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Cochrane Database of Systematic Reviews 2006, Issue 1. Art. No.: CD005654.
DOI: 10.1002/14651858.CD005654.

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TABLE OF CONTENTS

[Intervention Review]

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

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Editorial group: Cochrane Incontinence Group.
Publication status and date: Unchanged, published in Issue 4, 2009.

Citation: Hay-Smith J, Dumoulin C. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2006, Issue 1. Art. No.: CD005654. DOI: 10.1002/14651858.CD005654.

ABSTRACT

Background

Pelvic floor muscle training is the most commonly used physical therapy treatment for women with stress urinary incontinence. It is sometimes recommended for mixed and less commonly urge 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

The Cochrane Incontinence Group Specialised Trials Register was searched. The date of the most recent search was 1 December 2004.

Selection criteria

Randomised or quasi-randomised trials in women with stress, urge 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 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 (Higgins 2005). Trials were subgrouped by diagnosis. Formal meta-analysis was not undertaken because of study heterogeneity.

Main results

Thirteen trials involving 714 women (375 PFMT, 339 controls) met the inclusion criteria, but only six trials (403 women) contributed data to the analysis. Most studies were at moderate to high risk of bias, based on the trial reports. There was considerable variation in interventions used, study populations, and outcome measures.

Women who did PFMT were more likely to report they were cured or improved than women who did not. PFMT women also experienced about one fewer incontinence episodes per day. There were too few data to draw conclusions about effects on other outcomes such as condition specific quality of life. Of the few adverse effects reported, none were serious. The trials in stress urinary incontinent women

which suggested greater benefit recruited a younger population and recommended a longer training period than the one trial in women with detrusor overactivity (urge) incontinence.

Authors' conclusions

Overall, the review provides some support for the widespread recommendation that PFMT be included in first-line conservative management programmes for women with stress, urge, or mixed, urinary incontinence. Statistical heterogeneity reflecting variation in incontinence type, training, and outcome measurement made interpretation difficult. The treatment effect might be greater in younger women (in their 40's and 50's) with stress urinary incontinence alone, who participate in a supervised PFMT programme for at least three months, but these and other uncertainties require testing in further trials.

PLAIN LANGUAGE SUMMARY

Pelvic floor muscle training helps reduce urinary incontinence in women.

Stress incontinence is the involuntary leakage of urine with a physical activity such as coughing or sneezing and can happen if the pelvic floor muscles are weak. Urge leakage occurs with a strong need to urinate, but the person cannot make it to the toilet in time and is caused by an involuntary contraction of the bladder muscle. A combination of stress and urge leakage is called mixed incontinence. The review of trials found that pelvic floor muscle training (muscle-clenching exercises) helps women with all types of incontinence although women with stress incontinence who exercise for three months or more benefit most.

BACKGROUND

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 (Hunskaar 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 10 to 40% in most studies (Hunskaar 2002). Data from what is probably the largest cross-sectional study of urinary incontinence in women (27,936 Norwegian women) suggest a gradual increase in prevalence with age to an early peak prevalence around mid life (50 to 54 years), followed by a slight decline or stabilisation until about 70 years of age when prevalence begins to rise steadily (Hannestad 2000).

Stress and urge urinary incontinence are the two most common types of urine leakage in women. 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 (Abrams 2002).

Stress urinary incontinence

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. When urodynamic studies demonstrate involuntary loss of urine during increased intra-abdominal pressure, but the leakage is not caused by a contraction of the detrusor muscle (bladder smooth muscle), this is called urodynamic stress incontinence. Stress urinary incontinence 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, and/or dysfunction of the neuromuscular components that help control urethral pressure, or both. As a result, the bladder outlet (urethra) is not closed off properly during exertion and this results in leakage.

Urge urinary incontinence

The symptom of urge urinary incontinence is present when a woman reports involuntary leakage associated with or immediately preceded by a sudden compelling need to void (that is urgency). Urge urinary incontinence usually results from an involuntary increase in bladder pressure due to contraction of the detrusor muscle. When urodynamic investigations show that the leakage is caused by involuntary contraction of the detrusor muscle then this is called detrusor overactivity incontinence. 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

Many women have symptoms or signs of both stress and urge urinary incontinence, and urodynamics studies sometimes reveal that urine leakage results from a combination of urodynamics stress incontinence and detrusor overactivity. When women have both conditions this is called mixed urinary incontinence.

Treatment of urinary incontinence

A wide range of treatments has 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, pelvic floor muscle training.

Pelvic floor muscle training (PFMT)

Pelvic floor muscle training (PFMT) for the management of urinary incontinence was popularised by Arnold Kegel (Kegel 1948), although in a review of the literature prior to 1949 Bø (2004) identified several records the use of pelvic floor muscle exercise (Bø 2004). PFMT has principally been recommended in the management of stress and mixed urinary incontinence, but has increasingly become part of the conservative treatment programme offered to women with urge urinary incontinence. The use of PFMT in the management of urinary incontinence is based on two functions of pelvic floor muscle: support of the pelvic organs, and a contribution to the sphincteric closure mechanism of the urethra.

For stress urinary incontinence, the aims of PFMT are to improve pelvic organ support (particularly of the bladder, bladder neck, and urethra) and increase intraurethral pressure during exertion. Bø (2004) neatly summarised the three common approaches and biological rationale for PFMT for stress urinary-incontinent women as described in the literature: the use of a well-timed, fast and strong voluntary pelvic floor muscle contraction before and during the exertion, pelvic floor muscle strength training, and facilitation of pelvic floor muscle contraction through abdominal muscle contraction. Bø found evidence to support the used of the first two muscle training activities. With regard to the first, a strong, fast and well-timed pelvic floor muscle contraction will clamp the urethra to increase intraurethral pressure (DeLancey 1988a); may press the urethra against the symphysis pubis, further increasing the urethral pressure (DeLancey 1988b); and may prevent urethral descent during effort and exertion (Peschers 2001). A small randomised controlled trial demonstrated that the use of a well-timed voluntary pelvic floor muscle contraction (called 'The Knack'), could reduce leakage with coughing (Miller 1998). For the second, strength training of sufficient intensity may raise the position of the levator muscle plate in the pelvis through increased muscle hypertrophy and muscle 'stiffness' , and might facilitate a more automatic pelvic floor muscle response to changes in intra-abdominal pressure (Bø 2004). For the third, there is a small but increasing body of evidence that contraction of abdominal muscles (in particular transversus abdominus) is accompanied by a co-contraction of the pelvic floor muscles (see for example Neuman 2002). Recent experimental data suggest that contraction of the deep abdominal muscles is associated with increased pelvic floor muscle electromyographic activity (Sapsford 2001a; Sapsford 2001b). However, it seems a transversus abdominus contraction might not elevate the pelvic floor (to support the organs) in all women (Bø 2003). To date, the role of transversus abdominus muscles might play in PFMT is not well understood. Clinical trials will be needed to evaluate the efficacy of this approach to PFMT in the management of urinary incontinence.

The biological rationale for the use of PFMT for the management of urge urinary incontinence is less clear, but a reflex inhibition of detrusor contraction has been demonstrated with an electrically stimulated contraction of the pelvic floor muscles (Godec 1975). It has also been suggested that reflex inhibition of detrusor contraction may accompany repeated voluntary pelvic floor muscle contractions (Polden 1990).

Many women are referred for PFMT on the basis of symptoms or clinical signs of stress, urge, or mixed, urinary incontinence. There is currently no consensus about the need for urodynamic investigations before PFMT, but a single randomised controlled trial indicated that there was no statistically significant difference in 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.

The earlier Cochrane review of PFMT (Hay-Smith 2002b) 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 an update of the earlier Cochrane review was warranted.

The scope and complexity of the earlier Cochrane review of PFMT was also unwieldy. For this reason the original review has been divided into five separate reviews. This review investigates whether pelvic floor muscle training is an effective treatment in the management of female urinary (stress, urge, and mixed) incontinence compared to no treatment, placebo, sham or control treatments. Other reviews will address whether (a) one type of PFMT is better than another, (b) PFMT is better than other treatments (for example other physical therapies, medication and surgery), and (c) if the addition of PFMT to other therapies adds benefit.

OBJECTIVES

To determine the effects of pelvic floor muscle training in the management of female urinary (stress, urge, and mixed) incontinence.

The following hypothesis was tested:

- that pelvic floor muscle training is better than no treatment, placebo, sham, or any other form of inactive control treatment.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials, and quasi-randomised studies (for example using allocation by alternation), were included. Other forms of controlled clinical trial were excluded.

Types of participants

All women with urinary incontinence and diagnosed as having stress, urge, 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.

Studies 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. Studies investigating nocturnal enuresis in women were also excluded.

Studies that specifically recruited antenatal or postnatal women (up to three months from delivery) 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 will be addressed in another Cochrane review (Hay-Smith 2002a).

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 and 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 health care professional. All types of PFMT programmes were considered, including using variations in purpose and timing of PFMT (for example PFMT for strengthening, PFMT for urge suppression), 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 urge and/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, 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 Organisation 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 interrelationships between a woman's impairment of body functions and structures (e.g. 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 the women's activities and participation, while a measure of impairment (for example of pelvic floor muscle function) was of secondary importance.

The primary outcomes of interest were:
1) symptomatic cure or improvement (reported by the woman and not the clinician)
2) symptom and condition specific quality of life assessment (for example Incontinence Impact Questionnaire, Kings Health Questionnaire)

Secondary outcomes of interest were:
3) number of leakage episodes;
4) number of micturitions;
5) measures of pelvic floor muscle function (for example electromyography, vaginal squeeze pressure);
6) other quality of life measures (for example Short Form-36);
7) formal economic analysis (for example cost effectiveness, cost utility).

Other outcomes of interest were:
8) treatment adherence;
9) any of the primary or secondary outcomes in the longer term (that is 12 months or more);
10) adverse events;
11) any other outcome not pre-specified, but judged important when performing the review.

Search methods for identification of studies

This review drew on the search strategy developed for the Cochrane Incontinence Group (For more details please see the 'Specialized Register' section of the Group's module in The Cochrane Library). Relevant trials were identified from the Cochrane Incontinence Group Specialised Register, which is also described under the Incontinence Group's details in *The Cochrane Library*. The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, CINAHL, and handsearching of journals and conference proceedings. The trials in the Cochrane Incontinence Group Specialised Register are also contained in CENTRAL. The date of the last search was 1 December 2004.

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

({design.cct*} or {design.rct*})
AND
{topic.urine.incon*}
AND
({intvent.phys.biofeed*} or {intvent.phys.pfe*})
(All searches were of the keyword field of Reference Manager 9.5 N, ISI ResearchSoft).

We also searched for other possible relevant trials in the reference lists of relevant articles.

We did not impose any restrictions on language of publication or publication status (that is full publication, grey literature, etc).

Data collection and analysis

Screening for eligibility

Reports of all possibly eligible studies were evaluated for appropriateness for inclusion by both review authors without prior consideration of the results. Any disagreements were resolved by discussion, and where these were not resolved, final responsibility rested with a third person. Studies were excluded from the review if they were not randomised or quasi-randomised controlled trials, or made comparisons other than those pre-specified. Excluded studies are listed with reasons for their exclusion in the Table of excluded studies.

Assessment of methodological quality

Assessment of methodological quality was undertaken by both review authors using the Cochrane Incontinence Group's criteria, which includes assessment of quality of random allocation and concealment, description of dropout and withdrawal, analysis by intention to treat, and blinding during treatment and at outcome assessment. Any disagreements were resolved as previously described.

Data extraction

Data extraction was undertaken independently by the two review authors 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) trialists were contacted for data from the completed trial. All included trial data were processed as described in the Cochrane Collaboration Handbook for Systematic Reviews of Interventions (Higgins 2005).

Analysis

For categorical outcomes we related the numbers reporting an outcome to the numbers at risk in each group to derive a relative risk. For continuous variables we used means and standard deviations to derive mean differences. We had planned to undertake formal meta-analysis, where appropriate. In the event, this was not performed because of heterogeneity amongst the studies.

Subgroup analysis

Analysis within subgroups was used to address the effect of type of incontinence on outcome. Because the rationale for PFMT is different for the two main types of urinary incontinence (stress and urge) 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 stress urinary incontinence and that it may be effective, in combination with behavioural interventions, for women with mixed urinary incontinence. In the past, PFMT has rarely been the first-choice treatment for women with urge urinary incontinence alone.

The four pre-specified diagnostic subgroups were trials that recruited women with:
1) only women with stress urinary incontinence (symptom, sign, urodynamic stress incontinence);
2) only women with urge urinary incontinence (symptom, idiopathic detrusor overactivity incontinence);
3) only women with mixed urinary incontinence (symptom, sign, idiopathic detrusor overactivity incontinence with urodynamic stress incontinence);
4) a range of diagnoses.

Sensitivity analysis

Sensitivity analysis with respect to trial quality was planned as there is some evidence that this may have an impact on the findings of meta-analysis (Moher 1998), but there were insufficient trials and too many other potential causes of heterogeneity to make this useful.

Heterogeneity

The extent of heterogeneity was assessed in three ways: visual inspection of data plots; chi-squared test for heterogeneity and the I^2 statistic. Possible explanations were sought and discussed.

Publication bias

Although planned, formal analysis of publication bias was not possible because there were insufficient trials in any comparison to make this useful.

RESULTS

Description of studies

Included and excluded studies

Sixteen trials were identified, and three excluded for the following reasons. In two trials the comparison intervention was a home PFMT programme (Burgio 2002; Goode 2003). The PFMT programme was not supervised, but the participants completed a daily urinary diary and returned this to the researchers weekly. These two trials were considered to be comparisons of two approaches to PFMT, and were excluded. The third excluded study was reported as a conference abstract; it was not clear if this was a randomised trial and the report contained no data (Yoon 1999).

Of the 13 included trials six contained no usable data for analysis (for example means given without measure of dispersion) and/or did not report or collect data for any of the pre-specified outcomes of interest (Aksac 2003; Bidmead 2002; Henalla 1989; Henalla 1990; Miller 1998; van Leeuwen 2004), and in one it was not clear if the only potentially usable data (for 'cure') were generated from a urinary diary or self-report (Hofbauer 1990). Six trials contributed to the analysis of primary outcomes (Bø 1999; Burgio 1998; Burns 1993; Lagro-Janssen 1991; Ramsay 1990; Yoon 2003). Lagro-Janssen and colleagues recruited women with stress, urge, or mixed, urinary incontinence, and those with urge or mixed urinary incontinence were offered bladder training. However, data from women with stress urinary incontinence (who received PFMT only) were reported separately, so this trial was eligible for the review. The primary reference for Ramsay and Thou was a conference abstract (Ramsay 1990); no further published report was found. Although the abstract stated the author name as Thou, the review authors are aware that this is a typographical error, and the correct spelling is Thow. The corrected spelling was used in this review.

Eight trials had more than two treatment arms (Bidmead 2002; Bø 1999; Burgio 1998; Burns 1993; Henalla 1989; Henalla 1990; Hofbauer 1990; van Leeuwen 2004). Only descriptions and data relating to the PFMT and control arms were given in this review. Of the 13 included studies, nine (Bø 1999; Burgio 1998; Burns 1993; Henalla 1989; Henalla 1990; Hofbauer 1990; Lagro-Janssen 1991; Miller 1998; Ramsay 1990) were included in the previous version of the review (Hay-Smith 2002b). Of the four new trials only Yoon and colleagues (Yoon 2003) reported usable data for any of the prespecified outcomes of interest.

Sample characteristics

Diagnosis

Three trials diagnosed the type of urinary incontinence based on symptoms or signs, or both; the symptomatic diagnoses were urinary incontinence (Yoon 2003), and stress urinary incontinence (Miller 1998; Ramsay 1990). The other ten trials reported urodynamic diagnoses. Six of these included women with urodynamic stress incontinence only (Aksac 2003; Bidmead 2002; Bø 1999; Henalla 1989; Henalla 1990; Hofbauer 1990). Lagro-Janssen and co-workers included women with stress, urge, or mixed, urinary incontinence although a subset of data was available for women with urodynamic stress incontinence only (Lagro-Janssen 1991). Schagen van Leeuwen et al (van Leeuwen 2004) included women with urodynamic stress incontinence or clinical signs of stress urinary incontinence (SUI) (van Leeuwen 2004). Burns et al. included women with urodynamic stress incontinence with or without detrusor overactivity incontinence, but the proportion with mixed symptoms was small (9%) (Burns 1993). In contrast, Burgio et al. included women with detrusor overactivity incontinence with or without urodynamic stress incontinence, and about half had mixed urinary incontinence (51%) (Burgio 1998).

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

- Stress urinary incontinence (Aksac 2003; Bidmead 2002; Bø 1999; Burns 1993; Henalla 1989; Henalla 1990; Hofbauer 1990; Lagro-Janssen 1991; Miller 1998; Ramsay 1990; van Leeuwen 2004)
- Urinary incontinence, range of diagnoses (Burgio 1998; Yoon 2003).

Other characteristics

In five trials leakage frequency was one of the inclusion criteria, being twice or more per month (Lagro-Janssen 1991), twice or more per week (Burgio 1998), three times or more per week (Burns 1993), one to five leakage episodes per day (Miller 1998), or two or more leakage episodes per day (van Leeuwen 2004). Two trials used amount of leakage from a pad test: more than 1g during a 30 minute test (Yoon 2003), or more than 4g 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 five trials restricted participation based on age. These trials recruited women aged 18 to 75 years (van Leeuwen 2004), 20 to 65 years (Lagro-Janssen 1991), 35 to 55 years (Yoon 2003), and 55 years and older (Burgio 1998; Burns 1993). Common exclusion criteria were untreated urinary

tract infection, post void residual greater than a specified amount, neurological disorders, and cognitive impairments.

Interventions

Pelvic floor muscle training (PFMT) (Additional table 01)

The biological rationale for PFMT is outlined in the introduction. Essentially, a PFMT programme may be prescribed to increase strength (the maximum force generated by a muscle in a single contraction); endurance (ability to contract repetitively, or sustain a single contraction over time); coordination of muscle activity or to suppress urge, or a combination of these. 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 one way to increase 'load' is to increase the amount of voluntary effort with each contraction. Endurance training is characterised by high numbers of repetitions or prolonged contractions with low to moderate loads. Training to improve coordination and urge suppression usually involve the repeated use of a voluntary pelvic floor muscle contraction (VPFMC) in response to a specific situation, for example VPFMC prior to cough, VPFMC with sensation of urge.

The PFMT programmes used are described in Additional Table: Table 1. Four studies gave no details of the PFMT programme used (Bidmead 2002; Henalla 1990; Hofbauer 1990; van Leeuwen 2004). Of the nine remaining trials, five stated that a correct VPFMC was confirmed prior to training (Aksac 2003; Bø 1999; Burgio 1998; Henalla 1989; Miller 1998). PFMT was taught by specialist nurses or physiotherapists in six studies, and in a seventh this was done by a family doctor.

Based on the descriptions of training, three trials had PFMT programmes that clearly or predominantly targeted co-ordination (Miller 1998) or strength training (Bø 1999; Ramsay 1990). 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 and Ramsay et al recommended programmes that comprised a relatively small number (four to eight) of maximal or near maximal contractions three (Bø 1999) or up to about 16 times (Ramsay 1990) per day; these were predominantly strength training programmes.

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 PFMT programmes described by Burgio (Burgio 1998) and Aksac (Aksac 2003) are indicative of strength training, but the training duration was relatively short (eight weeks) and this might have been insufficient for muscle hypertrophy to be established. Any training effects seen by Burgio et al might also be attributed to the motor learning component of training, used to prevent leakage with provocation (that is 'The Knack') and to suppress urge. Yoon et al stated the aim of PFMT was to increase strength and endurance. Although women were asked to hold some contractions for up to 12 seconds each relatively few repetitions were required, so neither duration nor repetitions may have been sufficient to increase fatigue resistance much. Burns and colleagues asked women to complete up to 200 contractions per day, so this programme might have affected predominantly endurance. In Lagro-Janssen et al, the number of repetitions per day was quite variable, so strength or endurance, or both, might have been affected depending on how much training each individual did. Henalla et al (1989) asked women to complete a small number of contractions with short hold (five seconds) approximately 16 times per day. The number of repetitions suggests endurance training, although the small numbers of short duration contractions are more characteristic of strength training; this programme might have affected strength or endurance, or both, partly depending on the amount of voluntary effort with each contraction.

Comparison groups

The comparison groups were assigned to no treatment (Aksac 2003; Bidmead 2002; Burns 1993; Henalla 1989; Henalla 1990; Miller 1998; Yoon 2003), placebo drug (Burgio 1998), sham electrical stimulation (Hofbauer 1990), sham PFMT (Ramsay 1990), imitation PFMT with placebo drug (van Leeuwen 2004), or a non-active control intervention (Bø 1999; Lagro-Janssen 1991). Sham PFMT comprised strong isometric hip adductor contractions with legs crossed at the ankles (Ramsay 1990). Imitation PFMT was not described (van Leeuwen 2004). The non-active control treatments comprised use of an anti-incontinence device (Bø 1999), and advice on incontinence pads (Lagro-Janssen 1991). More details are available in the Table of included studies

Outcome measures

Overall there was no consistency in the choice of outcome measures by trialists. This limited the possibilities for considering results from individual studies together. It was disappointing that half the eligible trials did not contribute any data to the main analyses because they did not measure any of the pre-specified outcomes of interest, or did not report their outcome data in a usable way (for example mean without a measure of dispersion, P values without raw data).

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 has been assumed the trialists chose to complete treatment and measure outcome when maximum benefit was likely to have been gained. Data from longer-term follow-up are reported in the text where available.

Risk of bias in included studies

Due to brevity of reporting it was difficult to assess the four trials that were published as a conference abstracts (Bidmead 2002; Henalla 1990; Ramsay 1990; van Leeuwen 2004). Six of the trials were small, with less than 25 women per comparison group (Aksac 2003; Henalla 1990; Hofbauer 1990; Miller 1998; Ramsay 1990; Yoon 2003); five were of moderate size with around 25 to 50 per group (Bø 1999; Burns 1993; Henalla 1989; Lagro-Janssen 1991; van Leeuwen 2004), and the other allocated more than 50 women per group (Burgio 1998). 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. Only one trial reported an a priori power calculation (Bø 1999).

Random allocation and allocation concealment

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 with inadequate allocation concealment rather than a randomized trial. Nine trials stated only that women were allocated at random, with no further description (Aksac 2003; Bidmead 2002; Henalla 1989; Henalla 1990; Hofbauer 1990; Miller 1998; Ramsay 1990; van Leeuwen 2004; Yoon 2003); it was not clear if allocation was adequately concealed in these studies. There was more detail of the methods of randomisation in two studies (for example computer generation of random numbers, block size), but neither gave sufficient detail to be sure that allocation was concealed (Burgio 1998; Burns 1993). Only Bø and colleagues reported adequate allocation concealment (Bø 1999).

Blinding during treatment and at outcome assessment

Given the nature of PFMT it is difficult, often impossible, to blind treatment provider and participants during treatment. Blinded outcome assessment should be possible.

Ramsay and Thow (Ramsay 1990) and Schagen van Leeuwen et al (van Leeuwen 2004) attempted to blind women to treatment by allocating them to sham and imitation PFMT programmes respectively. Ramsay and Thow described their sham training as strong isometric hip adductor contractions with legs crossed at the ankles. Women would probably be able to tell the difference between this and the more usual pelvic floor muscle exercise, which does not concentrate effort in the hip and buttock area. Schagen van Leeuwen and colleagues did not describe their imitation PFMT programme; it was not clear whether their attempt to blind women to treatment allocation was likely to be successful. It was not possible to blind women to PFMT in any of the other included studies.

Seven trials reported using blinded outcome assessors (Bidmead 2002; Bø 1999; Burgio 1998; Burns 1993; Lagro-Janssen 1991; Miller 1998; Yoon 2003).

Description of dropout and withdrawal

There were no dropouts or losses to follow up in two trials (Miller 1998; Ramsay 1990). In four studies it appeared there were no dropouts, but this was not clearly stated in the trial reports (Aksac 2003; Henalla 1989; Henalla 1990; Hofbauer 1990). There were losses to follow up in the study by Schagen van Leeuwen and colleagues (van Leeuwen 2004), but no data were given. In the remaining studies the proportion was less than 10% in two (Lagro-Janssen 1991; Burns 1993), between 11 and 15% in three (Bø 1999;Burgio 1998; Yoon 2003), and more than 25% in one (Bidmead 2002). The proportion of withdrawals or losses to follow up was higher in the control group in Burgio et al and Bidmead et al, with no clear differential in the other studies.

Analysis by intention-to-treat

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). It was not clear if any included study met the above criteria for intention to treat, but three stated the primary analysis was by intention to treat (Bidmead 2002; Burgio 1998; van Leeuwen 2004), and another that stated intention-to-treat analysis did not alter the findings of the primary analysis (Bø 1999). Six studies did not appear to have any losses to follow up, so satisfy one of the conditions, but none of these studies stated that the participants were analysed in their assigned group (Aksac 2003; Henalla 1989; Henalla 1990; Hofbauer 1990; Miller 1998; Ramsay 1990).

Effects of interventions

Thirteen randomised or quasi-randomised trials compared PFMT (375 women) with no treatment, placebo, sham or other non-active control treatments (339 women). In the six trials contributing data the two comparison groups comprised 197 and 206 women respectively.

Readers should note that when referring to the graphs (forest plots) for two of the four outcomes (patient perceived cure, patient perceived cure or improvement) the right hand side of the plot favours PFMT. For the remaining outcomes (number of leakage episodes in 24 hours, number of voids per day, number of voids per night) 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

Patient reported 'cure' or 'improvement' (Comparison 01.01 and 01.02)

Many different scales were used to measure patient response to treatment, including Likert scales, visual analogue scales and percent reduction in symptoms. Whatever the scale, data were included in the formal comparisons when the trialists stated the number of women who perceived they were cured or improved (as defined by the trials) 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.

Two trials reported data on cure: women reported "100% perceived improvement (that is dry)" (Burgio 1998), or that the participant's incontinence was now "unproblematic" (Bø 1999). Both trials found PFMT women were statistically significantly more likely to report they were cured. The estimated size of treatment effect was quite different in the two trials; PFMT women were about 17 times more likely to report cure than controls in Bø et al, but only about two and half times as likely in Burgio et al. The confidence intervals in both trials were wide.

Four trials contributed data to the patient perceived cure or improvement comparison; women reported they were "improved" (Ramsay 1990), had "75% or more perceived improvement" (Burgio 1998), were "dry" or "improved" (Lagro-Janssen 1991), and "continent" or "almost continent" (Bø 1999). Visual inspection of the forest plot showed that the trial by Ramsay and Thow (Ramsay 1990) differed from the other three studies. The trial by Ramsay and Thow might be confounded by the choice

of sham PFMT, which consisted of strong isometric hip adductor contractions that may have facilitated synergistic contractions in the muscles of the pelvic floor with a PFMT effect. Adherence rates in both groups were also very low. Assuming that PFMT has an effect, if exercise levels are suboptimal then a training effect might not be evident or the size of effect might be diminished to the point where it is not detected. It is possible that women in the PFMT group were doing insufficient training to demonstrate an effect on the pelvic floor muscles.

The two trials in women with urodynamic stress incontinence (Bø 1999; Lagro-Janssen 1991) suggested a high likelihood of cure or improvement (RR 20.0 and 14.4 respectively) and these were higher than the single study in women with detrusor overactivity with or without urodynamic stress incontinence (Burgio 1998) (RR 2.2., 95% CI 1.5 to 3.4).

Other data: Hofbauer et al (1990) reported data for 'cure' (Hofbauer 1990). It was not clear if the data were generated from a urinary diary or self reported symptom scale so it these data were not included in Comparison 01.01.

Symptom and condition specific quality of life assessment (Other data table 01.03)

Two trials used psychometrically robust questionnaires for assessment of incontinence symptoms and/or the impact of these symptoms on quality of life, or both. 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. The data were reported as frequencies, rather than mean scores. Fewer women in the PFMT group reported that urinary incontinence symptoms interfered with activity, or were problematic. Schagen van Leeuwen and co-workers (van Leeuwen 2004) reported mean change in the Quality of Life in Persons with Urinary Incontinence (I-QoL) score; I-QoL has established validity, reliability and responsiveness to change for assessing quality of life impact of urinary incontinence (Donovan 2005). Although quality of life was better in the PFMT group, it was not clear if there were important differences between PFMT and control groups; the means were presented without a measure of dispersion.

Measures of activity and participation were of primary importance in the review and two trials (Aksac 2003; Bø 1999) reported a symptom score that addressed participation in nine social situations (The Social Activity Index). In both trials the PFMT group has less activity and participation restriction but because it is not clear whether The Social Activity Index is a valid measure of activity and participation, it is difficult to interpret the data from these two trials.

Secondary outcome measures

Number of leakage episodes in 24 hours (Comparison 01.04)

Five of the studies used two (Yoon 2003), three (Bø 1999), seven (Lagro-Janssen 1991) or 14 day urinary diaries (Burgio 1998; Burns 1993) to collect data on leakage episodes, although Yoon and colleagues did not report these data. To enable comparison between trials the data were presented as number of leakage episodes in 24 hours. Visual inspection of the forest plot suggested the effect size might be greater in the trial by Lagro-Janssen and colleagues, while the effect size appeared similar in the three remaining trials. It was not clear why the data from Lagro-Janssen and coworkers might be different from the two other trials in stress urinary incontinent women, or the trials overall - a possible explanation was inadequate random allocation concealment, with an overestimate of treatment effect. The point estimates in the other three were similar, all were statistically significant. PFMT women experienced about one less leakage episode per 24 hours compared to controls.

Other data: two other studies measured incontinence frequency (Aksac 2003; van Leeuwen 2004). Aksac et al (Aksac 2003) used 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). Schagen van Leeuwen et al (van Leeuwen 2004) presented their data as the median percent decrease in incontinence episode frequency (PFMT 35%, controls 29%), but no measure of variation was given.

Number of voids per day (Comparison 01.05)

A single study in women with urinary incontinence (type not specified) reported data on frequency (Yoon 2003). PFMT women reported about three less voids per day than controls but with wide confidence intervals that included no difference (MD -3.1, 95% CI -4.7 to 1.5).

Number of voids per night (Comparison 01.06)

Data from the same study showed no statistically significant difference in the number of night time voids between PFMT and control groups (Yoon 2003).

Measures of pelvic floor muscle function (Other data table 01.07)

Four studies used perineometry to measure vaginal squeeze pressure (Aksac 2003; Bø 1999; Ramsay 1990; Yoon 2003). Other methods of assessing muscle function were vaginal electromyography (Burns 1993) and digital palpation (Aksac 2003; Miller 1998). Of the six studies, one did not report the data in such a way that it was possible to calculate the mean difference in vaginal squeeze pressure or digital palpation score (Aksac 2003). The comparability of the findings from the different measures of pelvic floor muscle function is not known so no attempt was made to combine the data from the five remaining trials.

There were contrasting findings: either no statistically significant difference between the groups, or a statistically significant difference in favour of PFMT. In two studies that did not show a statistically significant difference between the groups (Miller 1998; Ramsay 1990) there were reasonable explanations for the lack of difference. Miller et al reassessed muscle function after just one week of co-ordination training. It was not clear what changes in muscle function might have occurred after such a short training period, or if these would be discernable with digital palpation. Ramsay and Thow did not report their data, but stated that there was no statistically significant difference between the groups; this finding may be confounded (as discussed above under 'patient reported cure or improvement').

The two studies that measured vaginal squeeze pressure both found mean vaginal squeeze pressure was higher in the PFMT than control group; in one study this difference was statistically

significant while in the other it was not (Bø 1999; Yoon 2003). Yoon et al also found substantial and statistically significant differences between PFMT and control groups for peak pressure, and duration of contraction after treatment. It was not clear why the findings in these trials might be different. Finally, in the single trial that used electromyography, Burns et al (1993) did not find any statistically significant differences between the groups for fast or sustained contractions and the mean scores were very similar in both groups.

Other quality of life measures (Other data table 01.08)

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.

Formal economic analysis

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

Other outcomes of interest

Longer-term follow up

Few data are available from longer-term follow up after cessation of supervised training. In all trials supervised PFMT stopped at the end of the treatment period, except in trials where controls were then offered a period of supervised training. Because of this 'cross-over' of controls to training follow up data were usually presented for all women in the trial, rather than by original group allocation. Three trials have published longer-term follow up, at three and six months (Burns 1993), nine months (Henalla 1989), and 12 months and five years (Lagro-Janssen 1991).

Burns and colleagues (Burns 1993) found that those with mild leakage (less than seven leakage episodes per week) were more likely to have return of symptoms in contrast with those with moderate to severe leakage (eight to 21 and more than 21 leakage episodes per week respectively), who were more likely to continue to improve with PFMT. Henalla et al (Henalla 1989) reported that three of the 17 women who returned the nine month questionnaire (from 25 originally allocated to PFMT) had recurrent symptoms. Lagro-Janssen and van Weel (Lagro-Janssen 1991) contacted 101 of the 110 women included in their original trial five years later. Seven women had received surgery in that time, one had become pregnant, and five women did not wish to participate in the follow up. Data from the 88 women who consented showed that the proportion of continent women (about 25%) was similar after five years, but the number with severe incontinence (10 to 12 points on a 12 point severity scale) increased from 3 out of 88 women (3%) to 16 of 88 (18%). The number of leakage episodes per week had also increased significantly (P value 0.009), with a mean increase of 2.7 episodes (95% CI 0.7 to 4.6). Two thirds of women (67%) remained satisfied with the outcome of treatment, and did not want further treatment. Women with urge or mixed incontinence were less likely to be satisfied with outcome at five years, and stress urinary incontinent women were less likely to report their condition had worsened. Nearly half of the women (43%) who had received PFMT were no longer training at all, while 39% were training daily or "when needed". The relationship between age, parity, anxiety, incontinence severity, adherence and treatment success at five years was investigated in logistic regression. For stress urinary incontinent women, the only factor significantly associated with better outcome at five years was continued PFMT (P value 0.04).

Treatment adherence

Five trials attempted to measure treatment adherence using exercise diaries (Bidmead 2002; Bø 1999; Burns 1993; Ramsay 1990) and self-report (Lagro-Janssen 1991). Burns and colleagues did not present any data. Bø and co-workers reported the highest rate of adherence to PFMT (95%). Bidmead et al found 75% of women allocated to PFMT had excellent (daily) or good (training more than three times a week) adherence to exercise. Women in the study by Lagro-Janssen and others rated their adherence as excellent or good (62%), reasonable (20%), or poor or none (18%). Ramsay and Thow stated that adherence was poor, with PFMT occurring at "15% of the requested level", with similar rates of exercise between PFMT and sham PFMT groups.

Adverse events

Three trials specifically mentioned adverse events, and two did not report any in the PFMT group (Bø 1999; Burgio 1998). Lagro-Janssen and colleagues was the only trial to report adverse events with PFMT. These were: pain (1 participant), uncomfortable feeling during exercise (3 participants), and not wanting to be continuously bothered with the problem (2 participants).

Other outcomes - other measures of patient perceived response to treatment (Other data table 01.09), pad and paper towel tests (Other data table 01.10)

Other outcomes, not pre-specified but judged important when performing the review, were all measures of patient perceived response to treatment . Two of these were symptom scales: the Leakage Index (Bø 1999), and a urinary incontinence score (Yoon 2003). Participants were also asked about their perceptions of frequency and amount of leakage (Burgio 1998) and their desire for further treatment (Bø 1999; Burgio 1998). The symptom scores used by Bø et al and Yoon et al both evaluated leakage severity with specified activities, but the former addressed leakage frequency and the latter amount of leakage. Bø and colleagues have also tested the reliability of the Leakage Index. They found PFMT women had less perceived leakage frequency than controls; this was an average of 1.2 points difference, on a scale with a maximum score of 35 points and a minimum of five. Yoon et al (who did not cite any supporting data on the validity or reliability of their scale) also found lower scores in the PFMT group, but the difference was not statistically significant. Burgio et al found PFMT women were about one and a half times more likely to report a reduction in frequency and amount of leakage with each leakage episode than controls. Bø et al and Burgio et al asked if women wanted further treatment or not; in both trials PFMT women were significantly more likely to say they did not (RR 12.6; 95% CI 3.3 to 48.6; RR 3.5, 95% CI 2.1 to 5.8, respectively).

Although the review authors had concerns about the comparability and interpretation of findings from pad and paper towel tests (see Discussion, Outcome measures and reporting) these were used in nine of the 13 included studies, so the data were extracted and examined for consistency with other findings. In all trials the number cured or improved on pad test, or the mean or median pad test scores, were in favour of the PFMT group. Four trials (Aksac 2003; Bø 1999; Henalla 1989; Henalla 1990) dichotomised their pad test data into two groups using a variety of criteria (for

example cured versus not cured, cured or improved versus not cured or improved). Although three trials found that cure, or cure or improvement, was statistically significantly more likely in the PFMT group, most confidence intervals were wide. In addition, two of the three trials had no observed cases of cure, or cure or improvement, in the control group; this makes the estimate of the confidence intervals in these trials unstable. The one trial that did not find a statistically significant difference in pad test cure, or cure or improvement, was very small (less than 10 participants per group), and had no cases of cure or improvement in the control group (Henalla 1990).

DISCUSSION

This review is the first in a series of reviews of PFMT for urinary incontinence 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. Future reviews will consider whether: (a) one approach to PFMT is better than another, (b) PFMT is better than other treatments, and (c) PFMT adds benefit to other treatments.

General observations

Trial quality and reporting

Methodological quality was evaluated from the trial reports. Therefore, the quality of reporting might have affected the judgement of methodological quality. Four of the included studies were published only as an abstract (Bidmead 2002; Henalla 1990; Ramsay 1990; van Leeuwen 2004). Limited methodological detail was given, which made it particularly difficult to judge the quality of these trials. In addition, few data were reported.

It was disappointing that only one trial sufficiently described the randomisation process so that the review authors could be sure there was adequate concealment. On the other hand, it was encouraging, given the difficulties of blinding participants and treatment providers to PFMT, that seven of the 13 studies used blinded outcome assessors and two attempted to blind participants using a sham or imitation PFMT (Ramsay 1990, van Leeuwen 2004). Generally, the proportion of dropout and withdrawals was in the region of 0 to 15%. Sample sizes were small to moderate in 12 of the 13 studies, and only one reported an *a priori* power calculation. Three trials stated that intention to treat principles were used for the primary analysis, and one stated that intention to treat analysis did not change the findings of the primary analysis.

Based on the reported adequacy of allocation concealment and blinding one trial appeared to be a low risk (Bø 1999), seven at moderate risk (Bidmead 2002; Burgio 1998; Burns 1993; Miller 1998; Ramsay 1990; van Leeuwen 2004; Yoon 2003), and five at high or possible high risk of bias (Aksac 2003; Henalla 1989; Henalla 1990; Hofbauer 1990; Lagro-Janssen 1991). Sensitivity analysis on the basis of trial quality was not considered appropriate in view of the small number of trials contributing to each comparison. It is not known to what extent the variable quality of the trials has affected the findings of the review. It is interesting to note that of all the studies contributing data to the analysis, the largest treatment effect (for cure and improvement, and leakage episodes) was observed in a trial at the high risk of bias. This might be an example of the apparent overestimation of treatment effect (about 30%) observed in trials with inadequate or unclear concealment of random allocation (Egger 2002).

Outcome measures and reporting

About half the studies did not report data for any of the pre-specified outcomes of interest, and/or did not report any data in ways that could be used in meta-analysis. Common problems were reporting a measure of central tendency without a measure of dispersion (for example mean without standard deviation), or inexact P values (for example P<0.01) without any other supporting data. Overall, there was a lack of consistency in the outcome measures used and reported for the included studies. No single outcome was common to all the trials, and similar outcomes were measured and presented in different ways (for example urinary diary data presented as number 'dry', or mean number of leakage episodes). Quite a number of the continence outcome measures had not undergone reliability or validity testing. These factors meant that comparisons across studies were limited.

Five of the pre-specified outcome measures were reported by one or more study in such a way that data could be displayed on a forest plot. These were patient reported cure, cure and improvement, leakage episodes in 24 hours, number of voids per day, and number of voids per night. Only the first three forest plots contained data from more than one trial. In all three, visual inspection of the plots, and the statistical tests for heterogeneity, suggested important differences between the studies. The summary statistics were not therefore derived or displayed on the forest plots.

The most consistently reported outcome was a pad or paper towel test, although they were all different tests. Quantification of urine loss is one measurement domain recommended by The Outcome Research in Women Subcommittee of the Standardisation Committee of the International Continence Society (Lose 1998), but pad and paper towel tests were not among the pre-specified outcomes of interest for this review because they pose particular problems for analysis and interpretation when comparisons are being made between studies. There are many tests, short and long, office and home based. The activities within the tests vary, and the test may begin with a standardised bladder volume or not. It is therefore not clear how the results of these different tests can best be considered together. Data from short and long pad tests should be analysed separately, because these may measure different things (Ryhammer 1999), but the problem of the comparability of tests within each of these two categories remains. Another difficulty is that pad test data are presented in many different ways. Common ways of reporting pad test data are number cured (although the cut off for cure varies), amount of leakage (as a mean or median, with measure of dispersion), or a measure of change from baseline (either percent change or amount of change in ml). Finally, there is the problem of interpretation. Researchers and clinicians need to know what matters most to women (that is, whether it is the amount leaked in ml or grams, reduction in amount leaked in ml or grams, percent reduction, no leakage at all, or something else), so that pad test data can be presented in a meaningful way and usefully interpreted.

Other sources of heterogeneity

Four diagnostic subgroups were pre-specified for use in the analysis: stress incontinence only (symptoms and signs or urodynamic stress incontinence), urge urinary incontinence only (symptoms or idiopathic detrusor overactivity incontinence), mixed

urinary incontinence only (symptoms and signs or urodynamic stress incontinence with detrusor overactivity incontinence), and a range of diagnoses (to include samples where all three main types of urinary incontinence were included). Eleven of the included trials fit the criteria for stress urinary incontinence only and two included women with a range of diagnoses. There is likely to be some heterogeneity in the first subgroup, as it is well known that symptomatic and urodynamic diagnoses do not always agree. There is undoubtedly considerable diagnostic heterogeneity in the second group. Other sample characteristics might well affect treatment prognosis (for example age), and introduce further clinical heterogeneity. To investigate the effects of these characteristics on treatment outcome would require an individual patient data meta-analysis, which was beyond the scope of this review.

Variation in the programmes is another important potential source of clinical heterogeneity. The exercise content of PFMT programmes was often poorly described. It was difficult to make judgements about the similarities and difference between the training programmes, or their potential effectiveness. Clearly, including studies with a suboptimal exercise 'dose' could adversely affect the estimate of treatment effect; assessment of the interactions between quality and the effects of the intervention has been recommended (Herbert 2005). For this reason, data from Ramsay and Thow (1990) was not included in the estimates of effect presented in this review.

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

Of the 13 trials that addressed this question, only six reported data (suitable for analysis) for the outcomes of interest. Of these six studies, one was probably confounded by the choice of sham PFMT programme (Ramsay 1990) and another was at high risk of bias (Lagro-Janssen 1991). No more than four studies contributed data to each of the formal comparisons, and as discussed above heterogeneity was observed in each of the forest plots that contained data from more than one trial.

Primary outcomes

Patient perceived cure was more likely after PFMT than control, although the estimated effect size was much greater in one of the two trials. The trial with the greater effect size included women with urodynamic stress incontinence only; the other recruited women with detrusor overactivity with or without urodynamic stress incontinence. Of the two diagnoses, and based on biological rationale, it is reasonable to expect that PFMT might have more effect on stress than urge or mixed incontinence. However other factors might also contribute to the difference between the two trials. For example, the trial with the greater effect size defined cure as "unproblematic" incontinence, whereas in the other women reported they were "dry". These descriptors might measure different things. Cure was also more likely in the trial where women trained for longer (six months versus eight weeks), and were younger on average (mean age around 50 compared to 67 years).

Four studies grouped cure and improvement. The data from Ramsay and Thow (1990) were presented in the forest plot, but were thought to be confounded. The other three studies all found statistically significant differences in favour of PFMT, although the estimated size of treatment effect varied considerably. The two trials in women with urodynamic stress incontinence observed similarly large treatment effects, while the suggested effect was much less in the single study in women with detrusor overactivity incontinence with or without urodynamic stress incontinence. Women with urodynamic stress incontinence were about 17 times more likely to report cure and improvement with PFMT than controls. In contrast, women with detrusor overactivity incontinence, with or without urodynamic stress incontinence, were about two to two and a half times more likely to report cure and improvement. In a related outcome, desire for further treatment, Bø et al found urodynamic stress incontinent women were about 12 times less likely to want further treatment after PFMT than controls, while Burgio et al reported that women with detrusor overactivity incontinence (with or without urodynamic stress incontinence) were about three and a half times less likely to do so. As with patient reported cure, the trials with larger effect sizes recruited noticeably younger women. Finally, although there was some similarity in the exercise content of the PFMT programmes, the two trials with greater effects had the longer treatment durations (three and six months, versus eight weeks).

Overall, the differences in likelihood of cure or improvement after PFMT compared to control suggested by the review are sufficient to be of interest to women. As discussed above the proportion of women who are cured or improved might be greater if woman have stress rather than urge or mixed urinary incontinence and train for longer. When interpreting these data it is worth noting that there is a relationship between age and diagnosis; younger women are more likely to have stress urinary incontinence, and older women urge or mixed incontinence (Hannestad 2000). Without an individual patient data analysis it was not possible to tell if diagnosis, age, or duration of training, or all these factors that might be associated with greater treatment effect. The association between these factors and treatment outcome is a hypothesis that requires further testing.

Two studies used psychometrically robust symptom, condition-specific quality of life, or both measures. One study did not present data that enabled comparison between PFMT and control groups, and in the other study only two domains of the questionnaire (lifestyle and sex-life) were reported. The data were presented as frequencies rather than mean scores. While it appeared that fewer PFMT women experienced interference with lifestyle than controls, or problems with their sex-life, it is not clear if the difference in effect was clinically important.

Other symptom and quality of life measures were used. Two trials used the Social Activity Index, a measure of participation in nine specific activities that might precipitate urine leakage. Both found PFMT women were more able to participate than controls, but it is not clear if the difference in scores was statistically significantly different in one of the two studies. Finally, the Hopkins Symptom Checklist for psychological distress, and the Norwegian Quality of Life Scale, were used by one trial each. Neither found any statistically significant differences between the groups.

Based on evidence from single trials, it seems there might be improved condition specific quality of life (lifestyle and sex-life) in women treated with PFMT compared to controls, but there might be less or no effect on generic quality of life. Incontinence-specific quality of life measures have only recently been developed. Some of the included trials predated the development of these instruments. It is interesting that although generic measures of quality of life have been available for longer, they too are

only recent additions in incontinence research. The inclusion of validated, reliable and responsive condition-specific and generic quality of life instruments in future studies of PFMT is imperative.

Secondary outcomes

For leakage episodes, there were statistically significantly fewer leakage episodes with PFMT in all four studies contributing data to the forest plot; one had a noticeably larger treatment effect. This trial was at high risk of bias, and might have overestimated the treatment effect. Apart from the quality of the methods it is not clear why this trial might have been different from the others. If the data from the other three studies is considered together the difference between PFMT and control is about one fewer leakage episode per day. It is not clear how important this difference might be for women; it might well depend on how often they leak, that is if they are leaking often then this difference might not seem important.

Interestingly, leakage frequency was similar between two trials in urodynamic stress incontinent women and the single study in women with detrusor overactivity with or without urodynamic stress incontinence, although the likelihood of self-reported cure and improvement appeared quite different in these diagnostic groups. It is possible that the effect of treatment on leakage episodes is similar, but women with detrusor overactivity incontinence (with or without urodynamic stress incontinence) probably also experience urgency and frequency in addition to urge incontinence. PFMT might be less effective in addressing urgency and frequency than incontinence. If so, then women with urge urinary incontinence will be less likely to report that PFMT has cured or improved their condition, because two of their symptoms might still be bothersome.

A single study presented data on number of voids in a sample of women with urinary incontinence (stress, urge or mixed). It is surprising no other included trial presented data on frequency, as this is a common problem for women with urinary incontinence; even if there is no physiological reason for frequency many women who fear leakage void often to keep bladder volumes low. In the single study with data, PFMT women reported fewer voids per day than controls, but there was no difference in the average number of night-time voids between the groups. Notably, the mean number of day time voids post treatment (approximately 14) in the PFMT group suggested daytime frequency persisted, because a 'normal' daytime voiding frequency might be up to seven to eight voids per day).

Pelvic floor muscle function was measured using vaginal squeeze pressure (perineometry), digital palpation, and vaginal surface electromyography. It is difficult to compare the data from these different tests. Interestingly, three of the studies reporting measures of pelvic floor muscle function also reported data on self-reported cure or cure and improvement, in women with stress urinary incontinence. While none of the three studies found any statistically significant differences between PFMT and control groups for vaginal squeeze pressure (Bø 1999; Ramsay 1990), or electromyography (Burns 1993), two found PFMT women were more likely to report cure or cure and /improvement (Bø 1999; Burns 1993). The trial that did not find a difference in cure rates was potentially confounded (see Results, Primary outcome measures). This suggests that a change in pelvic floor muscle function is not, or perhaps not, the only explanation for the effect of PFMT. It is also possible that other aspects of muscle function that were not measured in these two trials (for example better timing of pelvic floor muscle contraction during cough or sneeze or exertion) might contribute to the perception of improvement in incontinence.

Other outcomes

Treatment adherence is likely to have an impact on the size and direction of treatment effect, because adherence affects the exercise 'dose'. Although adherence data might be useful in interpreting trial results, treatment adherence is difficult to measure. An exercise or training diary was used by five studies, and self-reported adherence recorded in another. It is not clear how accurate the estimate of adherence from either measure is; both allow a woman to report what they think they should, or what the researchers want to hear, rather than what was actually done. However, it is interesting to note that the two trials that reported good to excellent rates of training adherence were also the two trials that demonstrated the greatest treatment effects for cure and improvement. Because these two trials also recruited young, urodynamic stress incontinence women, there are other potential explanations for this observation. Nevertheless, it is possible that treatment adherence contributed.

Two of the three studies that reported adverse events stated there were none with PFMT. The other trial recorded a few minor effects of PFMT (for example discomfort with training), and all of which were reversible with cessation of training. Although randomised trials are probably not the most appropriate way to address safety, neither these data nor the content of PFMT suggest that PFMT is likely to be unsafe.

The data on longer term follow up were quite difficult to interpret. It does appear that some women are able to maintain or even improve their response to PFMT over time (even as much as five years), although some do not. Effect might be maintained best in those with stress urinary incontinence. Some level of adherence to training might be a key factor in maintaining benefit.

None of the included studies was accompanied by a cost description, cost analysis or cost effectiveness study. Although the review suggested PFMT is better than control treatments, in the absence of economic data it was not possible to estimate at what costs these gains are made.

AUTHORS' CONCLUSIONS

Implications for practice

Based on the few data available, it seems PFMT is better than no treatment, placebo drug, or inactive control treatments for women with stress, urge, or mixed incontinence. Women treated with PFMT were more likely to report cure or improvement, and have fewer leakage episodes per day than controls. Condition specific quality of life might also be better after PFMT, but this finding needs confirmation from further studies. The trials suggested that the treatment effect might be greater in women with stress urinary incontinence only who tended to be younger (in their 40s and 50s), and participating in a supervised PFMT programme for at least three months. These are hypotheses that need further testing. It seems likely that treatment effect will be enhanced if the PFMT programme is based on sound physiological principles, a correct contraction is confirmed prior to training, and women are supported to maintain treatment adherence. Overall, there is

some support for the widespread recommendation that PFMT be included in first line conservative management programmes for women with stress, urge or mixed urinary incontinence.

The limited nature of follow up beyond the end of treatment means that the long-term outcomes of use of PFMT are less clear. It seems symptoms do deteriorate for some women, and some women choose alternative treatments. However, some women continue to be satisfied with the outcome of PFMT. Continued training adherence is likely to be associated with maintenance or increased treatment effect. Unfortunately, it is not known whether PFMT is cost effective in the short or long term.

Implications for research

Most of the data in the review comes from small to moderate sized studies, of poor to moderate methodological quality. In planning future research trialists are encouraged to consider the following:

- The choice of primary outcome, the size of clinically important effect, and subsequent estimation of sample size.
- The choice of secondary outcome measures.
- The duration of follow up.
- The reporting of methods and data.

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 domains, and opted for tools with established validity, reliability and responsiveness. Domains that require particular attention in future are quality of life (condition specific and generic) and socioeconomics, as these have been poorly addressed to date. Researchers might reconsider the past emphasis on self-reported cure or improvement as the principal means to collect data in the domain of women's observations. Two recent trials included in the review asked women if they wanted further treatment and/or were satisfied with treatment outcome, or both. Questions such as these have potential merit; 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. As PFMT often precedes other more invasive treatment options, such as surgery, the proportion of women satisfied with outcome of PFMT (and for how long they remain so) might be important information for women, for clinicians, and for service planners. 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.

The reporting of methods and data could be much improved. Some included studies 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; 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 clinical effectiveness of PFMT. Such a trial would recruit women with symptoms of stress, urge, or mixed urinary incontinence based on clinical history and physical examination; and with a sample size based on a clinically important difference in condition-specific quality of life, and sufficient for subgroup analysis on the basis of diagnosis and age. Stratification or minimisation procedures would ensure even distribution of women with different diagnoses across both arms of the trial. One arm of the study would comprise a supervised PFMT programme derived from sound exercise science, confirmation of a correct voluntary pelvic floor muscle contraction, and incorporate appropriate adherence measures. 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 health care delivery systems. The other arm of the trial would be a control treatment, for example explanation of anatomy and physiology of the bladder and pelvic floor, advice on good bladder habits, with the same explanation and advice given in both arms. Such a trial would require substantial funding, and multiple recruitment centres.

ACKNOWLEDGEMENTS

The authors of this review would like to acknowledge the following.

- The considerable contribution made by Kari Bø, Bary Berghmans, Erik Hendriks, Rob de Bie and Ernst van Waalwijk van Doorn, co-authors of the previous version of the PFMT review (Hay-Smith 2002b).
- The assistance of Michael Albert and Peter Dietz in translating papers from German to English.

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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.
Notes	Post-treatment evaluation at 8 weeks, no longer-term follow up. Dropouts: not stated.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

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	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

Bidmead 2002 *(Continued)*

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

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 arhythmias, 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
Allocation concealment?	Unclear risk	B - Unclear

Burns 1993

Methods	3 arm RCT, parallel design. Not clear if adequate allocation concealment. Blinded outcome assessment.

Burns 1993 *(Continued)*

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
Allocation concealment?	Unclear risk	B - Unclear

Bø 1999

Methods	4 arm RCT, parallel design. Stratified by severity of leakage on pad test. Adequate allocation concealment. Blinded outcome assessment. Secondary analysis by intention to treat. A priori power calculation.
Participants	122 women, with urodynamic SUI. Inclusion: women with a history of SUI, waiting for surgery or recruited through advertising, >4g leakage on pad test with standardised bladder volume. 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. Mean age, years: PFMT 49.6 (SD 10.0), control 51.7 (SD 8.8). Mean duration symptoms, years: PFMT 10.2 (SD 7.7), control 9.9 (SD 7.8). Mean leakage episodes 24 hours: PFMT 0.9 (SD 0.6), control 1.0 (SD 1.0). Diagnosis: 122 urodynamic SUI (100%). 5 centres, Norway.
Interventions	1. PFMT (n=29). Explanation of anatomy, physiology, and continence mechanism by physiotherapist. Audiotape of home training programme. Weekly 45 minute exercise class to urodynamic SUI 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.

Bø 1999 *(Continued)*

	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). 3. Electrical stimulation (n=32). 4. Vaginal cones (n=29).
Outcomes	Primary outcomes: 60 second pad test with standardised bladder volume, self-report (very problematic to unproblematic). 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.
Notes	Post-treatment evaluation at 6 months, no longer-term follow up. Dropouts: 4/29 PFMT, 2/32 controls, 7/32 electrical stimulation, 2/29 vaginal cones. ITTA: baseline values used for losses to follow up.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

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	1. PFMT (n=26). Correct VPFMC taught by physiotherapist. Weekly clinic visit for 12 weeks. Details of PFMT programme in Data Table 01.03. 2. Control (n=25). No treatment. 3. Electrical stimulation (n=25). 4. 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.
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
Allocation concealment?	Unclear risk	B - Unclear

Henalla 1990

Methods	3 arm RCT, parallel design. 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
Allocation concealment?	Unclear risk	B - Unclear

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 contrrol.
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).
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 peformed. Further follow-up at 6 months. Dropouts: none?

Risk of bias

Bias	Authors' judgement	Support for judgement

Hofbauer 1990 *(Continued)*

Allocation concealment?	Unclear risk	B - Unclear

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.
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**
Allocation concealment?	High risk	C - Inadequate

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).

Miller 1998 *(Continued)*

	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.
Outcomes	Primary outcome measure: Paper towel test. Secondary outcome measures: digital palpation.
Notes	Post-treatment evaluation: one week, no longer-term follow-up. Dropouts: none.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Ramsay 1990

Methods	2 arm RCT, parallel design. Not clear if adequate allocation concealment. Blinded participants.
Participants	44 women, with symptoms of SUI. inclusion: women whose only symptom was SUI. Exclusion: no additional criteria reported. Diagnosis: 44 SUI (100%). Single centre, Scotland.
Interventions	1. PFMT (n=22). Taught by physiotherapist. PFMT for 2 weeks. Details of PFMT programme in Data Table 01.03. 2. Controls (n=22). As above, but with sham PFMT programme comprising hip abductor muscle contraction with feet crossed at the ankles.
Outcomes	Primary outcome: not stated. Other outcomes: self-reported severity (worse to improved), pad test, vaginal squeeze pressure.
Notes	Post-treatment evaluation at 12 weeks, with no longer-term follow up. Dropouts: none. ITTA: data for all participants.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

van Leeuwen 2004

Methods	RCT, 2x2 design. Not clear if adequate random allocation concealment.

van Leeuwen 2004 *(Continued)*

	Blinded for drug but not PFMT components of intervention? Intention to treat analysis.
Participants	201 women with urodynamic SUI or positive cough test. Inclusion: women aged 18-75 years with two or more stress leakage episodes per day and normal voiding frequency. Exclusion: enuresis, urge incontinence. Five centes, 3 countries (The Netherlands, UK, USA).
Interventions	1. PFMT + placebo drug (n=50). 2. Control (n=47). Imitation PFMT (not defined) and placebo drug. 3. PFMT + drug (n=52). Duloxetine. 4. Imitation PFMT + drug (n=52).
Outcomes	Primary outcome: percent change in incontinence episode frequency. Secondary outcomes: change in Incontinence Quality of Life (I-QoL), percent change in pad use.
Notes	Post-treatment evaluation at 12 weeks, no longer term follow up. Dropouts: yes, but no data given.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Yoon 2003

Methods	3-arm RCT, parallel design. Not clear if adequate allocation concealment. Blinded outcome assessment.
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
Allocation concealment?	Unclear risk	B - Unclear

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
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.
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.
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 ongoing studies *[ordered by study ID]*

Leics MRC

Trial name or title	The evaluation of pelvic floor therapies in women with genuine stress incontinence: A randomised controlled trial in primary care.
Methods	
Participants	360 women with genuine stress incontinence (now called urodynamic stress incontinence) following failure of nurse led conservative management (pelvic floor awareness comprising a leaflet, verbal instruction but no pelvic examination).
Interventions	1. PFMT. Vaginal palpation of correct VPFMC, perineometry, 4 clinic visits over 12 weeks. 2. Vaginal cones. 3. Control. Pelvic floor awareness.
Outcomes	Urinary diary. 1 hour pad test. 24 hour pad test. Perineometry. Palpation of PFM strength. Urodynamics.
Starting date	Trial began June 1st 1997. Anticipated completion on April 1st 2001.
Contact information	Dr P Assassa, Senior Clinical Research Fellow, University of Leicester.
Notes	Details confirmed by lead researcher.

MRC = Medical Research Council (UK), PFMT = pelvic floor muscle training, VPFMC = voluntary pelvic floor muscle contraction.

DATA AND ANALYSES

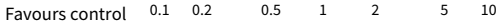
Comparison 1. PFMT versus no treatment, placebo or control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient perceived 'cure'	2		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 stress urinary incontinence	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 urge urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 mixed urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.4 urinary incontinence (all types)	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Patient perceived cure or improvement	4		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 stress urinary incontinence	3		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 urge urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.3 mixed urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.4 urinary incontinence (all types)	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Symptom and condition specific quality of life assessment			Other data	No numeric data
4 Number of leakage episodes in 24 hours	4		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 stress urinary incontinence	3		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.2 urge urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.3 mixed urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.4 urinary incontinence (all types)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Number of voids per day (frequency)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
5.1 stress urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.2 urge urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.3 mixed urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.4 urinary incontinence (all types)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Number of voids per night (nocturia)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 stress urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.2 urge urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.3 mixed urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.4 urinary incontinence (all types)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Pelvic floor muscle function			Other data	No numeric data
8 Non-incontinence symptom and generic quality of life assessment assessment			Other data	No numeric data
9 Other measures of patient perceived response to treatment			Other data	No numeric data
10 Pad and paper towel tests			Other data	No numeric data

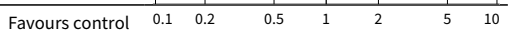
Analysis 1.1. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 1 Patient perceived 'cure'.

Study or subgroup	PFMT n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
1.1.1 stress urinary incontinence				
Bø 1999	14/25	1/30		16.8[2.37,119.04]
1.1.2 urge urinary incontinence				
1.1.3 mixed urinary incontinence				
1.1.4 urinary incontinence (all types)				
Burgio 1998	19/63	8/62		2.34[1.11,4.94]

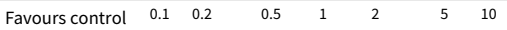


Analysis 1.2. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 2 Patient perceived cure or improvement.

Study or subgroup	PFMT n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
1.2.1 stress urinary incontinence				
Bø 1999	12/25	1/30		14.4[2.01,103.23]
Lagro-Janssen 1991	20/33	1/33		20[2.85,140.51]
Ramsay 1990	14/22	14/22		1[0.64,1.56]
1.2.2 urge urinary incontinence				



Study or subgroup	PFMT n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
1.2.3 mixed urinary incontinence				
1.2.4 urinary incontinence (all types)				
Burgio 1998	46/63	20/62		2.26[1.53,3.35]

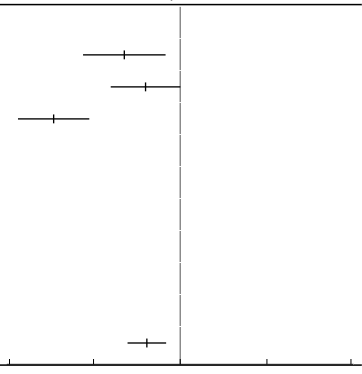


Analysis 1.3. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 3 Symptom and condition specific quality of life assessment.

		Symptom and condition specific quality of life assessment			
Study	**Outcome**	**Measure**	**PFMT**	**Control**	**Difference**
Aksac 2003	Social Activity Index. Sum of visual analogue scale scores for perceived difficulty participating in 9 specified social situations. A lower score indicates a more perceived problem	median (standard deviation)	7.5 (1.2), n=20.	3.6 (0.6), n=10.	Not estimable.
Bø 1999	Bristol Female Lower Urinary Tract Symptoms Questionnaire (BFLUTS). For analysis positive findings ('a little', 'somewhat' and 'a lot', or 'a bit of a problem', 'quite a problem' and 'a serious problem') were grouped together and reported as frequencies. Only the lifestyle questions (28-31, 33) and sex-life questions (21-24) were reported. Social Activity Index. Sum of visual analogue scale scores for perceived difficulty participating in 9 specified social situations. A lower score indicates a more perceived problem	number with positive findings mean score (standard deviation)	Avoiding places and situations: 7, n=25. Interference with social life: 1, n=25 Interference with physical activity: 11, n=25. Overall interference with life: 14, n=25 Unsatisfied if had to spend rest of life as now: 10, n=25. Sex-life spoilt by urinary symptoms: 3, n=20. Problem with sex-life being spoilt: 2, n=20. Problem with painful intercourse, 2, n=20. Urinary incontinence with intercourse: 2, n=20. 9.3 (1.0), n=25.	Avoiding places and situations: 10, n=30. Interference with social life: 12, n=30. Interference with physical activity: 24, n=30. Overall interference with life: 25, n=30. Unsatisfied if had to spend rest of life as now: 11, n=30. Sex-life spoilt by urinary symptoms: 13, n=25. Problem with sex-life being spoilt: 13, n=25. Problem with painful intercourse: 10, n=25. Urinary incontinence with intercourse: 10, n=25. 7.9 (2.2), n=30.	Avoiding places and situations: relative risk (RR) 0.84, 95% confidence interval (CI) 0.37 to 1.88 Interference with social life: RR 0.10, 95% CI 0.01 to 0.72 Interference with physical activity: RR 0.55, 95% CI 0.34 to 0.89 Overall interference with life: RR 0.67, 95% CI 0.46 to 0.99. Unsatisfied if had to spend rest of life as now: RR 0.11, 95% CI 0.02 to 0.79. Sex-life spoilt by urinary symptoms: RR 0.29, 95% CI 0.10 to 0.87. Problem with sex-life being spoilt: RR 0.19, 95% CI 0.05 to 0.76. Problem with painful intercourse: RR 0.25, 95% CI 0.06 to 1.01. Urinary incontinence with intercourse: RR 0.25, 95% CI 0.06 to 1.01. mean difference (MD) 1.4, 95% CI 0.4 to 2.4.
van Leeuwen 2004	Incontinence Quality of Life (I-QoL) score	Mean change (standard deviation)	7.8 (?), n=?	4.8 (?), n=?	Not estimable.

Analysis 1.4. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 4 Number of leakage episodes in 24 hours.

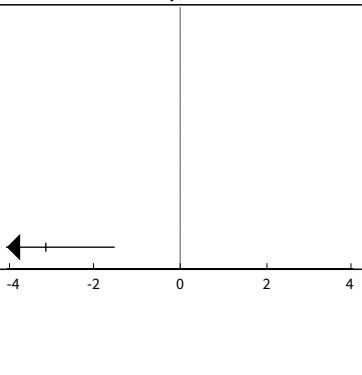
Study or subgroup	PFMT N	PFMT Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
1.4.1 stress urinary incontinence						
Burns 1993	43	1.1 (1.4)	39	2.4 (2.7)		-1.29[-2.24,-0.34]
Bø 1999	25	0.3 (0.7)	30	1.1 (2.1)		-0.8[-1.6,0]
Lagro-Janssen 1991	33	0.7 (0.8)	33	3.6 (2.3)		-2.92[-3.74,-2.1]
1.4.2 urge urinary incontinence						
1.4.3 mixed urinary incontinence						
1.4.4 urinary incontinence (all types)						
Burgio 1998	63	0.4 (0.7)	62	1.2 (1.7)		-0.77[-1.22,-0.32]



Favours PFMT — Favours control

Analysis 1.5. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 5 Number of voids per day (frequency).

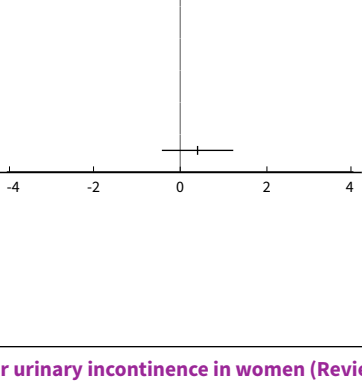
Study or subgroup	PFMT N	PFMT Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
1.5.1 stress urinary incontinence						
1.5.2 urge urinary incontinence						
1.5.3 mixed urinary incontinence						
1.5.4 urinary incontinence (all types)						
Yoon 2003	13	14.3 (2.4)	12	17.4 (1.6)		-3.1[-4.69,-1.51]



Favours PFMT — Favours control

Analysis 1.6. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 6 Number of voids per night (nocturia).

Study or subgroup	PFMT N	PFMT Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
1.6.1 stress urinary incontinence						
1.6.2 urge urinary incontinence						
1.6.3 mixed urinary incontinence						
1.6.4 urinary incontinence (all types)						
Yoon 2003	13	1.9 (1.1)	12	1.5 (1)		0.4[-0.42,1.22]



Favours PFMT — Favours control

Analysis 1.7. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 7 Pelvic floor muscle function.

Pelvic floor muscle function					
Study	**Outcome**	**Measure**	**PFMT**	**Control**	**Difference**
Aksac 2003	Vaginal squeeze pressure, cm water	median (standard deviation)	37.5 (8.7), n=20.	20.0 (3.9), n=10.	Not estimable
	Digital palpation score (6 point ordinal scale, 0 to 5)	median (standard deviation)	4.8 (0.4), n=20.	3.3 (0.6), n=10.	Not estimable
Burns 1993	Vaginal electromyography, mean of five fast contractions, microvolts	mean (standard deviation)	3.0 (3.4), n=38.	3.5 (4.4), n=40.	mean difference (MD) -0.5, 95% confidence interval (CI) -2.3 to 1.3.
	Vaginal electromyography, mean of five sustained contractions, microvolts	mean (standard deviation)	1.8 (2.0), n=33.	2.0 (1.8), n=34.	MD -0.2, 95% CI -1.1 to 0.7.
Bø 1999	Vaginal squeeze pressure, cm water	mean (standard deviation)	19.2 (10.0), n=25.	16.4 (9.8), n=30.	MD 2.8, 95% CI -2.6 to 8.2.
Miller 1998	Digital palpation score (0-21)	mean (standard deviation)	10.4 (4.7), n=13.	11.2 (5.1), n=13.	MD -1.1, 95% CI -5.1 to 2.9.
Ramsay 1990	Vaginal squeeze pressure		no data	no data	Not estimable. Abstract states that there was no statistically significant difference between the groups.
Yoon 2003	Vaginal squeeze pressure, mm Hg	mean (standard deviation)	26.1 (12.5), n=13.	12.2 (5.3), n=12.	MD 13.9, 95% CI 5.8 to 22.0.
	Peak vaginal squeeze pressure	mean (standard deviation)	39.7 (20.0), n=13.	19.9 (7.5), n=12.	MD 19.8, 95% CI 7.1 to 32.5
	Duration of contraction	mean (standard deviation)	14.5 (3.0), n=13.	5.9 (1.7), n=12.	MD 8.6, 95% CI 6.6 to 10.6.

Analysis 1.8. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 8 Non-incontinence symptom and generic quality of life assessment assessment.

Non-incontinence symptom and generic quality of life assessment assessment					
Study	**Outcome**	**Measure**	**PFMT**	**Control**	**Difference**
Burgio 1998	Hopkins Symptom Checklist, for psychological distress (SCL-90-R). A 90 item self administered questionnaire, with nine clinical subscales (somatization, obsessive/compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoia ideation, psychoticism) and 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 (standard deviation)	All n=57. Somatization: 51.8 (11.4). Obsessive/compulsive: 53.8 (13.9). Interpersonal sensitivity: 49.5 (12.0). Depression: 51.5 (11.5). Anxiety: 46.1 (14.6). Hostility: 44.9 (10.8). Phobia: 47.1 (11.2). Paranoia ideation: 45.8 (10.9). Psychoticism: 49.2 (11.7). Global severity: 50.8 (12.8).	All n=46. Somatization: 49.8 (13.0). Obsessive/compulsive: 55.4 (11.0). Interpersonal sensitivity: 49.2 (11.3). Depression: 51.4 (11.2). Anxiety: 45.8 (12.9). Hostility: 47.3 (11.2). Phobia: 45.1 (8.5). Paranoia ideation: 47.2 (12.0). Psychoticism: 49.6 (10.3). Global severity: 51.4 (10.9).	Somatization: mean difference (MD) 2.0, 95% confidence interval (CI) -2.8 to 6.8. Obsessive/compulsive: MD -1.6, 95% CI -5.7 to 2.5. Interpersonal sensitivity: MD 0.3, 95% CI -4.3 to 4.9. Depression: MD 0.1, 95%CI -4.4 to 4.6. Anxiety: MD 0.3, 95% CI -5.1 to 5.8. Hostility: MD -2.4, 95% CI -6.7 to 1.9. Phobia: MD 2.0, 95% CI -2.0 to 6.0. Paranoia ideation: MD -1.4, 95% CI (-5.9 to 3.1) Psychoticism: MD -0.4, 95% CI -4.8 to 4.0 Global severity: MD -0.6, 95% CI -5.3 to 4.1.
Bø 1999	Norwegian Quality of Life Scale (QoLS-N). A 16 item scale for use in populations with chronic illness. Uses a 7 point satisfaction scale per item.	mean total score, (standard deviation)	90.1 (9.5), n=25.	85.2 (12.1), n=30.	MD 4.9, 95% CI -1.1 to 10.9.

Non-incontinence symptom and generic quality of life assessment assessment

Study	Outcome	Measure	PFMT	Control	Difference
	A higher score indicates a higher quality of life.				

Analysis 1.9. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 9 Other measures of patient perceived response to treatment.

Other measures of patient perceived response to treatment

Study	Outcome	Measure	PFMT	Control	Difference
Burgio 1998	Patient perception of frequency of leakage.	Number reporting fewer leaks	58/58	35/52	relative risk (RR) 1.5, 95% confidence interval (CI) 1.2 to 1.8.
			48/55	27/50	
	Patient perception of amount per leakage episode.	Number who perceive reduced amount	49/57	12/49	RR 1.6, 95% CI 1.2 to 2.1.
	Desire for further treatment.	Number not desiring further treatment.			RR 3.5, 95% CI 2.1 to 5.8.
Bø 1999	Leakage Index. Perceived frequency of leakage with 7 prespecified types of exertion. Higher score indicates more perceived leakage.	Mean (standard deviation)	1.9 (0.5), n=25	3.1 (0.6), n=30	mean difference (MD) -1.2, 95% CI -1.5 to -0.9.
			21/25	2/30	
		Number not desiring further treatment			RR 12.6, 95% CI 3.3 to 48.6.
	Desire for further treatment.				
Yoon 2003	Urinary incontinence score. Sum of scores from 5 point Likert scales regarding severity of leakage with 18 prespecified activities.	Mean (standard deviation)	10.8 (6.2), n=13.	14.2 (3.6), n=12.	MD -3.4, 95% CI -7.6 to 0.8.

Analysis 1.10. Comparison 1 PFMT versus no treatment, placebo or control, Outcome 10 Pad and paper towel tests.

Pad and paper towel tests

Study	Outcome	Measure	PFMT	Control	Difference
Aksac 2003	Pad test (not defined), g.	median (standard deviation)	2.1 (0.4), n=20	28.2 (3.7), n=10	Not estimable
	Pad test cure (1g or less).	number cured	15/20	0/10	Relative risk (RR) 16.2, 95% confidence interval (CI) 1.1 to 246.5
			20/20	2/10	
	Pad test cure or improved (improvement = 50% reduction or more in pad weight from baseline).	number cured or improved			RR 5.0, 95% CI 1.5 to 17.2.
Bidmead 2002	Pad weight change from baseline, g.	mean (standard error)	-9.62 (3.37), n=40.	3.65 (1.17), n=20.	Mean difference (MD) -13.3, 95% CI -23.1 to -3.4.
Bø 1999	Pad test (60 second), g.	mean (standard deviation)	8.4 (11.5), n=25	38.7 (43.9), n=30.	MD -30.3, 95% CI -48.4 to -12.2
	Pad test (24 hour), g.		7.9 (16.7), n=25	35.4 (92.5), n=30.	MD -27.5, 95% CI -65.2 to 10.2
	Pad test cure (2g or less on 60 second test)	mean (standard deviation)	11/25	2/30	
		number cured			RR 6.6, 95% CI 1.6 to 27.0.
Henalla 1989	Pad test (Sutherst et al 1981). Cure (negative following postive test) or improved (50% or greater reduction in pad weight from baseline)	number cured or improved	17/26	0/25	RR 33.7, 95% CI 2.1 to 532.0.

		Pad and paper towel tests			
Study	**Outcome**	**Measure**	**PFMT**	**Control**	**Difference**
Henalla 1990	Pad test (not defined). Cured or improved (failure less than 50% reduction in pad weight from baseline)	number cured or improved	4/8	0/7	RR 8.0, 95% CI 0.5 to 126.7.
Miller 1998	Paper towel test, wet area in cm squared.	mean area on medium cough (standard deviation) mean area on deep cough (standard deviation)	0.4 (1.04), n=13. 5.4 (15.3), n=13.	21.2 (44.8), n=10. 26.8 (46.7), n=10.	MD -20.8, 95% CI -46.5 to 4.9. MD -21.4, 95% CI -50.0 to 7.2.
Ramsay 1990	Pad test (not defined), g.	mean change	-1.5, n=22.	2.1, n=22.	Not estimable
van Leeuwen 2004	Decrease in pad use.	median percent decrease (?)	25% (?), n=?	10% (?), n=?	Not estimable
Yoon 2003	Pad test (30 minute), g.	mean (standard deviation)	3.3 (4.5), n=13.	8.4 (9.8), n=12.	MD -5.1, 95% CI -11.3 to 1.1

ADDITIONAL TABLES

Table 1. PFMT programmes

Study ID	VPFMC confirmed	Description	VPFMC per day	Training	Supervision
Aksac 2003	Voluntary pelvic floor muscle contraction (VPFMC) confirmed by palpation. Relaxation of abdominal and buttock muscles.	Set: 10 VPFMC, with 5 second hold and 10 second rest. Progressed at 2 weeks to 10 second hold and 20 second rest. Sets per day:3.	30.	8 weeks.	Weekly clinic visits.
Burgio 1998	Anorectal biofeedback for teaching selective contraction and relaxation of pelvic floor muscles, while keeping abdominal muscles relaxed.	Set: 15 VPFMC, with 10 seconds hold. Sets per day: 3. Body position: lying, sitting, standing. Use of VPFMC to prevent leakage (the Knack), and to suppress urge. Interrupt urine stream once per day. 45.8 weeks. Fortnightly clinic visit with nurse practitioner.	45.	8 weeks.	Fortnightly clinic visit with nurse practioner.
Burns 1993		Set: 10 VPFMC with 3 second hold, and 10 VPFMC with 10 second hold. Progressed by 10 per set to daily maximum of 200. Sets per day:4. Videotape describing exercise protocol.	200.	8 weeks.	Weekly exercise reminder cards mailed between visits. Weekly clinic visits with nurse.
Bo 1999	VPFMC confirmed by palpation	Set: 8 to 12 high intensity (close to maximal) VPFMC, with 6 to 8 second hold and 3 to 4 fast contractions added at the end of each hold, 6 second rest between contractions. Sets	36.	6 months.	Weekly 45 minute exercise

Table 1. PFMT programmes *(Continued)*

		per day: 3. Body position: included lying, kneeling, sitting, standing; all with legs apart. Women used preferred position. Audiotape of home training programme. Weekly 45 minute exercise class to music, with PFMT in a variety of body positions, and back, abdominal, buttock and thigh muscle exercises.			class. Monthly clinic visit with physiotherapist.
Henalla 1989	Correct VPFMC taught by physiotherapist.	Sets: 5 VPFMC, with 5 second hold. Sets per day: 1 set per hour.	Approximately 80.	12 weeks.	Weekly clinic visit.
Lagro-Janssen 1991	Teaching from family doctor.	Sets: 10 VPFMC, with 6 seconds hold. Sets per day: 5 to 10.	50 to 100.	12 weeks.	
Ramsay 1990	Taught by physiotherapist.	Set: 4 maximum isometric VPFMC, with 4 second hold and 10 second rest. Sets per day: 1 set every waking hour.	Approximately 64.	12 weeks.	
Yoon 2003	Weekly surface electromyography biofeedback with nurse.	Set: not stated. Sets per day: 30 VPFMC for strength and endurance per day (not clear if 30 total or 30 each), taking 15 to 20 minutes per day. Strength: burst of intense activity lasting a few seconds. Endurance: 6 second holds progressed by 1 second per week to 12 seconds.	Not clear if 30 or 60.	8 weeks.	Weekly clinic visit with nurse.

WHAT'S NEW

Date	Event	Description
13 October 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 1, 1999
Review first published: Issue 1, 2001

Date	Event	Description
15 November 2005	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Both reviewer authors were involved in all stages of the review. Jean Hay-Smith wrote the first draft of the protocol and review.

DECLARATIONS OF INTEREST

Both authors have published trials investigating the effects of PFMT; both trials were clearly exclusions from this review based on the participants (antenatal and postnatal women) or the comparison intervention (one type of PFMT versus another).

SOURCES OF SUPPORT

Internal sources

- University of Otago, New Zealand.

External sources

- No sources of support supplied

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