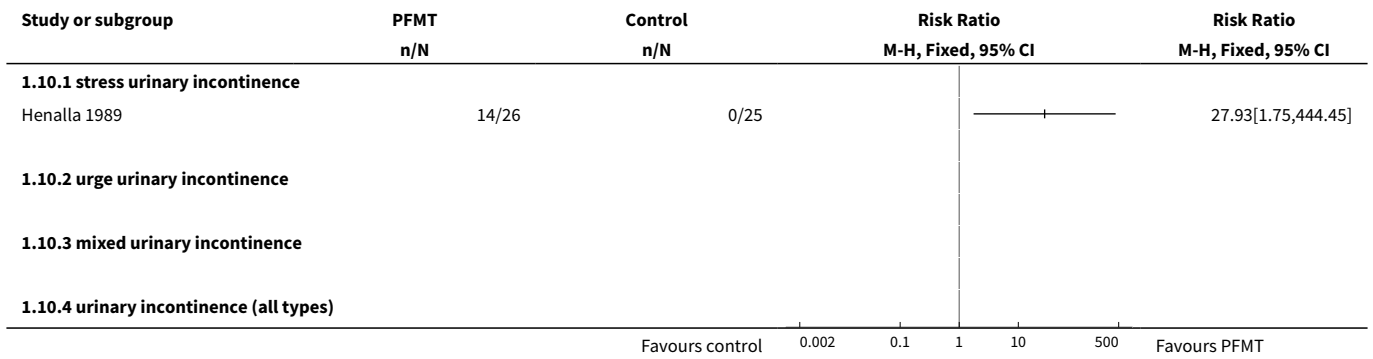
Analysis 1.8. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 8 Quality of life (King's Health Questionnaire/General health score).



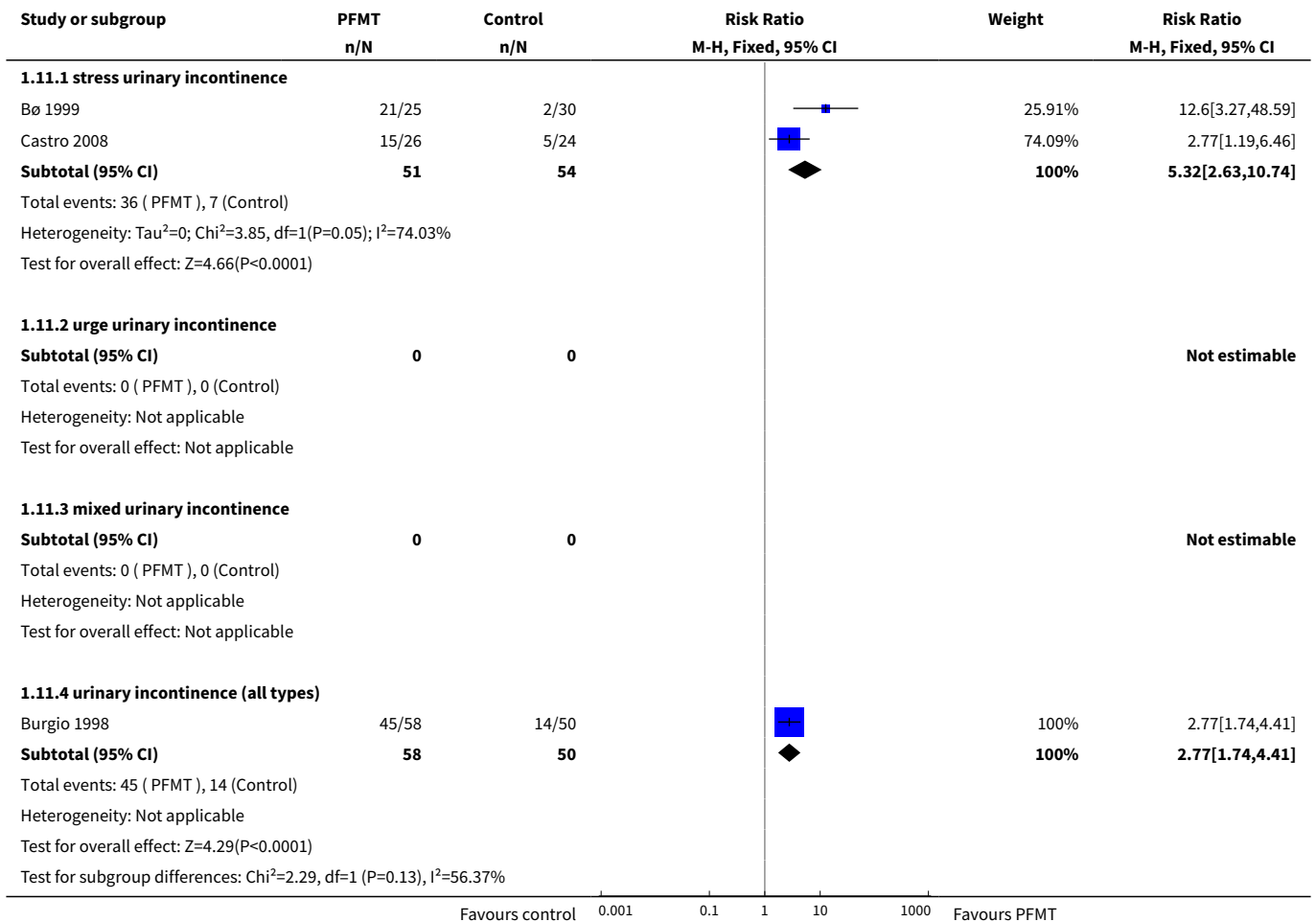
Analysis 1.9. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 9 Cure at up to one year.



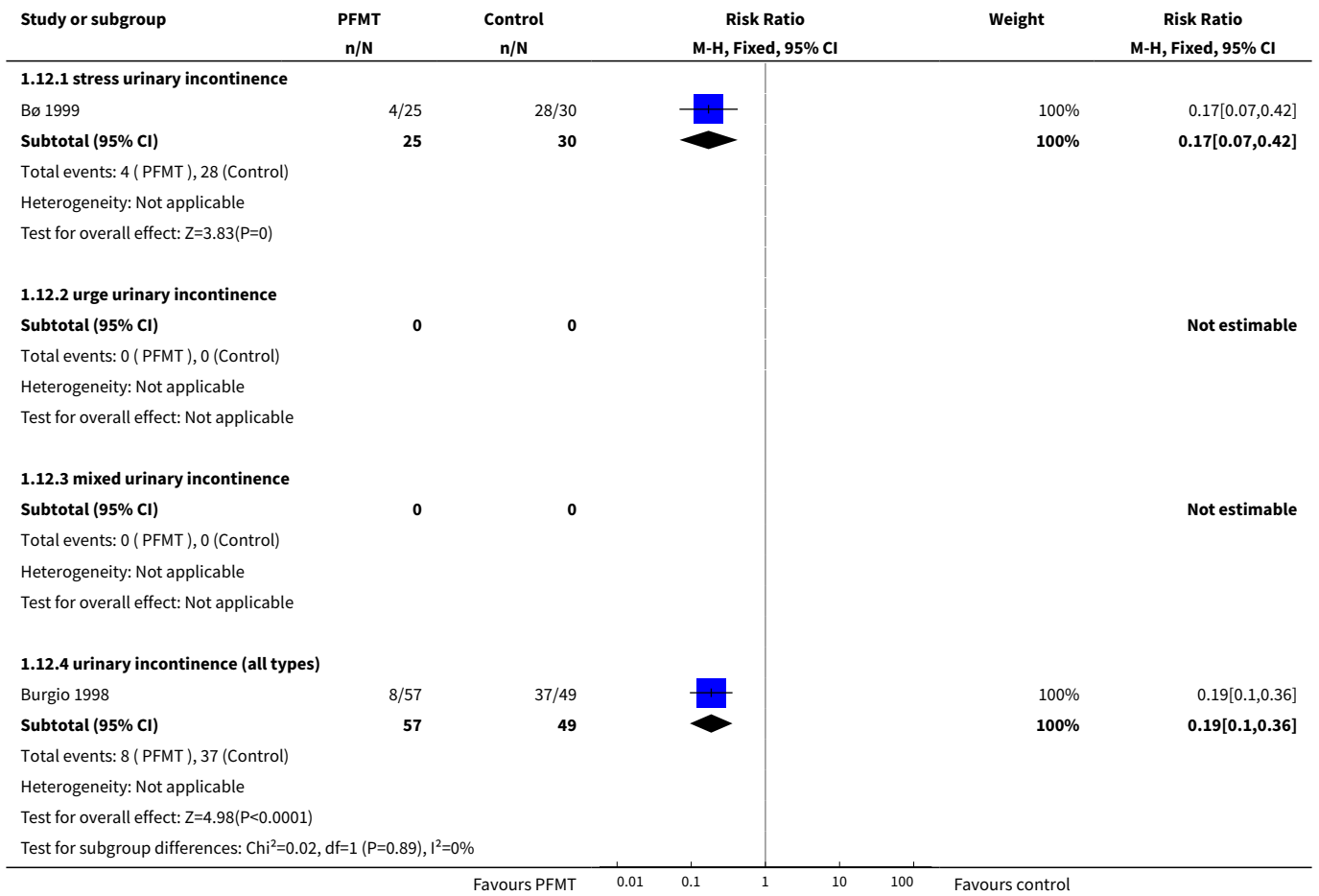
Analysis 1.10. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 10 Cure or improvement at up to one year.



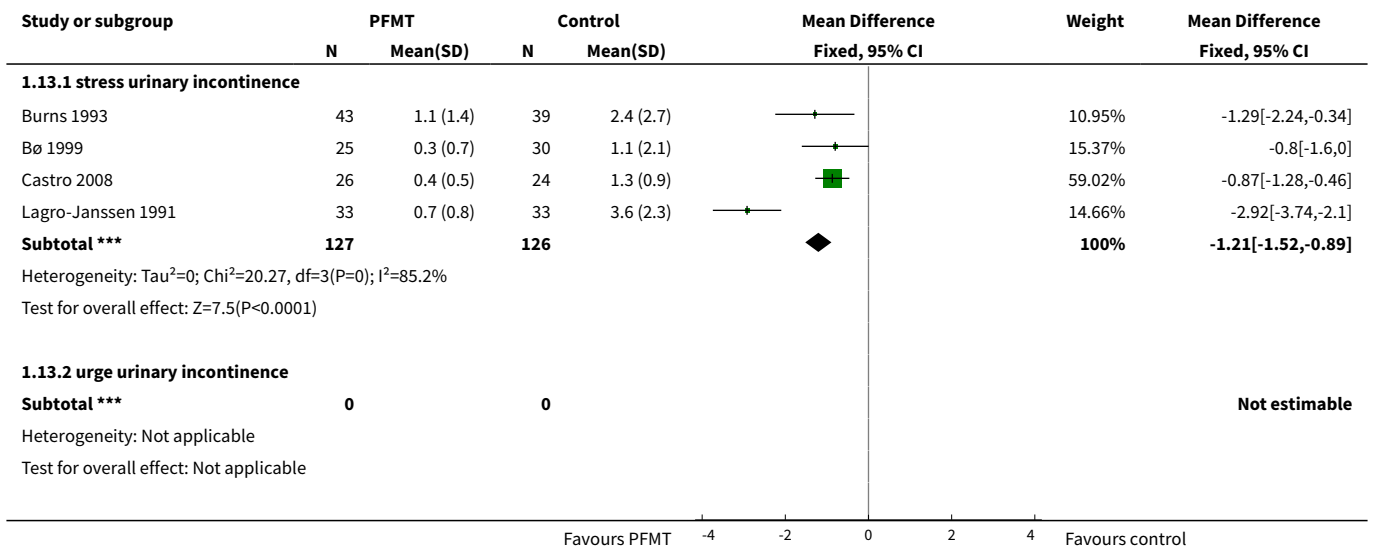
Analysis 1.11. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 11 Patient perceived satisfaction.

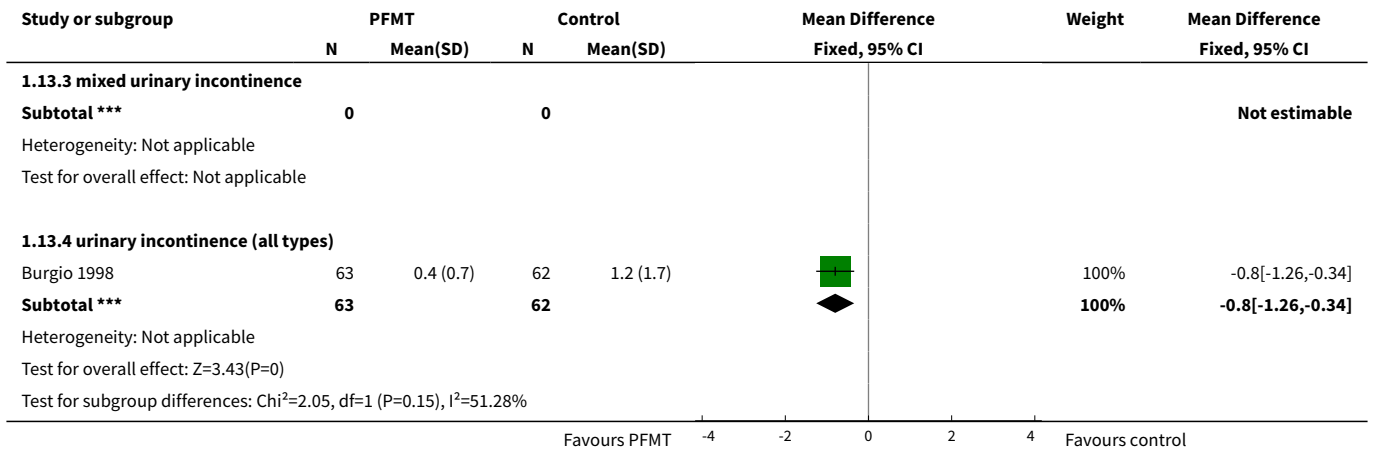


Analysis 1.12. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 12 Number of women needing further treatment.

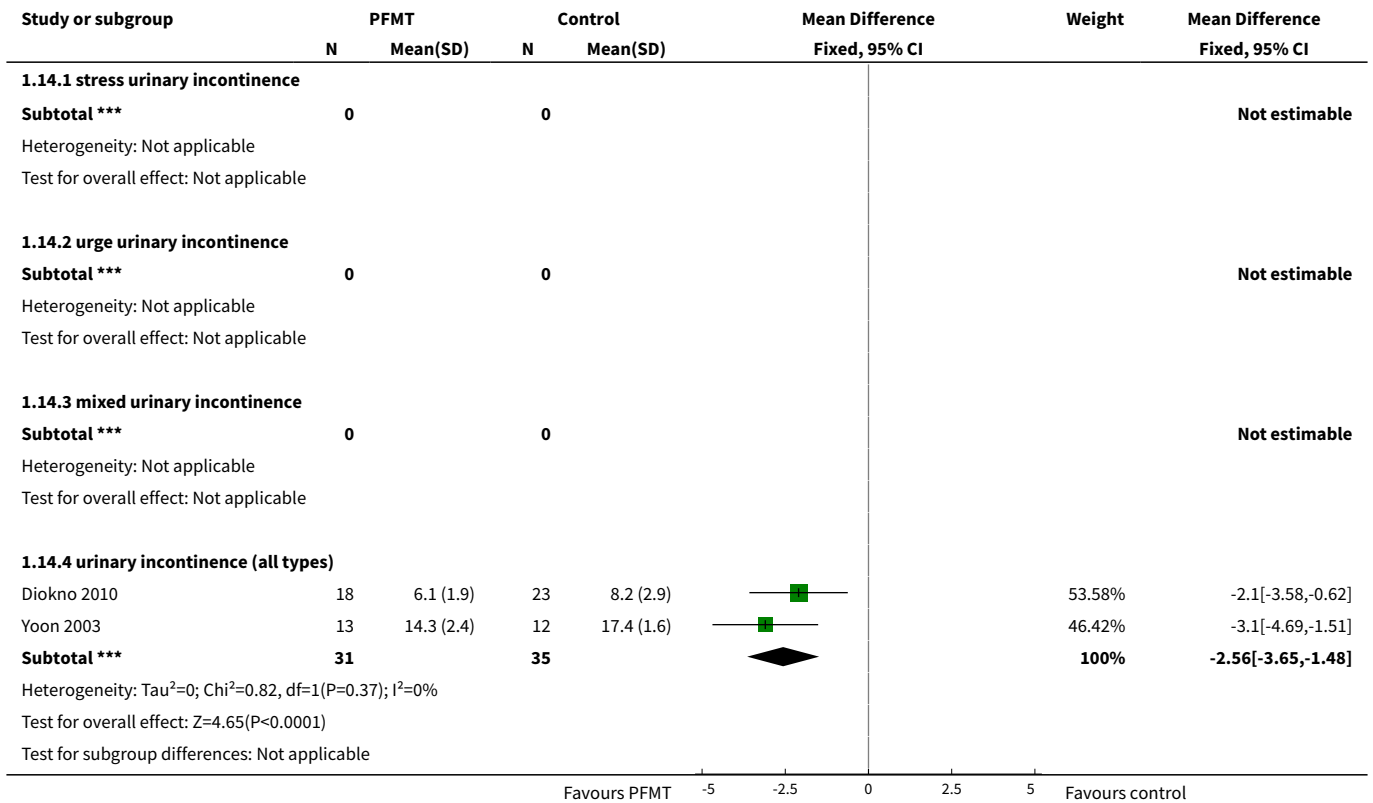


Analysis 1.13. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 13 Number of leakage episodes in 24 hours.

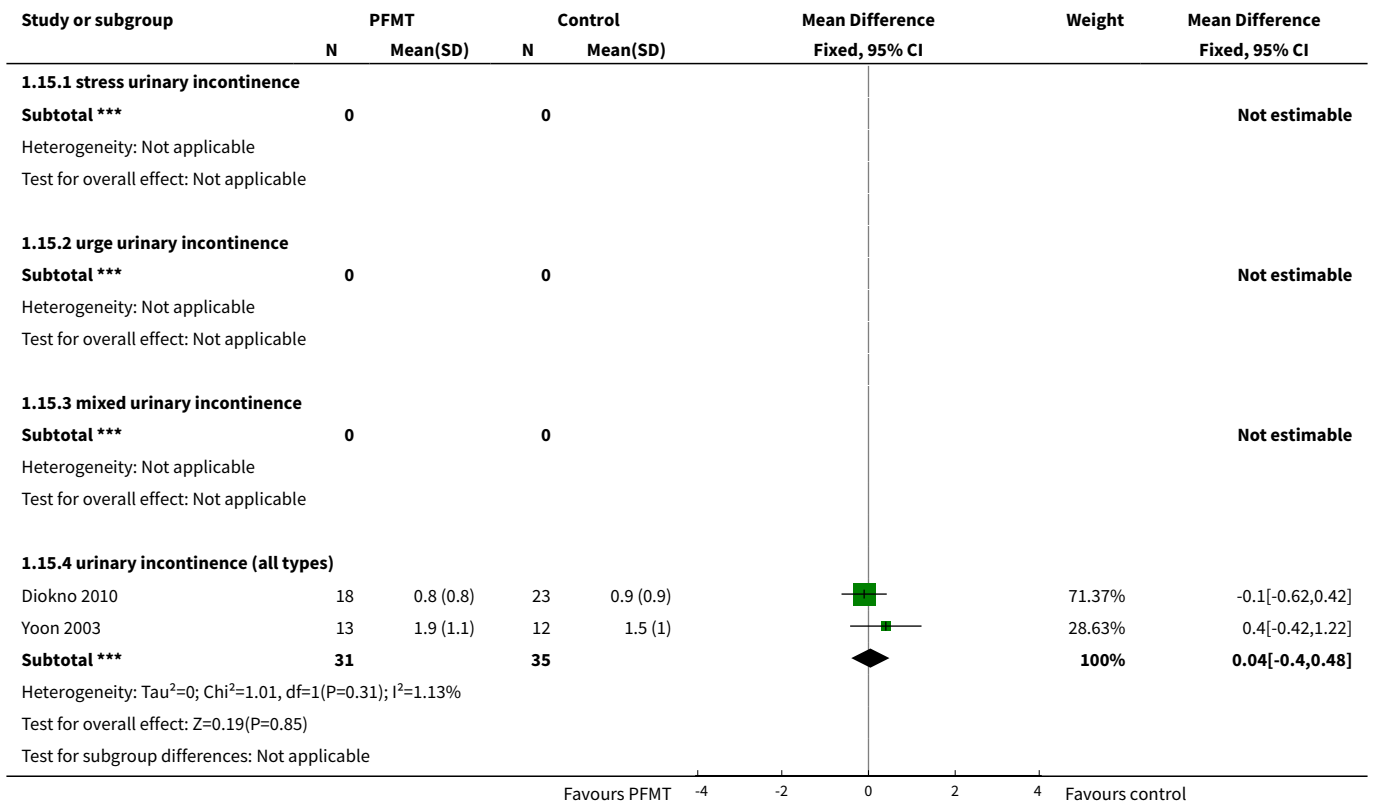




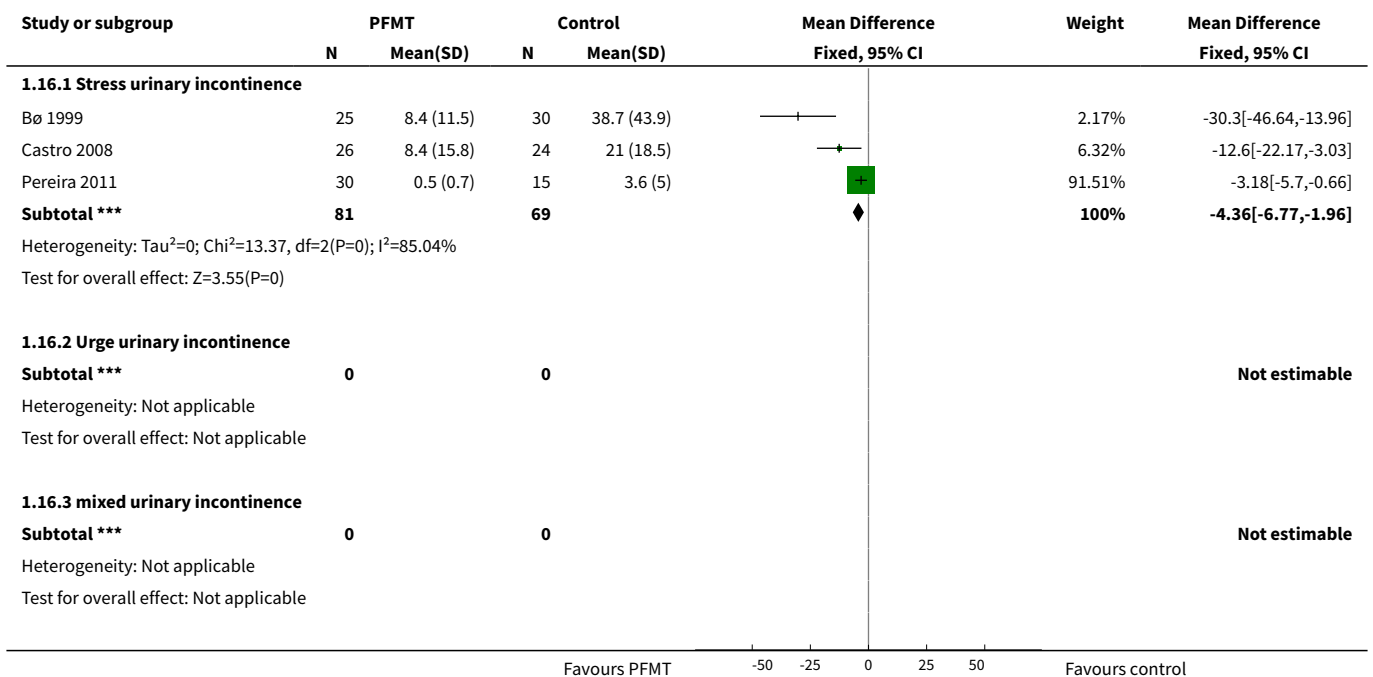
Analysis 1.14. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 14 Number of voids per day (frequency).

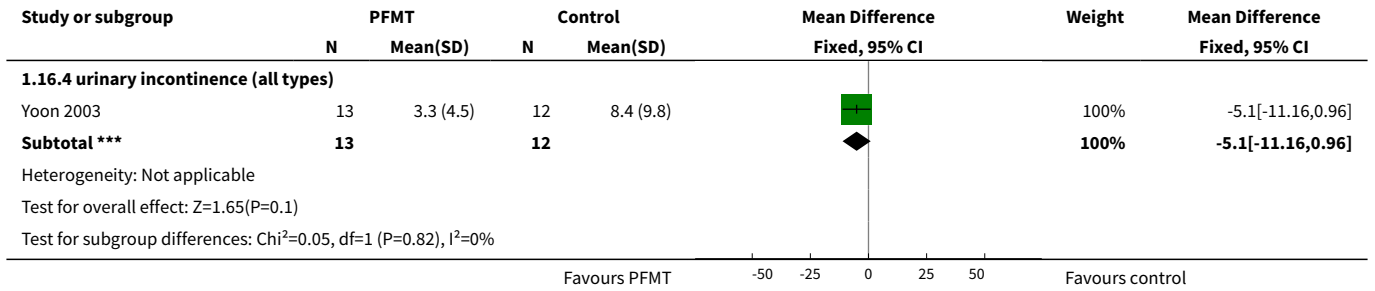


Analysis 1.15. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 15 Number of voids per night (nocturia).

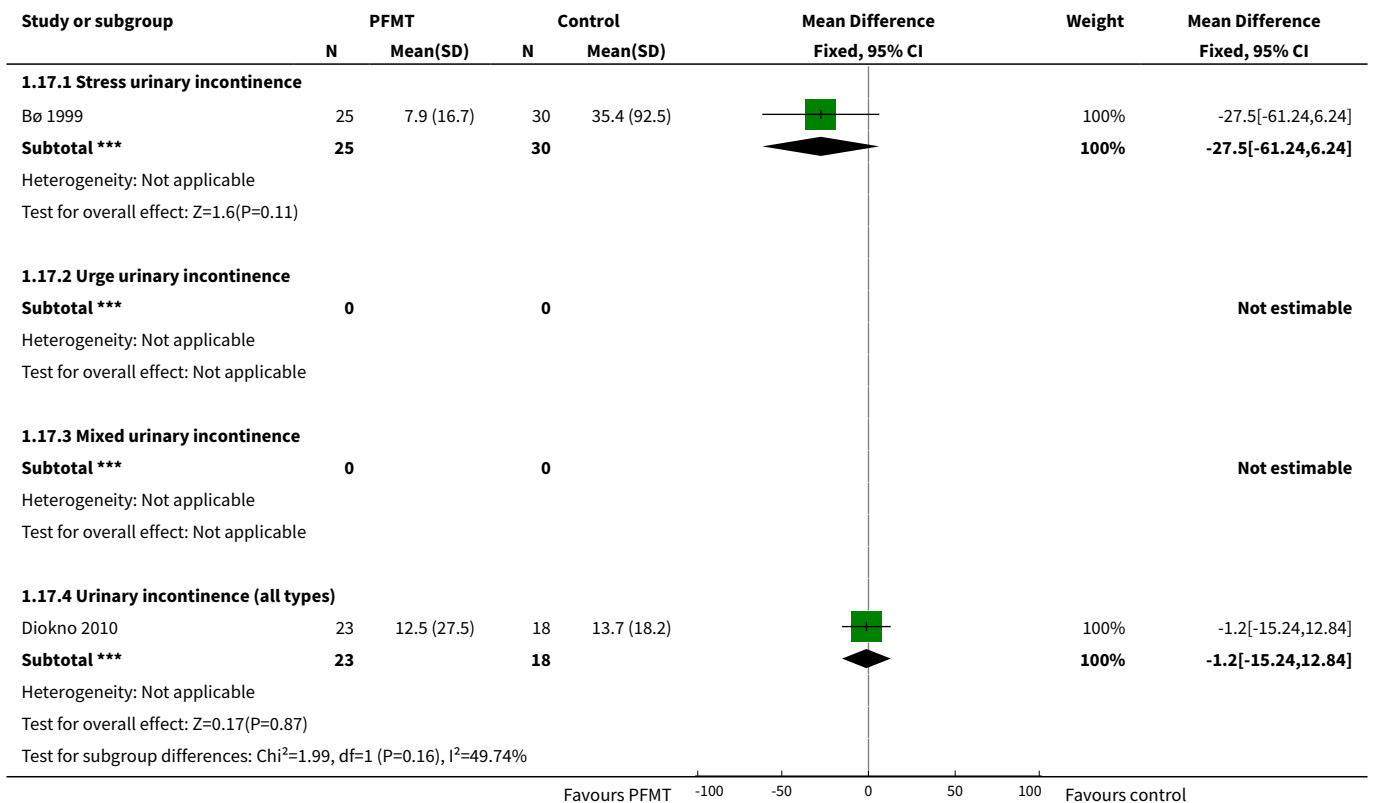


Analysis 1.16. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 16 Short (up to one hour) pad test measured as grams of urine.

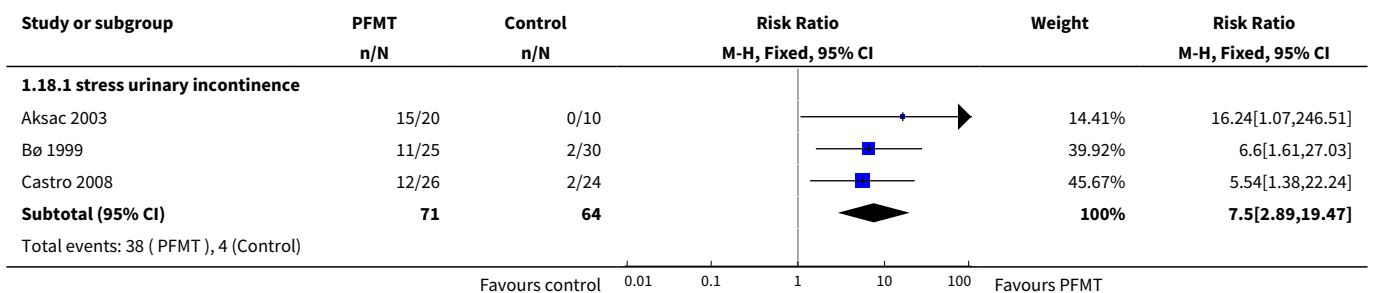


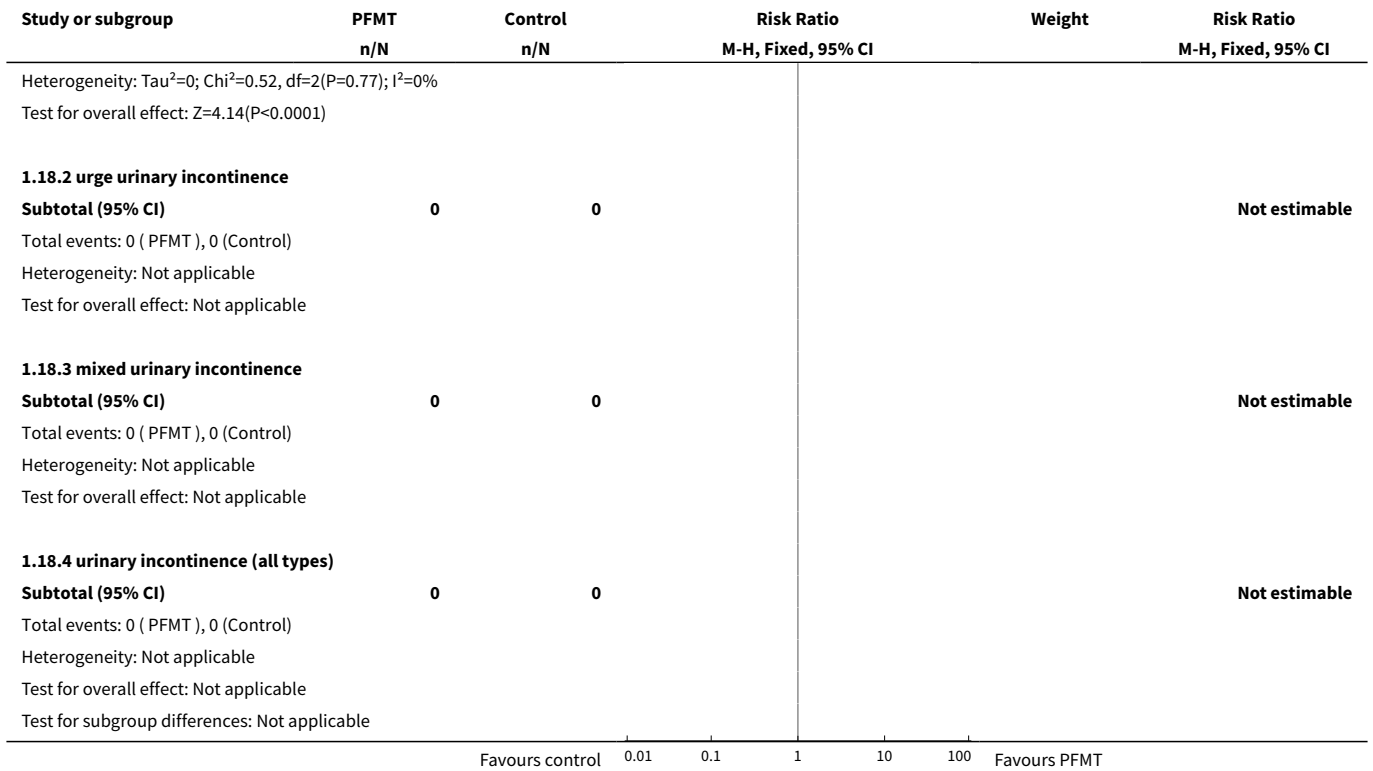


Analysis 1.17. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 17 24 hour pad test (grams).

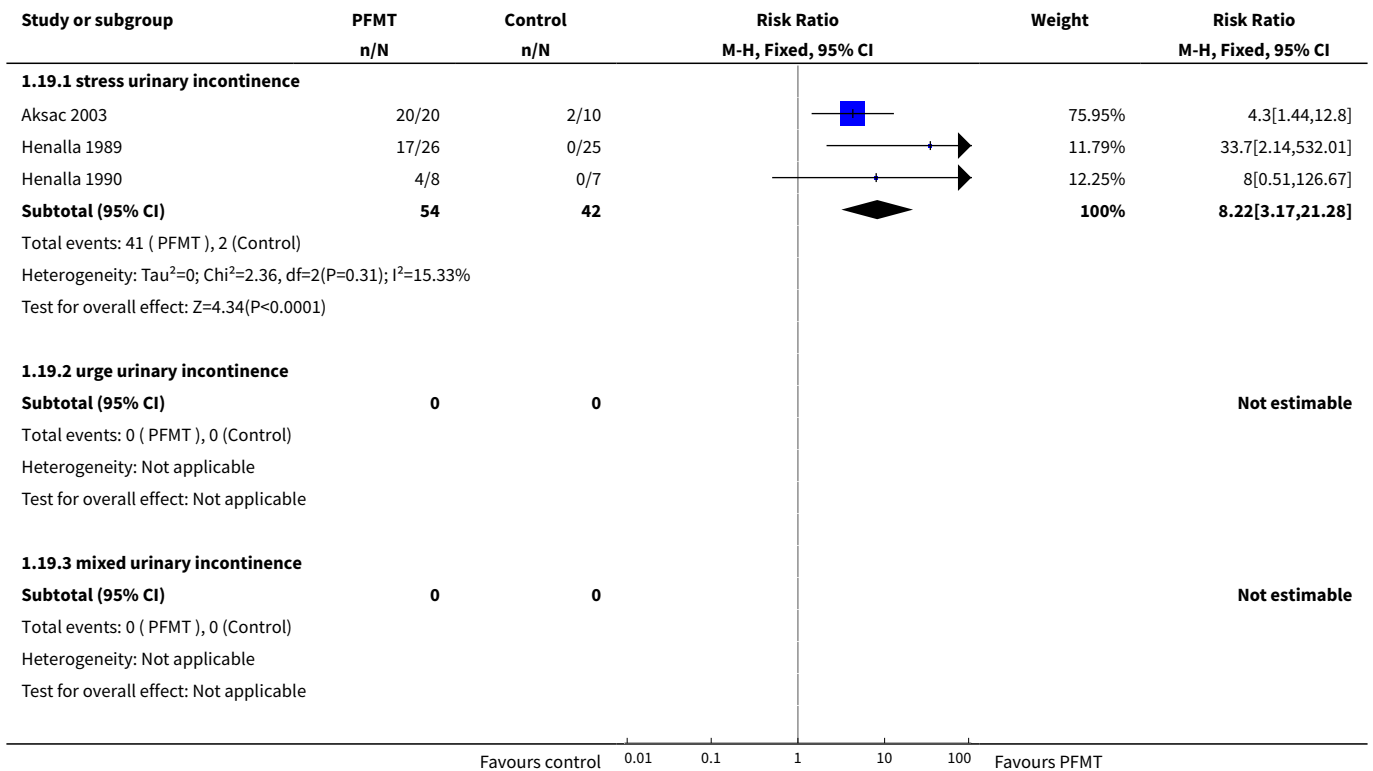


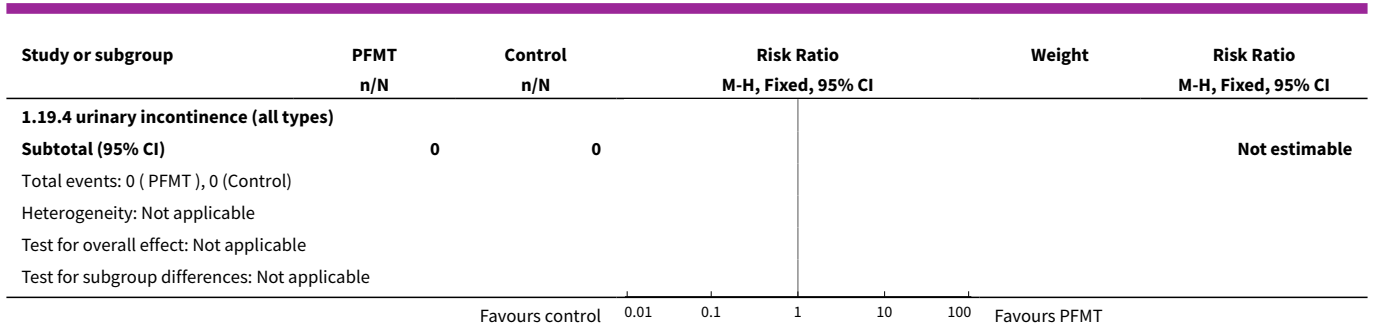
Analysis 1.18. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 18 Number cured on short pad test (objective) after treatment.



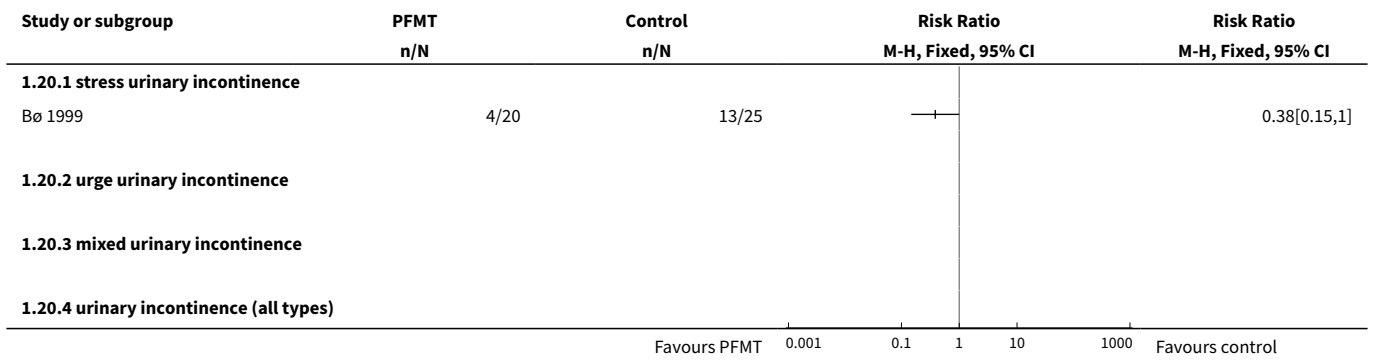


Analysis 1.19. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 19 Number cured or improved on short pad test (objective) after treatment.

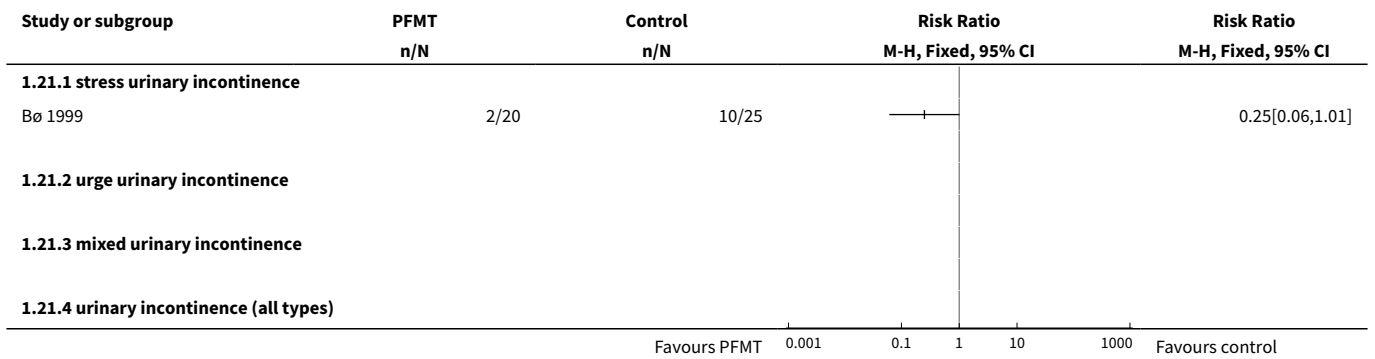




Analysis 1.20. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 20 Number of women with sex life spoilt by UI.



Analysis 1.21. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 21 Number of women with UI during intercourse.



APPENDICES

Appendix 1. PFMT protocol

Study ID	VPFMC taught/confirmed	Description	Total VPFMC per day	Duration of programme	Supervision
Aksac 2003	<p>Taught by: Therapist</p> <p>Confirmed by: Vaginal palpation, while keeping abdominal and buttock muscles relaxed</p>	<p>Number of VPFMC per set: 10</p> <hr/> <p>Duration of hold: 5 seconds</p> <hr/> <p>Duration of rest: 10 seconds</p> <hr/> <p>Number sets per day: 3</p> <hr/> <p>Body position(s): Not reported</p> <hr/> <p>Type(s) of contraction: Sustained</p> <hr/> <p>Other exercise(s): Contractions progressed at 2 weeks to 10 seconds hold and 20 seconds rest, home treatment</p> <hr/> <p>Adherence strategy(s): Not reported</p> <hr/> <p>Adherence measures: Not reported</p>	30	8 weeks	Weekly clinic visits
Beuttenmuller 2010	<p>Taught by: Physical therapist</p> <p>Confirmed by: Not reported, but assessed by the evaluator prior to treatment</p>	<p>Number of VPFMC per set: 8</p> <hr/> <p>Duration of hold: 5 seconds</p> <hr/> <p>Duration of rest: Not reported</p> <hr/> <p>Number sets per day: Not reported</p> <hr/> <p>Body position(s): Supine with knee bent, sitting on a chair or gym ball, on all fours, and standing</p> <hr/> <p>Type(s) of contraction: Submaximal, maximal/long and short contractions</p> <hr/> <p>Other exercise(s): Proprioceptive exercises such as sitting and hopping around a ball, movements that raise the pelvis (e.g., anteversion, retroversion, lateralisation and circumduction)</p> <hr/> <p>Adherence strategy(s) : Not reported</p> <hr/> <p>Adherence measures: Not reported</p>	Not reported	6 weeks	<p>20-minut twice-weekly clinic visits</p> <p>* Except during menstruation or due to other complications</p>
Bidmead 2002	<p>Taught by: Physical therapist</p> <p>Confirmed by: Not reported</p>	<p>Number of VPFMC per set: Not reported</p> <hr/> <p>Duration of hold: Not reported</p> <hr/> <p>Duration of rest: Not reported</p> <hr/> <p>Number sets per day: Not reported</p> <hr/> <p>Body position: Not reported</p>	Not reported	14 weeks	Five clinic visits over fourteen week period (weeks 1, 3, 6, 10 and 14)

(Continued)

Type(s) of contraction: Not reported

Other treatment(s): Not reported

Adherence strategy(s): None reported

Adherence measure: Treatment diary;

compliance with PFM exercises was generally good with three quarters of subject performing the exercises more than 3 times per week

Burgio 1998	Taught by: Nurse practitioner	Number of VPFMC per set: 15	45	8 weeks	4 clinic visits at 2-week intervals	
		Duration of hold: Based on each patient's ability and gradually increased across multiple sessions to a maximum of 10 seconds				
	Confirmed by: VPFMC confirmed with anorectal biofeedback while keeping abdominal muscles relaxed	Duration of rest: Based on each patient's ability				
		Number sets per day: 3				
		Body position(s) Supine, sitting, standing				
		Type(s) of contraction: Not reported				
		Other treatment(s): Knack and interrupting or slowing urine stream once per day				
		Adherence strategy(s): Not reported				
Adherence measures: Not reported						
Burns 1993	Taught by: Nurse trained in biofeedback techniques	Number of VPFMC per set: 10 (x 2 sets)	200	8 weeks	Weekly clinic visits	
		Duration of hold: 10 contractions held for 3 seconds and 10 contractions held for 10 seconds				
		Duration of rest: Not reported				
	Confirmed by: Biofeedback to teach the subject to relax and contract the pelvic muscles	Number sets per day: 4				
		Body position(s): Not reported				
		Type(s) of contraction: Sustained				
		Other treatment(s): Videotape describing exercise protocol for home exercises				
		Intervention progressed 10 per set to a daily maximum of 200				

(Continued)

Adherence strategy(s): Weekly and post treatment 3-and 6-month telephone reminder calls for the appointments; weekly home exercise reminder cards mailed between visits

Adherence measures: Not reported

Bø 1999	Taught by: Physical therapist	Number of VPFMC per set: 8-12 high-intensity (close to maximal) with 3-4 fast contractions added at the end of each hold	36	6 months	45-minute weekly exercise class
	Confirmed by: Vaginal palpation	Duration of hold: 6-8 seconds for the high intensity contractions			
		Duration of rest: 6 seconds			Monthly clinic visit with physical therapist
		Number sets per day: 3			
		Body position(s): Supine, kneeling, sitting, standing; all with legs apart. Subject used preferred position.			
		Type(s) of contraction: Sustained high-intensity contractions and quick contractions			
		Other treatment(s): Verbal information on the PFM and lower urinary tract anatomy and physiology and on continence mechanisms			
		Body awareness, breathing, relaxation exercises and strength training exercises for the back, abdominal and thigh muscles			
		Adherence strategy(s): Audiotape with verbal guidance for home training			
		Adherence measures: Training diary			
Carneiro 2010	Taught by: Physical therapist	Number of VPFMC per set: 8-12 (5 sets total)	50	8 weeks	30-minute, twice-weekly clinic visits
	Confirmed by: Vaginal palpation	Duration of hold: 6-10 seconds			
		Duration of rest: Not reported			
		Number sets per day: Once			
		Body position(s): Sitting, standing			
		Type(s) of contraction: Sustained			
		Other treatment(s): Verbal information about PFM function and visualization of pelvic floor components using anatomical figures			

(Continued)

5 minutes of proprioceptive exercises sitting on a 75-cm diameter therapeutic ball

Adherence strategy(s): Not reported

Adherence measures: Not reported

Castro 2008	Taught by: Physical therapist	Number of VPFMC and duration of hold and rest: - 5 contractions held 10 seconds with 10-second recovery -10 contractions held 5 seconds with 5-second recovery	60	6 months	3 group sessions per week
	Confirmed by: Vaginal palpation	-20 contractions held 2 seconds with 2-second recovery -20 contractions held 1 second with 1-second recovery -5 contractions with cough			
		Number sets per day: Once, 3 times per week			
		Body position(s): Not reported			
		Type(s) of contraction: Sustained and quick contractions			
		Other treatment(s): Verbal information on the PFM and lower urinary tract anatomy and physiology and on continence mechanisms			
		Warm-up exercises for the joints and stretching exercises targeting the hip, adductor, hamstring and paravertebral muscles			
		Adherence strategy(s): Not reported			
		Adherence measures:			
Diokno 2010	Taught by: Urology nurse	Number of VPFMC per set: 25 (5 short and 20 long contractions) and, when needed, the Knack (sneezing)	50	6-8 weeks	1 teaching session
	Confirmed by: Not reported	Duration of hold: Long contractions held up to 6 seconds Duration of rest: Not reported Number sets per day: 2 Body position(s): Not reported Type(s) of contraction: Short and long contractions			1 follow-up session after 2 to 4 weeks with a vaginal exam if needed and a written test on new knowledge acquired
		Other treatment(s): 2-hour Microsoft PowerPoint presentation, BMP lecture with printed handouts on the lower urinary tract anatomy, the mechanism of urinary bladder function, and UI			
		Bladder training tips, if needed			

(Continued)

		Knack, if needed			
		Audiotape for daily use			
		Adherence strategy(s): 2-4 week follow-up, including a vaginal examination if needed, measurement of pelvic floor muscle strength and an ability test			
		Adherence measures: Not reported			
Henalla 1989	Taught by: Physical therapist	Number of VPFMC per set: 5	~80	12 weeks	Weekly clinic visit
		Duration of hold: 5 seconds			
		Duration of rest: Not reported			
	Confirmed by: Vaginal palpation	Number sets per day: 1 set per hour during the day			
		Body position(s): Not reported			
		Type(s) of contraction: Not reported			
		Other treatment(s): Not reported			
		Adherence strategy(s): Not reported			
		Adherence measure: Not reported			
Henalla 1990	Taught by: Physical therapist	Number of VPFMC per set: Not reported	Not reported	6 weeks	Not reported
		Duration of hold: Not reported			
		Duration of rest: Not reported			
	Confirmed by: Not reported	Number sets per day: Not reported			
		Body position(s): Not reported			
		Type(s) of contraction: Not reported			
		Other treatment(s): Not reported			
		Adherence strategy(s): Not reported			
		Adherence measures: Not reported			
Hofbauer 1990	Taught by: Physical therapist	Number of VPFMC per set: Not reported	??	6 months	20-minute twice-weekly clinic visits
		Duration of hold: Not reported			
		Duration of rest: Not reported			
	Confirmed by: Not reported	Number sets per day: Not reported			
		Body position(s): Not reported			
		Type(s) of contraction: Not reported			

(Continued)

		Other treatment(s): Abdominal wall and adductor exercises and home training			
		Adherence strategy(s): Not reported			
		Adherence measures: Not reported			
Kim 2007	Taught by: Nurse	During the 12 weeks intervention: Number of VPFMC per set: 10 (x 2 sets)	~30	12 weeks	Exercise class, twice a week
	Confirmed by: Subjects were trained to exert force only on the PFM but did not give detail on how it was done	Duration of hold: 10 contractions held 3 seconds and 10 additional contractions held 6-8 seconds			
		Duration of rest: 10 seconds			
		Number sets per day: twice per week			
		Body position(s): Sitting, Supine and standing positions with the legs apart			
		Type(s) of contraction: Fast and sustained contractions			
		Other treatment(s): Body awareness, breathing, and relaxation exercises. Strength training for the thigh, abdominal, and back muscles (ie: bending the knees, tilting the pelvis backward and forward, lifting the buttocks on the back with the knees bent, raising one leg while lying on the back)			
		Exercises using two types of training balls			
		Adherence strategy(s): Home training reinforced through a pamphlet illustrating PFM and strengthening exercises and a record-keeping sheet			
		Adherence measures: Measured adherence to exercise treatment			
		During one-year follow up: Number of VPFMC per set: 13			
	Sets per day: 2 to 3 sets at least twice a week				
Kim 2011	Taught by: Nurse	Number of VPFMC per set: 10 fast and 10 sustained contractions	60	12 weeks	1-hour, twice-weekly group sessions
	Confirmed by: Subjects were trained to exert force on just the PFMs, but details on how this was done were lacking	Duration of hold: 3 seconds for fast contractions, 6 to 8 seconds for sustained contractions			
		Duration of rest: 5 seconds for fast contractions, 10 seconds for sustained contractions			
		Number sets per day: 3			
		Body position(s): PFM contractions, without excessively straining the abdomen, performed in supine, sitting, and standing positions with legs apart			

(Continued)

		Type(s) of contraction: Fast and sustained contractions			
		Other treatment(s): Warm-up and stretching exercises 10 to 15 minutes. Thigh and abdominal muscle strength training exercises between PFM trainings, and weight bearing and ball exercises			
		Home exercises 2 to 3 sets (PFM +13 other exercises) at least 3 times a week (duration: approximately 30 minutes)			
		Adherence strategy(s): Not reported			
		Adherence measures: Not reported			
Kim 2011a	Taught by: Nurse	Number of VPFMC per set: 10 fast and 10 sustained contractions	60	12 weeks	1-hour, twice-weekly group sessions
	Confirmed by: Subjects were trained to exert force on just the PFMs, but details on how this was done were lacking	Duration of hold: 3 seconds for fast contractions, 6 to 8 seconds for sustained contractions			
		Duration of rest: 5 seconds for fast contractions, 10 seconds for sustained contractions			
		Number sets per day: 3			
		Body position(s): PFM contraction without excessively straining the abdomen, performed in supine, sitting, and standing positions with legs apart			
		Type(s) of contraction: Fast and sustained contractions			
		Other treatment (s): Warm-up and stretching exercise for 10 to 15 minutes. Strength training of the thigh and abdominal muscles, back, legs, trunk and use of an exercise ball.			
		Adherence strategy(s): ??			
		Adherence measures: Training diary			
		Follow-up:			
		After the 12 weeks intervention, participants attended a 1-hour exercise classes once a month for 7 months and continued a home-based program (2-3 sets of PFM plus 13 other exercises taught during the intervention)			
La-gro-Janssen 1991	Taught by: General practitioner	Number of VPFMC per set: 10	50 to 100	12 weeks	No supervision, the participants received written instructions for home practice
	Confirmed by: Vaginal palpation	Duration of hold: 6 seconds			
		Duration of rest: Not reported			
		Number sets per day: 5 to 10			
		Body position(s): Not reported			

(Continued)

		Type(s) of contraction: Not reported			
		Other treatment(s): Verbal information on PFM			
		Adherence strategy(s): Not reported			
		Adherence measures: Patient were asked how many exercises per day they completed and how well they complied with the exercise programme:			
Miller 1998	Taught by: Nurse	Number of VPFMC per set: Not reported	Not reported	One week	No supervision
		Duration of hold: Not reported			
	Confirmed by: Vaginal palpation	Duration of rest: Not reported			
		Number sets per day: Not reported			
		Body position(s): Not reported			
		Type(s) of contraction: Coordination			
		Other treatment(s):			
		Verbal information on PFM physiology and functional properties			
		Participants were taught to practice the Knack			
		Adherence strategy(s): Not reported			
		Adherence measures: Not reported			
Pereira 2011	Taught by: Physical therapist	For Group and individual PFMT intervention	100	6 weeks	Two 1-hour weekly sessions in clinic
		Number of VPFMC per set: on average, 100 contractions were performed,			
	Confirmed by: Vaginal palpation and instructed not to use compensatory muscles	Duration of hold: 5-10 seconds			
		Duration of rest: 10-20 seconds			
		Number sets per day: Not reported			
		Body position(s): Supine, sitting and standing positions			
		Type(s) of contraction: Phasic and tonic contractions			
		Other treatment(s): Verbal information on the PFM anatomy and continence mechanisms. The degree of difficulty progressed according to the positions adopted, the number of repetitions, and the time of sustained contractions			
		Adherence strategy(s): Not reported			
		Adherence measures: Not reported			

(Continued)

Sar 2009	Taught by: Nurse	Number of VPFMC per set: 30	90	6 weeks	Weekly telephone call by the nurse
		Duration of hold: 1-10 seconds			
	Confirmed by: Vaginal palpation	Duration of rest: Same as contraction time			
		Number sets per day: 3			
		Body position(s): Supine, sitting and standing			
		Type(s) of contraction: quick flicks (1-2 second contractions), sustained progressive (5-10 seconds) contractions			
		Other treatment(s): Verbal information on the PFM and lower urinary tract anatomy and physiology and on continence mechanisms			
		Knack			
		Adherence strategy(s): Weekly telephone call to encourage exercises practice and answer questions			
		Adherence measures: Not reported			
Wells 1999	Taught by: Nurse practitioner	Number of VPFMC per set: 80	80	5 months	Monthly visits for observation, coaching and encouragement
		Duration of hold: 10 seconds			
		Duration of rest: 10 seconds			
	Confirmed by: Able to contract PFM was confirmed through a physical examination	Number sets per day: 1 set during the day			
		Body position(s): Not reported			
		Type(s) of contraction: Sustained			
		Other treatment(s): Not reported			
		Adherence strategy(s): Training diary			
		Adherence measures: Not reported			
Yoon 2003	Taught by: Nurse	Number of VPFMC per set: 30 strength and endurance VPFMC per day (unclear if this is 30 for both combined or 30 per type of exercise; i.e., 60), approximately 15 to 20 minutes per day	Not clear if 30 or 60	8 weeks	Weekly clinic visit with nurse
		Duration of hold:			
	Confirmed by: Weekly surface electromyography biofeedback	Strength: Burst of intense activity lasting a few seconds.			
		Endurance: 6-second hold progressed by 1-second per week to 12 seconds.			
	Duration of rest: Not reported				

(Continued)

Number sets per day: Not reported

Body position(s): Not reported

Type(s) of contraction: Strength and endurance

Other treatment(s): Not reported

Adherence strategy(s): Not reported

Adherence measures: Not reported

* Voluntary pelvic floor muscle contraction (VPFMC)

Appendix 2. Other UI specific quality of life outcomes

Study ID	Outcome	Measure	Subscale	PFMT	Control	Difference
Bø 1999	Bristol Female Lower Urinary Tract Symptoms (BFLUTS) Questionnaire For analysis, positive findings ('a little', 'somewhat' and 'a lot', or 'a bit of a problem', 'quite a problem' and 'a serious problem') were regrouped and reported as frequencies. Only the lifestyle (28-31, 33) and sex-life questions (21-24) were reported.	Number and %	Avoiding places and situations	n=25 7	n=30 10	RR 0.84, 95% CI (0.37 to 1.88)
			Interference with social life	n=25 1	n=30 12	RR 0.10, 95% CI (0.01 to 0.72)
			Interference with physical activity	n=25 11	n=30 24	RR 0.55, 95% CI (0.34 to 0.89)
			Overall interference with life	n=25 14	n=30 25	RR 0.67, 95% CI (0.46 to 0.99)
			Unsatisfied if had to spend rest of life as now	n=25 10	n=30 11	RR 0.11, 95% CI (0.02 to 0.79)
			Sex-life spoiled by urinary symptoms	n=20 3	n=25 13	RR 0.29, 95% CI (0.10 to 0.87)
			Problem with sex-life being spoiled	n=20 2	n=25 13	RR 0.19, 95% CI (0.05 to 0.76)
			Problem with painful intercourse	n=20 2	n=25 10	RR 0.25, 95% CI (0.06 to 1.01)
			Urinary incontinence with intercourse	n=20 2	n=25 10	RR 0.25, 95% CI (0.06 to 1.01)

(Continued)

	Social Activity Index	Mean score (SD)	NA	n=25 9.3 (1.0)	n=30 7.9 (2.2)	MD 1.4, 95% CI (0.4 to 2.4)
	Provides a summation of scores for a visual analogue scale for perception of difficulty participating in 9 specified social situations. A lower score indicates problem is perceived to be greater.					
Diokno 2010	Sandvik's Severity Index for Female Urinary Incontinence (3-point scale)	Number and %		n=23	n=18	
	<p>Questions assess the degree of UI: Frequency: 1. How often do you experience urinary leakage? Scale: 1 = less than once a month, 2 = a few times a month, 3 = a few times a week, 4 = every day and/or night.</p> <p>Quantity: 2. How much urine do you lose each time? Scale: 1 = drops, 2 = small splashes, and 3 = more. Note: on the 3-level severity index, responses to this question are aggregated into drops (1) or more (2).</p> <p>The Severity Index is created by multiplying the result of questions 1 (quantity) and 2 (frequency), resulting in the following index values whereby 1-2 = slight, 3-4 = moderate, and 6-8 = severe</p>					
		Slight		13 (56.5%)	5 (22.2%)	RR 2.03, 95% CI (0.89 to 4.65)
		Moderate		5 (21.7%)	7 (38.9%)	RR 0.78, 95% CI (0.27 to 2.29)
				5 (21.7%)	7 (38.9%)	RR 0.78, 95% CI (0.27 to 2.29)
Kim 2011a	Urine leakage score	Mean score (SD)	N.A	n = 59 3.0 (2.0)	n = 61 4.4 (1.6)	MD -1.4, 95% CI (-2.1 to -0.8)
	This is calculated based on the self-reported 1-week urinary diary (score of 0-4; with 0 = no urine leakage, 1 = less than once a week, 2 = once a week, 3 = two or three times a week, and 4 = every day)					

NA = Not Applicable

Appendix 3. Other leakage outcomes

Study ID	Outcome	Measure	PFMT	Control	Difference
Bø 1999	Leakage Index	Mean (SD)	n=25 1.9 (0.5)	n=30 3.1 (0.6)	MD -1.2, 95% CI (-1.5 to -0.9)
	*Perceived frequency of leakage with 7 prespecified types of exertion. Higher score indicates more perceived leakage.				

(Continued)

Yoon 2003	Urinary incontinence score	Mean (SD)	n=13	n=12	MD -3.4, 95% CI (-7.6 to 0.8)
	*Sum of scores from 5-point Likert scales regarding severity of leakage with 18 prespecified activities.		10.8 (6.2)	14.2 (3.6)	

Appendix 4. Other pad or paper towel test

Study ID	Outcome	Measure	PFMT	Control	Difference
Aksac 2003	One-hour pad test (g)	Median (SD)	n=20 2.1 (0.4)	n=20 28.2 (3.7)	Not estimable
Bidmead 2002	Short pad test, weight change from baseline (g)	Mean (SD)	n=40 -9.62 (3.37)	n=20 3.65 (1.17)	MD -13.3, 95% CI (-23.1 to -3.4)
Diokno 2010	Cough test (cm)	Mean (SD)	n=23 12.6 (41.6)	n=18 19.6 (48.8)	MD 25.30, 95% CI (-2.9 to 53.5)
Miller 1998	Paper towel test, wet area (cm ²)	Mean (SD) on medium cough	n=13 0.4 (1.04)	n=10 21.2 (44.8)	MD -20.8, 95% CI (-46.5 to 4.9)
		Mean (SD) on deep cough	n=13 5.4 (15.3)	n=10 26.8 (46.7)	MD -21.4, 95% CI (-50.0 to 7.2)

Appendix 5. Other non-specific quality of life outcomes

Study ID	Outcome	Measure	Subscale	PFMT	Control	Difference
Burgio 1998	Hopkins Symptom Checklist for psychological distress (SCL-90-R) * A 90-item self-administered questionnaire with nine clinical subscales aggregated into a total score: the Global Severity Index. A score of 50 is normal. A score of more than 63 is a 'case' on any of the subscales.	Mean score (SD)	All	n=57	n=46	
			Somatization	51.8 (11.4)	49.8 (13.0)	MD 2.0, 95% CI (-2.8 to 6.8)
			Obsessive compulsive	53.8 (13.9)	55.4 (11.0)	MD -1.6, 95% CI (-5.7 to 2.5)
			Interpersonal sensitivity	49.5 (12.0)	49.2 (11.3)	MD 0.3, 95% CI (-4.3 to 4.9)

(Continued)

Depression	51.5 (11.5)	51.4 (11.2)	MD 0.1, 95% CI (-6.7 to 1.9)
Anxiety	46.1 (14.6)	45.8 (12.9)	MD 0.3, 95% CI (-6.7 to 1.9)
Hostility	44.9 (10.8)	47.3 (11.2)	MD (-2.4, 95% CI (-6.7 to 1.9)
Phobia	47.1 (11.2)	45.1 (8.5)	MD 2.0, 95% CI (-2.0 to 6.0)
Paranoia ideation	45.8 (10.9)	47.2 (12.0)	MD -1.4, 95% CI (-5.9 to 3.1)
Psychoticism	49.2 (11.7)	49.6 (10.3)	MD -0.4, 95% CI (-4.8 to 4.0)
Global severity	50.8 (12.8)	51.4 (10.9)	MD -0.6, 95% CI (5.3 to 4.1)

Bø 1999	Quality of Life Scale in Norwegian (QoLS-N)	Mean total score (SD)	NA	n=25	n=30	MD 4.9, 95%
				90.1 (9.5)	85.2 (12.1)	CI (-1.1 to 10.9)
* A 16-item scale used in populations with chronic illness. Uses a 7-point satisfaction scale per item whereby a higher score indicates a higher quality of life.						

*NA = Not Applicable

Appendix 6. PFMT function assessment

	PFMT Outcomes and Study ID	Outcome	Measure	PFMT	Control	Difference
US measurements	Carneiro 2010	Transperineal US	Mean (SD)	n=25 12.63 (4.35)	n=25 17.53 (4.33)	MD -4.90, 95% CI -7.3 to -2.5
		Bladder neck mobility (mm)				
		Transperineal US	Mean (SD)	n=25 12.87 (1.02)	n=25 10.74 (2.26)	MD 2.13, 95% CI 0.4 to 3.9
		PFM thickness (mm)				
Pressure measurements	Aksac 2003	Intra-vaginal (cmH ₂ O)	Median (SD)	n=20 37.5 (8.7)	n=10 20.0 (3.9)	Non-estimable
	Beuttenmuller 2010	Intra-vaginal (cmH ₂ O)	Mean (SD)	n=25	n=25	MD 5.04, 95% CI 1.9 to 8.2
			Slow twitch	22.74 (5.65)	Slow twitch 17.70 (5.86) Fast twitch 28.09 (9.89)	MD 4.63, 95% CI -0.03 to 9.3
Fast twitch			32.72 (10.34)			
Bø 1999	Intra-vaginal (cmH ₂ O)	Mean (SD)	19.2 (10.0) n=25	16.4 (9.8) n=30	MD 2.8, 95% CI (-2.6 to 8.2)	

(Continued)

Pereira 2011	Intra-vaginal (cmH ₂ O)	Group PFMT	Individual PFMT	n=15		
		Mean (SD)	n=15	n=15	11.91 (5.57)	MD 25.92, 95% CI 18.45 to 33.0)
		37.13 (19.24)	38.53 (19.34)			
Yoon 2003	Average pressure, intra-vaginal (mm Hg)	Mean (SD)	n=13	n=12		
			26.1 (12.5)	12.2 (5.3)		MD 13.9, 95% CI (5.8 to 22.0)
	Peak pressure, intra-vaginal (mm Hg)	Mean (SD)	39.7 (20.0)	19.9 (7.5)		MD 19.8, 95% CI (7.1 to 32.5)
	Duration of PFM contraction(s)	Mean (SD)	14.5 (3.0)	5.9 (1.7)		MD 8.6, 95% CI (6.6 to 10.6)
Digital measurements	Aksac 2003	Intra-vaginal	Median (SD)	n=20	n=10	
		Number of fingers not stated		4.8 (0.4)	3.3 (0.6)	
		Scale: 5-point scale				
Beuttenmuller 2010	Intra-vaginal	Mean (SD)	n=25	n=25		
					Slow twitch 2.95 (0.90)	MD 0.45, 95% CI (-0.02 to 0.92)
	1 finger		Slow twitch	3.84 (0.8)	Fast twitch 2.86 (0.77)	
	Scale: Oxford		Fast twitch			MD 0.94, 95% CI 0.6 to 1.3)
			3.80 (0.65)			

(Continued)

Carneiro 2010	Intra-vaginal		n=25	n=25	MD 0.7, 95%
	2 fingers	Mean (SD)	3.20 (1.05)	2.50 (0.76)	CI (0.2 to 1.21)
	Scale: Not stated				
Castro 2008	Intra-vaginal	Mean (SD)	n=26	n=24	MD 1.30, 95%
	Number of fingers not stated		3.6 (0.71)	2.3 (1.07)	CI (0.79, 1.81)
	Scale: Oxford				
Diokno 2010	Intra-vaginal		n=23	n=18	
	Number of fingers not stated				
	Scale: Not stated				
	Pressure	Mean (SD)	4.1 (1.1)	3.8 (0.9)	MD 0.30, 95%
					CI (-0.3 to 0.9)
Miller 1998	Intra-vaginal	Mean (SD)	n=13	n=13	MD -1.1, 95%
	Number of fingers not stated		10.4 (4.7)	11.2 (5.1)	CI (-5.1 to 2.9)
	Score: 0-21				
Pereira 2011	Intra-vaginal	Mean (SD)	Group PFMT	Individual PFMT	n=15
	2 fingers		n=15	n=15	1.47 (0.52)
	Scale: 6-point modified Oxford scale		3.07 (0.70)	2.73 (0.96)	MD 1.43, 95%
					CI (1.0 to 1.46)
Wells 1999	Intra-vaginal	Mean	8.8	8.2	Not estimable

(Continued)

Number of fingers not stated

Scale: Pressure and displacement digital score (4-12)

EMG measurements	Burns 1993	Intra-vaginal EMG	Mean (SD)	n=38	n=40	MD -0.5, 95%
		5 fast contractions		3.0 (3.4)	3.5 (4.4)	CI (-2.3 to 1.3)
		Intra-vaginal EMG	Mean (SD)	n=33	n=34	MD -0.2, 95%
		5 sustained contractions		1.8 (2.0)	2.0 (1.8)	CI (-1.1 to 0.7)
	Carneiro 2010	Intra-vaginal EMG	Mean (SD)	n=25	n=25	MD 5.31, 95%
		3 maximal contractions		13.56 (5.41)	8.25 (5.70)	CI 2.23 to 8.39)
	Wells 1999	Intra-vaginal or intra-anal EMG	Mean	48.8	24.2	Not estimable
		4 sustained and 4 short contractions				

WHAT'S NEW

Date	Event	Description
13 May 2014	New search has been performed	In this update, seven new trials have been added (Beuttenmuller 2010 ; Carneiro 2010 ; Diokno 2010 ; Kim 2011 ; Kim 2011a ; Pereira 2011 ; Sar 2009). One previously included trial has been removed because the control group was deemed to be receiving a form of active treatment (van Leeuwen 2004). Full risk of bias assessment has been completed for all trials. Data from 'Other data' tables have been incorporated into other sections. Quality of evidence was assessed by adopting the GRADE approach.
13 May 2014	New citation required but conclusions have not changed	In this update, seven new trials have been added (Beuttenmuller 2010 ; Carneiro 2010 ; Diokno 2010 ; Kim 2011 ; Kim 2011a ; Pereira 2011 ; Sar 2009). One previously included trial has been removed because the control group was deemed to be receiving a form of active treatment (van Leeuwen 2004). Full risk of bias assessment has been completed for all trials. Data from 'Other data' tables have been incorporated into other sections. Quality of evidence was assessed by adopting the GRADE approach.

HISTORY

Protocol first published: Issue 1, 1999

Review first published: Issue 1, 2001

Date	Event	Description
29 May 2009	Amended	Converted to new review format.
14 April 2009	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

All three review authors were involved in all stages of the review. Chantale Dumoulin wrote the first draft of the review update.

DECLARATIONS OF INTEREST

Two of the three authors (CD, JHS) have published trials investigating the effects of PFMT; both trials were excluded from this review based on the participants (antenatal and postnatal women) or the comparison interventions (one type of PFMT versus another).

SOURCES OF SUPPORT

Internal sources

- University of Montreal, Canada.

External sources

- National Institute for Health Research (NIHR), UK.

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INDEX TERMS

Medical Subject Headings (MeSH)

*Pelvic Floor; Biofeedback, Psychology; Exercise Therapy [*methods]; Muscle Contraction [*physiology]; Perineum; Randomized Controlled Trials as Topic; Urinary Incontinence [*rehabilitation]; Urinary Incontinence, Stress [rehabilitation]

MeSH check words

Female; Humans