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

Dumoulin C, Hay-Smith J

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2010, Issue 1

http://www.thecochranelibrary.com

TABLE OF CONTENTS

HEADER 1
ABSTRACT 1
PLAIN LANGUAGE SUMMARY 2
BACKGROUND 2
OBJECTIVES 5
METHODS 5
RESULTS 7
DISCUSSION 17
AUTHORS' CONCLUSIONS 21
ACKNOWLEDGEMENTS 22
REFERENCES 22
CHARACTERISTICS OF STUDIES 27
DATA AND ANALYSES 40
WHAT'S NEW 41
HISTORY 41
CONTRIBUTIONS OF AUTHORS 41
DECLARATIONS OF INTEREST 42
SOURCES OF SUPPORT 42
INDEX TERMS 42

[Intervention Review]

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

Chantale Dumoulin[1], Jean Hay-Smith[2]

[1]School of Rehabilitation, Faculty of Medicine, University of Montreal, Montreal, Canada. [2]Department of Women's and Children's Health, Dunedin School of Medicine, Dunedin, New Zealand

Contact address: Chantale Dumoulin, School of Rehabilitation, Faculty of Medicine, University of Montreal, 7077 avenue du Parc, Montreal, Quebec, H3N 1X7, Canada. dumoulin@sympatico.ca.

Editorial group: Cochrane Incontinence Group.
Publication status and date: Edited (no change to conclusions), published in Issue 1, 2010.
Review content assessed as up-to-date: 9 November 2009.

Citation: Dumoulin C, Hay-Smith J. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2010, Issue 1. Art. No.: CD005654. DOI: 10.1002/14651858.CD005654.pub2.

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 strategy

The Cochrane Incontinence Group Specialised Trials Register (searched 18 February 2009) and the reference lists of relevant articles were searched.

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 2008). Trials were subgrouped by diagnosis. Formal meta-analysis was not undertaken because of study heterogeneity.

Main results

Fourteen trials involving 836 women (435 PFMT, 401 controls) met the inclusion criteria; twelve trials (672) contributed data to the analysis. Many 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. Women who did PFMT also reported better continence specific quality of life than women who did not. PFMT women also experienced fewer incontinence episodes per day and less leakage on short office-based pad test. Of the few adverse effects reported, none were serious. The trials in stress urinary incontinent women which suggested greater benefit recommended a longer training period than the one trial in women with detrusor overactivity (urge) incontinence.

Authors' conclusions

The review provides 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 seems greater in women 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 versus no treatment for urinary incontinence in women.

Stress incontinence is the involuntary leakage of urine with a physical activity such as coughing or sneezing 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

A wide range of treatments has been used in the management of urinary incontinence, including conservative interventions (such as: physical therapies including pelvic floor muscle training, cones (Herbison 2002); lifestyle interventions, behavioural training for example bladder training (Wallace 2004), and anti-incontinence devices (Shaikh 2006)), pharmaceutical interventions (for example anticholinergics (Nabi 2006)), surgery (for example minimally invasive sling operations (Ogah 2009)) or absorbent products (Fader 2007; Fader 2008). This review will focus on one of the physical therapies, pelvic floor muscle training.

Description of the condition

Urinary incontinence

Urinary incontinence is a common problem amongst adults living in the community. It is more frequent in women, increasing with age, and is particularly common amongst those in residential care (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).

Not only is UI a serious medical condition in that it can lead to perineal rash, pressure ulcers and urinary tract infections (Resnick 1989), it is also an undeniable social problem, creating embarrassment and negative self-perception (Hunskaar 1991; Johnson 1998). UI has been found to reduce both social interactions and

physical activities (Resnick 1989) and is associated with poor self-rated health (Johnson 1998), impaired emotional and psychological well being (Johnson 1998) and impaired sexual relationships (Temml 2001). Women with UI often find themselves, in the medium or long term, isolated and relatively inactive (Fantl 1996). Moreover, UI in older women doubles the risk of admission to a nursing home, independent of age or the presence of co-morbid conditions (Hunskaar 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 sub-optimal 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.

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.

Description of the intervention

Pelvic floor muscle training (PFMT)

Pelvic floor muscle training (PFMT) has been part of exercise programs in Chinese Taoism for over 6,000 years (Chang 1984). It first entered modern medicine in 1936; a paper by Margaret Morris describing tensing and relaxing of the PFM introduced the use of PFMT as a preventative and treatment option for urinary and faecal incontinence to the British physiotherapy profession (Morris 1936). However, PFMT as a treatment for stress urinary incontinence (SUI) did not become widespread until after the mid-1900s when American gynaecologist Arnold Kegel reported on the successful treatment of 64 cases of female stress urinary incontinence using PFM exercises with a pressure biofeedback perineometer (Kegel 1948).

How the intervention might work

Biological rationale for PFMT for SUI and MUI

The biological rationale is three-fold. Firstly, an intentional, effective PFM contraction (lifting the PFM in a cranial and forward direction) prior to and during effort or exertion clamps the urethra and increases the urethral pressure, preventing urine leakage (DeLancey 1988a). Ultrasonography and MRI studies have demonstrated the cranial and forward movement of the PFM during active contraction and the resulting impact on the urethral position, which supports this rationale (Bø 2001; Thompson 2003). Miller (Miller 1998) named this counter-balancing PFM contraction prior to a cough the 'knack' and assessed its effectiveness in an RCT (Miller 1998); they demonstrated that a voluntary PFM contraction before or during coughing can reduce leakage after only one week of training. Other published research, employing the term 'PFM functional training', recommends pre-contracting the PFM not only during a cough but for any daily task that results in increased intra-abdominal pressure (Carrière 2006). Thus, research suggests that the timing of a PFM contraction might be an important factor in the maintenance of urinary continence. However, the optimal strength required to clamp the urethra and prevent urine leakage has not yet been determined. In healthy continent women, activation of the PFM before or during physical

exertion seems to be an automatic response that does not require conscious effort (Bø 1994; Deindl 1993; Peschers 2001). There is some evidence that this PFM 'reflex' contraction is a feed-forward loop and might precede bladder pressure rise by 200 to240 milliseconds (Constantinou 1982; Thind 1990). For incontinent women, learning to rapidly perform a strong, well-timed PFM contraction may actively prevent urethral descent during an intra-abdominal rise in pressure (Bø 1995).

Secondly, the bladder neck receives support from a strong, toned PFM (resistant to stretching), thereby limiting its downward movement during effort and exertion, preventing urine leakage (Bø 2004; DeLancey 1988a; Peschers 2001). Bø has suggested that intensive strength training may build up the structural support of the pelvis by permanently elevating the levator plate to a higher position inside the pelvis and by enhancing the hypertrophy and stiffness of its connective tissues (Bø 2004). In line with and supporting this hypothesis, differences in the anatomical position of the PFM have been demonstrated between continent and incontinent women (Hoyte 2001; Peschers 1997). Additionally, dynamometric studies have shown that SUI and MUI women demonstrate less PFM tone, maximal strength, rapidity of contraction and endurance as compared to continent women (Morin 2004; Verelst 2004). Further, in an uncontrolled MRI reconstruction study, a significant reduction in the internal surface area of the levator ani was observed after PFMT suggesting an increase in passive stiffness of the levator ani, which is indicative of the state of PFM tone (Dumoulin 2007). Griffin 1994, using a pressure probe inside the vagina, also showed a significant difference in subjects' PFM resting pressure three to four weeks after starting PFMT and increased resting pressure after PFMT was completed (Griffin 1994). Furthermore, Balmforth 2004 reported increased urethral stability at rest and during effort following 14 weeks of supervised PFMT and behavioural modifications (Balmforth 2004). Thus, there is a growing body of evidence to support the rationale that PFMT improves PFM tone and that it may facilitate more effective automatic motor unit firing of the PFM, preventing PFM descent during increased intra-abdominal pressure, which in turn prevents urine leakage (Bø 2007).

Thirdly, PFM may be activated with a transversus abdominus (TrA) muscle contraction; this has implications for coordination of muscle activity in and around the pelvis/abdomen during everyday activity. An increasing body of evidence suggests that the active contraction of the TrA muscle is associated with co-activation of the PFM. This has been demonstrated by US, EMG and MRI studies (Dumoulin 2006; Jones 2006; Neuman 2002; Sapsford 2001a; Sapsford 2001b). However, a TrA muscle contraction does not appear to elevate the PFM in all women (Bø 2003) and when it does, it does not appear to be as effective as a direct PFM contraction Dumoulin 2006; Jones 2006). Recent studies suggest that the relationship between PFM and TrA muscle differs between continent and incontinent women with the PFM being displaced less during a TrA muscle contraction in SUI women as compared to continent women (Jones 2006). More research is needed to better understand the relationship between the TrA and the PFM muscles as well as the effect on incontinence of rehabilitating the interaction between TrA muscle and the PFM.

Given the above biological rationale, for SUI the objective of PFMT is usually to improve the timing (of contraction), strength and stiffness of the PFM.

Biological rationale for PFMT for UUI

PFMT can also be used in the management of UUI. The biological rationale is based on Godec's observation that a detrusor muscle contraction can be inhibited by a PFM contraction induced by electrical stimulation (Godec 1975). Further, de Groat (de Groat 1997) demonstrated that during urine storage there is an increased pudendal nerve outflow response to the external urethral sphincter increasing intraurethral pressure and representing what he termed a 'guarding reflex' for continence (de Groat 1997; de Groat 2001). Additionally, Morrison (Morrison 1995) demonstrated that Barrington's micturition centre excitatory loop switches on when bladder pressures are between five to 25mmHg while the inhibitory loop is predominantly active above 25mmHg (Morrison 1995). Inhibition involves an automatic (unconscious) increase in tone for both the PFM and the urethral striated muscle. Thus, voluntary PFM contractions may be used to control UUI. After inhibiting the urgency to void and the detrusor contraction, the patient can reach the toilet in time to avoid urine leakage. However, the number, the duration, the intensity and the timing of the PFM contraction required to inhibit a detrusor muscle contraction is not known.

Why it is important to do this review

Earlier Cochrane reviews of PFMT (Hay-Smith 2002b, Hay-Smith 2006) and other previously published systematic reviews of PFMT (Berghmans 1998; Berghmans 2000; Bø 1996; de Kruif 1996; Fedorkow 1993; Wilson 1999) are outdated; new trials have been published. Although these reviews have identified a number of PFMT trials there were few data and considerable clinical heterogeneity in the studies. There is sufficient uncertainty about the effects of PFMT, particularly the size of effect, to suggest that continuing to update earlier Cochrane reviews is warranted. The present review is a minor update of Hay-Smith and Dumoulin (2006). 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 comparison was tested:

Pelvic floor muscle training versus 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 (childbearing women) were excluded. Given the physiological changes of the pregnancy and postpartum period, it is possible that the effect of PFMT might differ in this group. PFMT for the prevention and management of urinary incontinence in antenatal and postnatal women is addressed in another Cochrane review (Hay-Smith 2008).

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.

Primary outcomes

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

Secondary outcomes

The secondary outcomes of interest were:
4) number of leakage episodes;
5) number of micturitions during the day;
6) number of micturitions during the night;
7) pad and paper towel testing long and short (grams of urine lost; number cured based on pad testing) ;
8) measures of pelvic floor muscle function (for example electromyography, vaginal squeeze pressure);
9) non-incontinence symptom and generic quality of life measures (for example Short Form-36);
10) formal economic analysis (for example cost effectiveness, cost utility);
Other outcomes of interest were:
11) any of the primary or secondary outcomes in the longer term (that is 12 months or more);
12) treatment adherence;
13) adverse events;
14) any other outcome measures of perceived response to treatment;
15) any other outcome not pre-specified, but judged important when performing the review.

Search methods for identification of studies

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

Electronic searches

This review drew on the search strategy developed for the Cochrane Incontinence Group. Relevant trials were identified from the Cochrane Incontinence Group Specialised Trials Register (For more details of the search methods used to build the Specialised Register please see the 'Specialized Register' section of the Group's module 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's Specialised Register are also contained in CENTRAL. The date of the last search was: 18 Feburary 2009.
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 10, ISI ResearchSoft).

Searching other resources

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

Data collection and analysis

Screening for eligibility

Reports of all possibly eligible studies were evaluated for appropriateness for inclusion by two 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 two 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 2008).

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 or type of urinary incontinence not specified.

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

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

Twenty trials were identified, of which five were excluded. Of the 14 included studies, 11 were included in the previous version of the review (Hay-Smith 2006). Two trials from the previous review were excluded (Ramsay 1990; Ghoniem 2005) because they were considered to be confounded by the choice of sham PFMT.

Included studies

Of the 14 included trials, one contained no usable data for analysis (Wells 1999), 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). Four trials contributed to the analysis of primary outcomes (Bø 1999; Burgio 1998; Castro 2008; Lagro-Janssen 1991). 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 (Lagro-Janssen 1991).
Nine trials had more than two treatment arms (Bidmead 2002; Bø 1999; Burgio 1998; Burns 1993; Castro 2008; Henalla 1989; Henalla 1990; Hofbauer 1990; Wells 1999). Only descriptions and data relating to the PFMT and control arms were given in this review.

Sample characteristics of included trials

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 (; Kim 2007; Miller 1998). The other 11 trials reported urodynamic diagnoses. Seven of these included women with urodynamic

stress incontinence only (Aksac 2003; Bidmead 2002; Bø 1999; Castro 2008; Henalla 1989; Henalla 1990; Hofbauer 1990). Wells and co-workers included women with stress or mixed urinary incontinence (Wells 1999). 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). 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; Castro 2008; Henalla 1989; Henalla 1990; Hofbauer 1990; Kim 2007; Lagro-Janssen 1991; Miller 1998)

- Urinary incontinence, range of diagnoses (Burgio 1998; Wells 1999; Yoon 2003).

Other characteristics

In six trials leakage frequency was one of the inclusion criteria, being more than once a month (Kim 2007) twice or more per month (Lagro-Janssen 1991), twice or more per week (Burgio 1998), three times or more per week (Burns 1993; Castro 2008), or one to five leakage episodes per day (Miller 1998). 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 20 to 65 years (Lagro-Janssen 1991), 35 to 55 years (Yoon 2003), 55 years and older (Burgio 1998; Burns 1993), 70 years and older (Kim 2007). 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) (Table 1)

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. Behavioural 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, and VPFMC with sensation of urge.

The PFMT programmes used are described in 'Table 1'. Three studies gave no details of the PFMT programme used (Bidmead 2002; Henalla 1990; Hofbauer 1990). Of the eleven remaining trials, seven stated that a correct VPFMC was confirmed prior to training (Aksac 2003; Bø 1999; Burgio 1998; Castro 2008; Henalla 1989; Miller 1998; Wells 1999). PFMT was taught by specialist nurses or physiotherapists in five studies and in a seventh it was done by a family doctor.

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.

Table 1. PFMT programmes (*Continued*)

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 practitioner.
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 per day: 3. Body position: included lying, kneeling, sitting, standing; all with legs apart. Women used preferred position. Audiotape of home training programme. Weekly	36	6 months	Weekly 45 minute exercise class. Monthly clinic visit with physiotherapist.

Table 1. PFMT programmes (*Continued*)

		45 minute exercise class to music, with PFMT in a variety of body positions, and back, abdominal, buttock and thigh muscle exercises.			
Castro, 2008	PFMC taught by trained physiotherapist	Sets: 5 VMPFC with 10 second hold, 10 VMPFC with 5 second hold, 20 VMPFC with 2 second hold, 20 VMPFC with 1 sec hold, 5 contractions with cough Sets per day: Once, three times per week	60	6 months	3 group session per week for 6 months
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.
Kim 2007	Taught structure of the PFM, taught to exert force only on the PFM without straining the abdomen	-During the 12 weeks intervention Sets:10 VPFMC with 3 second hold, 10VPFMC with 10 second hold in sitting, lying, and standing positions with the legs apart Sets per day: 2 times per week -During one-year follow up: Sets:13 VPFMC Sets per day: 2 to 3 sets at least two times per week warm-up and stretching 10 to 15 min, 10 fast PFM contraction (3 sec),10 sus-	Approximately 30	12 weeks	Exercise class twice a week

Table 1. PFMT programmes (*Continued*)

		tained PFM contraction (6 to 8 sec), 10 sec relaxation between each contraction performed in lying, sitting, standing position with legs apart. Fitness: back, legs, trunk and use of an exercise ball			
Lagro-Janssen 1991	Teaching from family doctor.	Set: 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	
Wells, 1999	Initial training with nurse practitioner	Set: 80 VPFMC, with 10 seconds hold Sets per day: 1set distributed during the day	80	5 months	Monthly visits for observation, coaching and encouragement
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.

Based on the descriptions of training, two trials had PFMT programmes that clearly or predominantly targeted co-ordination (Miller 1998) or strength training (Bø 1999). Miller and colleagues described a short (one week) programme to improve co-ordination between a VPFMC and a rise in intra-abdominal pressure. Bø et al recommended a programme that comprised 8 to 12 high intensity (close to maximal) VPFMC, with six to eight second hold and three to four fast contractions added at the end of each hold, six second rest between contractions three times per day. Exercises were done in different body position included lying, kneeling, sitting, standing; all with legs apart (Bø 1999).
It was more difficult to characterise or categorise the other PFMT programmes, because they were either a mixed (for example strength and endurance) programme or had not described a key training parameter (for example amount of voluntary effort per contraction):

- The 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 and behavioural component of training, used to prevent leakage with provocation (that is 'The Knack') and to suppress urge.
- Yoon et al (Yoon 2003) 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 (Burns 1993) and Wells and co-workers (Wells 1999) asked women to complete up to 80 to 200 contractions per day, so these programmes might have affected predominantly endurance.
- In Lagro-Janssen et al (Lagro-Janssen 1991), 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 (Henalla 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.
- Finally, the most recent trials by Kim et al and Castro et al described a mixed program of short and long contraction times in addition to contraction prior and during a cough (Castro 2008) and in different body positions (Kim 2007). The trial by Kim tended to favour strength training while the one by Castro included strength, coordination and endurance training.

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),
- a non-active control intervention (Bø 1999; Castro 2008; Lagro-Janssen 1991; Wells 1999), or
- even refraining from special exercises aiming to increase muscle strength, walking speed, to reduce BMI or to improve dietary habits (Kim 2007).

The non-active control treatments comprised use of an anti-incontinence device (Bø 1999), advice on incontinence pads (Lagro-Janssen 1991), motivational phone calls once per month (Castro 2008) or advice on simple life-style alterations (Wells 1999). 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 two eligible trials did not contribute any data to the main analyses because they did not report their outcome data in a usable way (for example mean without a measure of dispersion, P values without raw data) (Hofbauer 1990; Wells 1999).
As the length of intervention and timing of post-intervention assessment varied, no attempt was made to report outcomes at a particular time point. Post-intervention outcomes were used as it 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 as a secondary outcome.

Excluded studies

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.
Two further trials were excluded because the PFMT versus sham PFMT comparison was considered to be confounded by the choice of sham PFMT (Ghoniem 2005; Ramsay 1990). In all trials, sham PFMT consisted of strong isometric hip abductor contractions and according to EMG, dynamometric and MRI studies, both hip abduction and external rotation result in a synergic contraction of the PFM (Bø 1994; Morin 2004; Dumoulin 2006). These three trials were also considered to be comparisons of two approaches to PFMT.

The fifth 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).

Risk of bias in included studies

Due to brevity of reporting it was difficult to assess the two trials that were published as a conference abstracts (Bidmead 2002; Henalla 1990).

- Five of the trials were small, with fewer than 25 women per comparison group (Aksac 2003; Henalla 1990; Hofbauer 1990; Miller 1998Yoon 2003);
- Six were of moderate size with around 25 to 50 per group (Bø 1999; Burns 1993; Henalla 1989; Lagro-Janssen 1991; Kim 2007; Castro 2008),
- and the other two allocated more than 50 women per group (Burgio 1998; Wells 1999).

Bidmead et al randomised participants in a 2:1 ratio, with 40 in the PFMT group and 20 as controls (Bidmead 2002). There were no large or very large trials. Three trials, including the two most recent ones reported an *a priori* power calculation (Bø 1999; Castro 2008; Kim 2007).

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.

Eight 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; Yoon 2003; Wells 1999); it was not clear if allocation was adequately concealed in these studies.

There was more detail of the methods of randomisation in three studies (for example computer generation of random numbers, block size), but they did not give sufficient detail to be sure that allocation was concealed (Burgio 1998; Burns 1993; Kim 2007). Two trials reported adequate allocation concealment (Bø 1999; Castro 2008).

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. It was not possible to blind women to PFMT in all included studies.

Eight trials reported using blinded outcome assessors (Bidmead 2002; Bø 1999; Burgio 1998; Burns 1993; Castro 2008; Lagro-Janssen 1991; Miller 1998; Yoon 2003;).

Description of dropout and withdrawal

There were no dropouts or losses to follow up in one trial (Miller 1998). 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). In the remaining studies the proportion was less than 10% in three (Lagro-Janssen 1991; Burns 1993, Kim 2007), between 11 and 15% in four (Bø 1999; Burgio 1998; Castro 2008; Yoon 2003), and more than 25% in one (Bidmead 2002) to nearly 50% in another (Wells 1999). The proportion of withdrawals or losses to follow up was higher in the control group in (Burgio 1998) and (Bidmead 2002), 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 two stated the primary analysis was by intention to treat (Bidmead 2002; Burgio 1998), and another that stated intention-to-treat analysis did not alter the findings of the primary analysis (Bø 1999). Five trials did not appear to have any losses to follow up, so satisfy one of the conditions, but none of these five trials stated that the participants were analysed in their assigned group (Aksac 2003; Henalla 1989; Henalla 1990; Hofbauer 1990; Miller 1998).

Effects of interventions

Fourteen randomised or quasi-randomised trials compared PFMT (435 women) with no treatment, placebo, sham or other non-active control treatments (401 women). In the twelve trials contributing data the two comparison groups comprised 353 and 319 women respectively.

Readers should note that when referring to the graphs (forest plots) for four of the seven outcomes (patient perceived cure, patient perceived cure or improvement, short pad test (number cured; number cured or improved)) 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' (Analysis 1.1; Analysis 1.2)

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 single small trials reported data on cure only: 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 one of the two trials; PFMT women were about 17 times more likely to report cure than controls in Bø 1999(RR 16.8., 95% CI 2.4 to 119.0, Analysis 1.11), but only about two and half times as likely in Burgio 1998 (RR 2.3, 95% CI 1.1 to 4.9, Analysis 1.14). The confidence intervals in both trials were wide.

Three small trials contributed data to the patient perceived cure or improvement comparison (Analysis 1.2); women had "75% or more perceived improvement" (Burgio 1998), were "dry" or "improved" (Lagro-Janssen 1991), and "continent" or "almost continent" (Bø 1999). While all three trials were statistically significant in favouring PFMT, the confidence intervals were very wide: (two trials in women with urodynamic stress incontinence; RR 20.0, 95% CI 2.9 to 140.5, Lagro-Janssen 1991 Analysis 1.2.1 and 14.4, 95% CI 2 to 103.2, Bø 1999; Analysis 1.2.1 and in the single study in women with detrusor overactivity with or without urodynamic stress incontinence (RR 2.2, 95% CI 1.5 to 3.4,Burgio 1998: Analysis 1.2.4).

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 Analysis 1.1.1
- Kim reported data for 'cure' (Kim 2007) generated from the urinary diary. These data were not included in this comparison but can be found in the long term follow up section.
- Finally, Wells 1999reported patient perceived cure or improvement using measured on a 1 to 10 point analog scale. Although, cure and improvement was better in the PFMT group, it was not clear if there were significant differences between PFMT and control groups as the means were presented without a measure of dispersion.

Symptom and condition specific quality of life assessment (Analysis 1.3)

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.
- Castro (Castro 2008) 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). Quality of life was significantly better in the PFMT group than in controls (MD 24.6, 95% CI 11.5 to 37.8)

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 had less activity limitation 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 (Analysis 1.4)

Seven of the studies used two (Yoon 2003), three (Bø 1999), four (Wells 1999), seven (Castro 2008; Lagro-Janssen 1991;) or 14 day urinary diaries (Burgio 1998; Burns 1993) to collect data on leakage episodes. Yoon 2003 did not report these data and Wells 1999reported means without a measure of dispersion. To enable comparison between trials the data were presented as number of leakage episodes in 24 hours.

While all five trials with data showed statistically significant results favouring PFMT, visual inspection of the forest plot suggested the effect size might be greater in the trial by Lagro-Janssen and colleagues, while the effect sizes appeared similar in the four 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 of the overestimate of treatment effect might be an inadequate concealment of the randomisation process (alternation). The point estimates in the other four were similar, and all were statistically significant. SUI women doing PFMT experienced about one leakage episode less per 24 hours compared to controls; similarly, those with detrusor overactivity with or without urodynamic stress incontinence experienced about one less leakage episode per 24 hours compared to controls.

Other data:

Two other studies measured incontinence frequency (Aksac 2003; Kim 2007).

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

Number of voids per day (Analysis 1.5) and per night (Analysis 1.6)

A single very small trial 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, Analysis 1.5). Data from the same study showed no statistically significant difference in the number of night time voids between PFMT and control groups (, Analysis 1.6; Yoon 2003).

Pad and paper towel tests (Analysis 1.7; Analysis 1.8; Analysis 1.9)

Eight trials reported data on pad and paper towel tests. Seven trials used office-based short pad tests (Aksac 2003; Bidmead 2002;Bidmead 2002; Castro 2008; Henalla 1989; Henalla 1990; Yoon 2003;) while one used a paper towel test (Miller 1998). In addition to short pad test, Bø used a 24 hour home based pad test (Bø 1999. Aside from differences in the type of test, trialists also presented their data differently. Data were usually categorised (such as cured, improved, not improved) or reported as a mean weight of urine loss with standard deviation.

Five trials in SUI women (Aksac 2003; Bø 1999;Castro 2008; Henalla 1989; Henalla 1990) dichotomised their short pad test data into either cured versus not cured (Aksac 2003; Bø 1999; Castro 2008; Analysis 1.7), or cured and improved versus not improved (Aksac 2003; Henalla 1989; Henalla 1990, Analysis 1.8). Four of the five trials found that cure or cure and improvement was statistically significantly more likely in the PFMT group, although all confidence intervals were wide. In addition, three of the five trials had no observed cases of cure or cure and improvement in the control group making 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 improvement, was very small (fewer than 10 participants per group), and no women in the control group reported cure or improvement (Henalla 1990). Three trials (Bø 1999; Castro 2008; Yoon 2003; Analysis 1.9) reported their data as mean and SD, and another as mean change in pad weight from baseline (Bidmead 2002). The two trials in women with urodynamic stress incontinence (Bø 1999; Castro 2008) found respectively that PFMT women had on average about 30 g (MD -30.3, 95% CI -48.4 to -12.2) and 12 g less of urine loss than controls (MD -12.6, 95% CI -22.2 to -3.0). Yoon (2003), in women with unspecified urinary incontinence reported PFMT women had about 5 g less urine loss than controls but with wide confidence intervals that included no difference (MD -5.1, 95% CI -11.3 to 1.1). Finally, Bidmead (2002) found PFMT women reported a pad weight change from baseline of 13 g more than controls (MD -13.3, 95%, CI -23.1 to -3.4).

The only trial reporting 24 hour home based pad test (Bø 1999) reported data as mean and SD. PFMT women reported about 28 grams less leakage than controls but with wide confidence intervals that included no difference (MD -27.5, 95%, CI -65.2 to 10.2).

The only trial reporting a paper towel test (Miller 1998) reported data as mean wet area and SD on either a moderate or a deep cough. PFMT women reported about 20 cm^2 less wet area than controls on a medium cough (MD -20.8, 95% CI -46.5 to 4.9) and 21 cm less wet area than controls on a deep cough (MD -21.4, 95% CI -50 to 7.2). However, in both cases, the wide confidence intervals included no difference.

Measures of pelvic floor muscle function (Analysis 1.10)

Seven trials used some means of measuring pelvic floor muscle function (Aksac 2003; Bø 1999; Burns 1993;Castro 2008; Miller 1998; Wells 1999; Yoon 2003):

- Three studies used perineometry to measure vaginal squeeze pressure (Aksac 2003; Bø 1999; Yoon 2003).
- Two used vaginal electromyography (Burns 1993; Wells 1999) and
- Four used digital palpation (Aksac 2003; ; Castro 2008; Miller 1998; Wells 1999).

Of the eight studies, two did not report the data in such a way that it was possible to calculate the mean difference in vaginal squeeze pressure, EMG activity or digital palpation score (Aksac 2003; Wells 1999).

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 six remaining trials.

There were contrasting findings: either no statistically significant difference between the groups, or a statistically significant difference in favour of PFMT. In one study that did not show a statistically significant difference between the groups (Miller 1998) 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.

The three studies that measured vaginal squeeze pressure found that mean vaginal squeeze pressure was higher in the PFMT than in control group; this difference was statistically significant in two trials (Aksac 2003; Yoon 2003) while in the other it was not (Bø 1999). In addition to differences in mean vaginal squeeze, Yoon et al found substantial and statistically significant differences between PFMT and control groups for peak pressure, and duration of contraction after treatment.

Finally, in the trials 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 (Burns 1993). Although Wells found a significant difference for endurance, means were presented without measure of dispersion (Wells 1999).

Non-incontinence symptom and generic quality of life assessment (Analysis 1.11)

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 the end 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. Four trials have published longer-term follow up, at three and six months (Burns 1993), nine months (Henalla 1989), at 12 months (Kim 2007), 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, compared to 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.
- Kim and colleagues documented cure at 12 month, according to a bladder diary data, using the following scale: cure (leakage disappeared), improved (frequency of leakage episode reduced), unchanged and worsened (when frequency of leakage increased). They found that 18 of the 33 in the treatment group were cured compared to 3 of the 32 in the control group; this suggests a greater likelihood of continence after one year in the PFM group (RR 5.8, 95% CI 1.9 to 17.9).

- 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 = 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 = 0.04).

Treatment adherence

Six trials attempted to measure treatment adherence using exercise diaries (Bidmead 2002; Bø 1999; Burns 1993), self-reported adherence (Lagro-Janssen 1991) or attendance to exercise sessions (Castro 2008; Kim 2007;). 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%).
- Kim and colleagues reported that 70% of the subjects in the PFMT group adhered to at least 20 of the 24 intervention sessions (Kim 2007).
- Women in the Castro study completed 93% of the PFMT clinic sessions (Castro 2008).

Adverse events

Four trials (Bø 1999; Burgio 1998; Castro 2008; Lagro-Janssen 1991) specifically mentioned adverse events, of which three reported that there were none in the PFMT group (Bø 1999; Burgio 1998; Castro 2008). Only one trial (Lagro-Janssen 1991) reported adverse events with PFMT: pain (one participant), uncomfortable feeling during exercise (three participants), and not wanting to be continuously bothered with the problem (two participants).

Patient perceived response to treatment (Analysis 1.12)

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) or satisfaction with treatment (Castro 2008). 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.

- Bø 1999 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 1999and Burgio 1998 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). Castro and colleague suggested that women with PFMT were more likely to be satisfied with treatment and not want further treatment than the controls (RR 2.8, 95% CI 1.2 to 6.5) .

DISCUSSION

This is the first update of the current review, the previous version was led by Jean Hay-Smith (Hay-Smith 2006b). This review considers whether PFMT is better than no treatment, placebo, sham or non-active control, treatments. The review was originally part of a larger review of all aspects of PFMT, led by Jean Hay-Smith (Hay-Smith 2006a) This review is one of a series of reviews of PFMT for urinary for urinary incontinence in women, and it should be viewed in that context. Other reviews consider whether: (a) PFMT for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women (Hay-Smith 2008), (b) PFMT is better than other treatments (Patel 2008), and (c) PFMT adds benefit to other treatments (Kovoor 2008).

Summary of main results

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

Of the 14 trials that addressed this question, twelve reported data (suitable for analysis) for the outcomes of interest. Of these twelve studies, one was at high risk of bias (Lagro-Janssen 1991).

Primary outcomes (cure or improvement)

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. 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).

Three studies grouped cure and improvement. They 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.

Quality of life

Two studies used psychometrically robust symptom, condition-specific quality of life, or both measures. In one 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 in that study. In the second study, there was an important difference in continence related quality of life favouring PFMT. This is of importance to women as urinary incontinence as been linked associated with poor self-rated health (Johnson 1998) and according to a recent citizen's jury study quality of life is the most important outcome measure to urinary incontinent women (Herbison 2009).

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, there is improved condition specific quality of life in women treated with PFMT compared to controls, but there might be less or no effect on generic quality of life. Continence-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 more studies on PFMT with validated, reliable and responsive condition-specific and generic quality of life instruments is imperative.

Secondary outcomes

For leakage episodes, there were statistically significantly fewer leakage episodes with PFMT in all five 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 was 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 less leakage episode per day for SUI women and one fewer episode per day for all type of UI. 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 three 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.

Two other trials measured leakage episodes using different ordinal scales to quantify leakage episode frequency (Aksac 2003; Kim 2007). In both trials, post-treatment score was significantly better (indicative of lower frequency of leakage episode frequency) for PFMT group than for the control group. It is worth noting that one of these two trials included only older women suggesting treatment effect may not be associated with age.

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.

Short office based pad test data were presented either as number of cases cured or number of case cured/improved. In the three trials presenting number of case cured, PFMT women were more likely to be cured on pad test than controls. In the three other trials presenting number of case cured/improved, PFMT women were more likely to be cured/improved on pad test than controls. However confidence intervals were wide in all cases. It is possible that the high variability observed in the data be related to the variation of pad test definition (content, duration, mode of bladder filling and bladder volume).

Based on short office based pad test data, when presented as mean urine leakage, PFMT women were less likely to lose urine than controls. Interestingly, type of incontinence may have impacted on the results. PFMT might be less effective in UUI than SUI women.

Measures of pelvic floor muscle function

Pelvic floor muscle function was measured using vaginal squeeze pressure (perineometry), digital palpation, and vaginal surface electromyography. It was difficult to compare the data from these different PFM function measurement outcomes. Even within PFM measurement outcome, there was variability with different measurement protocols, different probe and electrode size and even different strength scales. Interestingly, four 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 only one of the four studies found statistically significant differences between PFMT and control groups for vaginal squeeze pressure (Castro 2008) three found PFMT women were more likely to report cure or cure and / improvement (Bø 1999; Burns 1993; Castro 2008). This suggests that a change in pelvic floor muscle function is not necessarily the only explanation for the effect of PFMT. It is also possible that other aspects of muscle function that were not measured in these three 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.

Adherence to treatment

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 four studies, and self-reported adherence recorded in another two. It is not clear how accurate the estimate of adherence from either measure is; some allow a woman to report what they think they should, or what the researchers want to hear, only two reported what was actually done (percentage of intervention sessions completed). However, it is interesting to note that the four trials that reported good to excellent rates of training adherence were also the four trials that demonstrated the greatest treatment effects for cure or cure improvement. Because these four trials also recruited stress incontinent women, there is another potential explanation for this observation. Nevertheless, it is possible that treatment adherence contributed.

Adverse effects

Three of the four 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.

Long term follow up

Four trials presented longer term follow up data. 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, and in trials where PFMT program was supervised for at least three months. Some level of adherence to training or the addition of periodic refresher sessions might be key factors in maintaining benefit in the long term but this needs to be studied. 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.

Overall completeness and applicability of evidence

Outcome measures and reporting

Two 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 (Hofbauer 1990; Wells 1999). 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 is less than 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, pad tests presented as number 'cured' and or mean grams of leakage). Quite a number of the continence outcome measures had not undergone reliability or validity testing. These factors meant that comparisons across studies were limited. Seven 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, numbers cured and cure or improved on short pad test. Four forest plots contained data from more than one trial.

Limitations of the pad test

The most commonly reported outcome was the pad test. 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). Pad tests have also been identified as desirable adjunctive measure to be used in RCT by the 3rd International Consultation on Incontinence recommendations for clinical research methodology (Tubaro 2005). However, there appear to be two very important issues regarding pad test.

First, there is a lack of standardization: there are many pad 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. We analysed data from short and long pad tests separately, because these may measure different things (Ryhammer 1999).

In addition, ways of reporting pad test data (number cured, amount of leakage) were considered separately. If included as a secondary outcome measure in a RCT, researchers and clinicians need to use standardised recommended pad tests (Tubaro 2005) and report the mean amount leakage (g) in addition to number of cure and improved according to known standardised cut off points (Tubaro 2005) so that pad test data can be presented in a consistent way and interpreted.

Secondly, we have to question the pertinence of pad testing as an outcome measure for urinary incontinence. We can argue that present standardization and interpretation may not reflect what really matters to women. For example: is the change in the amount lost or the proportional change in the amount lost important to women? A recent citizen's jury research studying urinary incontinence outcome measures pertinent to women found that women considered quality of life as a much more important research outcome than pad tests (Herbison 2009). Women considered that pad tests were likely to lack validity or reproducibility given the circumstance in which women completed them (Herbison 2009). Pad tests data are surrogate outcomes; of interest to researchers as a way of justifying the efficacy of an intervention, but may as yet lack a meaningful (valid) or useful interpretation for women.

Quality of the evidence

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. Two of the included studies were published only as abstracts (Bidmead 2002; Henalla 1990). Limited methodological detail was given, which made it particularly difficult to judge the quality of these trials. In addition, few data were reported.

In one way, it was disappointing that only two trials 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 eight of the 14 studies used blinded outcome assessors. Generally, the proportion of dropout and withdrawals was in the region of 0 to 20%. Sample sizes were small to moderate in 12 of the 14 studies, and only three trials reported an *a priori* power calculation. Two 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, two trials appeared to be a low risk (Bø 1999; Castro, 2008), six at moderate risk (Bidmead 2002; Burgio 1998; Burns 1993; Kim 2007; Miller 1998; ; Yoon 2003;), and six at high or possible high risk of bias (Aksac 2003; Henalla 1989; Henalla 1990; Hofbauer 1990; Lagro-Janssen 1991; Wells 1999). Interestingly, the more recent trials tended to be of lower risk for bias based on the trial reports. 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).

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 fitted the criteria for stress urinary incontinence only and three 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) but again was beyond the scope of this review due to scarcity of data.

Other quality issues

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 standardised tools with established validity, reliability and responsiveness. Domains that require particular attention in future are quality of life (condition specific and generic) and socioeconomic outcomes, 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).

AUTHORS' CONCLUSIONS

Implications for practice

Based on the data available:

- PFMT is better than no treatment, placebo drug, or inactive control treatments for women with stress, urge, or mixed incontinence.

- Women treated with PFMT were more likely to report cure or improvement, report better quality of life, have fewer leakage episodes per day and have less urine leakage on short pad tests than controls.

The trials suggested that the treatment effect (especially self reported cure/improvement) might be greater in women with stress urinary incontinence participating in a supervised PFMT programme for at least three months. It seems older age may not decrease the effect of PFMT in stress urinary incontinent women: in trials with stress urinary incontinent older women it appeared both primary and secondary outcome measures were comparable to outcomes in trials in younger women.

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 supervised and supported to maintain treatment adherence but there was no evidence about this issue found in the review.

Overall, there is 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 in the majority of the studies means that the long-term outcomes of use of PFMT are less clear. Longer-term effects may be greater in women participating in a supervised PFMT for at least three months. Continued training adherence may be associated with maintenance or increased treatment effect, but this hypothesis

needs further testing. Unfortunately, at this time, it is not known whether PFMT is cost effective in the short or long term.

Implications for research

Although the quality of recent studies has improved (choice of outcome, duration of follow up, reporting method and data), most of the data in this review comes from small to moderate sized studies, of moderate methodological quality. In planning future research trialists are encouraged to consider the following:

- The choice of primary outcome important to women (incontinence, effect on quality of life), the size of minimum clinically important effect, and subsequent estimation of sample size.
- The choice and reporting of secondary outcome measures.
- The duration of follow up after treatment stops, especially in the long term.
- The reporting of methods and data following the CONSORT guidance.
- Evaluation of adherence and adherence strategies.
- Inclusion of formal economic analysis (for example cost effectiveness, cost utility)

In essence, there is a need for at least one large, pragmatic, well-conducted, and explicitly reported randomised 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 supervision and adherence measures to promote maintenance of knowledge acquisition. The choice of programme would have to be set against the resource implications of intensively supervised individual programmes and the opportunity cost this represents. The reporting of formal economic analysis would have to be added to the study. 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 while still delivering an effective intervention.

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 oral 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 one of the previous versions of the PFMT review (Hay-Smith 2006a).

The assistance of Michael Albert and Peter Dietz in translating papers from German to English.

REFERENCES

References to studies included in this review

Aksac 2003 *{published data only}*

Aksac B, Aki S, Karan A, Yalcin O, Isikoglu M. Biofeedback and pelvic floor exercises for the rehabilitation of urinary stress incontinence. *Gynecologic and Obstetric Investigation* 2003;**56**:23–7.

Bidmead 2002 *{published data only}*

* Bidmead J, Mantle J, Cardozo L, Hextall A, Boos K. Home electrical stimulation in addition to conventional pelvic floor exercises: A useful adjunct or expensive distraction? [abstract 68]. Neurourology and Urodynamics. 2002; Vol. 21:372–3.

Parsons M, Mantle J, Cardozo L, Hextall A, Boos K, Bidmead J. A single blind, randomised, controlled trial of pelvic floor muscle training with home electrical stimulation in the treatment of urodynamic stress incontinence [abstract 296]. Proceedings of the 34th Annual Meeting of the International Continence Society; 2004; Paris, France. 2004.

Burgio 1998 *{published data only}*

Burgio KL, Locher JL, Goode PS. Combined behavioral and drug therapy for urge incontinence in older women. *Journal of the American Geriatric Society* 2000;**48**:370–4.

* Burgio KL, Locher JL, Goode PS, Hardin JM, McDowell BJ, Dombrowski M, et al.Behavioral vs drug treatment for urge urinary incontinence in older women. *JAMA* 1998;**280**:1995–2000.

Burgio KL, Locher JL, Roth DL, Goode PS. Psychological improvements associated with behavioral and drug treatment of urge incontinence in older women. *The Journals of Gerontology Series B. Psychological Sciences and Social Sciences* 2001;**56**:46–51.

Goode PS, Burgio KL, Locher JL, Umlauf MG, Lloyd D, Roth DL.

Urodynamic changes associated with behavioral and drug treatment of urge incontinence in older women. *Journal of the American Geriatric Society* 2002;**50**:808–16.

Burns 1993 ***{published data only}***

Burns PA, Nochajksi TH, Pranikoff K. Factors discriminating between genuine stress and mixed incontinence. *Journal of the American Academy of Nurse Practitioners* 1992;**4**:15–21.

Burns PA, Pranikoff K, Nochajski T, Desotelle P, Harwood MK. Treatment of stress incontinence with pelvic floor exercises and biofeedback. *Journal of the American Geriatric Society* 1990;**38**: 341–4.

* Burns PA, Pranikoff K, Nochajski TH, Hadley EC, Levy KJ, Ory MG. A comparison of effectiveness of biofeedback and pelvic muscle exercise treatment of stress incontinence in older community dwelling women. *Journal of Gerontology* 1993;**48**:M167–74.

Bø 1999 ***{published data only}***

Bø K, Talseth T, Home I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999;**318**:487–93.

Castro 2008 ***{published data only}***

Castro, R. A, Arruda, R. M, Zanetti, M. R, Santos, P. D, Sartori, M. G, & Girao, M. J. Single-blind, randomized, controlled trial of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in the management of stress urinary incontinence. *Clinics (Sao Paulo, Brazil).* 2008;**63**(4):465–72.

Henalla 1989 ***{published data only}***

Henalla SM, Hutchins CJ, Robinson P, MacVicar J. Non-operative methods in the treatment of female genuine stress incontinence of urine. *Journal of Obstetrics and Gynaecology* 1989;**9**:222–5.

Henalla 1990 ***{published data only}***

Henalla SM, Millar DR, Wallace KJ. Surgical versus conservative management for post-menopausal genuine stress incontinence of urine [abstract 87]. Neurourology and Urodynamics. 1990; Vol. 9: 436–7.

Hofbauer 1990 ***{published data only}***

* Hofbauer VJ, Preisinger F, Nurnberger N. The value of physical therapy in genuine female stress incontinence [Der stellenwert der physiokotherapie bei der wieblichen genuinen seb–inkontinenz]. *Zeitschrift Fur Urologie Und Nephrologie* 1990;**83**:249–54. [: 6332]

Preisinger E, Hofbauer J, Nurnberger N, Sadil S, Schneider B. Possibilities of physiotherapy with stress incontinence [Moglichkeiten der physikalischen therapie bei strebinkontinenz]. *Zeitschrift fur Physikalische Medizin, Balneologie Med Klimatologie* 1990;**2**:75–9. [: 19147]

Kim 2007 ***{published data only}***

Kim H, Suzuki T, Yoshida Y, Yoshida H. Effectiveness of multidimensional exercises for the treatment of stress urinary incontinence in elderly community-dwelling Japanese women: A randomized, controlled, crossover trial. *Journal of the American Geriatrics Society* 2007;**55**(12):1932–9.

Lagro-Janssen 1991 ***{published data only}***

Lagro-Janssen ALM, Debruyne FMJ, Smits AJA, van Weel C. The effects of treatment of urinary incontinence in general practice. *Family Practice* 1992;**9**:284–9.

Lagro-Janssen T, van Weel C. Long-term effect of treatment of female incontinence in general practice. *British Journal of General Practice* 1998;**48**:1735–8.

* Lagro-Janssen TLM, Debruyne FMJ, Smits AJA, van Weel C. Controlled trial of pelvic floor exercises in the treatment of urinary stress incontinence in general practice. *British Journal of General Practice* 1991;**41**:445–9.

Miller 1998 ***{published data only}***

Miller JM, Ashton-Miller JA, DeLancey JOL. A pelvic muscle precontraction can reduce cough-related urine loss in selected women with mild SUI. *Journal of the American Geriatric Society* 1998;**46**:870–4.

Wells 1999 ***{published and unpublished data}***

Wells TJ, Mayor RD, Brink CA, Brown R. Pelvic floor muscle exercise: a controlled clinical trial. Unpublished Work - however portions of the work were presented at the Sixteen Annual Scientific Meeting of the American Urogynecologic Society, Seattle, October 12-15, 1995. 1999.

Yoon 2003 ***{published data only}***

Yoon HS, Song HH, Ro YJ. A comparison of effectiveness of bladder training and pelvic muscle exercise on female urinary incontinence. *International Journal of Nursing Studies* 2003;**40**: 45–50.

References to studies excluded from this review

Burgio 2002 ***{published data only}***

Burgio KL, Goode PS, Locher JL, Umlauf MG, Roth DL, Richter HE, et al.Behavioral training with and without biofeedback in the treatment of urge incontinence in older women. A randomized controlled trial. *JAMA* 2002;**288**:2293–9.

Ghoniem 2005 ***{published data only}***

* Ghoniem GM, Van Leeuwen JS, et al.A randomized controlled trial of duloxetine alone, pelvic floor muscle training alone, combined treatment and no active treatment in women with stress urinary incontinence. *Journal of Urology* 2005;**173**(5):1647–53.

Van Leeuwen JH, Elser D, Freeman R, Ghoniem G, Zhao Y, Yalcin I, et al.Controlled trial of duloxetine alone, pelvic floor muscle training alone, combined treatment in women with stress urinary incontinence. *European Urology Supplements* 2004;**3**(2):52.

Goode 2003 ***{published data only}***

Goode PS, Burgio KL, Locher JL, Roth DL, Umlauf MG, Richter HE, et al.Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women. A randomized controlled trial. *JAMA* 2003;**290**:345–52.

Ramsay 1990 ***{published data only}***

Ramsay IN, Thou M. A randomised, double blind, placebo controlled trial of pelvic floor exercises in the treatment of genuine stress incontinence [abstract 59]. Neurourology and Urodynamics. 1990; Vol. 9:398–9.

Yoon 1999 ***{published data only}***

Yoon HN, Hong JY, Choi YH, Back SH. The effect of pelvic floor muscle exercises on genuine stress incontinence among Korean

women: focusing on its effects on the quality of life. Proceedings of the 29th Annual Meeting of the International Continence Society. Denver, USA, 1999.

Additional references

Abrams 2002
Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, et al.The standardisation of terminology of lower urinary tract function: Report from the Standardisation Sub-committee of the International Continence Society. *Neurourology and Urodynamics* 2002;**21**(2):167–78.

Balmforth 2004
Balmforth J, J Bidmead, et al.Raising the tone: A prospective observational study evaluating the effect of pelvic floor muscle training on bladder neck mobility and associated improvement in stress urinary incontinence. *Neurourology and Urodynamics* 2004; **23**(5):553–4.

Begg 1996
Begg CB, Cho MK, Eastwood S, Horton R, Moher D, Olkin I, et al.Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 1996;**276**(8):637–9.

Berghmans 1998
Berghmans LC, Hendriks HJ, Bø K, Hay-Smith EJ, de Bie RA, van Waalwijk van Doorn ES. Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials. *British Journal of Urology* 1998;**82**(2):181–91. [MEDLINE: 98389975]

Berghmans 2000
Berghmans LCM, Hendriks HJM, de Bie RA, van Waalwijk van Doorn ESC, Bø K, van Kerrebroeck PhEV. Conservative treatment of urge urinary incontinence in women: a systematic review of randomized clinical trials. *BJU International* 2000;**85**:254–63.

Bø 1994
Bø K, Stien R. Needle EMG registration of striated urethral wall and pelvic floor muscle activity patterns during cough, Valsalva, abdominal, hip adductor, and gluteal muscle contractions in nulliparous healthy females. *Neurourology and Urodynamics* 1994; **13**(1):35–41.

Bø 1995
Bø K. Pelvic floor muscle exercise for the treatment of stress urinary incontinence: an exercise physiology perspective. *International Urogynecology Journal and Pelvic Floor Dysfunction* 1995;**6**:282–91.

Bø 1996
Bø K. Physiotherapy to treat genuine stress incontinence. *International Continence Survey* 1996;**6**:2–8.

Bø 2001
Bø K, F Lilleas, et al.Dynamic MRI of the pelvic floor muscles in an upright sitting position. *Neurourology and Urodynamics* 2001;**20** (2):167–74.

Bø 2003
Bø K, Sherburn M, Allen T. Transabdominal ultrasound measurement of pelvic floor muscle activity when activated directly or via a transversus abdomius muscle contraction. *Neurourology and Urodynamics* 2003;**22**:582–8.

Bø 2004
Bø K. Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work?. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2004;**15**:76–84.

Bø 2007
Bo K, Bergmans B, Morkved S, Van Kampen M. *Evidence based physical therapy for the pelvic floor*. Edinburgh: Harrison, H, 2007.

Carrière 2006
Carrière B. *The pelvic floor*. Stuttgard: Georg Thieme Verlag, 2006.

Chang 1984
Chang S. *Internal exercise*. Stuyvesant Publishing Co., 1984.

Constantinou 1982
Constantinou CE, DE Govan. Spatial distribution and timing of transmitted and reflexly generated urethral pressures in healthy women. *The Journal of Urology* 1982;**127**(5):964–9.

de Groat 1997
de Groat WC. A neurologic basis for the overactive bladder. *Urology* 1997;**50**(6A Suppl):36-52; discussion 53-6.

de Groat 2001
de Groat WC, MO Fraser, et al.Neural control of the urethra. *Scandinavian Journal of Urology and Nephrology. Supplementum* 2001;**207**:35–43.

de Kruif 1996
de Kruif YP, van Wegen EE. Pelvic floor muscle exercise therapy with myofeedback for women with stress urinary incontinence: A meta-analysis. *Physiotherapy* 1996;**82**(2):107–13.

Deindl 1993
Deindl FM, DB Vodusek, et al.Activity patterns of pubococcygeal muscles in nulliparous continent women. *British Journal of Urology* 1993;**72**(1):46–51.

DeLancey 1988a
DeLancey JOL. Structural aspects of urethrovesical function in the female. *Neurourology and Urodynamics* 1988;**7**:509–19.

Donovan 2005
Donovan J, Bosch R, Gotoh M, Jackson S, Naughton M, Radley S, et al.Symptom and quality of life assessment. *Incontinence. Volume 1 Basics & Evaluation. Edition 2005*. Health Publication Ltd, 2005.

Dumoulin 2006
Dumoulin C, Thorarinsdotirr H, et al.Bladder neck elevation during different pelvic floor activation techniques: An MRI study. International Continence Society annual meeting Christchurch, New Zealand Read by title. December 2006.

Dumoulin 2007
Dumoulin C, Q Peng, et al.Changes in levator ani anatomical configuration following physiotherapy in women with stress urinary incontinence. *Journal of Urology* 2007;**178**(3 Pt 1):970-7; quiz 1129.

Egger 2002
Egger M, Ebrahim S, Davey Smith, G. Where now for meta-analysis?. *International Journal of Epidemiology* 2002;**31**(1):1–5.

Fader 2007
Fader M, Cottenden AM, Getliffe K. Absorbent products for light urinary incontinence in women. *Cochrane Database of Systematic*

Reviews 2007, Issue 2. [DOI: 10.1002/14651858.CD001406.pub2; : CD001406]

Fader 2008
Fader M, Cottenden AM, Getliffe K. Absorbent products for moderate-heavy urinary and/or faecal incontinence in women and men. *Cochrane Database of Systematic Reviews* 2008, Issue 4. [DOI: 10.1002/14651858.CD007408; : CD007408]

Fantl 1996
Fantl J, Newman D, Colling J, et al.Urinary incontinence in adults: acute and chronic management. *Clinical Practice Guidelines update*. AHCPR Publication No 96-0682, 1996:Book chapter 3.

Fedorkow 1993
Fedorkow DM. Nonsurgical management of stress urinary incontinence. *Journal SOGC* 1993;**15**(6):695–705.

Ferguson 2002
Ferguson D, Aaron SD, Guyatt G, Hébert P. Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. *BMJ* 2002;**325**:652–4.

Godec 1975
Godec C, Cass AS, Ayala GF. Bladder inhibition with functional electrical stimulation. *Urology* 1975;**6**(6):663–6. [MEDLINE: 76082481]

Griffin 1994
Griffin C, MC Dougherty, et al.Pelvic muscles during rest: responses to pelvic muscle exercise. *Nursing Research* 1994;**43**(3): 164–7.

Hannestad 2000
Hannestad YS, Rortveit G, Sandvik H, Hunaskaar S. A community-based epidemiological survey of female urinary incontinence: The Norwegian EPICONT study. *Journal of Clinical Epidemiology* 2000;**53**:1150–7.

Hay-Smith 2002b
Hay-Smith EJC, Bø K, Berghmans LCM, Hendriks HJM, de Bie RA, van Waalwijk van Doorn ESC. Pelvic floor muscle training for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2006, Issue 1. [DOI: 10.1002/14651858.CD001407.pub2]

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

Hay-Smith 2006a
Hay-Smith J, Bo K, Berghmans B, Hendriks E, de Bie R, van Waalwijk van Doorn E. Pelvic floor muscle training for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2006, Issue 1. [DOI: 10.1002/14651858.CD001407.pub2]

Hay-Smith 2006b
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. [DOI: 10.10002/14651858.CD005654]

Hay-Smith 2008
Hay-Smith J, Morkved S, Fairbrother KA, Herbison GP. Pelvic floor muscle training for prevention and treatment of urinary and faecal in continence in antenatal and postnatal women. *Cochrane Database of Systematic Reviews* 2008, Issue 4. [DOI: 10.1002/14651858.CD007471]

Herbert 2005
Herbert R, Bø K. Analysis of quality of interventions in systematic reviews. *BMJ* 2005;**331**:507–9.

Herbison 2009
Herbison P, Hay Smith J, Paterson H, Ellis G, Wilson D. Research priorities in urinary incontinence: results from citizen's juries. *BJOG* 2009;**116**:713–8.

Herbison 2002
Herbison GP, Dean N. Weighted vaginal cones for urinary incontinence. *Cochrane Database of Systematic Reviews* 2002, Issue 1. [DOI: 10.1002/14651858.CD002114; : CD002114]

Higgins 2008
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.1 [updated September 2008]. The Cochrane Collaboration, 2008. Available from www.cochrane-handbook.org.

Hoyte 2001
Hoyte L, L Schierlitz, et al.Two- and 3-dimensional MRI comparison of levator ani structure, volume, and integrity in women with stress incontinence and prolapse. *American Journal of Obstetrics and Gynecology* 2001;**185**(1):11–9.

Hunskaar 1991
Hunskaar S, Vinsnes A. The quality of life in women with urinary incontinence as measured by the sickness impact profile. *Journal of American Geriatrics Society* 1991;**39**:378–82.

Hunskaar 2002
Hunskaar S, Burgio K, Diokno AC, Herzog AR, Hjalmas K, Lapitan MC. Epidemiology and natural history of urinary incontinence (UI). In: Abrams P, Cardozo L, Khoury S editor(s). *Incontinence*. 2nd Edition. Health Publication Ltd, 2002.

Johnson 1998
Johnson TM, Kincade JE, Bernard SL. The association of urinary incontinence with poor self-rated health. *Journal of American Geriatrics Society* 1998;**46**:693–9.

Jones 2006
Jones R, Q Peng, et al.Ultrasonic imaging and motion tracking of the pelvic floor muscle (PFM) activity during abdominal manoeuvres in stress urinary incontinent (SUI) women. *Neurourology and Urodynamics* 2006;**25**(6):596–7.

Kegel 1948
Kegel AH. Progressive resistance exercise in the functional restoration of the perineal muscles. *American Journal of Obstetrics and Gynecology* 1948;**56**:238–48.

Kovoor 2008
Kovoor ET, Datta S, Patel A. Pelvic floor muscle training in combination with another therapy compared with the other therapy alone for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2008, Issue 2. [DOI: 10.10002/14651858.CD007172]

Lose 1998
Lose G, Fantl JA, Victor A, Walter S, Wells TL, Wyman J, et al.Outcome measures for research in adult women with symptoms

of lower urinary tract dysfunction. *Neurourology and Urodynamics* 1998;**17**(3):255–62. [MEDLINE: 98250359]

Moher 1998

Moher D, Pham B, Jones A, Cook DJ, Jadad AR, Moher M, et al.Does quality of reports of randomised trials affect estimates of intervention efficacy reported in meta-analyses?. *Lancet* 1998;**352** (9128):609–13. [MEDLINE: 98417104]

Moher 2001

Moher M, Schulz KF, Altman DG, for the CONSORT group. The CONSORT statement: revised recommendations for improving the quality of parallel group randomized trials. *JAMA* 2001;**285**: 1987–91.

Morin 2004

Morin M, D Bourbonnais. Pelvic floor muscle function in continent and stress urinary incontinent women using dynamometric measurements. *Neurourol Urodyn* 2004;**23**(7): 668–74.

Morris 1936

Morris M. *Maternity and post-operative exercises*. london: William Heinemann ltd, 1936:pp 5-11, 60-65..

Morrison 1995

Morrison JFB. The excitability of the micturition reflex. *Scandinavian Journal of Urology and Nephrology* 1995;**29**(Suppl 175):21–25.

Nabi 2006

Nabi G, Cody JD, Ellis G, Hay-Smith J, Herbison GP. Anticholinergic drugs versus placebo for overactive bladder syndrome in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 4. [DOI: 10.1002/14651858.CD003781.pub2; : CD003781]

Neuman 2002

Neuman P, Gill V. Pelvic floor and abdominal muscle interaction: EMG activity and intra-abdominal pressure. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2002;**13**(2): 125–32.

Ogah 2009

Ogah J, Cody JD, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2009, Issue 4. [DOI: 10.1002/14651858.CD006375.pub2; : CD006375]

Patel 2008

Patel A, Datta S, Kovoor ET. Pelvic floor muscle training versus other active treatments for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2008, Issue 2. [DOI: 10.1002/14651858.CD007173]

Peschers 1997

Peschers UM, GN Schaer, et al.Levator ani function before and after childbirth. *British Journal of Obstetrics and Gynaecology* 1997; **104**(9):1004–8.

Peschers 2001

Peschers UM, Vodusek DB, Fanger G, Schaer GN, DeLancey JOL, Schuessler B. Pelvic muscle activity in nulliparous volunteers. *Neurourology and Urodynamics* 2001;**20**:269–75.

Ramsay 1995

Ramsay IN, Ali HM, Hunter M, Stark D, Donaldson K. A randomised controlled trial of urodynamic investigations prior to conservative treatment of urinary incontinence in the female [abstract 74]. *International Urogynecology Journal* 1995;**6**:277–81.

Resnick 1989

Resnick NM, Yalla SV, Laurino E. The pathophysiology of urinary incontinence among institutionalized elderly persons. *New England Journal of Medecine* 1989;**320**:1–7.

Ryhammer 1999

Ryhammer AM, Djurhuus JC, Laurberg S. Pad testing in incontinent women: A review. *International Urogynecology Journal and Pelvic Floor Dysfunction* 1999;**10**:111–5.

Sapsford 2001a

Sapsford RR, Hodges PW. Contraction of pelvic floor muscles during abdominal maneuvers. *Archives of Physical Medicine and Rehabilitation* 2001;**82**(8):1081–8.

Sapsford 2001b

Sapsford RR, Hodges PW, Richardson CA, Cooper DH, Markwell SJ, Jull GA. Co-activation of the abdominal and pelvic floor muscle during voluntary exercises. *Neurourology and Urodynamics* 2001;**20** (1):31–42.

Shaikh 2006

Shaikh S, Ong EK, Glavind K, Cook J, N'Dow JMO. Mechanical devices for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2006, Issue 3. [DOI: 10.1002/ 14651858.CD001756.pub4; : CD001756]

Temml 2001

Temml C, Haidinger G, Schmidbauer J. Urinary incontinence in both sexes: prevalence rates and impact on quality of life and sexual life. *Neurourology and Urodynamics* 2001;**19**:259–71.

Thind 1990

Thind P, G Lose, et al.Variations in urethral and bladder pressure during stress episodes in healthy women. *British Journal of Urology* 1990;**66**(4):389–92.

Thompson 2003

Thompson JA, PB O'Sullivan. Levator plate movement during voluntary pelvic floor muscle contraction in subjects with incontinence and prolapse: a cross-sectional study and review. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2003;**14**(2):84–8.

Tubaro 2005

Tubaro A, Artibani W, Bartram C, Dietz HP, Khullar V, Delancey JD, et al.Imaging and other investigations. In: Abrams P, Cardozo L, Khoury S, Wein A editor(s). *Incontinence: 3rd International Consultation on Incontinence, June 26-29 2004. Basics & Evaluation*. 2005. Vol. **1**, Plymouth: Health Publication Ltd, 2005:774–9.

Verelst 2004

Verelst M, G Leivseth. Are fatigue and disturbances in pre-programmed activity of pelvic floor muscles associated with female stress urinary incontinence?. *Neurourology and Urodynamics* 2004; **23**(2):143–7.

Wallace 2004

Wallace SA, Roe B, Williams K, Palmer M. Bladder training for urinary incontinence in adults. *Cochrane Database of Systematic*

Reviews 2004, Issue 1. [DOI: 10.1002/14651858.CD001308.pub2; : CD001308]

WHO 2002

World Health Organization. *International Classification of Functioning, Disability and Health*. Geneva, Switzerland: World Health Organization, 2002.

Wilson 1999

Wilson P, Bø K, Bourcier A, Hay-Smith J, Staskin D, Nygaard I, et al.Conservative management in women. In: Abrams P, Khoury S, Wein A editor(s). *Incontinence*. UK: Health Publication Ltd, 1999: 579–636.

* *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

Item	Authors' judgement	Description
Allocation concealment?	Unclear	Patient drew sealed envelope on first visit

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.

Bidmead 2002 (*Continued*)

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

Item	Authors' judgement	Description
Allocation concealment?	Unclear	"randomised"

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).

Burgio 1998 (*Continued*)

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

Item	Authors' judgement	Description
Allocation concealment?	Unclear	"within each stratum, randomization was performed with computer-generated random numbers using a block size of 6 to avoid inequity in group size"

Burns 1993

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

Burns 1993 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	"randomized blocking was employed to balance the number of subjects in each group"

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 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. 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.

Bø 1999 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	Publication states "random". Contact with author confirms random number generation, and sealed opaque envelopes.

Castro 2008

Methods	4 arm RCT, parallel design Adequate allocation concealment. Blinded outcome assessment. A priori power calculation.
Participants	118 women, with urodynamic SUI without DO. Inclusion: women with urodynamic stress urinary incontinence, no detrusor overactivity, a positive cough test, more than 3 g leakage measured on pad test with standardize bladder volume (200ml); average of 3 episodes of UI per week Exclusion: Chronic degenerative disease that would affect muscular or nerve tissues, advanced genital prolapse, pregnancy, active or recurrent UTI, vulvovaginitis, atrophic vaginitis, continence surgery within a year, subjects with pacemaker,Valsalva leak point pressure less than 60 mmH_2O in sitting with 250 ml in bladder or UCP less than 20 cmH_2O in sitting position at maximal cystometric capacity. Mean age, years: PFMT 56.2 (SD 12.5), Control 52.6 (11.2). Leakage episodes in 7 days: PFMT 10.3 (SD 10.1), Control 10.5 (7.0). Mean BMI: PFMT 25.9 (SD 5.0), Control 26.9 (SD 5.1) Single centre?, Sao Paulo, Brazil
Interventions	1. PFMT (n=26): Three 45 minute exercises classes per week (including PFMT) for 6 months with supervision by physiotherapist 2. Control (n=24): No visit with therapist but motivational phone calls once per month
Outcomes	Primary outcomes: Objective cure of stress incontinence based on a negative pad test with a standardized bladder volume (<2g in weight). Secondary outcomes: I-QoL, voiding diary (number of leakage in 7 days), PFM digital evaluation using oxford scale, urodynamics evaluation, subjective cure "satisfied" or "dissatisfied"
Notes	Post-treatment evaluation at 6 months, no longer-term follow up. Dropouts and withdrawal: 3/26 PFMT, 5/24 controls.

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	"Once enrolled by a physician investigator, subjects were assigned to four distinct groups: pelvic floor ex-

Castro 2008 (*Continued*)

		ercises, electrical stimulation, vaginal cones, or untreated controls. The division of the four groups was undertaken by using computer-generated random numbers prepared by the Biostatistics Center of the Federal University of São Paulo"

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

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	"random"

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.

Henalla 1990 (*Continued*)

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

Item	Authors' judgement	Description
Allocation concealment?	Unclear	"random"

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

Item	Authors' judgement	Description
Allocation concealment?	Unclear	Translated from German, "random"

Kim 2007

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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	"categorisation using computer-generated random number"

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

Lagro-Janssen 1991 (*Continued*)

	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

Item	Authors' judgement	Description
Allocation concealment?	No	assigned consecutively to the treatment or control group

Miller 1998

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

Miller 1998 (*Continued*)

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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	"randomly assigned in blocks of two"

Wells 1999

Methods	4-arm RCT, parallel design. Not clear if adequate allocation concealment Outcome assessment not blind No intention to treat analysis
Participants	286 community living women, with symptoms of stress or mixed urinary incontinence Inclusion: aged over 21, self described as having uncontrolled urine loss and-or excessive day toiletting frequency, independent in self care, able to speak and ear a conversation in English adequately over the phone, negative urinalysis, able to contract the PFM as demonstrated on physical examination, able to read, understand and agree to the diagnostic consent form. Exclusion: diagnosis of degenerative neurological disorder,pregnancy, high risk of infection following urologic instrumentation. Mean age, years: 56 (SD 12.76) Single centre, USA
Interventions	1. PFMT(n =71): Initial training and active pelvic floor muscle exercises then monthly visits for observation, coaching and encouragement. 2. Control (n = 72): directed one week a month to keep a daily record of fluid intake, toileting and urine leakage and discern a pattern and make simple life style alterations if possible. Received diary by mail monthly.
Outcomes	Pelvic floor muscle strength, urethral pressure and wetting no details given on primary and secondary outcomes
Notes	Post treatment evaluation at 5 months, no longer term follow up. Drop outs: 30/71 PFMT, 35/72 Controls.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	subjects were randomly assigned

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

Item	Authors' judgement	Description
Allocation concealment?	Unclear	"assigned randomly to the control and treatment groups by using random numbers"

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]*

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.
Ghoniem 2005	PFMT versus sham PFMT comparison was considered to be confounded by the choice of sham PFMT
Goode 2003	3-arm RCT comparing PFMT + electrical stimulation, PFMT, and self help booklet (including advice on PFMT) . Considered to be a comparison of different approaches to PFMT.

(*Continued*)

Ramsay 1990	PFMT versus sham PFMT comparison was considered to be confounded by the choice of sham 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,

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)	Not estimable
1.2 urge urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 mixed urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 urinary incontinence (all types)	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 patient perceived 'cure or improvement'	3		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 stress urinary incontinence	2		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.2 urge urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.3 mixed urinary incontinence	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.4 urinary incontinence (all types)	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3 Symptom and condition specific quality of life assessment			Other data	No numeric data
4 Number of leakage episodes in 24 hours	5		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 stress urinary incontinence	4		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.2 urge urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.3 mixed urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.4 urinary incontinence (all types)	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
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)	Not estimable
5.2 urge urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
5.3 mixed urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
5.4 urinary incontinence (all types)	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
6 Number of voids per night (nocturia)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
6.1 stress urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
6.2 urge urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
6.3 mixed urinary incontinence	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
6.4 urinary incontinence (all types)	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
7 short pad test number cured	3		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

7.1 stress urinary incontinence	3	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
7.2 urge urinary incontinence	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
7.3 mixed urinary incontinence	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
7.4 urinary incontinence (all types)	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8 short pad test number of cure or improved	3	Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
8.1 stress urinary incontinence	3	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.2 urge urinary incontinence	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.3 mixed urinary incontinence	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.4 urinary incontinence (all types)	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9 pad and paper towel tests		Other data	No numeric data
10 Pelvic floor muscle function		Other data	No numeric data
11 Non-incontinence symptom and generic quality of life assessment assessment		Other data	No numeric data
12 Other measures of patient perceived response to treatment		Other data	No numeric data

WHAT'S NEW

Last assessed as up-to-date: 9 November 2009.

10 November 2009	New citation required but conclusions have not changed	Chantalle lead reviewer, one study added

HISTORY

Protocol first published: Issue 1, 1999

Review first published: Issue 1, 2001

13 October 2008	Amended	Converted to new review format
15 November 2005	New citation required and conclusions have changed	Jean lead reviewer

CONTRIBUTIONS OF AUTHORS

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

DECLARATIONS OF INTEREST

The two authors have published trials investigating the effects of PFMT; both trials were clearly excluded from this review as they did not meet the inclusion criteria (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 Montreal, Canada.

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