UPDATE
S O F T W A R E

Pelvic floor muscle training for urinary incontinence in women

Hay-Smith EJC, Bø K, Berghmans LCM, Hendriks HJM, de Bie RA, van Waalwijk van Doorn ESC

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ABSTRACT

Background
Pelvic floor muscle training is the most commonly recommended physical therapy treatment for women with stress leakage of urine. It is also used in the treatment of women with mixed incontinence, and less commonly for urge incontinence. Adjuncts, such as biofeedback or electrical stimulation, are also commonly used with pelvic floor muscle training. The content of pelvic floor muscle training programmes is highly variable.

Objectives
To determine the effects of pelvic floor muscle training for women with symptoms or urodynamic diagnoses of stress, urge and mixed incontinence, in comparison to no treatment or other treatment options.

Search strategy
Search strategy: We searched the Cochrane Incontinence Group trials register (May 2000), Medline (1980 to 1998), Embase (1980 to 1998), the database of the Dutch National Institute of Allied Health Professions (to 1998), the database of the Cochrane Rehabilitation and Related Therapies Field (to 1998), Physiotherapy Index (to 1998) and the reference lists of relevant articles. We handsearched the proceedings of the International Continence Society (1980 to 2000). We contacted investigators in the field to locate studies. Date of the most recent searches: May 2000.

Selection criteria
Randomised trials in women with symptoms or urodynamic diagnoses of stress, urge or mixed incontinence that included pelvic floor muscle training in at least one arm of the trial.

Data collection and analysis
Two reviewers assessed all trials for inclusion/exclusion and methodological quality. Data were extracted by the lead reviewer onto a standard form and cross checked by another. Disagreements were resolved by discussion. Data were processed as described in the Cochrane Handbook. Sensitivity analysis on the basis of diagnosis was planned and undertaken where appropriate.

Main results
Forty-three trials met the inclusion criteria. The primary or only reference for 15 of these was a conference abstract. The pelvic floor muscle training programs, and comparison interventions, varied markedly. Outcome measures differed between trials, and methods of data reporting varied, making the data difficult to combine.

Many of the trials were small. Allocation concealment was adequate in five trials, and nine trials used assessors masked to group allocation. Thirteen trials reported that there were no losses to follow up, seven trials had dropout rates of less than 10%, but in the remaining trials the proportion of dropouts ranged from 12% to 41%.

Pelvic floor muscle training was better than no treatment or placebo treatments for women with stress or mixed incontinence. 'Intensive' appeared to be better than 'standard' pelvic floor muscle training. PFMT may be more effective than some types of electrical stimulation but there were problems in combining the data from these trials. There is insufficient evidence to determine if pelvic floor muscle training is better or worse than other treatments.

The effect of adding pelvic floor muscle training to other treatments (e.g. electrical stimulation, behavioural training) is not clear due to the limited amount of evidence available. Evidence of the effect of adding other adjunctive treatments to PFMT (e.g. vaginal cones, intravaginal resistance) is equally limited. The effectiveness of biofeedback assisted PFMT is not clear, but on the basis of the evidence available there did not appear to be any benefit over PFMT alone at post treatment assessment.

Long-term outcomes of pelvic floor muscle training are unclear. Side effects of pelvic floor muscle training were uncommon and reversible. A number of the formal comparisons should be viewed with caution due to statistical heterogeneity, lack of statistical independence, and the possibility of spurious confidence intervals in some instances.

Reviewers' conclusions
Pelvic floor muscle training appeared to be an effective treatment for adult women with stress or mixed incontinence. Pelvic floor muscle training was better than no treatment or placebo treatments. The limitations of the evidence available mean that is difficult to judge if pelvic floor muscle training was better or worse than other treatments. Most trials to date have studied the effect of treatment in younger, premenopausal women. The role of pelvic floor muscle training for women with urge incontinence alone remains unclear. Many of the trials were small with poor reporting of allocation concealment and masking of outcome assessors. In addition there was a lack of consistency in the choice and reporting of outcome measures that made data difficult to combine. Methodological problems limit the confidence that can be placed in the findings of the review. Further, large, high quality trials are necessary.

BACKGROUND

Urinary incontinence is a common problem amongst adults living in the community. It is more frequent amongst women, increases with age, and is particularly common amongst those in residential care. Estimates of prevalence are influenced by the definition of incontinence. In a large survey of approximately 18,000 people living in the community in the UK, approximately 9% of women and 2% of men over the age of 15 years reported regular urinary incontinence (involuntary leakage of urine at an inappropriate place or time twice or more per month) (Thomas 1980). In a sample of nearly 2000 US men and women over the age of 60, approximately 38% of women and 19% of men reported urinary incontinence (defined as the involuntary loss of urine of any volume) (Diokno 1986). These figures are unlikely to reflect the true scope of the problem because embarrassment and other factors may lead to under-reporting.

Stress and urge incontinence are the two most common types of urine leakage in women. Urine leakage is classified according to what is reported by the woman (symptoms), what is observed by a clinician (signs) and on the basis of urodynamic studies. Stress incontinence is the self report of urine leakage with physical exertion (symptom) or the observation of urine leakage at the same time as the exertion (sign). Stress incontinence is usually due to anatomical defects in the structures that support the bladder and urethra resulting in suboptimal position of these structures at rest or on exertion, and/or dysfunction of the neuromuscular components that help control urethral pressure. If during urodynamic studies, the involuntary loss of urine is shown to occur during exertion but the leakage is not caused by an involuntary contraction of the bladder muscle this is called genuine stress incontinence. In women with genuine stress incontinence the problem appears to be that the bladder outlet (urethra) is not closed off properly during exertion and this results in leakage. Urge incontinence is the self report of involuntary leakage associated with a sudden, strong desire to void (symptom) or the observation of involuntary leakage at the same time as an uncontrollable need to void (sign). This condition usually results from an involuntary increase in bladder pressure due to detrusor (bladder smooth muscle) overactivity. If, during urodynamic investigations, the leakage is shown to be caused by uninhibited contraction of the detrusor muscle then detrusor instability is diagnosed. When symptoms of stress and urge incontinence, or genuine stress incontinence and detrusor instability, are present together this is called mixed incontinence.

A wide range of treatments have been used in the management of urinary incontinence, including conservative interventions (such as physical therapies, lifestyle interventions, behavioural training, anti-incontinence devices), pharmaceutical interventions, and surgery. The focus of this review is pelvic floor muscle training, the most commonly used physical therapy in the management of urinary incontinence. Pelvic floor muscle training (PFMT) is used in the management of symptomatic stress, urge and mixed incontinence. The other principal forms of management are considered in other Cochrane reviews.

Many women are referred for pelvic floor muscle training on the basis of symptoms or clinical signs of urine leakage. There is currently no consensus about the need for urodynamic investigations before pelvic floor muscle training but a single randomised controlled trial indicated that there was no statistically significant difference in response to conservative treatment if the referral was made on the basis of diagnosis by symptom reporting or urodynamics (Ramsay 1994). 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 (e.g. the difficulties of detecting detrusor overactivity). For these reasons diagnoses based on symptoms, signs, and urodynamic investigations are all included in this review.

In 1948 Arnold Kegel reported the successful treatment of 64 women with urinary incontinence using PFMT with a perineometer for resistance and biofeedback (Kegel 1948). The use of PFMT in the management of stress incontinence is based on the biological rationale that a strong, fast pelvic floor muscle contraction will clamp the urethra, thus increasing the intraurethral pressure, preventing leakage during abrupt increases in intra-abdominal pressure (DeLancey 1988a). It has also been suggested that an effective pelvic floor muscle contraction may press the urethra against the symphysis pubis, further increasing the urethral pressure (DeLancey 1988b). In addition, the co-ordination and timing of the pelvic floor muscle contraction seems to be important. A well timed, fast and strong contraction may prevent urethral descent during abrupt rises in intra-abdominal pressure (Bø 1995) and there is some evidence that a 'reflex' contraction of the pelvic floor muscles may precede rises in bladder pressure by 200-250 milliseconds (Constantinou 1981). The aim of PFMT in the management of stress incontinence is usually to improve the strength and/or timing of the voluntary pelvic floor muscle contraction.

The basis for the use of PFMT (or individual voluntary pelvic floor muscle contractions as part of a bladder training program) for the management of urge incontinence is less clear but a reflex inhibition of detrusor contraction has been demonstrated with an electrically stimulated contraction of the pelvic floor muscles (Godec 1975). It has also been suggested that reflex inhibition of detrusor contraction may accompany repeated voluntary pelvic floor muscle contractions (Polden 1990).

The primary aim of this review was to investigate whether pelvic floor muscle training is a safe and effective treatment in the management of female urinary (stress, mixed, urge) incontinence. Secondary aims were to compare the effectiveness of different pelvic floor muscle training programs, and the effectiveness of pelvic floor muscle training in comparison with other interventions.

Based on our previous knowledge of the PFMT literature, there is considerable variation in:
(a) the characteristics of participants in trials investigating PFMT (e.g. some trials include only women with urodynamically proven genuine stress incontinence, whilst others provide the intervention to women with symptoms of stress and/or mixed and/or urge incontinence)
(b) the parameters of PFMT programmes (e.g. number of contractions, number of exercise sessions per day, teaching and supervision of the programme)
(c) the use of PFMT as a single intervention, or in combination with a variety of other physical therapy adjuncts such as vaginal cones, electrical stimulation, biofeedback and intra-vaginal resistance devices.
The review will pay particular attention to these issues.

Five systematic reviews of physical therapies for female urinary incontinence have previously been published. The earliest publication (Fedorkow 1993) used methods of data aggregation (meta-analysis) but the subsequent systematic reviews relied on qualitative synthesis (Bø 1996, de Kruif 1996, Berghmans 1998, Wilson 1999). Fedorkow (Fedorkow 1993) investigated the effect of nonsurgical (physical therapies and pharmaceuticals) management of stress incontinence in women and concluded that while there was much indirect evidence to support the use of nonsurgical therapies there was little direct evidence of benefit. Bø (Bø 1996) considered the effect of physical therapies in women with genuine stress incontinence only and found that there was some evidence of benefit from PFMT but also clearly stated the limitations of the available evidence (e.g. small sample sizes, lack of valid measures of effect). Berghmans et al (Berghmans 1998) investigated the effect of physical therapies in women with stress incontinence or genuine stress incontinence and found "strong evidence" for the benefit of PFMT in decreasing symptoms of urine leakage. "Strong evidence" was evidence from multiple randomised controlled trials of sufficient methodological quality, where sufficient methodological quality was defined as scoring 6/10 or more on a quality scale. Wilson et al (Wilson 1999) investigated the efficacy of physical therapies for women with urinary leakage and in their summary reported that there was "Level 1B" evidence to suggest that PFMT was better than control treatments for women with stress, mixed or urge incontinence. "Level 1B evidence" was defined as evidence obtained from at least one randomised controlled trial. In summary, three previous reviews (Bø 1996, Berghmans 1998, Wilson 1999) concluded that PFMT is of benefit for women with urinary leakage.

However, there were also contrasting findings in the existing systematic reviews. One of the clearest examples is the question of whether including biofeedback with PFMT confers added benefit over PFMT alone. De Kruif & van Wegen (de Kruif 1996) investigated the added benefit of electromyographic biofeedback with PFMT over PFMT alone in women with stress incontinence and reported a trend toward greater benefit with electromyographic biofeedback assisted PFMT. In contrast Berghmans et al (Berghmans 1998) and Wilson et al (Wilson 1999) found no apparent benefit of biofeedback assisted training over PFMT alone at post treatment assessment. Weatherall (Weatherall 1999) questioned the conclusion reached by Berghmans et al (Berghmans 1998) and re-evaluated the findings using pooled data from three of the five trials identified by Berghmans et al (Berghmans 1998) that compared biofeedback assisted PFMT with PFMT alone. While the effect of biofeedback assisted PFMT did not reach statistical significance in comparison to PFMT alone (OR 2.1, 95% CI 0.99,4.4) Weatherall concluded that there was a trend in favour of biofeedback. One possible criticism of the meta-analysis by Weatherall (Weatherall 1999) was that it pooled data for a single outcome, 'cure'. Cure was assessed differently in each of the trials that contributed data to the analysis (pad test, "complete remission of symptoms", and in the other the definition of cure was not stated).

There is clearly a need for a regularly updated and comprehensive systematic review of the effectiveness of PFMT for women with urinary incontinence, with meta-analysis where appropriate.

OBJECTIVES

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

The following hypotheses will be tested:
1. That pelvic floor muscle training is better than no treatment.
2. That pelvic floor muscle training is better than placebo treatments.
3. That there are differences in the effectiveness of different pelvic floor muscle training programmes.
4. That pelvic floor muscle training is better than other 'single' treatments (e.g. a physical therapy such as vaginal cones, a pharmaceutical such as an anticholinergic, or a type of surgery)
5. That pelvic floor muscle training adds benefit to another therapy when compared with the same therapy alone (e.g. pelvic floor muscle training with electrical stimulation is better than electrical stimulation alone)
6. That pelvic floor muscle training in combination with another therapy is better than pelvic floor muscle training alone (e.g. pelvic floor muscle training combined with biofeedback is better than pelvic floor muscle training alone).

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised controlled trials were included. Quasi-randomised studies (e.g. allocation by alternation) and other forms of controlled clinical trial were excluded.

Types of participants

All adult women with urinary incontinence diagnosed as having stress, mixed or urge incontinence on the basis of symptoms or urodynamic evaluation, as defined by the trialists.

Studies of women with urinary incontinence whose symptoms might be due to significant factors outside the urinary tract were excluded, e.g. neurological disorders, cognitive impairment, homebound women. Studies investigating nocturnal enuresis in adult women were also excluded.

Types of intervention

One arm of the trial had to include the use of a pelvic floor muscle training program to ameliorate symptoms of existing urine leakage. Thus, studies of PFMT for primary prevention of urinary incontinence were excluded.

PFMT was defined as a programme of repeated voluntary pelvic floor muscle contractions taught by a health care professional. All types of PFMT programme were considered: including variations in purpose and timing of PFMT (e.g. PFMT for strengthening, PFMT for urge suppression, etc), ways of teaching PFMT, types of contractions (quick or held), and number of contractions etc.

Types of outcome measures

A subcommittee (Outcome Research in Women) of the Standardisation Committee of the International Continence Society has suggested that research investigating the effect of therapeutic interventions for women with urinary incontinence should consider five outcome categories; the woman's observations (symptoms), quantification of symptoms (e.g. urine loss), the clinician's observations (anatomical and functional), quality of life and socioeconomic measures (Lose 1998).

These categories have been adapted for this review, and the outcome measures of interest were:

1. Women's observations - e.g. symptom scores, perception of cure/improvement, satisfaction with outcome.
2. Quantification of symptoms - e.g. number of leakage episodes (urinary diary), pad tests.
3. Clinicians' measures - e.g. measures of pelvic floor muscle activity (e.g. perineometry, palpation).
4. Quality of life - general (e.g. SF36) and condition specific quality of life measures (e.g. Incontinence Impact Questionnaire), and psychosocial measures.
5. Socioeconomics - direct and indirect costs of interventions (for women and providers), resource implications of differences in outcome, formal economic analysis (e.g. cost effectiveness, cost utility), desire or need for further treatment.
6. Other - e.g. adverse events, compliance measures, incontinence at long term follow up and any other outcome not pre-specified but judged important when performing the review.

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

Search strategy for identification of studies
See: Collaborative Review Group search strategy.
This review has drawn on the search strategy developed for the Incontinence Review Group. Relevant trials were identified from the Group's specialised register of controlled trials which is described under the Incontinence Group's details in The Cochrane Library. The register contains trials identified from MEDLINE, CINAHL, The Cochrane Controlled Trials Register and handsearching of journals. Date of most recent search of register for this review: May 2000. The trials in the Incontinence Group's specialised register are also
contained in The Cochrane Controlled Trials Register (CENTRAL). There was no restriction on language of publication or publication status (ie full publication, grey literature, etc). For this review extra specific searches were performed by the reviewers. These are detailed below.

Electronic bibliographic databases were searched in 1998, the years covered by the search were 1980 to 1998. The following three sets of search terms were used in MEDLINE, EMBASE, the database of the Dutch National Institute of Allied Health Professions, and the database of the Cochrane Rehabilitation and Related Therapies Field at the University of Maastricht: a set of condition terms - incontinence, urinary incontinence, SUI and GSI; a set of intervention terms - conservative management, surgical and non-surgical treatment, behavioural modification, physiotherapy, PFM exercises, biofeedback, myofeedback, electrical stimulation, vaginal cones, and prevention; and a set of trial design terms - RCTs, controlled trials, evaluation, effectiveness, efficacy and outcome. Each set of terms was combined using the Boolean operator 'OR' then the three sets of terms were combined together using the Boolean operator 'AND'.

One non-electronic bibliographic database was also searched: Physiotherapy Index (to 1998).

Handsearching of the proceedings of the International Continence Society, for the years 1980 to 2000 inclusive, was undertaken (read by title
abstracts, 1996 to 2000 inclusive, abstracts published in Neurourology and Urodynamics 1980 to 2000 inclusive). Some physiotherapy journals not covered by MEDLINE were also handsearched.

The reference lists of relevant articles were searched for other possible relevant trials.

Known trials and experts in the field were contacted to ask for other possible relevant trials, published or unpublished.

METHODS OF THE REVIEW

SCREENING FOR ELIGIBILITY

Reports of all possibly eligible studies were evaluated for appropriateness for inclusion by two reviewers (EJCHS, KB) 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 controlled trials or made comparisons other than those pre-specified. Excluded studies have been listed with reasons for their exclusion.

ASSESSMENT OF METHODOLOGICAL QUALITY

Assessment of methodological quality was undertaken by two reviewers (EJCHS, KB) 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 'masking' (or 'blinding') during treatment and at outcome assessment. Any disagreements were resolved as previously described. Trials that contributed to the formal comparisons were presented in order of quality of allocation concealment (A=adequate, B=unclear, C=inadequate).

DATA EXTRACTION

Data extraction was undertaken independently by two reviewers (EJCHS, KB) and cross checked. Any differences of opinion related to the data extraction were resolved by discussion. Where 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 (i.e. data from abstracts of ongoing trials) trialists were contacted for data from the completed trial. Data from ongoing trials were not included in the formal comparisons but are reported in the text. All included trial data were processed as described in the Cochrane Collaboration Handbook (Mulrow 1997).

SUBGROUP ANALYSIS

Subgroup analysis was planned because it was plausible to expect a difference in the outcome of PFMT on the basis of the type of incontinence. However, it subsequently became apparent that the sample populations of a significant proportion of the included trials were not homogeneous with respect to diagnosis (e.g. a study population might include women with genuine stress incontinence, urge incontinence and mixed incontinence). In such cases it was not possible to describe the population using one diagnostic classification. Therefore subgroup analysis was rejected in favour of grouping all the trials together, followed by sensitivity analysis on the basis of diagnosis if appropriate (see below).

SENSITIVITY ANALYSIS

Two sensitivity analyses were planned. The first was on the basis of diagnosis. It is commonly believed that PFMT is most effective for women with stress incontinence, and may be effective in combination with behavioural interventions for women with mixed incontinence. PFMT is rarely the first choice

treatment for women with urge incontinence alone. Therefore sensitivity analysis by diagnosis was planned (e.g. effect of PFMT in women with symptoms, or urodynamic evidence, of stress incontinence only). The second sensitivity analysis was planned with respect to trial quality as there is some evidence that this may have an impact on the findings of meta-analysis (Moher 1998). In the event none of the formal comparisons contained sufficient data to make the latter analysis appropriate.

HETERTOGENEITY

Data plots were examined for evidence of heterogeneity, and a formal test of heterogeneity was used. Where significant statistical heterogeneity was observed an explanation is offered in the text. Where three or more trials contributed to a single data plot, the data were reanalysed after removal of the trial that was the apparent cause of the dissimilarity. The secondary analysis is presented in the text.

Some clinical heterogeneity may have been introduced in the analysis from the grouping of the trials. The authors were aware that PFMT is commonly used in conjunction with behavioural interventions (e.g. bladder training, urge or frequency strategies) or other physical therapies (e.g. electrical stimulation, biofeedback), and that the trials located during the search would reflect the common practice of combined conservative therapies. To prevent the number of comparisons becoming unwieldy the authors made a pragmatic decision to classify some combined therapies as 'PFMT' for the purposes of the review. For example trials that included behavioural intervention(s) with PFMT (e.g. Burgio 1998) were classified as trials of PFMT for the purposes of analysis except where the trial design was clearly intended to investigate the effect of a behavioural intervention (e.g. Wyman 1998; PFMT with bladder training versus PFMT alone). Similarly, some trials that combined other physical therapies with PFMT (e.g. Cammu 1998; PFMT with biofeedback versus vaginal cones) were classified as trials of PFMT for the purposes of analysis. The exceptions to this system of classification were trials that clearly intended to investigate the effect of adding PFMT to another therapy (e.g. Hofbauer 1990; PFMT with electrical stimulation versus stimulation alone) or the effect of adding another therapy to PFMT (e.g. Berghmans 1996; PFMT with biofeedback versus PFMT alone). In the results section the text accompanying each comparison clearly states where such pragmatic decisions have been taken. The Table of Included Studies clearly describes all the interventions used in each trial. This and other reviews may show whether this classification process was appropriate or not.

During the course of data analysis it became clear that some trials would contribute to a single comparison more than once. For example the trial by Knight et al (Knight 1998) had three intervention groups; PFMT with biofeedback, PFMT with low intensity electrical stimulation, and PFMT with acute maximal stimulation. Both intervention groups receiving electrical stimulation were able to contribute data to the comparison between PFMT with electrical stimulation versus PFMT alone. However, in view of the difference in the stimulation protocols

the reviewers did not think it was appropriate to combine the data from the two stimulation groups as this might mask the true effect of each type of stimulation. To differentiate two data sets the trial has been entered twice (with the suffix 'a' for the low intensity stimulation group and 'b' for the acute maximal stimulation group) and compared with the data from the PFMT group. Therefore data from the PFMT group appears twice in the same comparison and lacks statistical independence. This will have affected the width of the confidence intervals and heterogeneity to an unknown extent.

PUBLICATION BIAS
Publication bias was not formally assessed. There were not sufficient trials in any comparison to make this appropriate.

CONFLICT OF INTEREST
Two of the review authors (KB, LCMB) had trials that contributed to the review. These authors were excluded from the process of assessing eligibility and quality, and performing the data extraction, for their own trials. In each case a third person was selected for this process.

DESCRIPTION OF STUDIES

INCLUDED/EXCLUDED STUDIES
Fifty-six trials were identified that used PFMT in at least one arm of the trial and apparently met the review criteria. Some of these trials were published in multiple reports. Once all reports were retrieved five trials were immediately excluded as they were not randomised (Burgio 1986; Voigt 1996; Wang 1997) or used quasi-random methods of group allocation (Haig 1995; Wilson 1987). A further three studies (Borrie 1992; Fonda 1994; Holtedahl 1998) were excluded because they investigated the effect of a conservative management package (i.e. any combination of PFMT, bladder training, oestrogen therapy, incontinence aids, advice on fluids and weight) individualised for each participant. Another five trials were excluded as an identical PFMT programme was used in both arms of the trial in addition to another therapy. The review authors considered that these trials had therefore investigated the efficacy of electrical stimulation versus sham stimulation (Blowman 1991; Shepherd 1984), vaginal cones versus electrical stimulation (Bourcier 1994; Olah 1990), and biofeedback from perineometry versus biofeedback from electrical conductance (Mayne 1988). The remaining 43 trials were included in the review.

Since completion of the search for included trials, two studies that might be eligible for inclusion in the review have been presented as conference abstracts (Aukee 2000; Berghmans 2000). These trials are currently awaiting assessment. If eligible for inclusion the trials will add data from 30 more women to the comparison of PFMT versus PFMT with biofeedback (Aukee 2000), and data from 57 women to the comparisons PFMT versus no treatment, and PFMT versus electrical stimulation (Berghmans 2000)

PUBLICATION TYPE

The primary (or only) reference for 15 of the 43 included trials was a conference abstract (Haken 1991; Henalla 1990; Klingler 1995; Laycock 1988; Laycock 1999; Peattie 1988; Prashar 1997; Ramsay 1990; Tapp 1987; Tapp 1989; Terry 1996; Wilson 1997; Wise 1993; Wong 1997a; Wong 1997b). All the abstracts reported limited details of method, and few results. Four abstracts reported trials in progress (Laycock 1988; Peattie 1988; Prashar 1997; Wong 1997a). No further published report was found for 14 of the 15 abstracts. It was not clear whether a paper by Moore et al (1999) was a full publication of the previously reported trial by Prashar et al (Prashar 1997) but it was assumed that it was. Further (unpublished) information was available from the authors of two of the abstracts (Peattie 1988; Wilson 1997).

The primary reference for two of the 43 included trials stated that it was the report of a "pilot study" (Shepherd 1983, Taylor 1986). The numbers randomised in both these trials were small. Twenty-two women were randomised in a two arm RCT by Shepherd et al (Shepherd 1983), and Taylor et al (Taylor 1986) conducted a four arm RCT in a sample of 13 women. No further report was identified for either of these two trials. One trial was published in German (Hofbauer 1990) and information and data were extracted by two reviewers (KB, LCMB) who were able to read German.

SAMPLE CHARACTERISTICS
There were 31 trials undertaken only in women with stress incontinence. Most trials included women with a urodynamic diagnosis of genuine stress incontinence only (23 trials). Six trials included women who reported symptoms of stress leakage only (Castleden 1984; Klingler 1995; Laycock 1999; Miller 1998; Ramsay 1990; Taylor 1986). The two remaining trials in this subgroup were Berghmans (Berghmans 1996) who included women with genuine stress incontinence or a clinical history suggestive of genuine stress incontinence, and Henalla (Henalla 1990) who included women "complaining of genuine stress incontinence".

Twelve trials included samples of women with a range of symptom or urodynamic diagnoses. Four trials diagnosed incontinence on the basis of symptoms alone. Prashar et al (Prashar 1997) included women with stress and/or urge leakage, and 'urine leakage' was the presenting problem in the remaining three trials (O'Brien 1991, Wilson 1997, Wilson 1998). In the other seven trials in this group the women had a mixture of urodynamic diagnoses. The combinations were genuine stress incontinence with or without detrusor instability (Burns 1993, Lagro-Janssen 1992, Sherman 1997, Wells 1991), detrusor instability with or without genuine stress incontinence (Burgio 1998), and two trials in which women had genuine stress incontinence or detrusor instability alone or mixed incontinence (Nygaard 1996, Wyman 1998). Three trials (Lagro-Janssen 1992; Wilson 1997; Wyman 1998) presented some post treatment data separately for women with genuine stress incontinence (Lagro-Janssen 1992; Wyman 1998) and stress incontinence alone (Wilson 1997). Where the data were

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available separately they are presented in this way to allow for sensitivity analysis if appropriate. The suffixes 'a' and 'b' are used to differentiate the data sets; 'a' for data from women with stress incontinence and 'b' for data from women with other diagnoses.

Most trials indicated that women were recruited on the basis of symptoms of urine leakage or urodynamic diagnosis and few other inclusion or exclusion criteria were reported. Six trials made age one of the inclusion criterion (Berghmans 1996; Burgio 1998; Knight 1998; Miller 1998; Nygaard 1996; Wyman 1998) and in two of these trials the focus was older women (Burgio 1998, 55 years and over; Miller 1998, 60 years and over). There were no other consistently reported inclusion criteria. The most commonly reported exclusion criterion was a previous history of bladder and/or other pelvic surgery (e.g. for prolapse) (Berghmans 1996; Bø 1999; Cammu 1998; Ferguson 1990; Glavind 1996; Hahn 1991; Henalla 1989; Lagro-Janssen 1992; Miller 1998; Pieber 1995; Tapp 1987; Tapp 1989; Wong 1997a). No other exclusion criterion was reported by a quarter or more of trials. However, other criteria common to several trials were exclusion on the basis of urinary tract infection, severe urogenital prolapse, psychological disorder or low score on the Mini-Mental State Examination, or another concurrent disorder that might cause or affect the outcome of incontinence (e.g. neurological disorder).

PFMT PROGRAMMES
In most trials women were individually taught how to contract their pelvic floor muscles. However three trials used group teaching (Hofbauer 1990; Klarskov 1986; O'Brien 1991), another compared a standard (group) to an individualised programme (Wilson 1998), and in three trials the approach was not stated (Ferguson 1990; Henalla 1990; Wilson 1997). PFMT was provided by physiotherapists in 16 trials (Berghmans 1996; Bø 1990; Bø 1999; Cammu 1998; Castleden 1984; Hahn 1991; Henalla 1989; Klarskov 1986; Klingler 1995; Knight 1998; Laycock 1988; Laycock 1993; Peattie 1988; Pieber 1995; Shepherd 1983; Wilson 1998). Other health care professionals providing PFMT included nurses, nurse practitioners or clinical nurse specialists (Burgio 1998; Burns 1993; Gallo 1997; O'Brien 1991; Wells 1991; Wilson 1997; Wyman 1998), and continence advisors (Haken 1991; Prashar 1997; Tapp 1987; Tapp 1989). Two trials used an undefined "therapist" (Hofbauer 1990; Sherman 1997) and in the remaining 14 trials it was not clear who provided the training. Only 16 trials specifically stated that a correct voluntary pelvic floor muscle contraction was checked by vaginal palpation or some other means before PFMT began (Berghmans 1996; Bø 1990; Bø 1999; Burgio 1998; Cammu 1998; Gallo 1997; Hahn 1991; Henalla 1989; Knight 1998; Lagro-Janssen 1992; Laycock 1993; Miller 1998; Nygaard 1996; Pieber 1995; Smith 1996; Wise 1993).

Thirty-seven trials stated or implied that a daily home PFMT programme was used. In the remaining six trials it was not clear if daily training was expected (Henalla 1990; Laycock 1988; Prashar 1997; Tapp 1989; Terry 1996; Wong 1997a). Variation

in daily training programmes was considerable. Some trials recommended a specific length of time per day (e.g. Nygaard 1996, five minutes twice a day), others a specific number of contractions per hour (e.g. Henalla 1989, five per hour), or a specific number of contractions per day (e.g. Wyman 1998, 50 per day), and some stated the number of contractions to be repeated a specific number of times each day (e.g. Bø 1990, 12 contractions three times a day). In 22 trials it was possible to estimate the maximum number of contractions women were asked to complete and the daily totals ranged from 36 (Bø 1990; Bø 1999) to 200 contractions per day (Burns 1993).

Other characteristics of the showed similar variation. Both 'quick 'and 'held' (sustained) contractions were recommended. The maximum length of hold ranged from four seconds (Ramsay 1990) to 30 - 40 seconds (Berghmans 1996; Hahn 1991). Nine trials recommended that 'quick' contractions were done in addition to 'held' contractions (Berghmans 1996; Bø 1990; Bø 1999; Burns 1993; Cammu 1998; Knight 1998; Smith 1996; Wilson 1998; Wyman 1998). Few trials stated the rest time between contractions but the shortest reported time was four seconds (Knight 1998) and the longest 10 seconds (Gallo 1997; Ramsay 1990; Sherman 1997; Wells 1991; Wyman 1998). Five trials reported that they included 'The Knack' (a voluntary contraction of the pelvic floor muscles preceding rises in intra-abdominal pressure, e.g. with cough) in addition to other PFMT (Berghmans 1996; Burgio 1998; Hahn 1991; Pieber 1995; Wyman 1998), and in one trial (Miller 1998) use of 'The Knack' in daily life was the entire PFMT program. Only seven reports documented that women were asked to train their muscles in a variety of postures (e.g. sitting, standing, kneeling, lying) (Berghmans 1996; Bø 1990; Bø 1999; ; Burgio 1998; Glavind 1996; Hahn 1991; Klarskov 1986).

The length of training was not uniform. The total length of training was as little as one week (Miller 1998) but was also continued for up to six months (Bø 1990; Bø 1999; Hahn 1991; Knight 1998; Wells 1991) or nine months (Wilson 1997; Wilson 1998). The most commonly used training period was three months/12 weeks (Cammu 1998; Henalla 1989; Lagro-Janssen 1992; Laycock 1999; Nygaard 1996; O'Brien 1991; Pieber 1995; Ramsay 1990; Tapp 1987; Tapp 1989; Wise 1993; Wyman 1998).

THE COMPARISON INTERVENTIONS
The comparison groups used a wide range of treatments: surgical, pharmaceutical and conservative. During the course of the review it became clear that, like the differences in the , there were also differences in the comparison interventions that had been grouped together (e.g. within the biofeedback group a range of biofeedback devices had been used). Where differences were observed these are noted in the relevant section of the text. For the purposes of this review all treatments have been grouped so that interventions of the same type are treated alike, e.g. all electrical stimulation treatments regardless of type have been grouped, as have treatments with oestrogens, or

surgery. Other reviews may show whether this was appropriate or not.

OUTCOME MEASURES

Overall there was a lack of consistency in the choice of outcome measures by trialists (e.g. variability in types of pad test used). It was also notable that some trials concentrated their measures in a particular outcome category (e.g. clinician's measures) and no trial included a measure or measures from each of the outcome categories. The lack of similarity has limited the possibility to combine results from individual studies.

Women were commonly asked to give their opinion of the results of treatment but many different scales were used including Likert scales, visual analogue scales, and estimates of percentage reduction in symptoms. Any rating scale was considered acceptable and the data were included in the formal comparisons when the trial report stated the number of women who considered they were cured or improved with treatment. Unfortunately a number of trial reports did not differentiate self reported cure from self reported improvement. This necessitated the use of two separate outcomes, self reported cure and cure/improvement, so that significant amounts of data were not lost. Some trials also created measures of cure/improvement that combined findings from subjective and objective tests (e.g. cure was defined as less than two grams of leakage on pad test and subjective cure). Data from these combined measures was not suitable for inclusion in the meta-analysis. Three trials (Bø 1990; Bø 1999; Nygaard 1996) used a Leakage Index that asked women to indicate severity of leakage associated with particular activities (e.g. run, jump) before and after treatment.

The two most common methods used to quantify symptoms of urine loss were the urinary diary and pad test. Urinary diaries were collected for different lengths of time (from one to seven days) and the data presented variously. In order for data to be comparable between trials it is presented as number of leakage episodes in 24 hours in the formal comparisons. Pad tests varied in length and the stressors used to provoke leakage. Short pad tests were more often used than long pad tests (24 hours or more). Short pad tests ranged from a standing stress test (e.g. the paper towel test) to one hour home pad tests, and some were carried out with known bladder volumes while others were not. The data were also presented in a range of ways (e.g. amount of leakage, change in amount of leakage, number of women with less than two grams of leakage, etc). As the comparability of the short pad tests is not known, and the data were presented in so many ways, it was not possible to combine the data from these tests in the formal analysis. A summary of pad test findings is presented in the text.

Clinicians' measures usually included a measure of pelvic floor muscle activity or the results of cystometry or other urodynamic investigation. Measures of pelvic floor muscle activity are indirect measures of muscle 'strength'. The tools used included digital palpation, vaginal squeeze pressure (i.e. perineometry) and electrical activity (i.e. electromyography). The

comparability of findings from these different measures is not known therefore the data were not combined or presented in the formal comparisons. However, despite the lack of established reliability for some measures of pelvic floor muscle activity, the unknown comparability of findings gained through different tools, and the poorly substantiated relationship between muscle strength and leakage symptoms these data have been presented in the text. The express intention of PFMT in some trials was to increase muscle volume (hypertrophy) and strength of the pelvic floor muscles (e.g. Bø 1990) and as these are the measures that have been used to demonstrate change in strength the data are presented for the reader to interpret. A number of trials reported measures taken during cystometry or other urodynamic investigations (e.g. bladder capacity, maximal urethral closure pressure, functional urethral length). While these measures might be considered more 'objective' indicators of change, current evidence suggests that there is a lack of correlation between the findings of standard laboratory urodynamics and clinical outcome (e.g. McClish 1991). Therefore urodynamic measures were not included in this edition of the review.

Very few trials used validated methods of measuring generic or condition specific quality of life, and even fewer reported economic outcomes. No economic or quality of life outcome was reported by more than two trials within a comparison so data were included in the text where appropriate rather than in formal comparisons. Some data were omitted from formal comparisons. For example, data from outcomes not prespecified in the method were excluded (e.g. Sherman 1997, able to perform mid stream urine stop; Shepherd 1983, change in frequency post treatment). Where data for outcomes used in the formal comparisons were presented by the original authors but not in useable form (e.g. Castleden 1984, mean and range; Glavind 1996, median and 95% CI) these were omitted unless further information was gained from the authors.

As the length of treatment varied so much, and the timing of post treatment assessment also varied, no attempt was made to report outcomes at particular time after beginning or end of treatment. Post treatment outcomes were used as it has been assumed that the original authors chose to complete treatment and/or measure outcome when the maximum benefit was likely to have been gained. Follow up data (beyond post treatment assessment) are reported in the text where available.

METHODOLOGICAL QUALITY

Due to brevity of reporting it was difficult to assess the quality of the 15 trials that were published as abstracts (Haken 1991, Henalla 1990, Klingler 1995, Laycock 1988, Laycock 1999, Peattie 1988, Prashar 1997, Ramsay 1990, Tapp 1987, Tapp 1989, Terry 1996, Wilson 1997, Wise 1993, Wong 1997a, Wong 1997b). Further information was available from the authors of one trial (Wilson 1997), which confirmed that randomisation allocation was adequately concealed. None of the remaining

trials gave details of group allocation other than it was at "random". Only one trial (Ramsay 1990) reported that the assessors of outcome were masked to group allocation. With PFMT it is generally impossible to mask participants to the treatment they are receiving but one trial (Ramsay 1990) compared PFMT with a placebo training program and indicated women were 'masked' to group allocation.

Of the remaining 29 trials seven had adequately concealed group allocation (Berghmans 1996; Bø 1990, unpublished data; Bø 1999; Cammu 1998; Glavind 1996; Knight 1998; Wilson 1998), in four it was not clear if group allocation was adequately concealed (Burgio 1998; Burns 1993; Nygaard 1996; Pieber 1995), and in two trials it was possible that concealment was inadequate (Gallo 1997; Lagro-Janssen 1992). The remaining 16 trials reported only that group allocation was at "random". Nine trials stated that those assessing outcome of treatment were masked to group allocation (Berghmans 1996; Burgio 1998; Burns 1993; Bø 1990; Lagro-Janssen 1992; Miller 1998; Nygaard 1996; O'Brien 1991; Wilson 1998), in two trials assessors were not masked (Laycock 1993; Wyman 1998), and in the remaining 18 trials this was not stated.

A power calculation was reported by only six trials (Bø 1990, unpublished data; Bø 1999; Gallo 1997; Nygaard 1996; Wilson 1998; Wyman 1998). In general the trials were small and in just under half (21 of 43) the comparison groups numbered less than 25 women per group. Six trials randomised more than 50 women to each comparison group (Burgio 1998; Lagro-Janssen 1992; O'Brien 1991; Wells 1991; Wilson 1997; Wyman 1998) and in 16 trials group size ranged from 25 to 49 (Bø 1990; Bø 1999; Burns 1993; Cammu 1998; Gallo 1997; Haken 1991; Henalla 1989; Klarskov 1986; Knight 1998; Laycock 1999; Nygaard 1996; Pieber 1995; Prashar 1997; Terry 1996; Wilson 1998; Wong 1997b).

Thirteen trials reported that there were no dropouts or losses to follow up at post treatment assessment (Berghmans 1996; Castleden 1984; Ferguson 1990; Hahn 1991; Henalla 1990; Hofbauer 1990; Klarskov 1986; Klingler 1995; Miller 1998; Ramsay 1990; Smith 1996; Tapp 1987; Wong 1997b). The proportion of dropouts was below 10% in seven trials (Bø 1990; Burns 1993; Henalla 1989; Lagro-Janssen 1992; O'Brien 1991; Taylor 1986; Terry 1996) and only five trials clearly reported some or all of their analysis on the basis of intention to treat (Burgio 1998; Bø 1999; Cammu 1998; Knight 1998; Nygaard 1996). Dropout rates varied in the remaining trials from 12.3% (Wyman 1998) to 41.3% (Pieber 1995).

RESULTS

Please note when referring to the meta-analysis that for two of the three outcomes (self reported cure, self reported cure/improvement) the right hand side of the plot favours PFMT. For the remaining outcome, the number of leakage episodes in 24 hours, the left hand side of the plot favours

PFMT. This decision has been made in order to keep interpretation of the forest plots clinically intuitive.

In situations where a single trial has contributed data to a formal comparison the data, rather than the summary statistic, have been used in the text. Readers are referred to the relevant graphs of the formal comparisons to view the summary statistics.

1. PELVIC FLOOR MUSCLE TRAINING (PFMT) VERSUS NO TREATMENT

Seven trials compared PFMT with no treatment (Bø 1999; Burns 1993; Henalla 1989; Henalla 1990; Lagro-Janssen 1992; Miller 1998; O'Brien 1991). In two of these seven trials the 'no treatment' group was offered some advice or intervention. Lagro-Janssen et al (Lagro-Janssen 1992) provided advice on the use of protective pads, and Bø et al (Bø 1999) offered women the use of a Continence Guard (Coloplast AG), an intravaginal anti-incontinence device, and about half the women used this. These two trials were grouped with the 'no treatment' trials as the authors considered that neither of the treatments were designed to alter pelvic floor muscle function (i.e. the treatment did not contain any intervention that might affect the neuromuscular supports of the bladder/urethra), which is a primary objective of PFMT.

Three trials included women with genuine stress incontinence only (Bø 1999; Henalla 1989; Henalla 1990). One trial included women with a urodynamic diagnosis of genuine stress or mixed incontinence (Burns 1993) and three trials included women with symptoms of urine leakage (Lagro-Janssen 1992; Miller 1998; O'Brien 1991). Burns et al (Burns 1993) was a three arm RCT. The three comparison groups received PFMT, PFMT with biofeedback, or no treatment. This trial has contributed two data sets to the analysis; PFMT versus no treatment (Burns 1993a), and PFMT with biofeedback versus no treatment (Burns 1993b).

There was variability in the PFMT programmes. Two programmes were based on individual training supervised by a physiotherapist (Henalla 1989) or nurse (Burns 1993) plus a home programme of exercise. One trial included a weekly exercise class in addition to individual training with a physiotherapist (Bø 1999), and one programme was based on group training with a nurse (O'Brien 1991). In the remaining trials these details were unclear (Henalla 1990; Lagro-Janssen 1992; Miller 1998). The recommended number of contractions per day ranged from 36 (Bø 1999, one set of 8-12 contractions three times day) to a maximum of 200 (Burns 1993, one set of 20-50 contractions 4 times a day). Length of hold varied from eight (Bø 1999) to 10 seconds Burns 1993. One trial (Bø 1999) recommended that women did their training in a range of body positions (e.g. sitting, standing, lying, kneeling). There were differences in the length of training, and this ranged from as little as one week (Miller 1998) to six months (Bø 1999), with most in the range of six to twelve weeks.

Limited data were available from the abstract (Henalla 1990). As the trial report from O'Brien et al (O'Brien 1991) did not

present data from control and treatment groups separately it was excluded from the analysis.

1.1 Women's observations
Three trials did not report whether women were asked about cure or improvement after treatment (Henalla 1989, Henalla 1990, Miller 1998). O'Brien et al (O'Brien 1991) did include a subjective rating but the data cannot be used because the data from the intervention and control groups were not reported separately. The three remaining trials all used a different measure for women to rate the outcome of treatment.

1.1.1 Self reported cure
Combined data from two trials suggested that PFMT was much more effective than no treatment (RR 7.3, 95% CI 2.0, 26.5). The trials included women with genuine stress incontinence (Bø 1999) and women with genuine stress or mixed incontinence (Burns 1993). Some caution is required in interpreting this result as one trial contributed two data sets to the summary (Burns 1993a, Burns 1993b). In addition the trial by Bø et al (Bø 1999) had 'no events' (i.e. 0/30) in one arm and as a result the confidence interval may be spurious, disguising the true treatment effect.

1.1.2 Self reported cure/improvement
The combined data from two trials (Bø 1999; Lagro-Janssen 1992) suggested that women were much more likely to report cure or improvement following PFMT than no treatment (RR 23.0, 95% CI 7.6, 70.2). It should be noted that one trial contributed two sets of data to the analysis (Lagro-Janssen 1992a; Lagro-Janssen 1992b). If data from the two trials in women with genuine stress incontinence only (Bø 1999; Lagro-Janssen 1992a) are grouped a similar benefit is seen (RR 23.6, 95%CI 6.0, 92.7).

1.1.3 Other
Women were asked to make a wide range of observations about other effects of treatment but none were replicated consistently. For example women were asked about pad usage (O'Brien 1991), severity of leakage (Lagro-Janssen 1992), activities provoking leakage (Lagro-Janssen 1992; Bø 1999, Leakage Index) and whether leakage was problematic (Bø 1999).

1.2 Quantification of symptoms

1.2.1 Urinary diary (leakage episodes)
Three trials did not ask women to complete a post treatment urinary diary (Henalla 1989; Henalla 1990; O'Brien 1991). In Miller et al (Miller 1998) women completed a seven day pre treatment urinary diary but were not asked to repeat this post treatment (i.e. one week later). Two trials used seven day urinary diaries (Burns 1993; Lagro-Janssen 1992), and one trial used a three day diary (Bø 1999).

Combined data from three trials (Bø 1999; Burns 1993; Lagro-Janssen 1992) demonstrated a significant reduction in leakage episodes in 24 hours for women who received PFMT compared with no treatment (WMD -1.3, 95% CI -1.6, -0.9). Some caution is required in the interpretation of this result as

statistically significant heterogeneity was observed (p=0.0059). The source of the heterogeneity appears to be the trial by Bø et al (Bø 1999). There are two possible explanations. Firstly the quality of the trial (rated A) might reflect a more accurate treatment effect. Secondly, women in the no treatment group were offered the use of an anti-incontinence device and if the device was worn during the three days in which the urinary diary data was recorded this may have reduced leakage in the no treatment group. Readers should also note that one trial contributed two data sets to this comparison (Burns 1993a; Burns 1993b).

1.2.2 Pad test
Three trials did not ask women to complete any form of pad test (Burns 1993; Lagro-Janssen 1992; O'Brien 1991). Henalla et al (Henalla 1990) used a pad test (not described) and reported four of the eight women in the PFMT group had a 50% reduction or more in pad weight post treatment versus none of seven in the control group (p<0.05).

Three trials asked women to complete a short pad test. Miller et al (Miller 1998) used a standing stress test (the paper towel test) and reported that women who used a voluntary pelvic floor muscle contraction with deep cough had significantly less leakage than controls (p=0.031) after one week of treatment. Henalla et al (Henalla 1989) used a one hour pad test and found that 17/26 women in the PFMT group versus 0/25 controls were cured (negative after previously positive test) or had a 50% reduction in pad weight (p<0.001). Bø et al (Bø 1999) asked women to complete a clinic based 60 second stress test with standardised bladder volume and found the reduction in leakage was significantly greater in the PFMT versus control group (p=0.02). Bø et al (Bø 1999) also reported the number of women who were cured at post treatment pad test (less than two grams of leakage); 11/25 in the PFMT group versus 2/30 in the no treatment group.

Only Bø et al (Bø 1999) included a long pad test (24 hours). There was no significant difference between PFMT and no treatment groups for this outcome.

1.3 Clinicians' measures
Digital palpation (Miller 1998), perineometry (Bø 1999) and EMG (Burns 1993) were used to assess pelvic floor muscle activity. Miller et al (Miller 1998, unpublished data) found no significant changes in pelvic floor muscle function had occurred over the treatment period of one week. Mean (standard deviation) pre treatment palpation scores (possible range 0-21) were 10.1 (sd 5.0) and 11.1 (sd 5.3) in PFMT and no PFMT groups respectively. Post treatment scores were similar, 10.4 (sd 4.7) and 11.2 (sd 5.1) respectively. Bø et al (Bø 1999) found significant improvement in vaginal squeeze pressure in the PFMT group compared with the no treatment group (p<0.001). Burns et al (Burns 1993) found significant improvements in both quick and sustained (p<0.005) contraction performance in the biofeedback assisted PFMT group when compared with the no treatment group. However, a significant improvement

in EMG scores was not observed in the group receiving PFMT without biofeedback when compared with the no treatment group.

1.4 Quality of life
None of the trials contributing to this comparison used a generic or condition specific quality of life questionnaire with established validity and reliability. Bø et al (Bø 1999) reported that women in the PFMT group had significant improvements on a Social Activity Index (p<0.01) when compared with the no treatment group.

1.5 Socioeconomics
None of the trials included any formal economic analysis. However, Bø et al (Bø 1999) asked women on completion of the treatment phase if they wished for further, alternative, treatment. Four of 25 in the PFMT group versus 28/30 in the no treatment group desired further treatment.

1.6 Other

1.6.1 Adverse events
Only two trials specifically mentioned adverse events. Bø et al (Bø 1999) stated that no adverse events were found in either PFMT or no treatment groups. Lagro-Janssen et al (Lagro-Janssen 1992) found that one woman in the PFMT group reported pain with the contractions, three had an uncomfortable feeling during the exercises, and two women felt that they did not want to be continually occupied with the problem.

1.6.2 Withdrawals/losses to follow up
Two trials reported there were no withdrawals or losses to follow up post treatment (Henalla 1990; Miller 1998). Three trials reported numbers lost but not by group allocation (Burns 1993, Henalla 1989, O'Brien 1991). Bø et al (Bø 1999) reported 2/29 and 2/32 dropouts from PFMT and no treatment groups respectively. In Lagro-Janssen et al (Lagro-Janssen 1992) 1/54 women in the PFMT group versus 3/56 in the no treatment group withdrew. Total losses to follow up were 3/83 (3.6%) from the PFMT groups versus 5/88 (5.7%) from the control groups.

1.6.3 'Compliance'
Four trials tried to measure how well women managed to fulfil the requirements of the PFMT programme (Bø 1999; Burns 1993; Lagro-Janssen 1992; O'Brien 1991). Two trials included an exercise diary (Bø 1999; Burns 1993), one trial used self-report (Lagro-Janssen 1992), and one trial recorded how many of the four exercises classes that were recommended had been attended (O'Brien 1991). No data were presented by Burns et al (Burns 1993), and O'Brien et al (O'Brien 1991) did not separate data for men and women. Bø et al (Bø 1999) found the highest rate of 'compliance' with PFMT (mean 93%, SE 1.5%). Lagro-Janssen et al (Lagro-Janssen 1992) asked women to rate how well they had kept to the programme and reported results at three and 12 months after PFMT began. Women indicated they had complied excellently or well (62%), reasonably (20%), poorly or not at all (18%) at three months; at 12 months the rates were 51%, 18%, and 31% respectively.

1.6.4 Incontinence at long term follow up
Data from long term follow up was sparse and difficult to interpret. Usually participants in the no treatment group had gone on to receive treatment after the trial was complete. Therefore follow up data were usually presented for all women participating in the trial, and not by original group allocation. Henalla et al (Henalla 1989) reported that at nine months 3/17 women in the PFMT group had return of symptoms, and three months after treatment Burns et al (Burns 1993) found that those with mild leakage were more likely to have return of symptoms in contrast to those with moderate to severe leakage who were more likely to continue to improve with PFMT.

Lagro-Janssen & Van Weel (Lagro-Janssen 1998) contacted 101 of the 110 women included in their original trial (Lagro-Janssen 1992) five years post treatment. Seven women had surgery in the five years, one had become pregnant and five women did not wish to participate in the follow up trial. Data from the 88 women who consented to participate was reported. The number of continent women was the same after five years (25%) but a significant number of women reported their condition had worsened (p=0.02). The number of leakage episodes per week had also increased significantly (p=0.009) with a mean increase of 2.65 episodes (95% CI 0.67, 4.62). 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 women with an initial diagnosis of stress incontinence were less likely to report their condition had worsened. Nearly half (43%) of women who had received advice on PFMT were no longer training at all, while 39% were training daily or "when needed". For women with stress incontinence continued training was the only significant predictor of outcome at five years (p=0.04).

2. PFMT VERSUS PLACEBO TREATMENTS
Three trials compared PFMT with a placebo treatment; placebo PFMT (Ramsay 1990), placebo medication (Burgio 1998), and placebo electrical stimulation (Hofbauer 1990). The trials included women with symptoms of stress incontinence only (Ramsay 1990), genuine stress incontinence (Hofbauer 1990) and women with detrusor instability with or without genuine stress incontinence (Burgio 1998). It should be noted that Burgio et al (Burgio 1998) included urge strategies as an adjunct to PFMT where appropriate. Hofbauer et al (Hofbauer 1990) was a four arm RCT. The four comparison groups received exercise (including PFMT), exercise with electrical stimulation, electrical stimulation, or placebo stimulation. This trial has contributed two data sets to this analysis; PFMT versus placebo stimulation (Hofbauer 1990a), PFMT with stimulation versus placebo stimulation (Hofbauer 1990b).

There was variability in the PFMT training programmes. One programme was based on individual training supervised by a nurse (Burgio 1998) plus a home programme of exercise. Another was based on group training with an undefined "therapist" Hofbauer 1990. In the remaining trial the details of

training were not clear (Ramsay 1990). The recommended number of contractions ranged from 45 (Burgio 1998) to 64 (Ramsay 1990) per day. Length of hold varied from 4 seconds (Ramsay 1990) to 10 seconds (Burgio 1998). One trial (Burgio 1998) recommended that women did their training in a range of body positions (e.g. sitting, standing, lying, kneeling). Length of training ranged from 8 weeks (Burgio 1998) to 3 months (Ramsay 1990).

Limited data were available from the trial that was reported only as an abstract (Ramsay 1990).

2.1 Women's observations
All three trials asked women to report change in leakage symptoms after treatment but two trials (Hofbauer 1990); Ramsay 1990) did not describe the measurement tool.

2.1.1 Self reported cure
Combined data from two trials (Burgio 1998, Hofbauer 1990) found that women in the PFMT group were more likely to be cured than those receiving placebo treatment (RR 3.1, 95% CI 1.56, 6.2). The trial by Hofbauer et al (Hofbauer 1990) contributed two data sets (PFMT versus placebo stimulation, PFMT with stimulation versus placebo stimulation) to the analysis. Caution is required in interpretation as the two data sets are not independent. In addition data from this trial included 'no events' (i.e. 0/10) in one arm and as a result the confidence interval may be spurious, disguising the true treatment effect.

2.1.2 Self reported cure/improvement
Combined data from three trials (Burgio 1998, Hofbauer 1990, Ramsay 1990) suggested that women receiving PFMT were more likely to report cure or improvement than women in the placebo treatment groups (RR 1.53, 95% CI 1.3, 1.9). However significant heterogeneity was observed for this comparison (p=0.027). Two data sets in the comparison came from the same trial (Hofbauer 1990a; Hofbauer 1990b) and these data may also have spurious confidence intervals due to the 'no event' rate in one arm (i.e. 0/10). Observation of the forest plot suggests that the source of the heterogeneity may be the trial by Ramsay & Thow (Ramsay 1990). This trial compared PFMT and placebo PFMT. Placebo training consisted of hip abductor exercise with the feet crossed at the ankles. Strong isometric hip abductor activity may have indirectly trained the pelvic floor muscles as the muscles of the abdomen, gluteal region and pelvis are known to work synergistically. The observed heterogeneity may result from the difference in the placebo treatments across the three trials, an indirect training effect in the placebo PFMT group, or from the two data sets from the single trial.

2.1.3 Other
Women were asked to make other observations about other effects of treatment but none were replicated consistently. For example women were asked about pad usage (Burgio 1998) and changes in the amount of leakage per 'accident' (Burgio 1998).

2.2 Quantification of symptoms

2.2.1 Urinary diary (leakage episodes)
One trial did not ask women to complete a post treatment urinary diary (Ramsay 1990) and in one trial it was not clear whether this measure was used (Hofbauer 1990). Burgio et al (Burgio 1998) asked women to complete a seven day diary. Data from this single trial indicated that women in the PFMT group had significantly fewer leakage episodes in 24 hours than women in the placebo medication group (PFMT, n=63, mean 0.40 sd 0.67 versus placebo medication, n=62, mean 1.16 sd 1.66).

2.2.2 Pad test
Women were not asked to complete any form of pad test in two trials (Burgio 1998; Hofbauer 1990). Ramsay & Thow (Ramsay 1990) did use a pad test, but did not describe it and did not present useable data.

2.3 Clinicians' measures
Ramsay & Thow (Ramsay 1990) used perineometry to measure vaginal squeeze pressure. No data were reported but the abstract stated there was no significant difference in mean perineometry scores between PFMT and placebo PFMT groups although both groups improved when compared with baseline values.

2.4 Quality of life
None of the trials contributing to this comparison used a generic or condition specific quality of life questionnaire with established validity and reliability.

2.5 Socioeconomics
None of the trials included any formal economic analysis. However, Burgio et al (Burgio 1998) asked women on completion of the treatment phase if they wished for further, alternative, treatment. Eight of 57 in the PFMT group versus 37/49 in the control group wanted further treatment.

2.6 Other

2.6.1 Adverse events
Only one trial specifically mentioned adverse events. Burgio et al (Burgio 1998) reported that women in the PFMT group had significantly less dry mouth than women in the placebo medication group (p<0.03).

2.6.2 Withdrawals/losses to follow up
Two trials apparently had no withdrawals or losses to follow up post treatment (Hofbauer 1990; Ramsay 1990). Burgio et al (Burgio 1998) recorded 4/65 and 12/65 dropouts from PFMT and placebo medication groups respectively.

2.6.3 'Compliance'
Ramsay & Thow (Ramsay 1990) used an exercise diary to measure how well women managed to fulfil the requirements of the PFMT programme and found that both PFMT and placebo PFMT groups performed approximately 15% of the recommended training per week.

3. 'STANDARD' VERSUS 'INTENSIVE' PFMT (comparisons of PFMT)

Six trials essentially compared a 'standard' with a more 'intensive' PFMT programme (Bø 1990; Gallo 1997; Nygaard 1996; Wilson 1997; Wilson 1998; Wong 1997b). Three of the trials included women with genuine stress incontinence only (Bø 1990, Gallo 1997, Wong 1997b), two included postnatal women with symptoms of urine leakage (Wilson 1997, Wilson 1998), and the remaining trial was in women with genuine stress incontinence, detrusor instability and mixed incontinence (Nygaard 1996).

In four of the trials (Bø 1990; Gallo 1997; Nygaard 1996; Wong 1997b) the same basic home PFMT programme was recommended for both 'standard' and 'intensive' groups. The difference for the 'intensive' groups was the addition of a weekly exercise class (including PFMT) with a physiotherapist (Bø 1990), an audiotape with a PFMT exercise programme for use at home (Gallo 1997; Nygaard 1996), and eight clinic visits over 4 weeks (compared with one clinic visit in the 'standard' treatment group) (Wong 1997b). All four programmes were based on individual teaching, and three trials checked that a correct voluntary pelvic floor muscle contraction was being performed (Bø 1990; Gallo 1997; Nygaard 1996). Women were asked to complete five (Nygaard 1996) or ten (Gallo 1997) minutes of training twice a day, or one set of eight to 12 contractions three times a day (Bø 1990), or up to 50 contractions per day (Wong 1997b). Contractions were held for a maximum of eight (Bø 1990; Nygaard 1996) to 10 seconds (Gallo 1997; Wong 1997b).

In the remaining two trials (Wilson 1997; Wilson 1998) it was very difficult for the trialists to accurately describe 'standard' PFMT. 'Standard' PFMT was any training women had received during antenatal or postnatal classes, from an audiotape of PFMT, or through contact with midwives and physiotherapists during their antenatal and postnatal care. In contrast 'intensive' PFMT constituted an individual appointment between each postnatal woman and a nurse (Wilson 1997) or physiotherapist (Wilson 1998) for the specific purpose of teaching a PFMT programme. In Wilson et al (Wilson 1998) women were asked to do 10 contractions, eight to 10 times a day.

Gallo & Staskin (Gallo 1997) collected only measures relating to compliance (i.e. no leakage related measures) and Nygaard et al (Nygaard 1996) presented results by diagnostic group not by group allocation therefore neither trial contributed any data to the formal comparisons. Limited data were available from the two abstracts (Wilson 1997, Wong 1997b) but unpublished data were available for Wilson et al (Wilson 1997).

3.1 Women's observations
Three trials did not report self reported cure or improvement (Gallo 1997; Nygaard 1996, Wong 1997b). Bø et al (Bø 1990) asked women to state the outcome of treatment on a five point scale (worse to continent). Wilson et al (Wilson 1997) and Wilson & Herbison (Wilson 1998) presented prevalence of urinary and faecal incontinence. The absence of urinary leakage where this had previously been reported was taken as 'cure'.

3.1.1 Self reported cure
Combined data from three trials (Bø 1990, Wilson 1997, Wilson 1998) found that women receiving more 'intensive' training were more likely to report cure than those in 'standard' treatment groups (RR 1.5, 95% CI 1.17, 1.84). The trial by Wilson et al (Wilson 1997) contributed two data sets to the analysis; for women with symptoms of stress incontinence only (Wilson 1997a) and women with other diagnoses (Wilson 1997b). If the data from women with stress incontinence alone (Wilson 1997a) and genuine stress incontinence only (Bø 1990)) are combined a similar effect is seen (RR 1.5, 95% CI 1.1, 2.0). It should be noted that one arm of the trial by Bø et al (Bø 1990) recorded no events (i.e. 0/29) and this may have had an effect on the confidence intervals in this comparison.

3.1.2 Self reported cure/improvement
A single trial (Bø 1990) indicated that women with genuine stress incontinence were more likely to report cure or improvement with 'intensive' rather than 'standard' PFMT (intensive PFMT 22/23, standard PFMT 19/29).

3.1.3 Other
Other observations made by women in the trials included the use of the Continence Efficacy Scale (Wong 1997b, visual analogue scale of feelings of control over continence), subjective rating of the severity of the problem (Wilson 1997), and the Leakage Index (Bø 1990, Nygaard 1996).

3.2 Quantification of symptoms

3.2.1 Urinary diary (leakage episodes)
Women were asked to complete a urinary diary in three trials (Nygaard 1996; Wilson 1997; Wong 1997b). The number of leakage episodes from the diary was not reported by one trial (Wilson 1997), and the other two trials did not present the data by comparison group (Nygaard 1996; Wong 1997b).

3.2.2 Pad test
Four trials used a variety of short pad tests (Bø 1990; Nygaard 1996; Wilson 1997; Wilson 1998; Wong 1997b). Wong et al (Wong 1997b) stated that 26 of 47 women with genuine stress incontinence had less than two grams leakage post treatment and were therefore considered to be cured. Group allocation of these 26 women was not recorded but the authors stated there was no difference between the groups. Bø et al (Bø 1990) assessed women with genuine stress incontinence with a 90 second stress test and found a significant reduction in leakage in the group receiving more training contact with a physiotherapist (27.0g, 95% CI 8.8,45.1 reduced to 7.1g 95% CI 0.8,13.4) versus the standard treatment group (29.3g, 95%CI 14.4, 44.1 reduced to 22.0g, 95% CI 9.1, 34.9). Finally, in a group of postnatal women with mixed incontinence Wilson & Herbison (Wilson 1998) reported that there was no statistically significant difference between the standard postnatal exercise and individualised PFMT groups on one hour pad test post treatment (2.6g 95% CI 0.1,5.1, and 2.1g 95% CI -0.3,4.5 respectively).

3.3 Clinicians' measures

Digital palpation (Nygaard 1996) and perineometry (Bø 1990; Wilson 1998; Wong 1997b) were used to assess pelvic floor muscle activity. Bø et al (Bø 1990) reported significant improvements in maximum pelvic floor muscle strength in both groups when compared with baseline but by six months women in the group receiving greater training contact (mean 22.5 cm water, 95% CI 17.7, 27.3) had significantly higher values (p<0.01) than the standard treatment group (mean 15.3, 95% CI 12.0, 18.6). Wong et al (Wong 1997b) did not publish their perineometry data but stated that both groups improved significantly in pelvic floor muscle strength and endurance over baseline but that there were no differences between the groups. Wilson & Herbison (Wilson 1998) also noted a significant improvement in maximum and sustained perineometry values in those women receiving individualised postnatal training but there were no significant differences in post treatment values between these women and those receiving standard postnatal care.

3.4 Quality of life

None of the trials contributing to this comparison used a generic or condition specific quality of life questionnaire with established validity and reliability. Wilson & Herbison (Wilson 1998) reported sexual satisfaction scores (questionnaire modified from the Golombok and Rust Reference Inventory of Sexual Satisfaction) but found no differences between the comparison groups. The HAD anxiety and depression scales were used by Wilson et al (Wilson 1997) and data supplied in the abstract and by the authors suggest that women receiving individualised training were less anxious and less depressed. Mean (standard deviation) values for the HAD anxiety scale in 218 women receiving standard treatment and 238 women receiving individualised treatment were 6.83 (4.05) and 6.07 (3.47) respectively. Similarly values for the HAD depression scale were 5.22 (3.67) and 4.84 (3.44) respectively.

3.5 Socioeconomics

None of the trials included any formal economic analysis. However Wilson & Herbison (Wilson 1998) did record that the average teaching time for women receiving individualised PFMT was 32 minutes (95% CI 30,34).

3.6 Other

3.6.1 Adverse events

None of the trials contributing to this comparison made any statement about adverse events.

3.6.2 Withdrawals/losses to follow up

One trial did not report any withdrawals (Wong 1997b). Nygaard et al (Nygaard 1996) reported the numbers lost but not by group allocation. In the remaining trials withdrawals from 'standard' versus 'intensive' training were respectively 3/32 versus 2/25 (Bø 1990), 9/43 versus 4/43 (Gallo 1997), 126/369 versus 86/365 (Wilson 1997), and 26/117 versus 20/39 (Wilson 1998). In total withdrawals from standard treatment were

164/561 (29.2%) and from intensive treatments were 112/472 (23.7%).

3.6.3 'Compliance'

Three trials (Gallo 1997; Wilson 1997; Wilson 1998) used questionnaires to measure how much PFMT had been completed. All three trials found that women receiving more 'intensive' treatment completed more of the recommended training. In the trial by Wilson & Herbison (Wilson 1998) only eight of 91 postnatal women receiving standard care did daily PFMT compared with 13 of 19 in the individualised PFMT group. Similarly women in the latter group performed more contractions per day (mean 86, 95% CI 68,104 versus 35, 95% CI 30,40). In another sample of postnatal women Wilson et al (Wilson 1997) reported similar results with 48% of the standard treatment group performing pelvic floor muscle contractions within the last month versus 79% of the individualised treatment group. Women in the individualised treatment group also did more contractions than the standard treatment group on average (27 versus 10 contractions per day respectively). Finally, Gallo & Staskin (Gallo 1997) who studied women with genuine stress incontinence who received home PFMT with or without an audiotape to reinforce teaching found that women in the audiotape group were more likely to perform PFMT twice a day as instructed (p<0.001), and had a greater duration of PFMT per day (p<0.0001).

One trial (Bø 1990) asked women to complete a training diary. The trial report stated that compliance was "close to 100%" in both groups although the diary data were not presented.

3.6.4 Incontinence at long term follow up

Three trials followed women beyond post treatment assessment, at six months (Nygaard 1996), 15-35 months (Wilson 1998) and five years (Bø 1990). Nygaard et al (Nygaard 1996) did not report results by group allocation but found that of the women with genuine stress incontinence 10/37 had undergone surgery and 10 women were satisfied and did not want further treatment. Of the women with detrusor instability 2/17 had begun anticholinergic therapy and 7/17 did not want further therapy. One woman from the mixed incontinence group had begun medication and 5/17 were satisfied with current progress. Wilson & Herbison (Wilson 1998) reported results for the standard treatment group but combined the results from the three other groups receiving intervention by a physiotherapist. No significant differences between the standard and combined physiotherapy groups were shown. Nine of the 168 women followed up had undergone surgery and 70 women were pregnant at the time of follow up and/or had delivered another child. Of the 89 women remaining 50 reported urine leakage, 50 had done some PFMT within the last month, and six were doing daily PFMT. The number of contractions per day had reduced significantly from post treatment assessment. Bø et al (Bø 1990) followed up 23 women who had completed 'intensive' training and found three had undergone surgery, 16 were exercising the pelvic floor muscles once a week or more, and of the 20 women not treated surgically 14 were satisfied and

did not want further treatment and 15 had no visible leakage with stress test. Statistically significant increases in leakage with pad test and Leakage Index scores from post treatment assessment were noted but there was no significant change in Social Activity Index scores.

4. PFMT VERSUS ELECTRICAL STIMULATION

Six trials compared PFMT with electrical stimulation in women with genuine stress incontinence (Bø 1999; Hahn 1991; Henalla 1989; Hofbauer 1990; Laycock 1988; Smith 1996). Two additional trials have been included in this comparison, both of which compared PFMT with vaginal cones versus electrical stimulation (Laycock 1993; Wise 1993).

There was the usual variability in . Minimal detail was provided in three trials (Hofbauer 1990; Laycock 1988; Smith 1996). Half the programmes were based on individual training supervised by a physiotherapist plus a home programme of exercise (Hahn 1991; Henalla 1989; Laycock 1988; Laycock 1993), one trial included a weekly exercise class in addition to the former (Bø 1999), another trial was based on group training with an undefined "therapist" (Hofbauer 1990), and in the remainder these details were unclear (Smith 1996; Wise 1993). The recommended number of contractions per day ranged from 36 (Bø 1999, one set of 8-12 contractions three times a day) to a maximum of 100 (Wise 1993, one set of 10 contractions 10 times a day). Length of hold varied from five seconds to 30-40 seconds (Hahn 1991). Two trials (Bø 1999; Hahn 1991) recommended that women did their training in a range of body positions (e.g. sitting, standing, lying, kneeling). In one trial the length of the treatment period was unknown (Hofbauer 1990), and in the remaining trials it ranged from six weeks (Laycock 1988; Laycock 1993; Smith 1996) to six months (Bø 1999; Hahn 1991).

Similarly there was considerable variation in the electrical stimulation protocols. Three trials used interferential currents (Henalla 1989; Laycock 1988; Laycock 1993), four trials used an pulsed alternating current (Bø 1999; Hahn 1991; Smith 1996; Wise 1993), and in one trial it is not clear what type of current was used (Hofbauer 1990). The latter trial provided little information other than that 10 minutes of stimulation was given three times a week for six weeks using extra vaginal and lumbar electrodes, with the current intensity increased to produce a noticeable contraction to which the woman added her own voluntary contraction (Hofbauer 1990).

Two of the interferential trials chose frequency modulation of 0-100 Hz (Henalla 1989) and 10-50 Hz (Laycock 1988), while the other chose a mixture of constant and sweep frequencies (Laycock 1993, 10 minutes at 1 Hz, 10 minutes at 10-40 Hz and 10 minutes at 40 Hz). Treatment intensity was not specified in one trial (Laycock 1988), was "as tolerated" in another (Henalla 1989) to the "maximum acceptable" in the third (Laycock 1993). Length of individual treatments ranged from 20 (Henalla 1989) to 30 minutes (Laycock 1993), with an average of 10 (Henalla 1989; Laycock 1993 to 11 treatments

(Laycock 1988) spread over four (Laycock 1988) to 10 weeks (Henalla 1989). All three trials provided clinic only stimulation. Only Laycock specified the type of electrode placement (Laycock 1993, perineal body and inferior to symphysis pubis) and equipment (Laycock 1988), Endomed 433, Enraf Nonius).

All trials that used an alternating pulsed current were based on daily home treatment and delivered the current through a vaginal electrode (Bø 1999; Hahn 1991; Smith 1996; Wise 1993). Current frequency was fixed in two trials (Bø 1999, 50 Hz; Wise 1993, 20 Hz) and variable in the other two (Hahn 1991, 12 & 20 & 50 Hz; Smith 1996, 12.5 & 50 Hz). Pulse duration ranged from 0.2 milliseconds (Bø 1999) to a maximum of 0.75 milliseconds (Wise 1993). Maximum treatment intensities were 80 mA (Smith 1996), 90 mA (Wise 1993) and 120 mA (Bø 1999). Individual treatment times varied from 20 minutes (Wise 1993) and 30 minutes per day (Bø 1999) to 60 minutes twice a day (Smith 1996) to a maximum of six to eight hours a night (Hahn 1991). Two trials provided additional detail such as duty cycle (Bø 1999; Smith 1996) and all four trials stated the equipment used (Bø 1999, MS106 Twin; Hahn 1991, Contelle; Smith 1996, Simtech Products Inc; Wise 1993, Conmax).

Limited data were available from the two abstracts (Laycock 1988; Wise 1993), one of which was a report of a trial in progress (Laycock 1988) and the data from this trial were excluded from the formal analysis. The four arm RCT by Smith (Smith 1996) compared PFMT and electrical stimulation for women with genuine stress incontinence only (2 arms) and medication and electrical stimulation for women with detrusor instability (2 arms). Only the data from the comparison of PFMT and electrical stimulation was included.

4.1 Women's observations

Five trials asked women if their leakage was improved or cured after treatment (Bø 1999; Hahn 1991; Hofbauer 1990; Laycock 1988; Laycock 1993) and one trial used a visual analogue scale of symptomatic improvement (Wise 1993) but no data were reported.

4.1.1 Self reported cure

Combined data from four trials (Bø 1999; Hahn 1991; Hofbauer 1990; Laycock 1993), all in women with genuine stress incontinence, found that there was no statistically significant difference in the rate of self reported cure between PFMT and electrical stimulation groups (RR 2.9, 95% CI 0.99, 8.7). However, this comparison is close to being in favour of PFMT. While no statistical heterogeneity was observed in the pooled data (p=0.74) there is considerable clinical heterogeneity in the stimulation protocols. If the data from the two trials using long term (six months) electrical stimulation with an intravaginal electrode were combined (Bø 1999; Hahn 1991) there was no statistically significant difference in the rates of self reported cure for PFMT and electrical stimulation groups (RR 1.5, 95% CI 0.3, 8.4). Despite the similarities in these two trials some practitioners may feel that the stimulation parameters were

sufficiently different that it is not appropriate to combine these trials.

4.1.2 Self reported cure/improvement

No statistically significant difference in the rates of self reported cure/improvement was found when data from four trials (Bø 1999; Hahn 1991; Hofbauer 1990; Laycock 1993) in women with genuine stress incontinence were combined (RR 1.2, 95% CI 0.97, 1.6). Data from a trial in progress (Laycock 1988) not included in the formal comparison reported 8/11 women in the PFMT group cured or improved versus 16/18 in the electrical stimulation group. As in the previous comparison there were considerable clinical differences in the electrical stimulation protocols although no statistically significant heterogeneity was observed (p=0.14). If the two trials (Bø 1999; Hahn 1991) using long term intravaginal stimulation are combined self reported cure/improvement is more likely in the PFMT group than the electrical stimulation group (RR 1.4, 95% CI 1.1, 1.7). The other logical grouping of trials are the two trials using short term interferential stimulation with extravaginal electrodes (Laycock 1988, Laycock 1993). However these data were not combined in a separate analysis as one data set came from a trial in progress (Laycock 1988).

4.1.3 Other

Few other measures from this category were used, although women were asked about changes in pad usage (Smith 1996), and whether their leakage had become subjectively unproblematic (Bø 1999). Bø et al (Bø 1999) stated that women in the PFMT group had significant improvement on a Leakage Index compared with the stimulation group (p<0.01).

4.2 Quantification of symptoms

4.2.1 Urinary diary (leakage episodes)

Urinary diaries were completed post treatment by women in four trials, but two presented no data (Hofbauer 1990; Laycock 1993), one reported mean and range (Smith 1996) and only one trial presented data that could be entered in the formal comparison (Bø 1999). There was no statistically significant difference in the number of leakage episodes in 24 hours for women between PFMT and stimulation groups (PFMT, n=25, mean 0.27 sd 0.34 versus stimulation, n=25, mean 0.56 sd 0.68). However this comparison is statistically nearly in favour of PFMT.

4.2.2 Pad test

A range of short pad tests were used including a 60 second stress test (Bø 1999), 40 minute pad test (Wise 1993), a 'standard' one hour pad test (Laycock 1993; Henalla 1989) and a modified one hour pad test (Hahn 1991). One trial did not state the type of pad test used (Laycock 1988).

Two trials (Bø 1999; Wise 1993) found greater reduction in leakage in the PFMT than electrical stimulation groups (p=0.02 and p=0.038 respectively). The four remaining trials found significant reduction in leakage in both groups with treatment (Hahn 1991; Henalla 1989; Laycock 1988; Laycock 1993). In

addition, three trials reported the number of women 'cured' with post treatment pad test although the definitions of cure differed. Hahn et al (Hahn 1991) defined cure as less than two grams of leakage, similarly Bø et al (Bø 1999) defined cure as less than or equal to two grams of leakage, while Laycock and Jerwood (Laycock 1993) defined cure as less than 0.5 grams of leakage. The number of women cured in the PFMT groups were 1/10, 11/25 and 3/17 versus 4/10, 7/25 and 1/23 in the stimulation groups respectively.

A single trial used a long pad test (24 hours) and found no difference between stimulation and PFMT groups (Bø 1999).

4.3 Clinicians' measures

Perineometry (Bø 1999) and digital palpation (Laycock 1993) were used to assess pelvic floor muscle activity. No data were reported in Laycock & Jerwood (Laycock 1993) but the authors stated that a significant improvement was seen in the stimulation group (p=0.0035) but not in the PFMT group (p=0.0679). Bø et al (Bø 1999) reported that the change in vaginal squeeze pressure (cm water) was significantly greater (p=0.03) in the PFMT group (pre treatment mean 11.0, 95% CI 7.7,14.3 versus post treatment mean 19.2, 95% CI 15.3, 23.1) than the electrical stimulation group (pre 14.8, 95% CI 10.9, 18.7 versus post 18.6, 95% CI 13.3, 23.9).

4.4 Quality of life

None of the trials that contributed to this comparison used a generic or condition specific quality of life questionnaire with established validity and reliability. Bø et al (Bø 1999) reported that intention to treat analysis showed significantly more improvement on a Social Activity Index for women in the PFMT group compared with the stimulation group, but the data were not presented.

4.5 Socioeconomics

None of the trials included any formal economic analysis. However Bø et al (Bø 1999) asked women on completion of treatment if they wished for further alternative treatment. Four of 25 in the PFMT group and 19/25 in the stimulation group wanted another treatment.

4.6 Other

4.6.1 Adverse events

Three trials recorded adverse events and all of these were in the electrical stimulation groups. Hahn et al (Hahn 1991) reported that one woman was not able to accept the stimulation device when this was offered as an alternative treatment. Adverse reactions reported by Smith (Smith 1996) included vaginal irritation (two women), urinary tract infection (two women), and tingling in the thigh (one woman). In Bø et al (Bø 1999) adverse effects included vaginal 'smarting' (two women) and difficulties with using the stimulator and maintaining motivation (eight women).

4.6.2 Withdrawals/losses to follow up

Two trials had no apparent losses to post treatment assessment (Hahn 1991; Hofbauer 1990). Two trials reported the numbers

lost but not by group allocation (Henalla 1989; Smith 1996) and one trial was incomplete (Laycock 1988). Dropouts in the PFMT groups were 4/29 (Bø 199), 6/23 (Laycock 1993) and 6/21 (Wise 1993), and from the stimulation groups 7/32, 0/23 and 4/20 respectively. In total the withdrawals from the PFMT groups numbered 16/73 (21.9%) versus 11/75 (14.7%) in the stimulation groups.

4.6.3 'Compliance'
Use of electrical stimulation was monitored electronically by the device in two trials (Bø 1999; Smith 1996). A similar proportion of the recommended treatment time was completed in both trials, 75% (Bø 1999) and "exceeded 80%" (Smith 1996). Only Bø et al (Bø 1999) reported on the use of a training diary for the PFMT group, and stated that mean "adherence" was 95%.

4.6.4 Incontinence at long term follow up
Three trials reported longer term follow up at nine months (Henalla 1989), approximately two years (Laycock 1993) and four years (Hahn 1991) post treatment. Henalla et al (Henalla 1989) found that three of the 17 women who had improved with PFMT, and one of the eight women who had improved with stimulation had recurrent symptoms nine months after completion of treatment. There was considerable inequity in the rate of questionnaire return between stimulation (15 of 23 women) and PFMT groups (four of 17 women) in the trial by Laycock & Jerwood (Laycock 1993) therefore no comparison was appropriate between the groups. However all women who returned questionnaires were doing "regular" PFMT. Follow up data from Hahn et al (Hahn 1991) was not reported by group allocation but 19 of the 20 women in the trial were assessed at four years. Five had subsequently undergone surgery (Burch colposuspension), four were further improved, eight unchanged, and two had recurrent symptoms. Five women claimed they were doing PFMT "regularly", six were training "now and then" and three were doing no training.

5. PFMT VERSUS VAGINAL CONES
Seven trials have been included in this comparison (Bø 1999; Cammu 1998; Haken 1991; Laycock 1999; Peattie 1988; Terry 1996; Wilson 1998), four of which were abstracts and presented limited data (Haken 1991; Laycock 1999; Peattie 1988; Terry 1996). One abstract (Peattie 1988) reported a trial in progress and unpublished data were provided by the author for inclusion in this review.

Five trials included women with genuine stress incontinence only (Bø 1999; Cammu 1998; Haken 1991; Peattie 1988; Terry 1996). Laycock et al (Laycock 1999) included women with stress incontinence symptoms only, and Wilson & Herbison (Wilson 1998) included women with symptoms of urine leakage. Two trials included adjuncts to PFMT, biofeedback (Cammu 1998) and electrical stimulation (Terry 1996). One trial has contributed two data sets to the formal analysis (Wilson 1998). Three of the four comparison groups in the trial by Wilson & Herbison (Wilson 1998) were standard PFMT, individualised

PFMT and vaginal cones. Data from this trial were entered in the formal comparisons as Wilson 1998a (standard PFMT versus cones) and Wilson 1998b (individualised PFMT versus cones).

Most of the PFMT interventions were based on individual training with a physiotherapist (Cammu 1998; Peattie 1988; Wilson 1998) or continence advisor (Haken 1991), and one trial included a weekly exercise class in addition to individual training with a physiotherapist (Bø 1999). In two trials training details were unclear (Laycock 1999; Terry 1996). All but one trial (Terry 1996) stated or implied that a daily home programme of PFMT was recommended. The suggested number of contractions per day ranged from 36 (Bø 1999, one set of 8-12 contractions three times a day) to a maximum of 100 (Wilson 1998). Length of hold was only documented in two trials, eight seconds (Bø 1999) and 10 seconds (Cammu 1998). Only one trial (Bø 1999) recommended that women did their training in a range of body positions (e.g. sitting, standing, lying, kneeling). The length of the treatment period ranged from six weeks (Peattie 1988; Terry 1996) to nine months (Wilson 1998).

Some detail of the vaginal cones protocol was given in all but one trial (Terry 1996). Treatment was recommended for 15 minutes twice a day (Cammu 1998; Haken 1991; Peattie 1988; Wilson 1998), or once a day for 10 minutes (Laycock 1999), or 20 minutes (Bø 1999). Women were asked to practice using the heaviest cone that they could retain vaginally (Cammu 1998) and to increase the cone weight as their ability to hold the cone improved (Bø 1999; Haken 1991; Laycock 1999). One trial offered women cones of two sizes (an empty 'shell') to which variable weights were added (Laycock 1999). The remaining trials offered women three (Bø 1999), five (Cammu 1998) and nine cones (Peattie 1988; Wilson 1998) of set weight ranging from 20 grams (Bø 1999; Cammu 1998; Peattie 1988; Wilson 1998) to a maximum of 70 grams (Bø 1999; Cammu 1998) and 100 grams (Peattie 1988; Wilson 1998). Length of treatment varied from four weeks (Peattie 1988) to nine months (Wilson 1998).

5.1 Women's observations
All seven trials asked women to rate their symptoms post treatment. Four trials used a visual analogue scale for this purpose, all of which used different wording, and three presented the data in a way that was unsuitable for inclusion in the formal analysis (Haken 1991; Laycock 1999; Terry 1996). One trial that used a visual analogue scale also reported the number of women who considered they were cured or significantly improved although it is not clear whether this was interpretation of the visual analogue data or some other measure (Cammu 1998).

5.1.1 Self reported cure
Combined data from two trials did not find any significant difference in the rate of self reported cure between the groups (RR 0.7, 95% CI 0.5, 1.1). Cautions in this comparison include the contribution of two data sets from a single trial (Wilson 1998a & Wilson 1998b), and that the other trial recorded 'no

events' in the control group and this may have led to altered confidence intervals (Bø 1999). While there was no statistically significant heterogeneity in the comparison one of the data sets strongly favoured cones (Wilson 1998b), in contrast to the other two data sets (Bø 1999, Wilson 1998a). The data that so strongly favoured cones came from a comparison of postnatal women randomised to receive standard postnatal care (i.e. teaching of PFMT was included in antenatal or postnatal education given by physiotherapists, midwives, through leaflets and/or audiotape) versus individual appointments with a physiotherapist to teach and monitor the use of vaginal cones. In contrast the data that compared individual teaching of vaginal cones and individualised teaching of PFMT (Wilson 1998b) did not show benefit of one treatment over the other (RR 1.00, 95% CI 0.56, 1.81). The difference in treatment effect might reflect the difference in teaching method rather than the effect of PFMT or cones. However If the data from Bø et al (Bø 1999) and Wilson et al (Wilson 1998b) were combined this does not alter the basic finding of no statistical difference between the groups (RR 1.2, 95% CI 0.7, 2.2).

5.1.2 Self reported cure/improvement

Three trials, all in women with genuine stress incontinence, contributed data to this comparison (Bø 1999; Cammu 1998; Peattie 1988) and there was no statistically significant difference in the rate of self reported cure/improvement between PFMT and vaginal cones groups (RR 1.1, 95% CI 0.9, 1.4). One of the three trials contributing to the analysis (Bø 1999) did find that PFMT was significantly better than cones. There was no statistically significant heterogeneity (p=0.12), and no obvious reason why these three trials would be clinically very different. In Peattie et al (Peattie 1988) treatment was undertaken for four weeks and in Cammu & Van Nylen the treatment period was 12 weeks (Cammu 1998) whereas in Bø et al (Bø 1999) treatment continued for six months. This might suggest the maximum difference in effect of the treatments was not reached in the shorter time period. It is also worth noting that approximately 50% of the women allocation to cones in the trial by Cammu & Van Nylen (Cammu 1998) did not use cones and were given a pelvic floor muscle training program confounding the outcome of the trial. However the authors did report trial outcomes by group allocation and by intervention received and did not find any significant differences in the intention to treat analysis.

5.1.3 Other

Other observations made by women included pad usage (Cammu 1998; Laycock 1999), the degree to which symptoms were problematic (Bø 1999), Leakage Index (Bø 1999), and symptom severity (Terry 1996).

5.2 Quantification of symptoms

5.2.1 Urinary diary (leakage episodes)

Three trials asked women to complete a post treatment urinary diary (Bø 1999; Cammu 1998; Laycock 1999). The data presented by Laycock et al (Laycock 1999) were not suitable for the formal comparison (being presented as the reduction in number of leakage episodes) but for women with symptoms of stress incontinence there were no significant differences in the reduction in number of leakage episodes per day between PFMT, PFMT with biofeedback, and vaginal cones groups. Combined data from the other two trials (Bø 1999; Cammu 1998), in women with genuine stress incontinence, found significantly fewer leakage episodes in 24 hours in the PFMT group (WMD -0.7, 95% CI -1.2, -0.2).

5.2.2 Pad test

Five trials included a short pad test or stress test. These ranged from a 60 second pad test with standardised bladder volume (Bø 1999), a 40 minute pad test (Haken 1991), a home pad test (Wilson 1998) and pad tests of unspecified length (Peattie 1988; Terry 1996). Two trials (Haken 1991; Peattie 1988) reported improvement (not defined) on pad test; 20/33 and 9/16 versus 23/31 and 12/17 in the PFMT and cones groups respectively. Terry & Whyte (Terry 1996) found "significant" improvement in both groups compared with baseline, and Bø et al (Bø 1999) found significant greater reduction (p<0.01) in leakage in the PFMT group. Wilson & Herbison (Wilson 1998) appeared to show less leakage in the cones group (mean 0.6 grams, 95% CI 0.1, 1.1) than the PFMT group (mean 2.1 grams, 95% CI -0.3, 4.5). Cure (less than two grams leakage with pad test) was reported by Bø et al (Bø 1999) and could be calculated from the data provided by the author of another (Peattie, personal communication). In the PFMT groups 11/25 and 4/16 versus 4/27 and 4/17 in the cones groups were cured respectively.

Only Bø et al (Bø 1999) included a long pad test (24 hours). There was no significant difference between PFMT and cones groups for this outcome.

5.3 Clinicians' measures

Digital palpation (Terry 1996), perineometry (Bø 1999; Terry 1996; Wilson 1998), EMG (Cammu 1998), cone weight that could be retained actively and passively (Peattie 1988), and an unspecified form of muscle testing (Laycock 1999) were used to assess pelvic floor muscle activity. No data were presented in the three abstracts (Laycock 1999; Peattie 1988; Terry 1996). Bø et al (Bø 1999) found significant improvements in strength in both PFMT and vaginal cones groups, but the change was significantly greater (p=0.03) in the PFMT group (mean 11.0 cm water, 95% CI 7.7, 14.3 before versus 19.2, 95% CI 15.3, 23.1 after) than vaginal cones group (11.8, 95% CI 8.5, 15.1 before versus 15.4, 95% CI 11.1, 19.7 after). Wilson & Herbison (Wilson 1998) reported significant improvements in both groups from baseline but no difference between the groups. Similarly Cammu & Van Nylen (Cammu 1998) found that both groups improved but there was no significant difference between the groups. Laycock et al (Laycock 1999) reported that there was no significant difference between the groups for the increase in maximal muscle contraction post treatment.

5.4 Quality of life

A single trial (Laycock 1999) used a validated condition specific quality of life measure, the King's Health Questionnaire. All groups (PFMT, PFMT with biofeedback, and cones) showed improvement but there was no significant difference between the groups. Other measures included the Social Activity Index (Bø 1999) and a visual analogue scale of psychological distress (Cammu 1998). Both trials found overall improvement in both groups with these measures, with no significant differences between the groups.

5.5 Socioeconomics

Wilson & Herbison (Wilson 1998) collected data on the average teaching time for both individualised PFMT and cones and there was no statistically significant difference between the groups. PFMT teaching took an average of 32 minutes (95% CI 30, 34) and cones took 30 minutes (95% CI 28, 32). Bø et al (Bø 1999) asked women on completion of treatment if they wished for further, alternative, treatment and four of the 25 women in the PFMT group wanted another treatment versus 23/27 in the cones group. Two trials documented the number of women who had been referred for surgery (Cammu 1998; Peattie 1988). Five of 30 women in the PFMT group and 9/30 women in the cones group subsequently had surgery in the trial by Cammu & Van Nylen (Cammu 1998), and in Peattie et al (Peattie 1988) these figures were 6/16 and 5/17 respectively.

5.6 Other

5.6.1 Adverse events
Three trials reported adverse events all of which related to the use of cones (Bø 1999; Cammu 1998; Haken 1991). Motivation problems and difficulty using cones was the most commonly reported problem in Bø et al (Bø 1999) (14 women), but other adverse events were abdominal pain (one woman), vaginitis (two women) and bleeding (one woman). Cammu & Van Nylen (Cammu 1998) reported the following effects; cones produced an unpleasant feeling (five women), cones were time consuming (three women), cones were difficult to insert when anxious or in a hurry (two women), cones interfered with menstruation (two women), and two women could not hold the same cone in the evening as they could in the morning (muscle fatigue). Haken et al (Haken 1991) stated that withdrawals from the cones group (8/31) were usually due to an "aesthetic dislike" of the treatment and "difficulties associated with prolapse". Laycock et al (Laycock 1999) stated that adverse events had been recorded but would be reported in a future paper.

5.6.2 Withdrawals/losses to follow up
All trials reported withdrawals by group allocation. In the PFMT groups these were 4/29 (Bø 1999), 0/30 (Cammu 1998), 3/33 (Haken 1991), 4/20 (PFMT group) and 18/40 (PFMT and biofeedback) (Laycock 1999), 6/22 (Peattie 1988), 1/30 (Terry 1996), 26/117 (standard PFMT) and 20/39 (individualised PFMT) (Wilson 1998). In the cones groups the figures were 2/29, 14/30, 8/38, 11/40, 5/22, 1/30, 15/36 respectively. In total withdrawals were 82/360 (22.8%) from PFMT groups and 56/225 (24.9%) from the cones groups.

5.6.3 'Compliance'
Three trials (Bø 1999, Laycock 1999, Peattie 1988) measured or commented on how well women managed to meet the requirements of PFMT and/or vaginal cones training protocols. In the trial by Peattie et al (Peattie 1988) three women (of 22) in the cones withdraw due to poor compliance but the remainder all used cones at least once a day. Five (of 22) women in the PFMT withdraw due to poor compliance, and six of the remaining women did PFMT only on alternate days or less often than this. Laycock et al (Laycock 1999) asked women to complete an exercise diary and on the basis of this the "compliance score" was 77.0% for the cones group, 78.8% in the PFMT with biofeedback group, and 81.3% in the PFMT group. Bø et al (Bø 1999) also used a training diary to check "adherence" to treatment and reported significantly greater "adherence" (p<0.001) in the PFMT group (mean 93%, standard error 1.5%) than the cones group (78%, 4.4%).

5.6.4 Incontinence at long term follow up
A single trial (Wilson 1998) reported follow up beyond post treatment assessment. Findings from a telephone questionnaire at 15-32 months post treatment from the standard PFMT, and the combined data from the three groups receiving intervention by a physiotherapist, were included in the paper. No significant differences between the standard and combined physiotherapy groups were shown. Nine of the 168 women followed up had undergone surgery and 70 women were pregnant at the time of follow up and/or had delivered another child. Of the 89 women remaining 50 reported urine leakage, 50 had done some PFMT within the last month, and six were doing daily PFMT. The number of contractions per day had reduced significantly from post treatment assessment.

6. PFMT VERSUS BEHAVIOURAL THERAPY (bladder training)
A single trial compared PFMT and behavioural (bladder) training in women with genuine stress incontinence, detrusor instability or both (Wyman 1998). PFMT included a graded home training programme that began with five fast (three second hold) and 10 sustained (10 second hold) contractions twice a day progressed to a maximum of 10 fast and 40 sustained contractions per day. The use of a voluntary pelvic floor muscle contraction prior to rises in intra-abdominal pressure, and for urge suppression, was encouraged. Four sessions of visual biofeedback were also included. Behavioural training consisted of a structured education programme, the use of voiding diaries, progressive timed voiding (progressing 30 minutes per week) and urge inhibition techniques. Both groups received 12 weeks of treatment with the same number of clinic visits and telephone contacts.

6.1 Women's observations

6.1.1 Self reported cure
Women used a 5 point Likert scale to rate the change in their symptoms (much worse to much better) so no data were available on 'subjective' cure.

6.1.2 Self reported cure/improvement
In a single trial (Wyman 1998) in women with genuine stress incontinence, detrusor instability or both, there was no statistically significant difference between the groups for the combined rating of somewhat and much better (PFMT 48/64, Behavioural training 43/68).

6.2 Quantification of symptoms

6.2.1 Urinary diary (leakage episodes)
A seven day urinary diary was completed by women in the trial by Wyman et al (Wyman 1998). The data were presented separately for women with stress incontinence only (Wyman 1998a) versus the women with detrusor instability with or without genuine stress incontinence (Wyman 1998b). Unfortunately the lack of variance in the PFMT group (standard deviation 0.0) for women with genuine stress incontinence has meant that a confidence interval cannot be calculated in the formal comparison. The data from women with detrusor instability with or without genuine stress incontinence found no statistically significant difference between the groups (PFMT, n=18, mean 1.7 sd 1.8 versus Behavioural training, n=19, mean 0.9 sd 1.3).

6.2.2 Pad test
A pad test was included in the trial but the amount of missing data for this outcome immediately after treatment and at 3 month follow up meant that the analysis was not reported.

6.3 Clinicians' measures
Digital palpation of the pelvic floor muscles was performed at initial assessment but this was not apparently repeated post treatment.

6.4 Quality of life
Validated generic and condition specific quality of life questionnaires were used: the SF36, Incontinence Impact Questionnaire - Revised, and the Urogenital Distress Inventory. Overall there was no difference between the groups for any of the quality of life measures immediately post treatment. However, Wyman et al (Wyman 1998) noted that women with detrusor instability who received PFMT tended toward higher symptom distress scores than women in the behavioural therapy group.

6.5 Socioeconomics
No formal economic analysis was undertaken but women were asked how satisfied they were with the outcome of treatment. Forty-two of the 68 women in the behavioural therapy group were very satisfied with the outcome of treatment, as were 46/64 in the PFMT group.

6.6 Other

6.6.1 Adverse events
There was no record of adverse events in the trial.

6.6.2 Withdrawals/losses to follow up
Reasons for withdrawal were reported, but group allocation was not. There was some inconsistency in the number of reported withdrawals and the number of women for whom data were reported immediately after treatment (three months). Of the 204 women originally randomised data were reported for 193 of them.

6.6.3 'Compliance'
The proportion of attendance for clinic visits, the mean number of recommended voids (behavioural therapy group), and the mean number of pelvic floor muscle contractions (PFMT groups) were used as measures of how well women managed to cope with the requirements of training. In the behavioural therapy group 57% of women attended all six clinic visits, compared with 53% in the PFMT group. Eight-five percent of women were able to complete the scheduled voiding programme as recommended, compared with 84% of women in the PFMT group who managed to complete their exercise programme.

6.6.4 Incontinence at long term follow up
Further follow up was undertaken three months after the end of treatment. Wyman et al (Wyman 1998) stated that there was no difference between the groups for number of incontinent episodes per week, quality of life measures, or satisfaction with outcome. However, it was noted that the number of women in the PFMT group reporting complete remission of leakage episodes continued to increase over the follow up period while there was no further change in the behavioural therapy group.

7. PFMT VERSUS MEDICATION
Four trials compared PFMT with pharmaceutical treatment (Burgio 1986; Henalla 1989; Henalla 1990; Wells 1991). Burgio et al (Burgio 1998) compared PFMT with anticholinergic medication (oxybutynin chloride) in women with detrusor instability with or without genuine stress incontinence. Oestrogens (Premarin) and PFMT were compared in two trials for women with genuine stress incontinence (Henalla 1989; Henalla 1990). Wells et al (Wells 1991) randomised women with stress or mixed incontinence to receive either PFMT or alpha adrenergic medication (phenylpropanolamine hydrochloride). It should be noted that for the purposes of analysis Burgio et al (Burgio 1998) has been classified as a comparison of PFMT versus medication but women in the PFMT group also received education in urge strategies.

The abstract of one trial gave no detail of the PFMT programme used (Henalla 1990). The remaining trials were based on individual training with a nurse practitioner (Burgio 1998; Wells 1991) or physiotherapist (Henalla 1989), and two checked a correct voluntary pelvic floor muscle contraction (Burgio 1998; Henalla 1989). Burgio et al (Burgio 1998) recommended 15 contractions three times a day, Henalla et al (Henalla 1989) asked women to do five contractions per hour, and Wells et al (Wells 1991) suggested 90-160 contractions per day. The length of held contractions ranged from five seconds (Henalla 1989) to 10 seconds (Burgio 1998; Wells 1991). The length of training ranged from six weeks (Henalla 1990) to six months (Wells 1991).

Three types of medications were investigated. In Burgio et al (Burgio 1998) women randomised to receive oxybutynin chloride began with 2.5 mg three times a day, progressing to a maximum of 5.0 mg three times a day, with the goal of getting the most effective dose while controlling for side effects. Two trials used vaginal oestrogen cream (Premarin), two grams per night for six weeks (Henalla 1990) and three months (Henalla 1989). Women who took phenylpropanolamine hydrochloride (Wells 1991) began with 50mg daily for two weeks, increasing to twice daily for two weeks if leakage continued.

Limited data were available from the single abstract (Henalla 1990) included in this comparison. In one trial (Wells 1991) the post treatment assessment was at different times for each group; four weeks for the medication group and six months for women in the PFMT group. Each medication has been considered separately in the formal comparisons but the results and discussion have been combined under a single heading for simplicity.

7.1 Women's observations
Two trials did not ask women if their leakage was cured or improved after treatment (Henalla 1989; Henalla 1990). Wells et al (Wells 1991) asked women to rate change on a three point scale (worse, same, better) and Burgio et al (Burgio 1998) asked women to estimate percentage improvement where 0% was no change and 100% was 'dry'. The reviewers have regarded women who reported they were 'dry' as cured.

7.1.1 Self reported cure
In a single trial (Burgio 1998) in women with detrusor instability with or without genuine stress incontinence there was no statistically significant difference in the effect of PFMT or oxybutynin chloride for self reported cure (PFMT 19/63, medication 15/65).

7.1.2 Self reported cure/improvement
In a single trial (Burgio 1998) in women with detrusor instability with or without stress incontinence those who had PFMT were marginally more likely to consider they were 50% - 100% improved than women receiving medication (PFMT 57/63, medication 50/65). In another single trial (Wells 1991) in women with stress or mixed incontinence there was no statistically significant difference between PFMT and alpha adrenergic for self reported cure/improvement (PFMT 42/54, medication 54/64).

7.1.3 Other
Burgio et al (Burgio 1998) also asked women about other effects of treatment such as pad usage and changes in the amount of leakage per accident.

7.2 Quantification of symptoms

7.2.1 Urinary diary (leakage episodes)
Two weeks of bladder diary was completed post treatment by women in one trial (Burgio 1998) and a 'wetting' diary of unspecified length was completed in another (Wells 1991). in a single trial (Burgio 1998) in women with detrusor instability

with or without genuine stress incontinence the PFMT group had significantly fewer leakage episodes in 24 hours than those receiving oxybutynin chloride (PFMT, n=63 mean 0.4 sd 0.7 versus medication, n=65, mean 0.8 sd 1.4). However in the trial in women with stress or mixed incontinence (Wells 1991) women there was no difference between the PFMT and alpha adrenergic medication groups (PFMT, n=51 mean 0.8 sd 0.2 versus medication, n=62 mean 0.7 sd 0.1).

7.2.2 Pad test
A one hour pad test, and a short pad test of unspecified length, were used in the trials by Henalla et al (Henalla 1989) and Henalla et al (Henalla 1990) respectively. Standing and lying stress tests were used in Wells et al (Wells 1991). Wells et al (Wells 1991) reported no significant difference in the number of women in PFMT and medication groups who had a negative lying or standing stress test post treatment. Henalla et al (Henalla 1989) reported that 17/26 women in the PFMT group were cured (negative after previous positive pad test) or improved (50% or greater reduction in leakage) versus 3/24 in the oestrogen group. Henalla et al (Henalla 1990) did not define cure or improvement but reported that four of eight women in the PFMT group were cured or improved on pad testing versus none of the 11 women in the oestrogen group.

7.3 Clinicians' measures
Digital palpation and vaginal EMG of the pelvic floor muscles was used in the trial by Wells et al (Wells 1991). Post treatment palpation scores were significantly greater in women receiving PFMT than alpha adrenergic (p=0.05) but there were no differences between the groups for EMG measures of endurance time or peak, mean value of six 10 second contractions or mean of six fast contractions.

7.4 Quality of life
No validated generic or condition specific quality of life instruments were reported.

7.5 Socioeconomics
None of the trials included any formal economic analysis. Burgio et al (Burgio 1998) asked women on completion of the treatment phase if they wished for further, alternative, treatment. Forty of the 53 women in the oxybutynin chloride group wanted alternative treatment compared with eight of 57 women in the PFMT group.

7.6 Other

7.6.1 Adverse events
One trial used an adverse events checklist in which known side effects of oxybutynin chloride were interspersed with 'dummy' symptoms (Burgio 1998). Two adverse effects in particular were reported by women; dry mouth and inability to void. Dry mouth was significantly more common in the medication group when compared with placebo medication (p<0.001) as was inability to void (p<0.002). The PFMT group had less dry mouth than the placebo medication group (p<0.03).

7.6.2 Withdrawals/losses to follow up

One trial apparently reported that there were no withdrawals (Henalla 1990), and another appeared to have lost four of 104 women to post treatment follow up but group allocation was not stated (Henalla 1989). Withdrawals from PFMT and medication groups were 4/65 and 12/67 (Burgio 1998) and 8/82 and 11/75 (Wells 1991) respectively.

7.6.3 'Compliance'
Wells et al (Wells 1991) asked women in the PFMT group to complete a training diary. Analysis of the data appeared to suggest that those women who completed a greater proportion of the expected training programme were more likely to show improvement in leakage episodes and PFMT strength measures. This trial also reported that women were more likely to meet the requirements of the medication rather than the PFMT regime.

7.6.4 Incontinence at long term follow up
A single trial included follow up beyond post treatment assessment (Henalla 1989). At nine months three women (of 17) in the PFMT group had recurrent leakage symptoms and all three women who had initially improved with oestrogen had recurrent symptoms on discontinuation of treatment.

8. PFMT VERSUS SURGERY
Two trials compared PFMT with surgery for women with genuine stress incontinence (Klarskov 1986; Tapp 1989). The surgical procedure in Klarskov et al (Klarskov 1986) varied on the basis of voiding cystourethrogram. Anterior suspension defects were repaired using Burch colposuspension, posterior bladder descent with vaginal repair, and if both defects were present a combined procedure was performed. All women randomised to surgery in the trial by Tapp et al (Tapp 1989) had a Burch colposuspension. Tapp et al (Tapp 1989) gave no detail of the PFMT programme, and in the trial by Klarskov et al (Klarskov 1986) PFMT was taught in a group session by a physiotherapist but no detail of the home training programme was provided. The trial by Tapp et al (Tapp 1989) was published in two abstracts but there were inconsistencies in the data reporting. As the reviewers were not able to check the data with the original authors data from Tapp et al (Tapp 1989) were excluded from the formal comparisons.

8.1 Women's observations
Klarskov et al (Klarskov 1986) asked women if their urine leakage was worse, unchanged, improved or cured four months post surgery.

8.1.1 Self reported cure
The single trial available in women with genuine stress incontinence (Klarskov 1986) indicated that self reported cure was much more likely four months following surgery than after a PFMT programme of unknown length (PFMT 3/24, surgery 16/26).

8.1.2 Self reported cure/improvement

The same trial indicated that there was no statistically significant difference in the rate of self reported cure/improvement between the groups (PFMT 17/24, surgery 23/26).

8.1.3 Other
Other observations made by women included change in symptoms (visual analogue scale) (Tapp 1989), and change in frequency of micturition (Klarskov 1986).

8.2 Quantification of symptoms

8.2.1 Urinary diary (leakage episodes)
Data subsequently obtained from the author of one trial (Klarskov 1986) on the number of post treatment leakage episodes obtained from the three day diary was sufficiently skewed to preclude presentation as mean with standard deviation (Klarskov, personal communication). In the original publication data were presented as the median number of leakage episodes per three days with the range. Pre training values in the PFMT group (n=24) were six (0-31) reduced to two (0-20) post treatment. In the surgical group (n=26) the number of leakage episodes decreased from six (0-39) to none (0-14). Both groups had a significant reduction in incontinent episodes (p<0.01) but the decrease was significantly greater in the surgical group (p<0.01).

8.2.2 Pad test
Both trials included pad testing. Tapp et al (Tapp 1989) did not describe the test nor present any data. Klarskov et al (Klarskov 1986) presented incomplete data as the use of a one hour pad test was only initiated sometime after the trial had begun.

8.3 Clinicians' measures
None of the prespecified outcomes in this domain were reported.

8.4 Quality of life
No validated generic or condition specific quality of life instruments were reported.

8.5 Socioeconomic
Klarskov et al (Klarskov 1986) asked women at four months after trial entry if they wanted the alternative treatment. Twelve of the 24 women in the PFMT group wanted surgery, and a further two women wanted surgery by 12 months. In the surgical group five of the 26 women want PFMT at four months, with two more wanting PFMT by 12 months.

8.6 Other

8.6.1 Adverse events
Klarskov (Klarskov 1986) clearly documented adverse events, all of which were post surgical. Complications included the post operative development of detrusor instability (two women), retropubic pain (one woman), persistent pelvic pain (one woman), persistent dyspareunia and loss of libido (1 woman).

8.6.2 Withdrawals/losses to follow up
It is not clear whether there were any withdrawals/losses to follow up in Klarskov et al (Klarskov 1986). The reporting in the two abstracts by Tapp et al (Tapp 1989) was inconsistent

but there appeared to be 13 dropouts from three groups for "a variety of reasons".

8.6.3 'Compliance'
Neither trial documented how well women managed the requirements of the PFMT programme.

8.6.4 Incontinence at long term follow up
Follow up data have already been presented where available (Klarskov 1986: 12 months).

9. PFMT WITH ELECTRICAL STIMULATION VERSUS ELECTRICAL STIMULATION ALONE
A single trial addressed this comparison in women with genuine stress incontinence (Hofbauer 1990). The trial report gave limited information about either intervention. PFMT comprised group exercise (including PFMT) with an unspecified therapist, for 20 minutes twice a week, and a home training programme. Ten minutes of stimulation was given three times a week for six weeks using extra vaginal and lumbar electrodes, with the current intensity increased to produce a noticeable contraction to which the woman added her own voluntary contraction. The length of the treatment period was not stated.

9.1 Women's observations

9.1.1 Self reported cure
On the basis of a single small trial in women with genuine stress incontinence (Hofbauer 1990) there was no statistically significant difference in the rate of self reported cure between PFMT/stimulation versus stimulation alone (PFMT with stimulation 3/11, stimulation 1/11)

9.1.2 Self reported cure/improvement
On the basis of the same small trial in women with genuine stress incontinence there was no statistically significant difference in the rate of self reported cure/improvement between the groups (PFMT with stimulation 7/11, stimulation 3/11).

9.1.3 Other
No other data relating to women's observations of change were reported.

9.2 Quantification of symptoms

9.2.1 Urinary diary (leakage episodes)
Data were collected from a urinary diary but not reported.

9.2.2 Pad test
A pad test was not used.

9.3 Clinicians' measures
None of the prespecified outcomes in this domain were reported.

9.4 Quality of life
No validated generic or condition specific quality of life instruments were reported.

9.5 Socioeconomics
No formal economic analysis was reported.

9.6 Other

9.6.1 Adverse events
There was no mention of adverse events in the trial report.

9.6.2 Withdrawals/losses to follow up
There were no apparent losses to follow up post treatment or six months later.

9.6.3 'Compliance'
There was no report of how well women had managed to meet the requirements of PFMT or stimulation programmes.

9.6.4 Incontinence at long term follow up
Hofbauer et al (Hofbauer 1990) reported that the number of women reporting cure or improvement post treatment remained the same at six month follow up.

10. PFMT WITH VAGINAL CONES VERSUS VAGINAL CONES ALONE
A single trial published as an abstract addressed this comparison in women with genuine stress incontinence (Wise 1993). Individual teaching of PFMT included vaginal palpation of a correct voluntary pelvic floor muscle contraction. Women were asked to do a home training programme of one set of 10 contractions 10 times a day for 12 weeks.

10.1 Women's observations

10.1.1 Self reported cure
This was not reported.

10.1.2 Self reported cure/improvement
Wise et al (Wise 1993) stated that both groups had significant symptomatic improvement (visual analogue scale) compared with baseline (p=0.028 for cones alone; p=0.002 for combination therapy), and that the amount of improvement was greater in the group receiving PFMT and cones versus than the cones alone group.

10.1.3 Other
No other data relating to women's observations of change were reported.

10.2 Quantification of symptoms

10.2.1 Urinary diary (leakage episodes)
Urinary diary data were not collected.

10.2.2 Pad test
A 40 minute pad test with standardised bladder volume was used. A significant reduction in leakage was reported for both groups (p=0.011 for cones; p=0.006 for combination) with no statistically significant difference between the groups (p=0.0530). Fourteen of the 19 women in the cones group were improved (not defined) on pad testing versus 14/15 of the combined PFMT/cones group.

10.3 Clinicians' measures
No measures were reported.

10.4 Quality of life
No validated generic or condition specific quality of life instruments were reported.

10.5 Socioeconomics
No formal economic analysis was reported.

10.6 Other

10.6.1 Adverse events
The abstract stated that "all treatments were found to be equally acceptable" but there was no mention of adverse effects.

10.6.2 Withdrawals/losses to follow up
Losses to follow up were 2/21 in the cones group and 6/21 in the combination therapy group post treatment.

10.6.3 'Compliance'
There was no indication of how well women managed to meet the requirements of the training programmes.

10.6.4 Incontinence at long term follow up
No follow up beyond post treatment was reported.

11. PFMT WITH BEHAVIOURAL THERAPY VERSUS BEHAVIOURAL THERAPY ALONE
A single trial addressed this comparison in women with genuine stress incontinence, detrusor instability or both (Wyman 1998). PFMT included a graded home training programme that began with five fast (three second hold) and 10 sustained (10 second hold) contractions twice a day and progressed to a maximum of 10 fast and 40 sustained contractions per day. The use of a voluntary pelvic floor muscle contraction prior to rises in intra-abdominal pressure, and for urge suppression, was encouraged. Four sessions of visual biofeedback were also included. Behavioural training used a structured education programme, the use of voiding diaries, progressive timed voiding (progressing 30 minutes per week) and urge inhibition techniques. Both groups received 12 weeks of treatment with the same number of clinic visits and telephone contacts.

11.1 Women's observations

11.1.1 Self reported cure
Women used a five point Likert scale to rate the change in their symptoms (much worse to much better) so no data were available on 'subjective' cure.

11.1.2 Self reported cure/improvement
On the basis of a single trial (Wyman 1998) in women with genuine stress incontinence, detrusor instability or both self reported cure/improvement was more likely with combined PFMT/bladder training than bladder training alone (PFMT/bladder training 55/61, bladder training alone 43/68).

11.1.3 Other
Wyman et al (Wyman 1998) also asked women to rate their perception of improvement and satisfaction with outcome of treatment.

11.2 Quantification of symptoms

11.2.1 Urinary diary (leakage episodes)
A seven day urinary diary was completed by women in the trial by Wyman et al (Wyman 1998). The data were presented separately for women with genuine stress incontinence only (Wyman 1998a and women with detrusor instability with or without genuine stress incontinence (Wyman 1998b). The combined data suggested that PFMT/bladder training resulted in fewer leakage episodes in 24 hours than bladder training alone (WMD -0.5, 95% CI -1.04, -0.04).

11.2.2 Pad test
Although a pad test was included in the trial the amount of missing data for this outcome immediately after treatment and at three month follow up meant that the analysis was not reported.

11.3 Clinicians' measures
Digital palpation of the pelvic floor muscles was performed at initial assessment but this was not apparently repeated post treatment.

11.4 Quality of life
Validated generic and condition specific quality of life questionnaires were used; the SF36, Incontinence Impact Questionnaire - Revised, and the Urogenital Distress Inventory. Immediately post treatment Wyman et al (Wyman 1998) noted that any difference in quality of life scores varied according to diagnosis. At three months after treatment there was no statistically significant difference between the groups for any quality of life measure.

11.5 Socioeconomics
No formal economic analysis was undertaken but women were asked how satisfied they were with the outcome of treatment. Fifty of the 61 women in the combination therapy group were very satisfied with the outcome of treatment, as were 42/68 in the behavioural therapy group.

11.6 Other

11.6.1 Adverse events
There was no record of adverse events in the trial.

11.6.2 Withdrawal/losses to follow up
Reasons for withdrawal were reported, but group allocation was not. There was some inconsistency in the number of reported withdrawals and the number of women for whom data were reported immediately after treatment (three months). Of the 204 women originally randomised data were reported for 193 of them.

11.6.3 'Compliance'
The proportion of attendance for clinic visits, the mean number of recommended voids (behavioural therapy), and the mean number of pelvic floor muscle contractions (PFMT) were used as measures of how well women managed to cope with the requirements of training. In the combination therapy group 73% of women attended all six clinic visits, compared with 57% in the behavioural therapy group. Eight-one percent of women in the combination therapy group were able to complete the scheduled voiding programme as recommended, and three months after completion of treatment 40% were still using the

scheduled voiding programme. In the behavioural training group these figures were 85% and 44% respectively. The combination therapy group also managed 78% of the recommended PFMT and at three months post treatment the numbers doing PFMT most of the time had decreased to 58%.

11.6.4 Incontinence at long term follow up
Further follow up was undertaken 3 months after the end of treatment. Wyman et al (Wyman 1998) stated that there were no statistically significant differences between the groups for the number of incontinent episodes per week, quality of life measures, or satisfaction with outcome.

12. PFMT AND ANTI-INCONTINENCE DEVICE VERSUS DEVICE ALONE
A single trial addressed this comparison in women with symptoms of urine leakage (Prashar 1997). In the PFMT and device group women received PFMT with or without bladder training as appropriate, and a nurse continence advisor demonstrated how to apply the urethral occlusive device (FemAssist). In the device group women were shown how to use the device and were given a leaflet on good bladder habits. Both groups had weekly clinic visits for six weeks. Two abstracts of this trial have been published and reported a trial in progress (Dowell 1997; Prashar 1997). Data were reported for 14/62 women and 26/46 respectively, but not by comparison group. It is not clear whether a subsequent paper (Moore 1999) was a full report of the trial but it was assumed that it was. The authors and method are similar in the final report, but the data were presented for a single cohort rather than for two comparison groups, there is no mention of randomisation, nor of PFMT/bladder training.

12.1 Women's observations
There was no report of women's observations of change with treatment.

12.2 Quantification of symptoms

12.2.1 Urinary diary (leakage episodes)
A voiding diary was not used.

12.2.2 Pad test
An unspecified pad test was used. Prashar et al (Prashar 1997) reported that 14/26 of the women who had so far completed the trial either had no leakage or less than two grams leakage with pad test with the device in situ and there were similar improvements in both groups.

12.3 Clinicians' measures
No clinicians' measures were reported.

12.4 Quality of life
Women were asked to complete the Incontinence Impact Questionnaire and Urogenital Distress Inventory. Prashar et al (Prashar 1997) reported that there were similar improvements in both groups on the basis of data from the 26/46 women who had thus far completed the trial.

12.5 Socioeconomics

A cost of incontinence questionnaire was included in the trial. On the basis of data from 26 women Prashar et al (Prashar 1997) found that the weekly cost of incontinence had fallen from a mean of Aus$3.90 to Aus$1.35 with decreases in the number of pads used and the number of items laundered.

12.6 Other

12.6.1 Adverse events
There were a number of withdrawals from the trial that appeared to be due to difficulty in using the device. Women withdrew as they could not apply the device correctly (six women), had a disinclination to touch the genitalia (five women) or dropped out with "extreme anxiety" (five women).

12.6.2 Withdrawals/losses to follow up
At the time of reporting 19/65 women who had been offered the device had declined or withdrawn (Prashar 1997).

12.6.3 'Compliance'
See data presented under adverse events.

12.6.4 Incontinence at long term follow up
No long term follow up was reported.

13. PFMT ALONE VERSUS PFMT WITH BIOFEEDBACK
For the purposes of this review all forms of biofeedback were acceptable (e.g. pressure perineometers with visual or auditory display, electromyography from vaginal probes, etc). To be classified as a trial including biofeedback, repeated use of a biofeedback device to monitor or assist PFMT was required. This excluded trials where biofeedback devices were used in the initial teaching of a voluntary pelvic floor muscle contraction but not thereafter. Some trials have also used an intravaginal device for the purpose of 'resisting' the work of the pelvic floor muscles (e.g. Ferguson 1990). Two trials in the review suggested that the intravaginal device provided gave biofeedback and also provided resistance to exercise (Klingler 1995; Shepherd 1983). As it was not possible to differentiate the primary purpose of the device these trials were included in both the biofeedback and intravaginal resistance device comparisons.

On this basis 10 trials compared PFMT alone versus biofeedback assisted PFMT (Berghmans 1996; Burns 1993; Castleden 1984; Glavind 1996; Klingler 1995; Laycock 1999; Shepherd 1983; Sherman 1997; Taylor 1986; Wong 1997a). One trial (Sherman 1997) included urge strategies as appropriate in both arms of the trial. Four trials included women with symptoms of stress leakage only (Castleden 1984; Klingler 1995; Laycock 1999; Taylor 1986) and four trials included women with genuine stress incontinence alone (Berghmans 1996; Glavind 1996; Shepherd 1983; Wong 1997a). Two trials included women with genuine stress incontinence with or without detrusor instability (Burns 1993; Sherman 1997).

All the trials indicated that women had individual PFMT with a physiotherapist (Berghmans 1996; Castleden 1984; Klingler 1995; Shepherd 1983), undefined "therapist" (Sherman 1997),

nurse (Burns 1993), or unspecified person (Glavind 1996; Laycock 1999; Taylor 1986; Wong 1997a). Three trials gave no other detail of the PFMT programme (Klingler 1995; Shepherd 1983; Wong 1997a). No trial stated that women receiving PFMT without biofeedback had been examined to check that a correct contraction was being performed. The recommended number of contractions per day ranged from approximately 80 (Castleden 1984, 4-5 contractions hourly) to 360 (Berghmans 1996, four sets of 10-30 contractions three times a day). Two trials gave length of time, rather than number of contractions per day (Laycock 1999, 10 minutes; Sherman 1997, 20 minutes twice a day).

In all trials it appeared that the home PFMT programme was the same for both groups. The content of clinic visits was generally different, with the addition of biofeedback for women randomised to receive this treatment. Biofeedback methods and protocols varied. Half of the trials used biofeedback from a vaginal probe with EMG electrode (Berghmans 1996; Burns 1993; Glavind 1996; Sherman 1997; Wong 1997a) and the other half used a pressure sensitive intravaginal device (Castleden 1984; Klingler 1995, Laycock 1999, Shepherd 1983; Taylor 1986). Some trials also used electrodes or rectal catheters to monitor muscle activity or abdominal pressure changes (Glavind 1996; Sherman 1997; Wong 1997a). All the devices provided women with visual biofeedback, and two systems also gave auditory feedback on performance (Berghmans 1996; Klingler 1995). Four trials were based on clinic only biofeedback (Berghmans 1996; Burns 1993; Glavind 1996; Wong 1997a), and three trials were based on daily home biofeedback (Castleden 1984; Laycock 1999; Shepherd 1983). Two trials apparently used a mix of home and clinic biofeedback (Klingler 1995; Sherman 1997). Taylor & Henderson (Taylor 1986) compared PFMT/home biofeedback, PFMT/clinic only biofeedback and PFMT alone. Overall, the number of treatments with biofeedback and length of treatment (in weeks) was highly variable. In the trials with clinic based biofeedback the number of sessions per week ranged from one (Burns 1993; Glavind 1996; Taylor 1986), or two (Sherman 1997; Wong 1997a) to a maximum of three (Berghmans 1996) for four weeks (Glavind 1996), eight weeks (Burns 1993; Sherman 1997), nine weeks (Taylor 1986) and 12 weeks (Berghmans 1996). The daily home based programmes ranged from two weeks (Castleden 1984) to three months in duration (Laycock 1999). In one trial (Glavind 1996) the women in the biofeedback group had more clinic visits (four) than the PFMT group (usually two or three). Limited data were available from the three abstracts (Klingler 1995; Laycock 1999; Wong 1997a). Taylor & Henderson (Taylor 1986) randomised 13 women to four comparison groups. This trial was reported as a pilot study and did not present any data. It was therefore excluded from the analysis. One of the trials (Castleden 1984) used a cross over design with random allocation to first treatment. Only the data from the first comparison were considered for inclusion in the analysis.

13.1 Women's observations

Three trials did not ask women to report cure or improvement (Glavind 1996; Sherman 1997; Wong 1997a). One trial used a symptom score but this did not identify women who considered themselves to be 'cured' (Berghmans 1996). Two trials used a visual analogue scale but the data are presented as the change in mean score so this cannot be used in the formal comparisons (Castleden 1984; Laycock 1999). Three trials (Burns 1993; Klingler 1995; Shepherd 1983) contributed data to the formal comparisons. Burns et al (Burns 1993) presented percentage reduction in symptoms and the reviewers have included women with 100% reduction in symptoms in the category of cure. Klingler et al (Klingler 1995) reported subjective improvement but did not describe the measurement tool. Shepherd et al (Shepherd 1983) also documented women's self report of cure or improvement.

13.1.1 Self reported cure
The combined data from two trials, in women with genuine stress incontinence alone (Shepherd 1983) and women with genuine stress incontinence with or without detrusor instability (Burns 1993), suggested that there was no statistically significant difference in the rate of self reported cure between PFMT and biofeedback assisted groups (RR 0.6, 95% CI 0.3, 1.1).

13.1.2 Self reported cure/improvement
Combined data from two trials, one in women with genuine stress incontinence (Shepherd 1983) and the other in women with symptoms of stress incontinence only (Klingler 1995), found no statistically significant difference in the rate of self reported cure/improvement between PFMT and biofeedback assisted PFMT groups (RR 0.9, 95% CI 0.8, 1.1). However, significant statistical heterogeneity (p=0.0007) was observed for this comparison. Neither trial report is very detailed and it is difficult to identify the most likely source of this observed heterogeneity. Both trials used intravaginal pressure biofeedback devices. The most obvious difference is in the length of treatment - six weeks in Shepherd et al (Shepherd 1983) and nine weeks in Klingler et al (Klingler 1995). It is possible that women receiving biofeedback see earlier improvement but over time this advantage diminishes.

13.1.3 Other
Women were also asked about pad usage (Klingler 1995; Laycock 1999), severity of leakage (Castleden 1984; Sherman 1997), and other symptoms such as frequency (Shepherd 1983) and urgency (Sherman 1997).

13.2 Quantification of symptoms

13.2.1 Urinary diary (leakage episodes)
Three trials used seven day urinary diaries (Berghmans 1996; Burns 1993; Wong 1997a), and one trial reported number of leakage episodes per day (Sherman 1997). Shepherd et al (Shepherd 1983) collected data on leakage episodes in a urinary diary but the data were presented as mean (with range) and cannot therefore be included in the analysis. Laycock et al (Laycock 1999) presented data on the reduction in leakage

episodes per day and found no difference between PFMT (mean 1.13, sd 1.42) and biofeedback groups (mean 1.20, sd, 1.29).

Combined data from three trials, in women with genuine stress incontinence (Berghmans 1996) and women with genuine stress incontinence with or without detrusor instability (Burns 1993; Sherman 1997), suggested that there was no difference in the number of leakage episodes per 24 hours across the groups {RR 0.2, 95% CI -0.1, 0.4). The lack of difference in effect is consistent across all three trials.

13.2.2 Pad test
Two trials used a one hour pad test (Glavind 1996; Wong 1997a). Klingler et al (Klingler 1995) did not describe the test used, the data were presented as mean/range, but an improvement in leakage with pad testing was noted in both groups. Glavind et al (Glavind 1996) reported the results of pad testing at baseline, one and three months. In the PFMT group the medians (95% CI) were 12.8 grams (9, 44), 19.0 grams (0, 51) and 10.0 grams (2, 27) at these time periods. In the biofeedback assisted group the values were 9.0 grams (5, 22), 2.5 grams (1, 10) and 0.8 grams (0, 4) respectively. Pad test data from the trial in progress by Wong (Wong 1997a) also favoured the biofeedback group (PFMT, n=7, mean 18.7g, sd 24.8; PFMT+BF, n=10, mean 7.4g, sd 6.1) but the difference was not significant. Glavind et al (Glavind 1996) also reported the number of women cured on post treatment pad test (less than two grams of leakage); 11/19 in the biofeedback group versus 3/15 in the PFMT group.

Only Berghmans et al (Berghmans 1996) included a long pad test (48 hours). Both groups had a significant reduction in leakage (p=0.00) after all twelve treatments. However the reduction in leakage on pad test was statistically significant after six treatments in the biofeedback group. There was no significant difference in the improvement between the two groups (p=0.40) post treatment.

13.3 Clinicians' measures
Perineometry (Castleden 1984; Shepherd 1983), EMG (Burns 1993; Taylor 1986), and an unspecified form of muscle testing (Laycock 1999) were used to assess pelvic floor muscle strength. Taylor & Henderson (Taylor 1986) presented no data. Both Castleden et al (Castleden 1984) and Shepherd et al (Shepherd 1983) reported mean pressure (cm water) but no indication of variation so the data were of limited value and it has not been presented here. Burns et al (Burns 1993) found the biofeedback group had significantly more improvement in the strength of sustained contractions when compared with the PFMT group (p<0.001) while Laycock et al (Laycock 1999) did not find any significant difference between the groups for the measure of maximal muscle contraction post treatment.

13.4 Quality of life
Two trials used a validated condition specific quality of life questionnaire: the King's Health Questionnaire (Laycock 1999) and the Incontinence Impact Questionnaire (Wong 1997a). The improvement in quality of life score was not different in

Laycock et al (Laycock 1999) but was significantly greater (p<0.05) for the biofeedback group in the trial in progress reported by Wong et al (Wong 1997a). Berghmans et al (Berghmans 1996) used a symptom questionnaire with five domains, two of which related to quality of life (level of limitation in social activities due to leakage, emotional state related to leakage). Unfortunately these data were not reported separately but the combined symptom score improved in both groups with no significant difference between the groups after six or twelve treatments.

13.5 Socioeconomics
No trial included any formal economic analysis. Both Shepherd et al (Shepherd 1983) and Sherman & Davis (Sherman 1997) reported on the number of treatments for each group. The mean number of treatments in the biofeedback group was 5.7 (range 4-10) versus 3.5 (range 2-8) in the PFMT group (Shepherd 1983). Sherman & Davis (Sherman 1997) found no statistically significant difference in the number of treatments by group (PFMT, n=14, mean number of treatments 3.37, sd 1.28; Biofeedback, n=23, mean 3.74, sd 1.29).

13.6 Other

13.6.1 Adverse events
Berghmans et al (Berghmans 1996) stated that no harmful effects were reported by women or physiotherapists. Laycock et al (Laycock 1999) reported that adverse events were recorded and would be published in a later paper.

13.6.2 Withdrawals/losses to follow up
Four trials apparently had no withdrawals (Berghmans 1996; Castleden 1984; Klingler 1995; Wong 1997a). Two trials reported drop outs but not by group allocation (Burns 1993, 12 of 135 women; Taylor 1986, one of 13 women). Losses to follow up numbered 5/20 (Glavind 1996), 4/20 (Laycock 1999), 3/11 (Shepherd 1983), and 7/23 (Sherman 1997) in the PFMT groups, and 1/20, 18/40, 0/11 and 0/23 in the biofeedback groups respectively. In total loss to follow up was 19/74 (25.7%) in the PFMT groups and 19/94 (20.2%) in the biofeedback groups.

13.6.3 'Compliance'
Four trials asked women how well they managed to meet training requirements (Burns 1993; Laycock 1999; Sherman 1997; Taylor 1986). Two trials used a training diary but neither reported any data (Burns 1993; Taylor 1986). Laycock et al (Laycock 1999) reported a compliance score: 78.8% and 81.3% in the biofeedback and PFMT groups respectively. Sherman & Davis (Sherman 1997) found that 6/23 women in the biofeedback group and 10/16 in the PFMT group reported that they were doing PFMT 'frequently' or 'all the time' at post treatment follow up.

13.6.4 Incontinence at long term follow up
Only Burns et al (Burns 1993) and Glavind et al (Glavind 1996) assessed outcome beyond the end of treatment. The follow up data from Burns was not presented by group allocation. At two

to three years post treatment Glavind et al (Glavind 1996) found that 0/14 and 5/19 in the PFMT and biofeedback assisted groups respectively were subjectively cured, with a further 4/14 and 8/19 reporting improvement. Seven of 14 in the PFMT group, and 17/19 in the biofeedback assisted group were regularly performing PFMT at follow up.

14. PFMT ALONE VERSUS PFMT WITH INTRAVAGINAL RESISTANCE

Two trials, one in women with genuine stress incontinence (Ferguson 1990) and the other in women with symptoms of stress incontinence only (Taylor 1986), clearly stated that an intravaginal device had been used to provide resistance to muscle work during PFMT. The reports of two further trials (Klingler 1995; Shepherd 1983) suggested that the intravaginal device provided resistance and biofeedback. Shepherd et al (Shepherd 1983) called the device an "exerciser", and Klingler et al (Klingler 1995) stated that the device had to be "compressed" by the woman. As it was not possible to differentiate the primary purpose of the device these trials were included in both the intravaginal resistance device and biofeedback comparisons. These trials included women with symptoms of stress leakage only (Klingler 1995) and women with genuine stress incontinence (Shepherd 1983).

None of the trials stated that a correct voluntary pelvic floor muscle contraction had been checked prior to training, but all seemed to have been taught individually by a physiotherapist (Klingler 1995; Shepherd 1983) or other unspecified person (Ferguson 1990; Taylor 1986). Neither Klingler et al (Klingler 1995) or Shepherd et al (Shepherd 1983) provided any detail of PFMT. Taylor & Henderson (Taylor 1986) asked women to do one set of 100 contractions per day. Alternating days of strength training (15-25 contractions held for six seconds) and endurance training (30 contractions held for 12 seconds) were recommended by Ferguson (Ferguson 1990). Training lasted from six weeks (Ferguson 1990; Shepherd 1983) to nine weeks (Klingler 1995; Taylor 1986). For women randomised to receive training with intravaginal resistance all trials recommended daily exercise with the device in situ. One trial used a perineometry sensor detached from the machine (Taylor 1986), and the other three trials used 'balloon' devices (Ferguson 1990; Klingler 1995; Shepherd 1983).

Limited data were available from the single abstract (Klingler 1995). Taylor & Henderson (Taylor 1986) randomised 13 women to four comparison groups. This trial was reported as a pilot study and did not present any data. It was therefore excluded from the analysis. It should be noted that neither the trial by Ferguson et al (Ferguson 1990) or Taylor & Henderson (Taylor 1986) that were both clearly comparisons of PFMT versus PFMT with intravaginal resistance contributed any data to the formal analysis. The only data in the formal comparisons were taken from the trials by Klingler et al (Klingler 1995) and Shepherd et al (Shepherd 1983) and there is some doubt whether these trials were investigating the effect of biofeedback or

intravaginal resistance. Therefore caution is required in the interpretation of the formal comparisons.

14.1 Women's observations
Ferguson et al (Ferguson 1990) did not ask women for a self report of cure or improvement. Klingler et al (Klingler 1995) reported subjective improvement but did not describe the measurement tool. Shepherd et al (Shepherd 1983) also documented women's self report of cure or improvement.

14.1.1 Self reported cure
Data from a single trial in women with genuine stress incontinence (Shepherd 1983) found there was no statistically significant difference in the rate of self reported cure between PFMT and PFMT with intravaginal resistance (PFMT 3/11, PFMT/resistance 8/11). It should be noted that this trial has also been classified as a trial comparing biofeedback assisted PFMT versus PFMT alone.

14.1.2 Self reported cure/improvement
Combined data from two trials in women with symptoms of stress incontinence only (Klingler 1995) and women with genuine stress incontinence (Shepherd 1988), found no statistically significant difference in the rate of self reported cure/improvement between PFMT and PFMT with intravaginal resistance groups (RR 0.9, 95% CI 0.8, 1.1). However, significant statistical heterogeneity (p=0.0007) was observed for this comparison. Neither trial report is very detailed and it is difficult to identify the most likely source of this observed heterogeneity. Both trials used intravaginal pressure devices that also gave biofeedback. The most obvious difference is in the length of treatment - six weeks in Shepherd et al (Shepherd 1983) and nine weeks in Klingler et al (Klingler 1995). It is possible that women receiving intravaginal resistance/biofeedback see earlier improvement but over time this advantage diminishes.

14.1.3 Other
Other observations included pad usage (Klingler 1995) and frequency of voids (Shepherd 1983).

14.2 Quantification of symptoms

14.2.1 Urinary diary (leakage episodes)
Two trials asked women to complete a urinary diary (Shepherd 1983; Taylor 1986). Taylor & Henderson (Taylor 1986) did not report any data. Shepherd et al (Shepherd 1983) collected data on leakage episodes in a urinary diary but the data were presented as mean (with range) and cannot therefore be included in the analysis.

14.2.2 Pad test
Two trials included pad testing (Ferguson 1990; Klingler 1995). Ferguson et al (Ferguson 1990) used both a 30 minute and a 24 hour pad test. Both groups had a significant reduction in leakage on the 30 minute (p<0.05) and 24 hour (p<0.05) pad tests. Klingler et al (Klingler 1995) did not describe the test used, the data were presented as mean/range, but an improvement in leakage with pad testing was noted in both groups.

14.3 Clinicians' measures

Perineometry (Ferguson 1990; Shepherd 1983) and EMG (Taylor 1986) were used to assess pelvic floor muscle activity. Taylor & Henderson (Taylor 1986) presented no data. Shepherd et al (Shepherd 1983) presented data as mean/range but demonstrated improvement in vaginal squeeze pressure in both groups. Ferguson et al (Ferguson 1990) found significant improvement in both groups in maximum intravaginal pressure (p<0.05) and endurance (p<0.05 resistance group, p<0.01 PFMT group).

14.4 Quality of life

No validated generic or condition specific quality of life instruments were reported.

14.5 Socioeconomics

No trial included any formal economic analysis. Shepherd et al (Shepherd 1983) reported on the number of treatments for each group. The mean number of treatments in the resistance group was 5.7 (range 4-10) versus 3.5 (range 2-8) in the PFMT group.

14.6 Other

14.6.1 Adverse events

None of the included trials referred to adverse events.

14.6.2 Withdrawals/losses to follow up

Two trials apparently had no losses to follow up (Ferguson 1990; Klingler 1995). Taylor & Henderson (Taylor 1986) had one withdrawal but group allocation was not stated, and Shepherd et al (Shepherd 1983) reported 3/11 drop outs in the PFMT group versus 0/11 in the resistance group.

14.6.3 'Compliance'

One trial used a training diary but did not report any data (Taylor 1986).

14.6.4 Incontinence at long term follow up

None of the included trials reported follow up beyond the post treatment assessment.

15. PFMT ALONE VERSUS PFMT WITH ELECTRICAL STIMULATION

Four trials, all in women with genuine stress incontinence, compared a combination of PFMT and electrical stimulation with PFMT alone (Hofbauer 1990; Knight 1998; Tapp 1987; Tapp 1989). One of the trials (Knight 1998) was a three arm RCT that compared PFMT/home biofeedback and low intensity stimulation, PFMT/home biofeedback and acute maximal stimulation, and PFMT/home biofeedback alone. Data from the two stimulation groups was referred to as Knight 1998a (low intensity stimulation) and Knight 1998b (acute maximal stimulation) and this trial contributed two data sets to the analysis.

Three trials were based on individual teaching of PFMT with a continence advisor (Tapp 1987; Tapp 1989) or physiotherapist (Knight 1998). The remaining trial used group teaching with an undefined "therapist" (Hofbauer 1990). Only Knight et al

(Knight 1998) checked that a correct voluntary pelvic floor muscle contraction was being performed. Tapp et al (Tapp 1989) gave no further detail of PFMT and the three remaining training programmes were different. Hofbauer et al (Hofbauer 1990) provided 20 minutes of group training twice a week for an unspecified length of time and Tapp et al (Tapp 1987) asked women to complete one set of four contractions hourly every day for three months. The training programme in Knight et al (Knight 1998) was based on one set of 20 contractions (10 sustained and 10 fast) six times a day, daily, for six months.

Two trials used faradic current (Tapp 1987; Tapp 1989). Tapp et al (Tapp 1987) delivered the stimulation through a vaginal electrode, twice a week for one month. Tapp et al (Tapp 1989) gave no detail of the stimulation protocol. Hofbauer et al (Hofbauer 1990) provided little information other than that 10 minutes of stimulation was given three times a week for six weeks using extra vaginal and lumbar electrodes, with the current intensity increased to produce a noticeable contraction to which the woman added her own voluntary contraction.

In Knight et al (Knight 1998) the low intensity stimulation was provided by a portable battery powered stimulator and vaginal electrode at a frequency of 10 Hz (with 35 Hz bursts), with a pulse duration of 200 microseconds. The duty cycle was five seconds on, five seconds off, and women were instructed to adjust the intensity to a barely perceptible tingling. The stimulator was used overnight for six months, but not during menstruation. The acute maximal stimulation was delivered by a mains powered stimulator and vaginal electrode at a frequency of 35 Hz and a pulse duration of 250 microseconds. The duty cycle was five seconds on and five seconds off and women were instructed to perform a voluntary pelvic floor muscle contraction with stimulation. Sixteen 30 minute treatments were given.

Limited data were available from the two abstracts (Tapp 1987; Tapp 1989). The trial by Tapp et al (Tapp 1989) was published in two abstracts but there were inconsistencies in the data reporting. As the reviewers were not able to check the data with the original authors data from Tapp et al (Tapp 1989) was excluded from the formal analysis.

15.1 Women's observations

Two trials asked women if their leakage was cured or improved after treatment (Hofbauer 1990; Knight 1998). Tapp et al (Tapp 1987) included a visual analogue scale to assess symptoms of stress leakage but these data were not suitable for inclusion in the analysis.

15.1.1 Self reported cure

Data from a single trial in women with genuine stress incontinence (Hofbauer 1990) found no statistically significant difference in rate of self reported cure between the PFMT and PFMT with electrical stimulation groups (PFMT 6/11, PFMT/stimulation 3/11).

15.1.2 Self reported cure/improvement

Combined data from two trials, both in women with genuine stress incontinence (Hofbauer 1990; Knight 1998) found no statistically significant difference in the rate of self reported cure/improvement between the groups (RR 1.0, 95% CI 0.7, 1.4). One of the trials contributed two data sets to the formal comparison(Knight 1998a & Knight 1998b) so there is some lack of independence in these data but the extent to which this has affected the summary statistic is unknown.

15.2 Quantification of symptoms

15.2.1 Urinary diary (leakage episodes)
There was no data available from urinary diaries. data were collected but not reported by two trials (Hofbauer 1990; Knight 1998), the latter because many data sets were incomplete.

15.2.2 Pad test
Three trials included a pad test (Knight 1998; Tapp 1987; Tapp 1989) but no data were presented by the latter two. Knight et al (Knight 1998) did not state the type of pad test used but the description indicated a short pad test on a standardised bladder volume. After twelve months PFMT, PFMT/low intensity stimulation and PFMT/maximal intensity stimulation groups all demonstrated a significant reduction in leakage on pad test (p=0.0012, p=0.0062, p=0.0003 respectively) but there was no statistically significant difference between the groups. In addition Knight et al (Knight 1998) reported the number of women from each group who were cured (less than two grams leakage) or greatly improved (75% reduction in leakage or more). The combined cure/greatly improved values were 13/21 (PFMT), 10/25 (PFMT/low intensity stimulation), and 16/24 (PFMT/maximal intensity stimulation).

15.3 Clinicians' measures
One trial used a perineometer to measure pelvic floor muscle activity (Knight 1998) and found significant improvement in all the parameters (strength, area under the curve, gradient) measured in all groups but no statistically significant difference between the groups post treatment.

15.4 Quality of life
No validated generic or condition specific quality of life instruments were reported.

15.5 Socioeconomics
None of the trials included any formal economic analysis. Tapp et al (Tapp 1987, Tapp 1989) reported the number of women from each group who requested surgery post treatment. Six of 14 and 8/23 from PFMT with stimulation groups and 10/15 and 11/21 from PFMT groups requested surgery respectively. Tapp et al (Tapp 1989) included six month follow up and at that time one more women in the PFMT group and three from the combination therapy group requested surgery.

15.6 Other

15.6.1 Adverse events
None of the four trials referred to adverse events associated with treatment.

15.6.2 Withdrawals/losses to follow up
Two trials apparently had no losses to follow up (Hofbauer 1990; Tapp 1987). In one trial the reporting of withdrawals was inconsistent (Tapp 1989). In Knight et al (Knight 1998) drop outs numbered 3/21 from the PFMT group, 6/25 from the low intensity stimulation group, and 4/24 from the maximal stimulation group.

15.6.3 'Compliance'
Knight et al (Knight 1998) asked women to rate the proportion of the requested treatment they had undertaken. With regard to PFMT the median percentage "compliance" with training was reported to be 90% in the PFMT group and 72.5% in the low intensity stimulation group. Data were not reported for the maximal stimulation group.

15.6.4 Incontinence at long term follow up
Follow up data was available from Knight et al (Knight 1998: 12 months) and Tapp et al (Tapp 1989: six months). The data from Tapp et al (Tapp 1989) has been presented in the socioeconomic section. Knight et al (Knight 1998) found the number of women who reported cure or great improvement at 12 months was 9/14 from the PFMT group, 7/15 from the low intensity stimulation group, and 17/20 from the maximal intensity stimulation group.

16. PFMT ALONE VERSUS PFMT WITH VAGINAL CONES
Two trials compared PFMT versus PFMT with vaginal cones. One trial included postnatal women with symptoms of urine leakage (Wilson 1998) and the other women with genuine stress incontinence (Pieber 1995). It should be noted that Wilson & Herbison (Wilson 1998) included two different PFMT training programmes. Women were randomised to receive standard postnatal care (i.e. usually includes PFMT in an group setting antenatally/postnatally) or individualised postnatal PFMT teaching with a physiotherapist. In addition a group were randomised to receive individualised postnatal PFMT in combination with vaginal cones. Consequently Wilson & Herbison (Wilson 1998) has contributed two data sets to the analysis: standard PFMT versus PFMT with vaginal cones (Wilson 1998a) and individualised PFMT versus PFMT with vaginal cones (Wilson 1998b).

In Wilson & Herbison (Wilson 1998) women receiving the individualised PFMT programme were asked to aim for eight to ten sets of 10 contractions per day (total 80 - 100) over nine months. The PFMT programme described by Pieber et al (Pieber 1995) included individual teaching and check of a correct voluntary pelvic floor muscle contraction, with a home programme of 100 contractions per day for 12 weeks. With regard to the vaginal cones training protocol women in the trial by Wilson & Herbison (Wilson 1998) had a set of nine cones ranging in weight from 20 - 100 grams. Women were asked to retain the heaviest cone possible for 15 minutes twice a day, progressing cone weight as able. In Pieber et al (Pieber 1995) the set of five cones ranged in weight from 20 - 70 grams and women were asked to retain the heaviest cone possible for 15

minutes per day while continuing with their normal daily activity.

16.1 Women's observations
Subjective 'cure' was not reported in either trial, however Wilson & Herbison (Wilson 1998) included data that indicated how many women no longer had symptoms of urine leakage and this was classified as 'cure'. Pieber did report 'cure' but it was a combined measure (subjective improvement and negative stress test) so this was excluded from the analysis.

16.1.1 Self reported cure
In postnatal women with symptoms of urinary incontinence there was no statistically significant difference between the PFMT and PFMT with cones for self reported cure (RR 0.8, 95% CI 0.5, 1.4). The two data sets that contributed to this comparison came from the same trial (Wilson 1998a; Wilson 1998b) and therefore the data lacks independence. While no statistical heterogeneity (p=0.14) was observed there was significant clinical heterogeneity in the comparisons. The data that favoured the combination therapy (Wilson 1998a) came from a comparison of standard postnatal care (i.e. teaching of PFMT was given antenatally or postnatally in group teaching or through the provision of leaflets or audiotape) versus individual appointments with a physiotherapist to teach PFMT and the use of vaginal cones. The data set (Wilson 1998b) that favoured PFMT came from a comparison of individualised PFMT with vaginal cones versus individualised PFMT. The difference in type of PFMT ('standard' versus 'individualised') might explain the possible difference in effect.

16.1.2 Self reported cure/improvement
A single trial in women with genuine stress incontinence (Pieber 1995) indicated that there was no statistically significant difference between the groups for self reported cure/improvement (PFMT 14/25, PFMT/cones 6/21).

16.1.3 Other
No other data relating to women's observations of change were reported.

16.2 Quantification of symptoms

16.2.1 Urinary diary (leakage episodes)
Neither trial reported data from a urinary diary.

16.2.2 Pad test
Pieber et al (Pieber 1995) did include a stress test, but the data were combined with a subjective rating of change in leakage, and was therefore unsuitable for analysis.

16.3 Clinicians' measures
Wilson & Herbison (Wilson 1998) used a perineometer to measure maximal and sustained (five seconds) vaginal squeeze pressure (cm water). The data did not show any difference between the groups for maximal contractions (standard PFMT (n=79, mean 13.1, 95% CI 11.3, 14.9), individualised PFMT (n=19, mean 13.6, 95% CI 9.8, 17.4), PFMT with cones (n=13, mean 13.0, 95% CI 8.1, 17.9)) or sustained contractions

(standard (n=79, mean 6.7, 95% CI 5.4, 8.1), individualised PFMT (n=19, mean 7.9, 95% CI 5.3, 10.6), PFMT with cones (n=13, mean 6.1, 95% CI 4.0, 8.2)).

16.4 Quality of life
Neither trial used a generic or condition specific quality of life questionnaire with established validity and reliability. Wilson & Herbison (Wilson 1998) reported sexual satisfaction scores (questionnaire modified from the Golombok and Rust reference inventory of sexual satisfaction) but found no statistically significant difference between the comparison groups.

16.5 Socioeconomics
Neither trial included any formal economic analysis. Wilson & Herbison (Wilson 1998) collected data on the average teaching time for individualised PFMT and combined PFMT/cones group. PFMT teaching took an average of 32 minutes (95% CI 30, 34) and the combined therapy 38 minutes (95% CI 34, 42).

16.6 Other

16.6.1 Adverse events
Adverse events were not mentioned in either trial report.

16.6.2 Withdrawals/losses to follow up
Losses to follow up post treatment were 11/25 in the PFMT group and 8/21 in the PFMT/cones group (Pieber 1995), and 26/117 in the standard PFMT group, 20/39 in the individualised PFMT group, and 24/38 in the PFMT/cones group (Wilson 1998).

16.6.3 'Compliance'
At nine months post treatment Wilson & Herbison (Wilson 1998) asked women how much PFMT they were performing. Some PFMT had been completed in the last month by 59/91 in the standard PFMT group, 19/19 in the individualised PFMT group, and 14/14 in the PFMT/cones group. Fewer women were performing daily training; 8/91, 13/19 and 9/14 respectively. The average (95% CI) number of daily contractions was 35 (30, 40), 86 (68, 104) and 73 (51, 42) respectively.

16.6.4 Incontinence at long term follow up
Wilson & Herbison (Wilson 1998) administered a telephone questionnaire at two or more years following delivery (i.e. 15 months or more after the end of treatment) but the results were not presented separately for all comparison groups. Data from the standard postnatal intervention was compared with all three interventions provided individually by physiotherapists (i.e. individualised PFMT, individualised PFMT with cones, and cones alone). No significant differences between the standard and combined physiotherapy groups were shown. Nine of the 168 women followed up had undergone surgery and 70 women were pregnant at the time of follow up and/or had delivered another child. Of the 89 women remaining 50 reported urine leakage, 50 had done some PFMT within the last month (although it is not known if they were necessarily the women with leakage), and six were doing daily PFMT. The number of contractions per day had reduced significantly from post treatment assessment.

17. PFMT ALONE VERSUS PFMT WITH BEHAVIOURAL THERAPY (BLADDER TRAINING)

A single trial addressed this comparison in women with genuine stress incontinence, detrusor instability or both (Wyman 1998). PFMT included a graded home training programme that began with 5 fast (three second hold) and 10 sustained (10 second hold) contractions twice a day and progressed to a maximum of 10 fast and 40 sustained contractions per day. The use of a voluntary pelvic floor muscle contraction prior to rises in intra-abdominal pressure, and for urge suppression, was encouraged. Four sessions of visual biofeedback were also included. Behavioural training used a structured education programme, the use of voiding diaries, progressive timed voiding (progressing 30 minutes per week) and urge inhibition techniques. Both groups received 12 weeks of treatment with the same number of clinic visits and telephone contacts.

17.1 Women's observations

17.1.1 Self reported cure
Women used a five point Likert scale to rate the change in their symptoms (much worse to much better) so no data were available on 'subjective' cure.

17.1.2 Self reported cure/improvement
On the basis of a single trial in women with genuine stress incontinence, detrusor instability or both (Wyman 1998), self reported cure/improvement was more likely with combined PFMT/bladder training than PFMT alone (PFMT 48/64, PFMT/bladder training 55/61).

17.1.3 Other
Wyman et al (Wyman 1998) also asked women to rate their perception of improvement and satisfaction with outcome of treatment.

17.2 Quantification of symptoms

17.2.1 Urinary diary (leakage episodes)
A seven day urinary diary was completed by women in the trial by Wyman et al (Wyman 1998). The data were presented separately for women with stress incontinence only (Wyman 1998a) versus the women with detrusor instability with or without genuine stress incontinence (Wyman 1998b). Unfortunately the lack of variation in the PFMT group (standard deviation 0.0) for women with genuine stress incontinence has meant that a confidence interval cannot be calculated in the formal comparison. The data from women with detrusor instability with or without genuine stress incontinence found no statistically significant difference between the groups (PFMT, n=18, mean 1.7 sd 1.8 versus PFMT/bladder training, n=16, mean 0.8 sd 1.3).

17.2.2 Pad test
Although a pad test was included in the trial the amount of missing data for this outcome immediately after treatment and at 3 month follow up meant that the analysis was not reported in the original publication.

17.3 Clinicians' measures
Digital palpation of the pelvic floor muscles was performed at initial assessment but this was not apparently repeated post treatment.

17.4 Quality of life
Validated generic and condition specific quality of life questionnaires were used: the SF36, Incontinence Impact Questionnaire - Revised, and the Urogenital Distress Inventory. Immediately post treatment Wyman et al (Wyman 1998) noted that women with detrusor instability in the combination therapy group reported significantly less life impact than those in the PFMT group . At three months after treatment there was no statistically significant difference between the groups for any quality of life measure.

17.5 Socioeconomics
No formal economic analysis was undertaken but women were asked how satisfied they were with the outcome of treatment. Fifty of the 61 women in the combination therapy group were very satisfied with the outcome of treatment, as were 46/64 in the PFMT group.

17.6 Other

17.6.1 Adverse events
There was no record of adverse events in the trial.

17.6.2 Withdrawal/losses to follow up
Reasons for withdrawal were reported, but group allocation was not. There was some inconsistency in the number of reported withdrawals and the number of women for whom data were reported immediately after treatment (three months). Of the 204 women originally randomised data were reported for 193 of them.

17.6.3 'Compliance'
The proportion of attendance for clinic visits, the mean number of recommended voids (behavioural therapy group), and the mean number of pelvic floor muscle contractions (PFMT groups) were used as measures of how well women managed to cope with the requirements of training. In the combination therapy group 73% of women attended all six clinic visits, compared with 53% in the PFMT group. Eighty-one percent of women in the combination therapy group were able to complete the scheduled voiding programme as recommended, and three months after completion of treatment 40% were still using the scheduled voiding programme. The combination therapy group managed 78% of the recommended PFMT compared with 84% of women in the PFMT group, and at three months post treatment the numbers doing PFMT most of the time had decreased to 58% and 64% respectively.

17.6.4 Incontinence at long term follow up
Further follow up was undertaken 3 months after the end of treatment. Wyman et al (Wyman 1998) stated that there were no statistically significant differences between the groups for the number of incontinent episodes per week, quality of life measures, or satisfaction with outcome. However it was noted

that the number of women in the PFMT group who reported complete remission of leakage episodes continued to increase over the follow up period while there was no further change in the combination therapy group.

DISCUSSION

1. Hypothesis one - PFMT is better than no treatment
Seven trials, that randomised a total of 679 women (371 PFMT, 308 no treatment), addressed this comparison.

All women
Three formal comparisons (self reported cure, self reported cure/improvement, and leakage episodes in 24 hours) suggested that PFMT was significantly better than no treatment in women with stress and/or mixed incontinence. Statistically significant heterogeneity was observed for the comparison of leakage episodes. The trial by Bø et al (Bø 1999) was of high methodological quality but also offered women in the no treatment group the use of an anti-incontinence device. Either of these might explain the smaller treatment effect seen in this trial although viewed alone it still showed significant benefit of PFMT.

A variety of short pad tests (three trials) consistently found a greater reduction in leakage in women who had PFMT. Three trials assessed pelvic floor muscle activity. Two trials, in women with stress and/or mixed incontinence, reported greater improvement in the pelvic floor muscle measures after training. One trial, in women with symptoms of urine leakage found no difference but the muscles were remeasured after a single week of training that this may be insufficient time for any effect to be observed.

Quality of life has not been addressed using a validated measure, but one trial indicated that women in the PFMT groups had significant improvements in the Social Activity Index compared with women receiving no treatment. Although no formal economic analysis has been done a single trial indicated that only 4/25 women with genuine stress incontinence wanted further treatment after PFMT compared with 28/30 women who had received no treatment.

Sensitivity analysis - women with stress incontinence alone (symptom or urodynamic)
Two data sets from women with stress incontinence alone contributed to the formal comparison of self reported cure/improvement. When the data were combined PFMT was significantly better than no treatment.

Adverse events, withdrawals
Few, minor, adverse events were reported with PFMT and all of them were reversible. The number of withdrawals from both PFMT and no treatment groups was similar.

Other comments
It is interesting to note the wide range of that appeared to be effective. This raises a number of questions about which

element, or combinations of elements, of training are most effective. Some trials (e.g. Bø 1990, Bø 1999) have based the PFMT training programme on accepted physiological principles of strength training. Other trials have been less explicit about the physiological reasoning underlying their choice of programme. The recent trial by Miller et al (Miller 1998) is the first trial to investigate the effect of the use of a voluntary pelvic floor muscle contraction prior to an anticipated change in intra-abdominal pressure without the more traditional strength training. The apparent benefit of this education/advice after one week suggests that learning to time a voluntary pelvic floor muscle contraction to prevent leakage might be one element of an effective training programme.

Anecdotally, contact with a health care professional for treatment of a urine leakage problem usually includes considerable advice/education on the anatomy and physiology of the bladder and pelvic floor, lifestyle advice (e.g. fluids, weight, posture and ergonomics of lifting etc), and information on good bladder habits. These elements of 'intervention' are rarely reported and their effect has not been investigated. It is therefore difficult to determine if the effect of an intervention such as PFMT in comparison to no treatment reflects the effect of PFMT, the effect of the advice/education given in addition to the training programme, or a combination of both.

PFMT is generally thought to be of greatest benefit for women with genuine stress incontinence. The formal comparisons suggest that women with symptoms and/or urodynamic diagnoses of stress or mixed incontinence may benefit. Sensitivity analysis, where appropriate, did not show a different effect in women with symptoms of stress or mixed incontinence versus women with urodynamic diagnosis of genuine stress incontinence. This raises the question whether women need urodynamic testing prior to referral for conservative management of a urine leakage problem. In the course of the search for trials suitable for inclusion in the review a single RCT was found in which women were randomised to receive urodynamics, or not, prior to conservative management (PFMT and/or behavioural training) of urine leakage (Ramsay 1994). The two groups had treatment based on their diagnosis by urodynamics or symptom reporting but there was no significant difference in outcome between the groups. It seems PFMT may be an effective first line treatment for women with symptoms of stress or mixed incontinence and that the need for urodynamic investigation prior to conservative management has not been established.

Other characteristics might well affect treatment prognosis (e.g. age, previous pelvic surgery, etc). Specific investigation of these characteristics and effects was beyond the scope of the review although their contribution to the observed heterogeneity in some comparisons is discussed where appropriate. It is worth noting some trials in the review used highly selected samples of women with a number of explicit inclusion/exclusion criteria while others were as inclusive of women with urine leakage problems as possible. Readers are advised to review the

characteristics of individual trials, see Table of Included Studies, as appropriate.

2. Hypothesis two - PFMT is better than placebo treatment
Three trials, that randomised a total of 208 women (109 PFMT, 99 placebo treatment), addressed this comparison.

All women
Three formal comparisons (self reported cure, self reported cure/improvement, and leakage episodes in 24 hours) suggested that PFMT was significantly better than placebo treatment in women with stress and/or mixed incontinence and/or detrusor instability. Statistically significant heterogeneity was observed for the comparison of self reported cure/improvement. The likely source of the heterogeneity is the comparison of PFMT and placebo PFMT, which did not show any difference between the treatments. It is possible that the placebo programme did in fact 'train' the pelvic floor muscles unintentionally. It does not appear to be appropriate to combine the placebo PFMT data with other placebo comparisons.

Quality of life was not investigated. No formal economic analysis was undertaken but one trial in women with detrusor instability with or without genuine stress incontinence did ask women if they wanted further treatment on completion of the trial. More than three-quarters of the women in the placebo medication group wanted further treatment.

Sensitivity analysis - women with stress incontinence (symptom or urodynamic)
No more than one trial in women with stress incontinence alone contributed to each comparison therefore formal sensitivity analysis was not appropriate.

Adverse events, withdrawals
Women receiving placebo medication were more likely to report a dry mouth than those in a comparison PFMT group. Two of the trials apparently had no withdrawals from either PFMT or placebo treatment arms, but there were three times more dropouts in the placebo medication group than the PFMT group.

Other comments
The formal comparisons suggest that the treatment effect is greater when PFMT is compared with no treatment than when PFMT is compared with placebo treatments. Placebo treatments are substantially different from no treatment. It is possible, for example, that women in placebo groups received the usual advice/education component of treatment, along with the sham treatment, as a result of their contact with a health professional. Unfortunately advice/education are rarely documented. The reduced treatment effect might reflect the anecdotal evidence of improvement many women with urine leakage experience with simple information and lifestyle changes (e.g. caffeine reduction).

3. Hypothesis three - There is a difference in the effectiveness of different PFMT programmes
Six trials, in 1080 women (580 'standard PFMT', 500 'intensive PFMT') addressed this comparison. Two trials compared

standard home based PFMT versus home-based training assisted by audiotape. Two trials, in postnatal women, compared standard antenatal/postnatal care (that probably included instruction in PFMT) versus an individualised programme of postnatal PFMT. The other two trials compared a standard home-based PFMT programme with a programme that included more contact with a physiotherapist resulting in more 'intensive' training. Therefore the comparison is 'intensive' versus 'standard' PFMT.

All women
The formal comparison for self reported cure suggested that 'intensive' PFMT was significantly better than 'standard' PFMT in women with genuine stress incontinence or postnatal symptoms of urine leakage. Two of the trials were in postnatal women while the other was in a group of women who were somewhat older at the time of treatment. In the two postnatal trials 'individualised' PFMT training was shown to be better than 'standard' postnatal care at reducing the prevalence of urinary leakage. In the other trial greater contact with the physiotherapist (home training plus weekly exercise class) was better than home training alone. Similarly self reported cure/improvement was significantly more likely with 'intensive' training in women with genuine stress incontinence.

There were contrasting findings for short pad tests. A trial in postnatal women with urine leakage found no difference between the groups, as did a trial in progress in women with genuine stress incontinence. However the other trial in women with genuine stress incontinence found that the 'intensive' training group had a significant reduction in leakage with a 90 second stress test. The same trials measured pelvic floor muscle activity and all found significant improvements over baseline. The trial in postnatal women found no difference between the groups post treatment. Two trials were in women with genuine stress incontinence (one of them a trial in progress), and found a significant difference in favour of the 'intensive' group while the other did not. The trial that found the difference measured women after six months of training while women in the other, incomplete trial, were remeasured after only four weeks.

One trial used a validated measure of anxiety and depression and found that postnatal women receiving 'individualised' PFMT appeared to be less anxious or depressed than the 'standard' treatment group. No other generic or condition specific quality of life measure was used and no formal economic analysis has been undertaken. The average time taken to teach the 'individualised' was 32 minutes.

Sensitivity analysis - women with stress incontinence (symptom or urodynamic)
Two data sets from women with stress incontinence alone contributed to the formal comparison of self reported cure. When the data were combined 'intensive' PFMT was significantly better than 'standard' training for women with stress incontinence.

Adverse events, withdrawals

No adverse events were reported but the withdrawal rate from 'standard' treatments was slightly higher than 'intensive' treatment groups.

Other comments

All the trials included in this comparison used outpatient based programmes, and this is the usual method of service delivery for conservative management of urinary incontinence in women. However, in the search for trials suitable for inclusion in the review an RCT comparing inpatient and outpatient conservative management (PFMT, behavioural training) for women with a mixed pattern of urinary symptoms (frequency, urgency, nocturia, urge and stress leakage) was found (Ramsay 1996). Seventy-four women were randomised to inpatient or outpatient care and both groups had significant improvement in symptoms but there was no statistically significant difference in the number of women in each group that required further treatment. The cost of outpatient care was half that of inpatient care. On the basis of the limited evidence available the current emphasis on outpatient based care seems appropriate.

4. Hypothesis four - PFMT is better than any other 'single' treatment

A. PFMT versus electrical stimulation

Eight trials, that randomised 295 women with genuine stress incontinence compared PFMT (145 women) and electrical stimulation (150 women). Three trials used Interferential Therapy, four trials used some other form of alternating current, and in one trial the type of stimulation was not specified. All the trials were undertaken in samples of women with genuine stress incontinence.

Women with stress incontinence

For women with stress incontinence the formal comparison suggested that there was no statistically significant difference between PFMT and electrical stimulation for self reported cure. Statistically however, this comparison is extremely close to favouring PFMT. While no statistical heterogeneity was observed there were considerable differences in the stimulation protocols. Some readers might consider the extent of the clinical heterogeneity should preclude pooling of these data. Similarly, no statistically significant difference in the rate of self reported cure/improvement was found in the formal comparison and no statistical heterogeneity was found. However, visual inspection of the data plot suggested clinical heterogeneity (i.e. the two trials comparing PFMT and interferential therapy appear different from the two trials that compared PFMT with long term stimulation). If the data from the two trials that used long term intravaginal stimulation are pooled PFMT is more effective than electrical stimulation for self reported cure/improvement. One trial found no difference between the groups for leakage episodes in 24 hours but this was statistically very close to favouring PFMT.

A variety of short pad tests were used. Two trials found that women in the PFMT groups had a greater reduction in leakage than the electrical stimulation groups. The remaining four trials found that both groups significantly improved with treatment but that there was no statistically significant difference between the groups. The single trial that used a long pad test found no statistically significant difference between the groups. Two trials measured pelvic floor muscle activity. One trial found significant change in the PFMT group (perineometry) and the other trial found significant change in the stimulation group (digital palpation).

Quality of life has not been addressed using a validated measure, but one trial found that women in the PFMT group had significant improvements in the Social Activity Index when compared with women in the stimulation group. While no formal economic analysis has been done a single trial found that 4/25 women wanted further treatment after PFMT in contrast to 19/25 in the stimulation group.

Adverse events, withdrawals

All the adverse events that were reported occurred in the electrical stimulation groups. Sixteen women (of 150) reported an adverse event. On the basis of the available data the dropout rate was slightly higher in the PFMT than stimulation groups. However one trial that contributed drop out data was incomplete and two further trials documented withdrawals without group allocation. It is not clear if there was a real difference in withdrawal rates between the treatments.

Other comments

It appears that the prior decision to combine all types of electrical stimulation trials might not be appropriate. For instance the effects of maximal short-term medium frequency current (e.g. interferential trials) might be different from the effects of low intensity long-term current. Interested readers are referred to the Protocol for a Cochrane Review: Electrical stimulation for the treatment of urinary incontinence in women.

B. PFMT versus vaginal cones

Seven trials, that randomised 539 women, compared PFMT (320 women) and vaginal cones (219 women).

All women

The three formal comparisons gave contrasting findings. There was no difference in the rates of self reported cure between the PFMT and cones groups for women with genuine stress incontinence or postnatal women with urine leakage. The rate of self reported cure/improvement in women with genuine stress incontinence was significantly greater in the PFMT group in one trial but not in two others. The combined data showed no significant difference between the interventions. The trial demonstrating benefit was longer (six months versus four weeks or twelve) and the longer training period might be necessary to show the true effect of PFMT. Finally the combined data from two trials in women with genuine stress incontinence found significantly fewer leakage episodes in 24 hours in the PFMT group.

Contrasting results were found using a variety of short pad tests. The trial in postnatal women with symptoms of urine leakage

found that the cones groups had less leakage than the PFMT group. However the remaining four trials, all in women with genuine stress incontinence, found either significant improvement in both groups with no difference between the groups (three trials) or greater benefit in the PFMT group (one trial).

One trial found no statistically significant difference in the groups post treatment for quality of life using an incontinence specific measure (King's Health Questionnaire). Similarly two further trials found improvements in both groups using non-validated measures. No formal economic analysis has been done. However, one trial found that women in the cones group were much more likely to want further treatment than women in the PFMT group. Two trials reported the number of women referred for surgery after treatment and there was no apparent difference between the groups. Finally, the trial in postnatal women found no statistically significant difference in the time taken to teach PFMT or vaginal cones.

Sensitivity analysis - women with stress incontinence (symptom and urodynamic)
No sensitivity analyses were appropriate. However readers are referred to the formal comparisons of self reported cure/improvement and leakage episodes (as above) as these comparisons included trials in women with genuine stress incontinence only.

Adverse events, withdrawals
All the reported adverse events were in the cones groups; 40 adverse events in 219 women. One further trial collected data on adverse events but this has not yet been published. Treatment withdrawals were similar in PFMT and cones groups. However, the conditions imposed by clinical research (e.g. repeated follow up) might not reflect usual practice. With the higher adverse events rate in the cones group it would be interesting to know if this is reflected in high dropout rates from cones treatment in clinical practice.

Other comments
The effectiveness of vaginal cones has been investigated in a separate Cochrane Review: Vaginal cones for women with urinary incontinence.

C. PFMT versus behavioural training
A single trial in 132 women with genuine stress incontinence, detrusor instability or both compared PFMT and behavioural (bladder) training. There was no statistically significant difference between the groups for rate of self reported cure/improvement, or number of leakage episodes in 24 hours. The trial used generic and incontinence specific, validated, quality of life measures and found no statistically significant differences between the groups. No formal economic analysis was undertaken but the proportion of women who were satisfied with the outcome of treatment was similar in both groups. A separate Cochrane Review: Bladder training for women with urinary incontinence is available.

D. PFMT versus medication
Four trials compared PFMT and a pharmaceutical treatment. One trial (132 women) compared PFMT and an anticholinergic (oxybutynin chloride) in women with detrusor instability with or without genuine stress incontinence. Two trials (69 women) compared PFMT and topical oestrogens (Premarin) in women with genuine stress incontinence. The remaining trial (159 women) compared PFMT and an alpha adrenergic (phenylpropanolamine hydrochloride) in women with stress or mixed incontinence.

Oestrogen medication
Neither of the trials investigating the effect of oestrogens versus PFMT for women with genuine stress incontinence contributed any data to the formal comparisons. Both trials found that women in the PFMT group were more likely to be cured or improved on short pad test. The combined data strongly favours PFMT (21/34 women cured/improved on short pad test after PFMT versus 3/35 women from the oestrogen group). No data on quality of life was reported and nor formal economic analysis completed.

Anticholinergic medication
For women with detrusor instability with or without genuine stress incontinence there was no statistically significant difference in the rate of self reported cure between PFMT and anticholinergic medication groups. However, PFMT was better than anticholinergic for self reported cure/improvement and the number of leakage episodes in 24 hours. Quality of life was not investigated and no formal economic analysis was undertaken. However noticeably fewer women in the PFMT group wanted further treatment on completion of the trial.

Alpha adrenergic medication
For women with stress or mixed incontinence there was no statistically significant difference in the rate of self reported cure/improvement between PFMT and alpha adrenergic medication groups. The medication group had fewer leakage episodes in 24 hours than the PFMT group but on pad test there was no statistically significant difference between the groups. Women in the PFMT group had higher digital palpation scores, but the EMG measures of pelvic floor muscle activity showed no statistically significant differences between groups. Quality of life was not investigated and no formal economic analysis was undertaken.

Adverse events, withdrawals
The trial that compared anticholinergic medication and PFMT used a adverse events checklist and found that two side effects of medication (dry mouth and inability to void) were more common in the medication than placebo medication group. There was no direct comparison of medication and PFMT groups but dry mouth was reported by significantly fewer women in the PFMT group than the placebo medication group. There were twice as many withdrawals from medication groups (23/142) than from PFMT (12/147).

Other comments

Only one of the medications (topical oestrogen) has been compared with PFMT in more than one trial. Both trials were small, and one of them was reported briefly in abstract form only. In view of the frequent use of both conservative therapies and pharmaceutical treatments in the management of urinary incontinence that lack of comparison of the effectiveness of these treatments is disappointing.

E: PFMT versus surgery
Two trials randomised a total of 94 women with genuine stress incontinence to PFMT or surgery, but only one trial contributed data to the formal analysis. Many more women were cured in the surgery group, but there was no statistically significant difference in the rate of self reported cure/improvement. Both groups showed significant reduction in the number of leakage episodes measured using a three day urinary diary but the surgical group had a significantly greater reduction. No validated quality of life measure was used and no formal economic analysis undertaken. Over a 12 month period 14/24 women in the PFMT group and 7/26 women in the surgical group wanted the alternative treatment. The adverse events reported were all post-surgical (five women). For readers interested in the effectiveness of surgery for women with urinary incontinence, separate Cochrane reviews are available, e.g. Sling operations for urinary incontinence in women.

5. Hypothesis five - PFMT adds benefit to another therapy when compared with the same therapy alone
A. PFMT with electrical stimulation versus electrical stimulation alone
Twenty-two women with genuine stress incontinence were randomised in a trial comparing electrical stimulation with PFMT versus stimulation alone and there was no statistically significant difference in the rate of self reported cure or self reported cure/improvement between the groups. No data for any other prespecified outcomes were reported.

B. PFMT with vaginal cones versus vaginal cones alone
No data from the single trial of 42 women with genuine stress incontinence was suitable for formal analysis. The trial report stated that women in both groups had significant symptomatic improvement (self-report) but the combined therapy group had greater improvement. A short pad test found significant improvement in both groups with no statistically significant differences between the groups, but more women in the combined therapy group were 'improved' (not defined) on pad test.

C. PFMT with behavioural training versus behavioural training alone
A single trial compared PFMT/behavioural training versus behavioural training in 129 women with genuine stress incontinence, detrusor instability or both. The combination therapy was better than behavioural training alone for self reported cure/improvement but there was no statistically significant difference between the groups for the number of leakage episodes in 24 hours. The trial presented the data on leakage episodes separately for women with stress incontinence separately and for these women combination therapy resulted in fewer leakage episodes in 24 hours. A validated incontinence specific quality of life questionnaire found no statistically significant difference between the groups at three months after treatment. No formal economic analysis was undertaken but slightly more women in the combined therapy group were very satisfied with the outcome of treatment.

D. PFMT with anti-incontinence device versus anti-incontinence device alone
The single trial in women with mixed incontinence that compared PFMT/incontinence device versus device alone did not contribute any data to the formal analysis. This trial was reported in two abstracts as a trial in progress. A full publication of what appeared to be the same trial was found but no mention of random allocation to treatment groups was made and the data for the whole cohort was reported. From the very limited, and incomplete, data available it appeared that quality of life was improved in both groups but the dropout rate was quite high as quite a number of women found the device difficult to apply or were not inclined to touch the genital area.

6. Hypothesis six - PFMT in combination with any other 'single' treatment is better than PFMT alone
A. PFMT with biofeedback versus PFMT alone
Ten trials that randomised 389 women compared PFMT with biofeedback (209 women) versus PFMT alone (180 women). Only three of the 10 trials contributed data to the formal analysis so the findings should be viewed with some caution. Two of the 10 trials were in women with genuine stress incontinence with or without detrusor instability. The eight remaining trials were all in women with genuine stress incontinence (four trials) or women with symptoms of stress leakage only (four trials).

All women
None of the three formal comparisons (self reported cure, self reported cure/improvement, leakage episodes in 24 hours) found any statistically significant difference between PFMT and PFMT/biofeedback groups. The formal comparison of self reported cure/improvement did show statistically significant heterogeneity. The lack of detail in the two trial reports makes it difficult to explore fully the reasons for this heterogeneity. One difference is the length of treatment (six weeks versus nine weeks) and it might be that biofeedback assisted groups see earlier improvement, but the difference between groups diminishes with time. Another difference was there was inequity in the number of treatments for biofeedback and PFMT groups in one study; women in the biofeedback group had more treatments on average than women in PFMT group. Both these trials were in women with genuine stress incontinence.

Three trials, all in women with stress incontinence only, included a short pad test. All found significant reductions in leakage in both groups, and in two trials this favoured the biofeedback group although the difference was not significant. Only one trial used a long pad test and while both groups had

significant reduction in leakage there was no statistically significant difference between the groups. While several trials in women with stress incontinence measured pelvic floor muscle activity none presented any viable data for interpretation. One of the two trials that included women with genuine stress incontinence with or without detrusor instability measured pelvic floor muscle activity and found that sustained contraction 'strength' was greater in the biofeedback than PFMT group.

Two trials, in women with stress incontinence, used validated incontinence specific quality of life measures. One trial found no statistically significant difference between the groups while the other found considerable improvements in the biofeedback group. However the latter trial was small and incomplete at the time of reporting. No formal economic analysis was undertaken. One trial did record the number of clinic treatments in each group and found no statistically significant difference between them.

Sensitivity analysis - women with stress incontinence (symptoms or urodynamic)
No sensitivity analyses were appropriate. However readers are referred to the formal comparison of self reported cure/improvement (as above) as this comparison included trials in women with genuine stress incontinence only.

Adverse events, withdrawals
One trial reported that no adverse events were noted in either group. In another trial adverse events were also recorded but these data have not yet been published. There were fewer losses from treatment in the biofeedback group but the difference was not marked being about five percent.

Other comments
This comparison contained the greatest number of trials of any comparison in the review. It is therefore disappointing that there were so few outcome measures in common and little consistency in reporting the outcomes that were used across several trials. This might in part reflect the uncertainty of how best to measure the effects of biofeedback assisted training. For example, does biofeedback improve 'compliance' or rate of improvement? However, the primary measure of effect needs to be one that matters to women, e.g. self report of change in leakage symptoms or desire for further treatment.

B. PFMT with intravaginal resistance versus PFMT alone
Four trials were included in this comparison. Two of the trials clearly compared PFMT versus resisted PFMT, while there was some uncertainty about the classification of the other two trials. Neither of the two trials that definitely compared PFMT and resisted PFMT contributed any data to the formal comparisons. Only the two trials that had also been included in the biofeedback comparison contributed data to the formal analysis, and both of these were in women with genuine stress incontinence. It does not seem appropriate to report the findings from the formal analysis twice under both subheadings. Readers are encouraged to refer to the data plots if they wish to interpret the data.

Pad test data from one trial that definitely investigated the effect of intravaginal resistance training in women with genuine stress incontinence found no statistically significant difference between the groups on short or long pad test. The same trial found that both groups had an improvement in the measures of pelvic floor muscle activity. Quality of life was not addressed using a validated measure and formal economic analysis was not undertaken.

C. PFMT with electrical stimulation versus PFMT alone
Four trials, all in women with genuine stress incontinence, compared PFMT with electrical stimulation versus PFMT alone. A total of 174 women were randomised. No statistically significant difference was observed between the groups for rate of self reported cure or self reported cure/improvement. One trial reported pad test data and found that both groups improved significantly but that there was no statistically significant difference between the groups. Similarly both groups had significant improvements in the measures of pelvic floor muscle activity but there was no statistically significant difference between the groups.

Quality of life was not addressed using a validated measure and no formal economic analysis was undertaken. Two trials reported the number of women who requested surgery following treatment and there was no apparent difference between the groups.

D. PFMT with vaginal cones versus PFMT alone
Two trials in 140 women compared PFMT with vaginal cones versus PFMT alone.

All women
Neither of the two formal comparisons (self reported cure, self reported cure/improvement) found a statistically significant difference between the groups. For self reported cure a single trial, in postnatal women with urine leakage, contributed two data sets to the comparison. One data set (PFMT/cones taught individually by a therapist versus standard postnatal care) favoured cones but the more equitable comparison (individual training in PFMT/cones or PFMT alone) found no statistically significant difference between the groups. A single trial in women with genuine stress incontinence did not find any difference between the groups for self reported cure/improvement.

In the trial of postnatal women with urine leakage no statistically significant difference was found between the groups in the measure of pelvic floor muscle activity post treatment. Neither trial addressed quality of life, and no formal economic analysis was undertaken. However the trial in postnatal women compared the time taken to teach PFMT/cones versus PFMT alone. The combined treatment took six minutes longer on average.

Sensitivity analysis - women with stress incontinence (symptom or urodynamic)
No sensitivity analyses were appropriate. However readers are referred to the formal comparison of self reported

cure/improvement (as above) as this comparison included trials in women with genuine stress incontinence only.

Adverse events, withdrawals
Adverse events were not mentioned in either of the two trials. The dropout rate was higher in the PFMT/cones group than the PFMT group.

Other comments
Readers who are interested specifically in the effectiveness of vaginal cones are referred to a separate Cochrane Review: Vaginal cones for women with urinary incontinence.

E. PFMT with behavioural training versus PFMT alone
A single trial of 125 women with genuine stress incontinence, detrusor instability or both compared PFMT/behavioural (bladder) training versus PFMT alone. Women found the combined therapy better for improvement in symptoms, but there was no statistically significant difference between the groups for the number of leakage episodes in 24 hours or validated incontinence specific quality of life measure. No formal economic analysis was undertaken but more women in the combined therapy group were very satisfied with the outcome of treatment. A separate Cochrane Review: Bladder training for women with urinary incontinence is available.

7. Other findings

A. 'Compliance'
The degree to which women were able to meet the requirements of and other interventions was measured in few studies. No clear picture emerged although it seemed women in 'intensive' PFMT groups were more likely to complete the recommended training requirements than women in 'standard' PFMT groups. Overall the degree to which women were able to complete the recommended PFMT varied from nearly all of it (i.e. reported compliance of 93%, Bø 1999) to very little (i.e. only 15% of recommended contractions, Ramsay 1990). On the limited data available it was not possible to determine if women were more or less likely to complete PFMT requirements than training with cones, stimulation etc. In view of the potential for confounding treatment effects readers should view each trial separately.

B. Long term follow up
Follow up beyond the end of the treatment period was reported by approximately a quarter of trials. The shortest length of follow up reported was three months after treatment was completed (Burns 1993; Wyman 1998) and the longest five years (Bø 1990). Unfortunately follow up data were difficult to interpret. Problems included trials that followed up only one of the comparison groups, or reported the findings for the whole cohort rather than by group allocation, or the difficulties imposed by inadequate questionnaire returns or inability to trace an adequate proportion of the original sample. With regard to PFMT it seemed that some women continued with training on a regular basis but many continued with irregular training or

not at all. Overall, training rates decreased between post treatment assessment and longer-term follow up.

C: Quality of life and socioeconomics
Validated and reproducible quality of life measures for women with urinary incontinence are now available. Very few trials included in the review used such a measure. Many of the included trials predated the development of these instruments. It is pleasing to see some of the included trials completed within the last few years have used validated quality of life measure. However it is disappointing that this outcome domain that has also been neglected in recent trials.

Very little socioeconomic data have been collected as part of the included trials. None of the included trials were accompanied by a cost description, cost analysis or cost effectiveness study.

8. Cautions
Although 43 trials were included in the review few trials have addressed similar hypotheses, and there was considerable variation in the choice of outcomes and outcome reporting between trials. This has lead to a large number of comparisons and has meant that much of the 'evidence' presented in the review is based on the findings of a single trial only. Due caution is advised in interpreting any evidence based on the findings of a single trial, particularly as many of the trials included in this review were small and of poor to moderate quality.

A number of the formal comparisons are based trials with small or zero cell counts resulting in some instability of the estimate of relative risk based on these data. In addition zero cells, in particular, may affect the estimate of the confidence interval and confidence intervals based on these data may be wider or narrower than the true confidence interval. Considerable caution is required in interpreting comparisons based on small or zero cell counts because it is not known to what extent the findings of the review have been affected by this problem.

About one third of the included trials were published only as abstracts and their reporting of method and data were extremely limited. The planned 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 what extent the variable quality of the included trials has affected the findings of the review.
Significant heterogeneity was found in some comparisons and where this was observed it has been noted in the text, and commented on. Any comparison affected in this way should be interpreted and used with some caution.

To reduce the complexity of comparisons in the review a number of trials were classified as comparisons of PFMT with another therapy although PFMT had been combined with another treatment (e.g. a trial comparing PFMT with biofeedback versus no treatment was classified as a trial comparing PFMT with no treatment). Trials affected in this

way were Burgio et al (Burgio 1998, PFMT with urge strategies), Burns et al (Burns 1993, PFMT with biofeedback), Cammu & Van Nylen (Cammu 1998, PFMT with biofeedback), Hofbauer et al (Hofbauer 1990, PFMT with electrical stimulation), Laycock & Jerwood (Laycock 1993, PFMT with vaginal cones), Terry & Whyte (Terry 1996, PFMT with electrical stimulation), and Wise et al (Wise 1993, PFMT with vaginal cones). On the basis of the limited evidence available it does not appear that the addition of any of these therapies to PFMT was likely to significantly alter the effect of PFMT one way or the other. The pragmatic classification of these trials was therefore considered to be acceptable.

9. Problems

A: Outcome measures

One of the major problems encountered by the authors of the review was the lack of consistency in the outcomes measures used. In part the lack of consensus is due to the limited number of measures with established reliability and validity designed for assessing outcome for women with urinary incontinence. However, the focus on surrogate endpoints (e.g. urodynamic measures, measures of pelvic floor muscle strength, pad tests etc) is disappointing. Some of the more recent trials included in the review (e.g. Wyman 1998) have used condition specific quality of life questionnaires, and other newer instruments with established reliability and validity, and this is encouraging.

Another problem was the variability in methods of reporting data. Unfortunately this has meant large amounts of data have been lost in the analysis, either through reduction to a common denominator (e.g. leakage episodes in 24 hours) or because the data could not be combined in its reported form.

The choice of outcomes presented in the formal analysis has partly been dictated by the information available. At present the only outcome domains represented in the formal analysis include the women's observations (self reported cure or cure/improvement) and quantification of symptoms (leakage episodes in 24 hours). Other outcome domains (i.e. clinician's measures, quality of life, socioeconomics) were not considered to be less important but as it was not appropriate to combine the data that were available, these elements have been omitted from the formal analysis. Even those outcomes that were included in the formal analysis are acknowledged to be less than ideal in some respects. For example the number of leakage episodes in 24 hours is a measure of limited usefulness if leakage is related to activity. If these activities are avoided then the amount of leakage is reduced and this may lead to a false impression of improvement. Perhaps more important for women is the range of activities they have curtailed or stopped to cope with leakage. The physical domain in a quality of life questionnaire is intended to assess such effects and this further supports the need for inclusion of validated quality of life measures in subsequent trials.

B: Descriptions of PFMT

In general, the PFMT programs used in the included trials were poorly reported. It was therefore difficult to make judgements about the similarities and differences between the training programs and to what extent this contributed to the heterogeneity observed in some comparisons. The programs varied widely and few included trials provided any theoretical rationale to support their choice of training program.

C: Subgroup analysis

As mentioned previously in the method, the planned subgroup analysis (by diagnosis) was rejected in favour of sensitivity analysis. This was because it became clear that it would not be possible to place the trials into three subgroups - stress incontinence, mixed incontinence, urge incontinence. Some trials included women with predominantly genuine stress incontinence only, with less than 10% of the sample having mixed incontinence (e.g. Burns 1993; Wells 1991). Other trials, such as that by Wyman et al (Wyman 1998) included women with genuine stress incontinence (71%), detrusor instability (14%) and women with both diagnoses (15%). Finally there were trials such as that by Burgio et al (Burgio 1998) that included women with detrusor instability with or without genuine stress incontinence. There was no easy way to group the trials without the analysis becoming unwieldy due to large numbers of subgroups to cater for all these combinations, or without severely compromising the homogeneity of the intended subgroups. Consequently the authors chose to group all the trials, and carry out sensitivity analysis on the basis of diagnosis where appropriate.

Some of the difficulty with subgrouping has arisen from the lack of consistency in the original trials with respect to describing the sample. Some trials have used the criteria standardised by the International Continence Society while others have not. In addition there have been changes in diagnostic procedures and classification criteria over the time span in which trials contributing to this review have been published. The use of the definitions and classification of urinary incontinence proposed by the International Continence Society is recommended.

REVIEWER'S CONCLUSIONS

Implications for practice

Is PFMT better than no treatment or placebo treatments?
PFMT appeared to be consistently better than no treatment and placebo treatments for women with both stress and/or mixed incontinence. Few side effects of PFMT were noted and all were minor and easily reversible. There is some evidence to support the widespread recommendation that PFMT should be offered as first line conservative management to women with stress and/or mixed incontinence.

Is 'intensive' PFMT better than 'standard' PFMT?
There is some evidence to suggest that more 'intensive' are of greater benefit than 'standard' training in women with stress

incontinence and postnatal women with symptoms of urine leakage. In the trials that demonstrated this effect the women in the 'intensive' training groups all had increased personal contact with a health care professional with special skill in teaching/supervising PFMT (e.g. in a weekly exercise class or in individual appointments).

Is PFMT better than electrical stimulation?
Trials comparing PFMT and electrical stimulation were difficult to interpret because there were limitations in combining the eight studies available. None of the three formal analyses show any statistically significant difference between PFMT and electrical stimulation in women with genuine stress incontinence. However, two of the three formal analyses almost reach the point of significance in favour of PFMT. If data on rates of self reported cure/improvement from the two trials that compared PFMT and long-term intravaginal stimulation are combined then PFMT appeared to offer greater benefit for women with genuine stress incontinence. It might be that a particular subgroup of women benefit from electrical stimulation, such as those who are unable to voluntarily contract the pelvic floor muscles. However, on the limited evidence available PFMT may be more effective than the types of stimulation that have been tested so far. Adverse events rates also appear to be higher with electrical stimulation.

Is PFMT better than vaginal cones?
The data from comparisons of PFMT and vaginal cones are also difficult to interpret due to differences in the design of the included trials. Improvement in the number of leakage episodes in women with genuine stress incontinence was found in the PFMT groups but other outcomes were less clear-cut. It is possible that improvement with PFMT is more likely after a reasonable training period (i.e. six months). Overall there was insufficient evidence to determine if PFMT was better or worse than cones. However, side effects of training were only reported in the cones group and clearly some women do not find cones acceptable or comfortable to use.

Is PFMT better than any other treatment?
For the remaining comparisons of PFMT with other conservative, pharmaceutical or surgical treatments the evidence is very limited. For most only a single trial was found and/or the trial reporting was very poor. The following statements should be viewed only as hypotheses that require further testing. On the basis of a single trial in women with genuine stress incontinence, detrusor instability or both there might be no statistically significant difference between PFMT and behavioural training. In women with stress and mixed incontinence there might be no statistically significant difference between PFMT and alpha adrenergic medication, but in women with detrusor instability with or without genuine stress incontinence PFMT might be better than anticholinergic medication. In women with genuine stress incontinence PFMT might be better than topical oestrogens, but surgery might be better than PFMT.

Does the addition of PFMT to another therapy add benefit?
Only single trials investigated the benefit of adding PFMT to electrical stimulation, vaginal cones, behavioural training, and to the use of an anti-incontinence device. Therefore, the following statements should be viewed only as hypotheses that require further testing. For women with genuine stress incontinence there is no benefit in adding PFMT to electrical stimulation but PFMT might add benefit to treatment with vaginal cones. In women with genuine stress incontinence, detrusor instability or both PFMT might add benefit to behavioural training.

Is biofeedback assisted PFMT better than PFMT alone?
The formal comparisons of biofeedback assisted PFMT versus PFMT alone consistently suggest that there is no added benefit of biofeedback in women with stress or mixed incontinence. Although there were 10 trials for this comparison only three trials contributed data to the formal analyses. Anecdotally many clinicians report that biofeedback is a useful addition to PFMT but from the review it is not clear what benefit it offers and if, long term, it makes a difference to outcome. Data from one trial (Berghmans 1996) suggested that the biofeedback group might experience more rapid improvement but this has not been confirmed in any other biofeedback trial as yet. A group that are anecdotally reported to benefit from biofeedback assisted PFMT are those women who are not able to voluntarily contract their pelvic floor muscles at pretreatment assessment but this hypothesis has not been investigated to date.

Is any other form of assisted PFMT better than PFMT alone?
There was very limited evidence to suggest that there was no further benefit from the addition of either electrical stimulation or intravaginal resistance to assist in PFMT for women with genuine stress incontinence. Similarly limited evidence was available on the effect of adding vaginal cones to PFMT for women with genuine stress incontinence or postnatal women with urine leakage. One trial in women with genuine stress incontinence, detrusor instability or both suggested that the addition of behavioural therapy to PFMT was more effective than PFMT alone.

Is PFMT effective for women with detrusor instability or urge incontinence alone?
Unsurprisingly the bulk of trials in the review have included populations of women with stress or mixed incontinence. Some trials have included women with detrusor instability alone but as the data for these women were not presented separately it was not possible to comment on the effect of PFMT for women with only detrusor instability or urge incontinence. Readers are directed to the findings of the three trials that did include women with detrusor instability alone for current best evidence on the effect of PFMT for this group of women (Burgio 1998; Nygaard 1996; Wyman 1998).

Is PFMT effective for older women?
The vast majority of trials were in populations of younger, pre-menopausal women. Some trials did include women with

a wide range of ages however only two included trials investigated the effect of treatment in older women alone (Burgio 1998, 55 years and over; Miller 1998, 60 years and over). Readers are directed to the findings of these two trials for current best evidence on the effect of PFMT in older, post-menopausal women .

What is the long-term outcome of PFMT?
The limited nature of follow up beyond the end of treatment means that the long-term outcomes of PFMT are not clear. In the few trials that have included long term follow up some women have gone on to pursue other treatments but some women continue to be satisfied with the outcome of treatment and are still doing some PFMT.

Is PFMT cost effective?
None of the trials included in the review have addressed this question. While PFMT appears to be an effective treatment for women with both stress and mixed incontinence it is not known if PFMT is cost effective when compared with no treatment, or any other treatment.

Implications for research

While PFMT appears to be an effective treatment for women with stress or mixed incontinence further evidence is needed to clarify the effectiveness of PFMT relative to other physical therapies, conservative management strategies, pharmaceuticals and surgery. Many trials to date have been small and of poor to moderate quality. Larger, well-conducted, explicitly reported trials are required. Four high priority areas for future research include:
1. The effect of advice/education about the bladder and pelvic floor muscles, life style recommendations etc.
2. Further comparisons of different types of pelvic floor muscle training to determine which components or combinations of components are most effective.
3. Further investigation of the effectiveness of electrical stimulation. It might be more appropriate to compare newer forms of stimulation with no treatment and placebo stimulation initially. However, once the effectiveness of any form of stimulation has been established in women with stress or mixed incontinence a direct comparison with PFMT would be warranted as PFMT is an effective physical therapy treatment in this population.
4. The effect of biofeedback assisted PFMT training in women who are not able to voluntarily contract their pelvic floor muscles at initial assessment, and the rate of improvement in biofeedback assisted training versus PFMT alone.

In planning future research trialists are encouraged to select or develop outcomes that matter to women, that cover a range of outcome domains, and to use tools that have established reliability and validity for women with urinary incontinence. Domains that require particular attention in future research are quality of life and socioeconomics as these have been poorly investigated until now. Researchers also need to carefully consider if the past emphasis on self reported cure or cure/improvement is the best approach to collecting data in the domain of women's observations. Three recent trials included in the review asked women if they wanted further treatment and/or were satisfied with outcome, or whether their symptoms were problematic (e.g. Bø 1999, Burgio 1998, Wyman 1998). 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 better to be satisfied with the outcome of treatment. Similarly a woman may find her leakage problem is 'cured' but that other concurrent symptoms such as nocturia continue to be troublesome and this may lead to her seeking further treatment.

Future researchers should also carefully consider the content and length of the PFMT period, as many previous trials have potentially chosen less than optimal programs and measured outcome before maximum effect might be expected. In addition the duration of follow up beyond the end of treatment needs attention. As the aim of treatment is long-term continence outcome should be measured at least one year after the end of treatment. Even longer-term follow up will be required if comparisons of PFMT, medication, and surgery are to be useful to women.

POTENTIAL CONFLICT OF INTEREST

Kari Bø (Bø 1990; Bø 1999) and Bary Berghmans (Berghmans 1996) were principal authors of trials included in the review.

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- University of Otago NEW ZEALAND

SYNOPSIS

Pelvic floor muscle training helps reduce stress and mixed incontinence but it is not clear if it is better than other treatments.

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 stress or mixed incontinence but there is not enough evidence to show whether it is better than other active treatments or its effect on urge leakage control.

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* Indicates the major publication for the study

Characteristics of included studies

Study	Berghmans 1996
Methods	2 arm RCT. Stratified by severity of leakage and source of referral. Gp allocation was masked. Assessors masked to gp allocation.
Participants	40 women. Some with urodynamically proven GSI and others with clinical history suggestive of GSI. Excluded if medication for lower urinary tract problems, pudendal nerve lesion, urinary tract infection, non compliance in diagnostic phase, previous urological or gynaecological surgery, <6 wk postnatal, concomitant rx, severe stress incontinence, psychological disorders, vaginitis, pacemaker, hip prosthesis, unable to understand Dutch. Mean age in the PFMT gp 50.35 yrs (sd 10.50), and in PFMT+BF gp 46.40 (sd 12.12). In both gps 55% had gd 1stress incontinence and 45% gd 2 stress incontinence. In both gps 75% of women had symptoms >2 yrs. Single centre, The Netherlands.
Interventions	1. PFMT (n=20). Individual training with physiotherapist. Clinic visits 3x wk, 25-35 min per visit, 12 rx over 4 wks. Explanation of pelvic anatomy, function of PFM and bladder. PFMT = 4 sets 10 VPFMC per day (5 quick, 5 sustained, 3-30 sec) progressed by 10 per set until 30 per set. Ex in sup ly, sd ly, st, pr kn. The Knack (VPFMC with cough, stair climbing, lifting, jumping). Home ex program 3x day. 2. PFMT + BF (n=20) Rx as above with addition of BF from vaginal probe (EMG) giving both visual and acoustic signals (Myaction 12, Uniphy BV).
Outcomes	Symptom questionnaire. Urinary diary. 48 hr pad test.
Notes	Post rx = 4 wks. No withdrawals.
Allocation concealment	A

Study	Burgio 1998
Methods	3 arm RCT. Stratified by type (urge/mixed) and severity of leakage. Not clear if gp allocation masked. Assessors masked to main outcome measure.
Participants	197 women with urodynamic evidence of DI (symptoms of urge leakage with or without stress leakage). Excluded if continual leakage, post void residual >200 ml, uterine prolapse past introitus, narrow angle glaucoma, unstable angina, decompensated heart failure, history of malignant arrhythmias, or MMSE <20. Mean age 67.7 yrs (sd 7.5). 18.3% mild incontinence (<5 leakage episodes per week), 28.9% moderate severity (5-10 per wk) and severe leakage in 52.8% (>10 leakage epidoes per wk). Mean duration of symptoms 10.6 yrs (sd 1.5). Single centre, USA.

Characteristics of included studies

Interventions	1. PFMT with urge strategies (n=65). Individual training with nurse practitioner fortnightly for 8 wks, total 4 rx. Home PFMT 3x day. Correct VPFMC taught using anorectal BF. PFMT = 15 VPFMC 3x day, progress to max 10 sec hold per contraction. Ex in ly, sitt, st. The Knack (VPFMC to prevent incontinence with triggers). Attempt mid stream urine stop 1x day. Urge strategies included delay and coping strategies for urgency, use of repeated VPFMC to inhibit detrusor contractions. 2. Medication (n=67). Rx from nurse practitioner and clinic visits as above. 2.5mg oxybutynin chloride 3x day progressing to max 5.0mg 3x day as required. Capsule contained 500mg riboflavin phosphate marker. 3. Placebo drug (n=65). Treatment and visits as for medication gp. Capsule contained marker only.
Outcomes	Subjective ratings. Urinary diary. Cystometry for 105/197.
Notes	Post rx = 2 wks after end of rx, ie 10 wks. Dropouts 4/65 from PFMT gp, 12/67 from medication gp, and 12/65 from placebo medication gp. Withdrawals included in analysis using most recent data. Women with less than 50% reduction in leakage episodes by 3rd clinic visit had repeat BF to teach use of VPFMC against sensation of increasing urgency.
Allocation concealment	B

Study	Burns 1993
Methods	3 arm RCT. Not clear if gp allocation masked. Assessor masked to gp allocation.
Participants	135 women with urodynamically proven GSI or GSI + DI. Excluded if <3 leakage episodes per wk, MMSE <23, glycosuria or pyuria, residual urine >50ml, max uroflow <15 ml/s. Mean age 63 yrs (sd 6). Single centre, USA.
Interventions	1. PFMT (n=43). Individual training with nurse 1x wk, 25-35 min per visit for 8wks. Home PFMT 4 sets per day. Telephone reminders for appointments, and ex reminder cards between follow up visits. PFMT = 4 sets 20 VPFMC (10 quick with 3 sec holds, 10 sustained with 10 sec holds) progessed by 10 contractions per set over 4 wks to daily max 200 VPFMC. 2. PFMT +BF (n=40). Training with nurse, clinic visits, and PFMT as above with addition of visual BF from vaginal probe (EMS-10, EMS-20, Farrell Instruments) attached to EMG (J&J Model M-53) and digital integrator (J&J Model D-200). 3. Control (n=40). No rx and no clinic visits. Choice or either of above on completion of study.
Outcomes	Urinary diary. EMG measures of PFM. Compliance measured from diary. Urodynamics.
Notes	Post rx = 8 wks. Follow up 3 and 6 months. 12 drop outs but gp not stated.
Allocation concealment	B

Characteristics of included studies

Study	Burns 1993a
Methods	As Burns 1993
Participants	As Burns 1993
Interventions	Used for PFMT versus no treatment comparison.
Outcomes	As Burns 1993
Notes	As Burns 1993
Allocation concealment	B

Study	Burns 1993b
Methods	As Burns 1993
Participants	As Burns 1993
Interventions	Used for PFMT with biofeedback versus no treatment comparison.
Outcomes	As Burns 1993
Notes	As Burns 1993
Allocation concealment	B

Study	Bø 1990
Methods	2 arm RCT. Stratified by degree of leakage. Gp allocation was masked. Masking of assessor not stated.
Participants	57 women with urodynamically proven GSI. Excluded if DI or infection. Mean age 45.4 yrs (range 24-64). Mean duration of symptoms in 'intensive' PFMT gp 8.5 yrs (range 2-27), and in std PFMT gp 45.9 yrs (range 35-63). Single centre, Norway.
Interventions	1. Std PFMT (n= 25). Individual instruction in pelvic anatomy and correct VPFMC with physiotherapist. Home PFMT 6 months with monthly clinic visit for BF (perineometer) of PFM strength. PFMT = 8-12 strong contractions per set, 3x day. 2. 'Intensive' PFMT (n=32). As above with addition of 45 minute ex class to music 1x wk for 6 months. Class included sets of 8-12 VPFMC with 6-8 second holds in st, sitt, ly, kn with legs apart. 3-4 fast contractions added after held contraction. Also strength training for back, thigh and abdominal muscles, relaxation training and body awareness.
Outcomes	Subjective rating. 90 second pad test. Perineometer. Urine leakage index. Social Activity Index. Compliance measured from training diary. Urodynamics.
Notes	Post rx = 6 months. Follow up 5 years (enhanced PFMT gp only). 3/32 dropouts from enhanced PFMT, 2/25 from std PFMT.
Allocation concealment	A

Characteristics of included studies

Study	Bø 1999
Methods	4 arm RCT. Stratified by severity of leakage. Gp allocation was masked. Assessor masked to gp allocation. Power calculation.
Participants	122 women with urodynamically proven GSI. Excluded if DI, residual urine >50ml, max uroflow <15ml/s, previous surgery for GSI, neurological or psychiatric disease, urinary tract infection, other disease interfering with participation, used of concomitant rx, inability to understand Norwegian. Mean age in control gp 51.7 yrs (sd 8.8), in PFMT gp 49.6 (sd 10.0), in ES gp 47.2 (sd 10.1) and VC gp 49.2 (sd 10.6). Mean number of leakage episodes in 3 days was 2.9 (sd 2.9) in control gp, 2.0 (sd 1.8) in PFMT gp, 2.3 (sd 2.0) in ES gp, and 2.7 (sd 2.4) in VC gp. Mean duration of symptoms in yrs was 9.9 (sd 7.8) in control gp, 10.2 (sd 7.7) in PFMT gp, 13.3 (sd 9.7) in ES gp, and 10.1 (sd 7.7) in VC gp. Multicentre, Norway.
Interventions	1. PFMT (n=29). Individual instruction by physiotherapist in anatomy, physiology and continence mechanisms, and correct VPFMC taught. Monthly clinic visit, weekly ex class (see Bø 1990), and daily home ex program, 6 months. PFMT = 8-12 high intensity VPFMC 3x day in preferred position, held 6-8 seconds, 6 seconds rest, 3-4 fast contractions at end. Audiotape available for home training. 2. ES (n=32). Individual instruction in anatomy etc as above. Monthly clinic visit, daily ES at home, 6 months. ES = 30 min per day, vaginal electrode, biphasic intermittent current, 50 Hz, pulse width 0.2 millisec, duty cycle progressed (on time 0.5-10 sec, off time 0-30 sec), intensity high as tolerated (0-120 mA). (MS106 Twin) 3. VC (n=29). Individual instruction as above. Monthly clinic visit, daily cones at home, 6 months. VC = 20 min per day, progressed through 3 cone weights (20, 40, 70g) according to ability to hold cones. (Mabella cones). 4. Control (n=32). Individual instruction as above. No contact with physiotherapist over 6 month period. Offered instruction in use of Continence Guard (Coloplast AS)
Outcomes	Subjective rating. Urinary diary. 60 second pad test. 24 hr pad test. Perineometry. Leakage Index. Social Activity Index. Compliance in PFMT and VC measured from training diary. Compliance with ES downloaded from stimulator.
Notes	Post rx = 6 months. Drop outs 4/29 in PFMT gp, 7/32 in ES gp, 2/29 in VC gp, 2/32 in control gp. Withdrawals included in analysis using baseline values. 14/32 women in control gp used Continence Guard.
Allocation concealment	A

Study	Cammu 1998
Methods	2 arm RCT. Gp allocation was masked. Masking of assessors not stated.

Characteristics of included studies

Participants	60 women with urodynamically proven GSI. Excluded if postpartum, genital prolapse, pathology needing surgery, DI, outflow obstruction, intrinsic sphincter deficiency. Mean age in PFMT+BF gp 55.9 yrs (sd 9.5) and in VC gp 56.3 yrs (sd 11.4). Number of leakage episodes per wk in PFMT+BF gp 14.4 (sd 10.0) and 13.6 (sd 12.0) in VC gp. Mean duration of symptoms 6.7 yrs (sd 7.2) in PFMT+BF gp and 5.3 (sd 5.2) in VC gp. Single centre, Belgium.
Interventions	1. PFMT + BF (n=30). Individual training with physiotherapist. Clinic visit 1x wk, 30 min per visit, for 12 wks. Home ex program without BF. Education on pelvic anatomy and purpose of rx. Vaginal palpation to teach correct VPFMC. PFMT = 10 brief forceful contractions, 10 sustained 10 sec contractions. Progress by increasing number of sets. BF = Vaginal probe with surface EMG giving visual BF, and abdominal wall electrode. At clinic visits only. 2. Cones (n=30). Individual training, vaginal palpation and education as above. Clinic visits fortnightly for 12 wks. Cones (Femina, 20, 32, 45, 57, 70g) = 15 min 2x day at home (except during menstruation) with heaviest cone that could be retained with VPFMC in st.
Outcomes	Subjective rating. Urinary diary. EMG measures of PFM. Psychological distress.
Notes	Post rx = 12 wks. Drop outs 0/30 from PFMT+BF gp, 14/30 VC gp.
Allocation concealment	A

Study	Castleden 1984
Methods	Crossover trial with random allocation to first treatment. Method of gp allocation not stated. Masking of assessors not stated.
Participants	19 women with demonstrable stress incontinence. Mean age 55 yrs (range 23-85). Mean duration of symptoms 9 yrs (range 3 months -32 yrs). Single centre, England.
Interventions	1. PFMT (n=19). 2 wks training supervised by physiotherapist. PFMT = 4-5 VPFMC every hr and midstream urine stop on every occasion. 2. PFMT + BF (n=19) As above with use of perineometer (Kingsdown Medical) with visual BF at least once per day.
Outcomes	Subjective rating. Perineometry.
Notes	Post rx = 2 weeks. Data following cross over not presented.
Allocation concealment	B

Study	Ferguson 1990
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	20 women with urodynamically proven GSI. Excluded if postmenopausal, previous urologic surgery, medications affecting bladder or skeletal muscle function, symptoms of urgency or frequency or nocturia, DI. Mean age in PFMT gp 35.8 yrs (sd 4.6) and PFMT+IVRD gp 37.1 (sd 6.4). Single centre, USA.

Characteristics of included studies

Interventions	1. PFMT (n=10). 6 wks home ex with weekly phone call. PFMT = 15 max VPFMC sustained 6 sec (progress to 25x), and 30 VPFMC sustained 6 sec (progressed to 12 sec hold). Audiotape. 2. PFMT + IVRD (n=10). As above but PFMT with intravaginal balloon in situ.
Outcomes	30 min pad test. 24 hr pad test. Perineometry. Urodynamics.
Notes	Post rx = 6 wks. Follow up at 12 - 24 months.
Allocation concealment	B

Study	Gallo 1997
Methods	2 arm RCT. Method of gp allocation is unclear and may be inadequate, ie. "every other patient was randomly assigned". Masking of assesors not stated. Power calculation.
Participants	86 women with urodynamically proven GSI. Excluded if pregnant or psychological disorders. Mean age 60 yrs (range 29-80). Single centre, USA.
Interventions	1. std PFMT (n=43). 45 min individual training with nurse including education and teaching correct VPFMC with BF. Daily home ex program. PFMT = 10 min ex 2x day, instruction sheet and verbal encouragement. 2. Reinforced PFMT (n=43). As above with addition of audiocassette for use 2x day. Cassette contained 25 consecutive VPFMC with 10 sec hold and 10 sec rest counted aloud.
Outcomes	Number of VPFMC per day. Time spent on PFMT per day. Length of hold. Cues to ex.
Notes	Post rx = 4-6 wks. Drop outs 9/43 from std PFMT gp, 2/43 for reinforced PFMT gp. No urinary leakage outcomes assessed.
Allocation concealment	C

Study	Glavind 1996
Methods	2 arm RCT. Gp allocation was masked. Masking of assessors not stated.
Participants	40 women with urodynamically proven GSI. Excluded if DI, previous urologic surgery. Median age 45 yrs (range 40-48). Single centre, Denmark.
Interventions	1. PFMT (n=20). 2-3 clinic visits over 4 wks and daily home ex program. PFMT = at least 3x day at home. 2. PFMT + BF (n=20). Home based ex as above and 4 clinic visits for BF. BF = vaginal surface electrode (Dantec 21L20) and rectal catheter with visual BF. 10 VPFMC sustained for 5-10 sec in sup ly, sitt, st.
Outcomes	Subjective rating. 1 hour pad test. Urodynamics.

Characteristics of included studies

Notes	Post rx = 4 wks. Follow up 12 wks, 2 and a half yrs. Drop outs 5/20 from PFMT gp, 1/20 PFMT+BF gp.
Allocation concealment	A

Study	Hahn 1991
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	20 women with urodynamically proven GSI. Excluded if previous urologic surgery, neurological pathology, DI. Mean age 47.4 yrs (range 34-64). Mean urine loss on pad test for PFMT gp 66.5g (se 14.38) and 55.6g (se 21.21) for ES gp. Single centre, Sweden.
Interventions	1. PFMT (n=10). Individual training with physiotherapist weekly for 4 wks, then monthly for 5 months. Daily home ex program. Instruction in pelvic floor anatomy and physiology. Vaginal palpation of correct VPFMC (and self palpation encouraged). PFMT = 5-10 max contractions with 5 sec hold, and submax contractions with 30-40 sec hold. Ex in sup ly, sitt, st. The Knack (VPFMC with provocation such as cough). 2. ES (n=10). Home rx. ES = 6-8 hrs per night, 6 months, vaginal electrode, intermittent stimulation with alternating pulse at repetition frequencies of 12, 20, 50 Hz. (Contelle).
Outcomes	Subjective rating. Pad test.
Notes	Post rx = 6 months. Follow up at 1 and 4 yrs.
Allocation concealment	B

Study	Haken 1991
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	64 women with urodynamically proven GSI. Mean age 48 yrs. Single centre, England.
Interventions	1. PFMT (n=33). Individual training with continence advisor. 3 clinic visits. Education in appropriate anatomy and physiology. PFMT = 5 VPFMC 10x day. 2. VC (n=31). 15 min 2x day. Progress cone weight when successful on 2 consecutive occasions.
Outcomes	Subjective rating. 40 minute pad test.
Notes	Abstract only. Post rx = 10 wks. Drop outs 3/33 from PFMT gp, 8/31 from VC gp.
Allocation concealment	B

Study	Henalla 1989
Methods	4 arm RCT. Method of gp allocation not stated. Masking of assessors not possible.
Participants	104 women with urodynamically proven GSI. Excluded if fistula, >1 surgical procedure for incontinence, major degree of prolapse, oestrogens contraindicated. Single centre, England.

Characteristics of included studies

Interventions	1. PFMT (n=26). Individual training with physiotherapist. Weekly clinic visit for 12 wks. Correct VPFMC taught with vaginal palpation. PFMT = 5 VPFMC per hr with 5 sec hold. 2. ES (n=25). 1x per wk for 10 wks. ES = interferential therapy, 0-100 Hz, 20 min, output as tolerated. 3. Medication (n=24) Vaginal oestrogen (Premarin) nightly for 12 wks. 2g (1.25mg conjugated oestrogens) via vaginal applicator. 4. Control (n=25). No rx.
Outcomes	Pad test. Urodynamics.
Notes	Post rx = 12 wks. Follow up 1 yr.
Allocation concealment	B

Study	Henalla 1990
Methods	3 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	26 post- menopausal women "complaining of genuine stress incontinence". Mean age 54 yrs (range 49-64). Single centre, England.
Interventions	1. PFMT (n=8) 2. Medication (n=11). 2g vaginal oestrogen per night (Premarin). 3. Control (n=7). No rx.
Outcomes	Pad test.
Notes	Abstract only. Post treatment = 6 wks.
Allocation concealment	B

Study	Hofbauer 1990
Methods	4 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	43 women with urodynamically proven GSI. Excluded if urge incontinence. Mean age 57.5 yrs (sd 12.0). 9 women with gd 1 stress incontinence, 20 gd 2, and 14 gd 3. Single centre, Austria.
Interventions	1. PFMT (n=11). Ex program (including PFMT, abdominal and hip ex) 2x wk for 20 min with therapist. Home ex program daily. 2. ES (n=11). 3x wk, 10 min per rx, 6 wks. ES = vaginal and lumbar electrodes, output increased to noticeable contraction and patient added voluntary effort. 3. PFMT + ES (n=11) Combination of above. 4. Sham ES (n=10). ES as above but current so low "no effect possible".
Outcomes	Subjective rating. Urinary diary. Urodynamics.
Notes	Post rx = ? Follow up 6 months post rx. German publication - translated to English.
Allocation concealment	B

Characteristics of included studies

Study	Hofbauer 1990a
Methods	As Hofbauer 1990
Participants	As Hofbauer 1990
Interventions	Used for PFMT versus placebo stimulation comparison.
Outcomes	As Hofbauer 1990
Notes	As Hofbauer 1990
Allocation concealment	B

Study	Hofbauer 1990b
Methods	As Hofbauer 1990
Participants	As Hofbauer 1990
Interventions	Used for PFMT with stimulation versus placebo stimulation comparison.
Outcomes	As Hofbauer 1990
Notes	As Hofbauer 1990
Allocation concealment	B

Study	Klarskov 1986
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not possible.
Participants	50 women with urodynamically proven GSI. Excluded if gynaecological surgery indicated, unable to follow instructions. Median age 48 yrs (range 31-66). Single centre, Denmark.
Interventions	2. PFMT (n=24) Group ex sessions with physiotherapist, at least 5 per patient. Home ex program in ly, sitt, st, with "increasing intensity". 2. Surgery (n=26). Surgery chosen on basis of cystometry, including Burch colposuspension for anterior suspension defect, vaginal repair for posterior bladder desent, or combined procedure.
Outcomes	Subjective rating. Urinary diary. Pad test. Urodynamics.
Notes	Post rx = ? Follow up at 4 and 12 months, and 4-8 yrs.
Allocation concealment	B

Study	Klingler 1995
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessor not stated.
Participants	41 women with clinical diagnosis of stress incontinence. Mean duration of symptoms 5 yrs. Mean age PFMT gp 53.0 yrs, Endotrainer gp 51.8 yrs

Characteristics of included studies

Interventions	1. PFMT (n=21). "Classic" PFMT. In depth instruction followed by 9 wk program (first weeks 30 minutes 3x wk under supervision of physiotherapist, then 3 wks home programme, finally 3 weeks with physiotherapist). 2. PFMT + BF + ?IVRD (Endotrainer) (n=20). As above with addition of audio-visual biofeedback from "intermittent gas-filled balloon placed in the vagina which has to be compressed by the patient".
Outcomes	Subjective rating Pad test Urethral pressure profile
Notes	Abstract only. Post rx = 3 months.
Allocation concealment	B

Study	Knight 1998
Methods	3 arm RCT. Gp allocation was masked. Masking of assessors not stated.
Participants	70 women with urodynamically proven GSI. Excluded if urinary tract infection, unstable bladder, unable to perform VPFMC, pregnant, breastfeeding, pelvic malignancy, cardiac pacemaker, neurological condition, diabetes, HRT started within previous 3 months. Single centre, England.
Interventions	1. PFMT + BF (n=21). Individual training with physiotherapist with vaginal palpation of correct VPFMC. Clinic visits wkly for 1 month, then fortnightly for 5 months and home ex program. PFMT = 6x day, individually tailored program with progression to 10 sustained 10 sec contractions followed by 10 fast contractions. BF = air filled vaginal probe (PRS900, InCare) with visual BF at clinic visits. Home BF with air filled vaginal probe (PFX, Cardio Design) for visual BF at home. 2. PFMT + BF + low intensity ES (n=25) PFMT + BF as above. ES = overnight at low intensity for 6 months (not during menstruation). Vaginal electrode, 10 Hz trains with 35 Hz bursts, pulse width 200 microsec, duty cycle 5 sec on, 5 sec off. (DMI Ltd). 3. PFMT + BF + acute maximal MES (n=24). PFMT + BF as above. ES = 16 rx, 30 min of maximal electrical stimulation (VSI). Vaginal electrode, 35 Hz, pulse width 250 microsec, duty cycle 5 sec on, 5 sec off. VPFMC performed with electrically stimulated contraction.
Outcomes	Subjective rating. Urinary diary. Pad test. Perineometry. Self reported of compliance.
Notes	Post rx = 6 months. Follow up at 12 months. Drop outs 3/21 in PFMT gp, 6/25 in low intensity ES gp, 4/24 in acute maximal ES gp post treatment. Further 3 in PFMT gp and 3 in LIES gp by 12 months. Withdrawals included in analysis at 6 months.
Allocation concealment	A

Study	Knight 1998a
Methods	As Knight 1998
Participants	As Knight 1998

Characteristics of included studies

Interventions	Used for PFMT with biofeedback versus low intensity stimulation comparison.
Outcomes	As Knight 1998
Notes	As Knight 1998
Allocation concealment	A

Study	**Knight 1998b**
Methods	As Knight 1998
Participants	As Knight 1998
Interventions	Used for PFMT with biofeedback versus acute maximal stimulation comparison.
Outcomes	As Knight 1998
Notes	As Knight 1998
Allocation concealment	A

Study	**Lagro-Janssen 1992**
Methods	2 arm RCT. Stratified by type and severity of leakage. Method of gp allocation not clear and may be inadequate, ie. "randomly assigned consecutively". Assessors masked to gp allocation.
Participants	110 women with urodynamically proven GSI or mixed incontinence. Excluded if previous incontinence surgery, neurological causes of incontinence, urinary tract infection, temporary causes of incontinence. Mean age in PFMT gp 44.6 yrs (sd 10.4) and 42.3 (sd 10.0) in control gp. 7 women had mild incontinence, 61 moderate symptoms, and 42 severe leakage. 39 women had symptoms <2 yrs, 29 from 2-5 yrs, and 42 women had problems of >5 yrs duration. Multicentre, The Netherlands.
Interventions	1. PFMT +/or BT (n=54) PFMT for those with stress incontinence, BT for those with urge leakage, and PFMT + BT for those with mixed incontinence. Practice assistant gave instructions about protective aids. Vaginal palpation by General Practitioner to check correct VPFMC. PFMT = 10 VPFMC with 6 sec hold, 5-10x per day at home. BT = education, progressive voiding schedule. 2. Control (n=56) Instruction in protective aids only. Rx above offered at 3 months.
Outcomes	Subjective rating. Urinary diary. Health locus of control questionnaire. General health questionnaire. Anxiety scale. Self reported compliance.
Notes	Post rx = 3 months. Drop outs 1/54 PFMT gp, 3/56 control gp. In comparison table GSI data present separately from mixed/urge incontinence group.
Allocation concealment	C

Study	**Lagro-Janssen 1992a**
Methods	As Lagro-Janssen 1992
Participants	Used to differentiate women with stress incontinence only

Characteristics of included studies

Interventions	As Lagro-Janssen 1992
Outcomes	As Lagro-Janssen 1992
Notes	As Lagro-Janssen 1992
Allocation concealment	C

Study	Lagro-Janssen 1992b
Methods	As Lagro-Janssen 1992
Participants	Used to differentiate women with mixed incontinence
Interventions	As Lagro-Janssen 1992
Outcomes	As Lagro-Janssen 1992
Notes	As Lagro-Janssen 1992
Allocation concealment	C

Study	Lagro-Janssen 1998
Methods	
Participants	
Interventions	
Outcomes	
Notes	
Allocation concealment	D

Study	Laycock 1988
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	36 women with urodynamically proven GSI. Mean age 44 yrs (range 30-74). Single centre, England.
Interventions	2. PFMT (n=16). Individual training with physiotherapist. Clinic visit 1x wk, 6-8 wks, and daily home ex program. 2. ES (n=20). Average 11 rx, 30 min per rx, 2-3x wk, 4-6 wks. ES = interferential therapy (Endomed 433, Enraf Nonius), 10-50 Hz.
Outcomes	Subjective rating. Pad test.
Notes	Abstract only. Post rx = 6-8 wks. Follow up 12 weeks. Data presented from 29/36 - ? study incomplete or 2/20 drop outs from ES group and 5/16 from PFMT group.
Allocation concealment	B

Characteristics of included studies

Study	Laycock 1993
Methods	2 arm RCT. Method of gp allocation not stated. Assessors not masked to gp allocation.
Participants	46 women with urodynamically proven GSI. Excluded if urinary tract infection, previous physiotherapy for GSI, pregnant, neurological dysfunction, present or previous pelvic malignancy, cardiac pacemaker. Mean age in PFMT gp 39.5 yrs (range 28-53) and 41.8 (range 29-59) in ES gp. Mean duration of symptoms 6.8 yrs (range 1-20) in PFMT gp, and 7.9 yrs (6 months - 40 yrs) in ES gp. Single centre, England.
Interventions	3. PFMT + VC (n=23). Individual instruction with physiotherapist with vaginal palpation to check correct VPFMC. Weekly clinic visit for 2 wks, then every 10 days for approx 6 wks. PFMT = patient specific rx progressing to 5 max VPFMC 1x hr per day. VC = 10 min 2x day. 2. ES (n=23). Average of 10 rx. ES = interferential therapy (Endomed 433, Enraf Nonius), bipolar technique (external electrodes on perineal body and inferior to symphysis pubis), 10 min at 1 Hz, 10 min at 10-40 Hz and 10 min at 40 Hz, max acceptable current intensity. Patients agreed not to perform PFMT during study.
Outcomes	Subjective rating. Urinary diary. Pad test. Palpation PFM stgth.
Notes	Post rx = ?8 wks. Follow up 2 yrs. Drop outs 6/23 from PFMT+VC gp, 0/23 from ES gp.
Allocation concealment	B

Study	Laycock 1999
Methods	3 arm RCT. Not clear if gp allocation masked. Masking of assessor not stated.
Participants	101 women with symptoms of stress urinary incontinence.
Interventions	1. PFMT (n=20). 10 min patient specific exercise per day. 5 clinic visits over 3 months. 2. PFMT + BF (n=40) 10 min per day in st and ly with BF from PFFX (CardioDesign, Australia). 5 clinic visits over 3 months. 3. Vaginal cones (n=41) 10 min per day. 2 cone shells with weight added according to ability to retain cone. 5 clinic visits over 3 months.
Outcomes	Subjective rating (VAS). Urinary diary. Pad usage. Muscle testing (? method). King's Health Questionnaire.
Notes	Post rx = 3 months. Dropouts 4/20 PFMT group, 18/40 PFMT + BF group, 11/41 cones group.
Allocation concealment	B

Study	Laycock 1999a
Methods	As for Laycock 1999
Participants	As for Laycock 1999

Characteristics of included studies

Interventions	Used for PFMT versus vaginal cones comparison.
Outcomes	As for Laycock 1999
Notes	As for Laycock 1999
Allocation concealment	B

Study	Laycock 1999b
Methods	As for Laycock 1999
Participants	As for Laycock 1999
Interventions	Used for PFMT with biofeedback versus vaginal cones comparison.
Outcomes	As for Laycock 1999
Notes	As for Laycock 1999
Allocation concealment	B

Study	Miller 1998
Methods	2 arm RCT. Method of gp allocation not stated. Assessors masked to gp allocation.
Participants	27 women with mild-moderate stress leakage (1-5 leakage episodes per day). Excluded if systemic neuromusclar disease, previous bladder surgery, urinary tract infection, delayed leakage after cough (assumed DI), more than moderate leakage with cough, unable to perform VPFMC, prolapse below hymenal ring. Mean age 68.4 yrs (sd 5.5). Mean number leakage episodes per day 1.36 (sd 1.39). Single centre, USA.
Interventions	1. PFMT (n=13). Education in basic physiology and function of PFM. Vaginal palpation to teach VPFMC. One clinic visit, and 1 wk home practice. PFMT = Knack of VPFMC prior to hard cough and maintained until abdominal wall relaxation. 2. Control (n=14). no treatment.
Outcomes	Urinary diary. Paper towel test. Palpation of PFM stgth.
Notes	Post rx = 1 wk.
Allocation concealment	B

Study	Nygaard 1996
Methods	2 arm RCT. Unlcear if gp allocation masked. Assessors masked to gp allocation. Power calculation.
Participants	71 women with urodynamically proven GSI, DI, mixed incontinence. Mean age 53 yrs (sd 13). 13% had symptoms for <1 yr, 38% 1-5 yrs, and 52% for >5yrs. Single centre, USA.
Interventions	1. std PFMT (n=?) VPFMC taught using vaginal palpation. 3 clinic visits and 3 telephone calls over 3 months. Daily home ex program. PFMT = 5 min 2x day, VPFMC held to count of 4 progressing to count of 8. 2. Reinforced PFMT (n=?). As above with audiotape. Tape contained 270 min of music and verbal instructions to guide women through 3 months of PFMT.

Characteristics of included studies

Outcomes	Subjective rating. Urinary diary. Pad test. Palpation of PFMT strength. Leakage Index. Urodynamics. Compliance assessed with daily log.
Notes	Post rx = 12 wks. Follow up at 9 months. 16 dropouts. Withdrawals included in data analysis using baseline values. Published data presented by diagnosis not gp allocation.
Allocation concealment	B

Study	O'Brien 1991
Methods	2 arm RCT. Method of gp allocation not stated. Assessors masked to gp allocation.
Participants	292 women reporting 2 or more leakage episodes per month. Aged 35 yrs or more. 268 women incontinent for >1 yr, 24 for <1 yr. Multicentre, England.
Interventions	1. PFMT (n=158). 1 gp session per wk for 4 wks run by nurse or home visits for elderly or immobile. Then 8 wks daily home ex program. PFMT for all women, then BT added after 4 weeks for those with urge symptoms. PFMT = "structured exercises aimed at improving pelvic tone". 2. Control (n=134). No rx for 3 months then offered treatment as above.
Outcomes	Subjective rating.
Notes	Post rx = 12 wks. Data from follow up after 12 wks not presented as control gp received PFMT.
Allocation concealment	B

Study	Peattie 1988
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	44 postmenopausal women with cystometrically proven GSI. Single centre, England.
Interventions	1. PFMT (n=22) Training with physiotherapist. 3 clinic visits, of 1 hr, 30 min and 15 min respectively and daily home ex program. PFMT = 50 VPFMC per day for 4 weeks. 2. VC (n=22) 15 minutes instruction in use of cones (Femina) and weekly phone call. Home program of 15 min 2x day for 4 weeks. Nine cone weights from 20-100g.
Outcomes	Subjective rating. Extended pad test.
Notes	Abstract only Post rx = 4 weeks Drop outs 6/22 from PFMT gp, 5/22 from VC gp.
Allocation concealment	B

Study	Pieber 1995
Methods	2 arm RCT. Unlcear if gp allocation masked. Masking of assessors not stated.

Characteristics of included studies

Participants	46 premenopausal women with urodynamically proven GSI. Mean age 43 yrs (sd 6). Single centre, Austria.
Interventions	1. PFMT (n=25). Individual instruction with physiotherapist. Vaginal palpation to teach correct VPFMC. Perineal sonography during examination to show PFM contraction. Education in anatomy of PFM and bladder. Clinic visits at intervals of 2-4wks for 12 wks and daily home ex program. PFMT = Individualised program with aim of 100 VPFMC during the day and the Knack (VPFMC with increased intra-abdominal pressure and lifting). 2. VC (n=21) Clinic visits and education as above. VC = retain heaviest cone possible 15 min per day. Set of 5 cones (Femcon), 20- 70g.
Outcomes	Subjective rating. Standing stress test. Palpation PFM stgth.
Notes	Post rx = 12 wks. Follow up 12 wks. Drop outs 9/25 from PFMT gp and 8/21 from VC gp at 6 wks. Further 2 from PFMT gp and none from VC gp at 12 wks.
Allocation concealment	B

Study	Prashar 1997
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	62 women with symptoms of stress, mixed or urge incontinence presenting at community clinics. Excluded if voiding difficulty, severe utero-vaginal prolapse, inablity to use device (FemAssist) safely, severe atrophic vaginitis resistant to topical oestrogen. Mean age 64.1 yrs (range 25-87).
Interventions	1. PFMT and continence device, with or without BT (n=?). Weekly clinic visits for 6 wks, with nurse continence advisor. Continence device = urethral occlusive device (FemAssist). 2. Continence device (n=?). Clinic visits as above. Also received leaflet on good bladder habits. 2.
Outcomes	Subjective rating. Pad test. Incontinence Impact Questionnaire. Urogential Distress Inventory. Cost questionnaire.
Notes	Post rx = 6 wks. Published data presented as complete cohort not by gp allocation.
Allocation concealment	B

Study	Ramsay 1990
Methods	2 arm RCT. Method of gp allocation not stated. Assessors masked to gp allocation.
Participants	44 women with stress incontinence symptoms only. Single centre, Scotland.

Characteristics of included studies

Interventions	1. PFMT (n=22) 3 months of daily home ex program. PFMT = 4 max VPFMC held for 4 sec, once every waking hr. 2. placebo PFMT (n=22). As above but women crossed feet at the ankles and performed a hip abductor contraction.
Outcomes	Subjective rating. Pad test. Perineometry. Compliance assessed using diary.
Notes	Abstract only. Post rx = 12 wks.
Allocation concealment	B

Study	Shepherd 1983
Methods	2 arm RCT. Matched for age and parity. Method of gp allocation not stated. Masking of assessors not stated.
Participants	22 women with urodynamically proven GSI. Mean age 48.4 yrs (range 28-67) in PFMT gp, and 48.2 (range 23-63) in combination gp. Mean duration of symptoms 9 yrs (8 months-16 yrs) in PFMT gp, and 11 yrs (range 6 months -30 yrs) in combination gp. Single centre, England.
Interventions	1. PFMT (n=11). Weekly clinic visit for 6 wks and home ex program. PFMT = "conventional" exercises from physiotherapist. 2. PFMT + IVRD + BF (n=11). Clinic attendance as above. Graded exercises from physiotherapist done daily aqt home with intravaginal 'exerciser' connected to visual BF.
Outcomes	Subjective rating. Urinary diary. Perineometer.
Notes	"Pilot study" Post rx = 12 wks after rx, ie 18 wks. Drop outs 3/11 from PFMT gp and 0/11 from PFMT+IVRD+BF gp.
Allocation concealment	B

Study	Sherman 1997
Methods	2 arm RCT. Stratified by type of incontinence. Method of gp allocation not stated. Masking of assessors not stated.
Participants	46 women with urodynamically proven GSI or mixed incontinence. Mean age 39.9 yrs (sd 7.8). Single centre, USA.
Interventions	1. PFMT + BT (n=23) Fortnightly clinic visits for 8wks. Intervention by "therapist" trained in PFMT + BF. Education on normal voiding. PFMT = 5 sets of 5 VPFMC held for 10 sec, with 30 sec rest between sets. Women used BF system for timing contractions but could not see screen. BT = timed voiding and reduction of urge with VPFMC (3 sec holds). 2. PFMT + BF + BT (n=23). As above with added BF. BF = in clinic visual BF using vaginal and abdominal EMG (I-410, J&J) and first wk daily home BF (MyoTrac2).

Characteristics of included studies

Outcomes	Subjective rating. Urinary diary. Urodynamics. Self report of compliance.
Notes	Post rx = 8 wks. Drop outs 7/23 from PFMT gp. Drop outs from PFMT+BF gp not stated.
Allocation concealment	B

Study	Smith 1996
Methods	4 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	57 women with urodynamically proven GSI. Excluded if type 3 stress incontinence, pregnant, history of urinary retention, vaginal vault prolapse, diminshed sensaation, cardiac pacemaker, mixed incontinence if major/minor component not determined. Mean age in women with GSI in PFMT group 48 yrs (range 36-70) and in ES gp 53 yrs (26-72). Single centre, USA.
Interventions	1. PFMT (n=9) Clinic visits 4-6 wks for 16 wks and daily home program. Correct VPFMC confirmed. PFMT = 60 "slow and quick" VPFMC per day. 2. ES (n=9) Clinic visits as above and 2x daily home stimulation. ES = 16 wks, 15 min 2x day progressing to 60 min 2x day over 16 wks, intravaginal probe, asymmetric balanced biphasic pulsed current, 12.5 and 50 Hz, pulse duration 300 microsec, 3-15 sec contraction time, duty cycle 1 to 2, 2 sec ramp up and 1 sec ramp down, output progressed from 5 - max 80 mA (Simtech Products Inc). 3. Medication (n=20) 4. ES (n=18)
Outcomes	Urinary diary.
Notes	Post rx = 16 wks. Details of interventions 3 & 4 not given as comparisons not used in this review. Interventions 1 & 2 women with GSI only, and groups 3 & 4 urodynamically proven DI only.
Allocation concealment	B

Study	Tapp 1987
Methods	2 arm RCT. Method of group allocation not stated. Masking of assessor not stated.
Participants	29 women with urodynamically proven GSI. Excluded if previous incontinence or prolapse surgery.
Interventions	1. PFMT (n=15). PFMT=4 times per hr, every hr. Individual training with continence advisor. Clinic visits 1x per wk for 3 months. 2. PFMT + ES (n=14). PFMT as above. ES= Faradic stimulation with vaginal probe 2x week for 1 month.
Outcomes	Symptom score. Pad test. Cystometry.

Characteristics of included studies

Notes	Abstract only. Post rx = 3 months. Follow up 6 months post trial of treatment continued.
Allocation concealment	B

Study	**Tapp 1989**
Methods	3 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	?80 or ?81 women with urodynamically proven GSI. Excluded if previous urologic or gynaecology surgery. Single centre, England.
Interventions	1. PFMT (n=27?). 14 clinic visits over 3 months. PFMT = training with continence advisor. 2. PFMT + ES (n=26?) PFMT as above. ES = faradism. 3. Surgery (n=27?). Burch colposuspension.
Outcomes	Subjective rating. Pad test. Urodynamics.
Notes	Abstract only. post rx = 3 months for PFMT gp, and 6 months for surgery gp. Drop outs ?6/27 PFMT gp, ?3/26 PFMT + ES gp, ?4/27 surgery gp.
Allocation concealment	B

Study	**Taylor 1986**
Methods	4 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	13 women with symptoms of stress incontinence. Excluded if neurogenic or neuromuscular disorders, urinary tract infection. Age range 55-79 yrs. Single centre, USA.
Interventions	1. PFMT (n=?) 8 weekly clinic visits after intitial assessment and daily home ex program. PFMT = 100 VPFMC with 10 sec hold, 1x day. Advice not to restrict fluid intake, and strategies to reduce frequency. 2. PFMT + home BF (n=?) As above plus home BF. BF = visual BF (Personal Perineometer™) 3. PFMT + home IVRD (n=?). As above plus vaginal probe insitu during PFMT but no visual BF. 4. PFMT + clinic BF (n=?). As for gp 2 with BF used only during clinic visits.
Outcomes	Subjective rating. Urinary diary. EMG measures of PFM. Compliance assessed using diary.
Notes	"Pilot study". 1 drop out, group not stated. No useable data presented.
Allocation concealment	B

Characteristics of included studies

Study	Terry 1996
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	50 women with "proven" GSI able to retain vaginal cone. Single centre, Scotland.
Interventions	1. PFMT + ES (n=30). 12 ES (interferential therapy) rx over 6 wks. PFMT = no details given. 2. VC (n=30). Enhance vaginal cones. No details given.
Outcomes	Subjective rating. Pad test. Perineometer. Palpation PFM stgth.
Notes	Abstract only. Post rx = 6 wks. Follow up at 6 months. Drop outs 1/30 PFMT+ES gp, and 1/30 in VC gp.
Allocation concealment	B

Study	Wells 1991
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	157 women with urodynamically proven GSI or mixed incontinence. Mean age 66 yrs (sd 8). 73% of women daily leakage episodes. Excluded if not community dwelling or hypertension. 8% symptoms <1 yr, 38% 1-5 yrs, 17% 5-10 yrs, 37% more than 10 years. Single centre, USA.
Interventions	1. PFMT (n=82) Individual training with nurse practitioner or clinical nurse specialist. Education on bladder function and diagnosis. Monthly clinic visits for 6 months and daily home ex program. PFMT = 3 step plan (Tuning into pelvic muscles, controlling pelvic muscles, putting pelvic muscle exercises into your life-style) with goal of 90-160 VPFMC with 10 sec hold, 10 sec rest spread over day. 2. Medication (n=75). 4 wks of phenylpropanolamine hydrochloride, 50 mg QD for 2 wks increasing to BID for further 2 wks if continued symptoms.
Outcomes	Subjective rating. Urinary diary. Palpation of PFM stgth. EMG measures of PFM.
Notes	Post rx = 6 months for PFMT gp, and 4 wks for medication gp. Drop outs 28/82 from PFMT gp, and 11/75 from medication gp.
Allocation concealment	B

Study	Wilson 1997
Methods	2 arm RCT. Stratified by parity, method of delivery and frequency of incontinence. Masked gp allocation. Masking of assessors not stated.

Characteristics of included studies

Participants	747 women, incontinent of urine 3 months postpartum. Mean age std PFMT gp 29.44 (sd 5.13) and individual PFMT gp 29.62 years (sd 5.15). 139 primipara in std PFMT group versus 134 in individual PFMT gp. No difference between groups in type of delivery, gestation, perineal injury, birthweight or head circumference. Multicentre, Scotland, New Zealand, England.
Interventions	1. std PFMT (n=376). "Standard postnatal exercises" which may include VPFMC. 2. Individualised PFMT + BT (n=371). Instruction in PFMT and BT by "suitably trained nurse". 3 visits in 9 months. PFMT=8-10 sets of fast and slow contractions per day with aim of 80-100 contractions per day.
Outcomes	Subjective rating. Urinary diary. Home pad test. HAD anxiety score. Self report of compliance.
Notes	Abstract, and unpublished data provided. Post rx = assessment 12 months following delivery. Drop outs 131/376 from std PFMT gp, and 91/371 from enhanced PFMT gp.
Allocation concealment	A

Study	Wilson 1997a
Methods	As Wilson 1997
Participants	Used to differentiate women with symptoms of stress incontinence only
Interventions	As Wilson 1997
Outcomes	As Wilson 1997
Notes	As Wilson 1997
Allocation concealment	A

Study	Wilson 1997b
Methods	As Wilson 1997
Participants	Used to differentiate women with symptoms of mixed incontinence
Interventions	As Wilson 1997
Outcomes	As Wilson 1997
Notes	As Wilson 1997
Allocation concealment	A

Study	Wilson 1998
Methods	2 arm RCT with factorial design in one arm. Stratified by parity, frequency of leakage, type of delivery. Gp allocation was masked. Assessors masked to gp allocation. Power calculation.

Characteristics of included studies

Participants	230 women with symptoms of urinary incontinence 3 months postpartum. Mean age in the std PFMT group was 27.8 yrs (95% CI 27.0-28.7) and in all other gps combined 29.0 (95% CI 28.8-29.2). 89% of women in the std PFMT gp had <1 leakage episode per day, as did 89% in the other gps combined. Single centre, New Zealand.
Interventions	1. std PFMT (n=117). Std PFMT as taught by PT in ante or postnatal classes. 2. Factorial design - women randomised to PFMT (n=39), PFMT + VC (n=38), VC (n=36). PFMT = Individual instruction by physiotherapist. Perineometer used to teach awareness of VPFMC. 4 clinic visits in 9 months and daily home ex program. Mix of slow and fast VPFMC 8-10x per day with aim of 80-100 per day. VC = 15 min 2x day, 9 wgts 20- 100g (Femina), 4 clinic visits.
Outcomes	Subjective rating. Home pad test. Perineometry. General well being. Sexual satisfaction. Self report of compliance.
Notes	Post rx = assessment at 12 months after delivery. Follow up at 2-4 yrs. Drop outs 26/117 from std PFMT gp, 20/39 from enhanced PFMT gp, 24/38 from PFT+VC gp, and 15/36 from VC gp.
Allocation concealment	A

Study	Wilson 1998a
Methods	As for Wilson 1998
Participants	As for Wilson 1998
Interventions	Usef or standard PFMT versus cones. Also used for standard PFMT versus individualised PFMT with cones.
Outcomes	As for Wilson 1998
Notes	As for Wilson 1998
Allocation concealment	A

Study	Wilson 1998b
Methods	As for Wilson 1998
Participants	As for Wilson 1998
Interventions	Used for individualised PFMT versus cones. Also used for individualised PFMT versus PFMT with cones.
Outcomes	As for Wilson 1998
Notes	As for Wilson 1998
Allocation concealment	A

Study	Wise 1993
Methods	3 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.

Characteristics of included studies

Participants	62 women with urodynamically proved GSI. Single centre, England.
Interventions	1. PFMT + VC (n=21). Vaginal palpation to teach correct VPFMC. 4 clinic visits over 12 wks and daily home ex program. PFMT = 10 VPFMC 10x day. VC = 15 min 2x day, progressing to heavier wgt when successful on two consecutive occasions. 2. VC (n=21) VC and clinic visits as above. No vaginal palpation to teach VPFMC. 3. ES (n=20). Clinic visits as above. ES = 20 min day, vaginal electrode, 20 Hz, pulse duration 0.75 millisec, 0-90 mA (Conmax).
Outcomes	Subjective rating. 40 min pad test.
Notes	Abstract only. Post rx = 12 wks. Drop outs 6/21 from PFMT+VC gp, 2/21 from VC gp, 4/20 from ES gp.
Allocation concealment	B

Study	Wong 1997a
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	Number randomised not stated. Data reported for 17 women with urodynamically proven GSI. Excluded if previous failure with PFMT, previous incontinence surgery. Mean age 48.2 yrs (sd 7.3). Single centre, Hong Kong.
Interventions	1. PFMT (n=7?) Clinic visits 2x wk, for 8 sessions. "Standard protocol of pelvic floor re-education". 1. PFMT + BF (n=10?) As above with addition of BF from vaginal electrode and rectal catheter (PRS9300).
Outcomes	Urinary diary. 1 hr pad test. Incontinence Impact Questionnaire.
Notes	Abstract only (Study incomplete and data reported for 17). Post rx = 8 wks.
Allocation concealment	B

Study	Wong 1997b
Methods	2 arm RCT. Method of gp allocation not stated. Masking of assessors not stated.
Participants	47 women with urodynamically proven GSI. Mean age 48.8 yrs (sd 9.4). Single centre, Hong Kong.
Interventions	1. std (home based) PFMT (n=26) Single clinic visit and daily PFMT at home for 4 wks. 2. 'Intensive' PFMT (n=21) 8 clinic visits over 4 wks for PFMT and daily PFMT at home.
Outcomes	Continence Efficacy Scale. Urinary diary. 1 hr pad test. Perineometry.
Notes	Abstract only. Post rx = 4 wks.
Allocation concealment	B

Characteristics of included studies

Study	Wyman 1998
Methods	3 arm RCT. Stratified by type of incontinence, severity, and treatment site. Method of gp allocation not stated. Assessors not masked to gp allocation. Power calculation.
Participants	204 women with urodynamically proven GSI, mixed incontinence or DI. Excluded if MMSE <23, unable to toilet independently, <1 leakage episode per week, reversible causes of incontinence, uncontrolled metabolic conditions, residual urine >100 ml, urinary tract infection, fistula or indwelling catheter, unable to perform VPFMC. Mean age PFMT gp 62 yrs (sd 10), BT gp 60 (sd 10), and combination gp 61 (sd 9). Mean duration of symptoms 7.9 yrs (sd 9.2) in PFMT gp, 8.6 (sd 8.3) in BT gp, and 7.5 (sd 7.7) in combination gp. Multicentre, USA.
Interventions	1. PFMT + BF (n=64) Individual instruction by trained registered nurses. Structured education programme (audiovisual and written). 6 wkly clinic visits, then fortnightly for 6 wks and phone calls in wks 7-12. Daily home ex program with audiocassette. PFMT = 5 VPFMC held for 3 sec and 10 VPFMC with 10 sec hold 2x day progressed total 10 fast and 40 sustained contractions per day. VPFMC to inhibit urge. The Knack (VPFMC prior to increases in intra-abdominal pressure). BF = vaginal pressure device with visual BF for 30 min per wk for 4 wks. 2.BT (n=68) Education and clinic visits as above. BT = progressive voiding schedule and urge strategies. 3. PFMT + BF + BT (n=61) Education and clinic visits as above. BT in wks 1 and 2, PFMT added wk 3.
Outcomes	Urinary diary. Pad test. Revised Incontinence Impact Questionnaire. Urogential Distress Inventory. Self report of compliance.
Notes	Post rx = 12 wks. Follow up at 6 months. 25 drop outs but gp allocation not stated.
Allocation concealment	B

Study	Wyman 1998a
Methods	As Wyman 1998
Participants	Used to differentiate women with genuine stress incontinence only
Interventions	As Wyman 1998
Outcomes	As Wyman 1998
Notes	As Wyman 1998
Allocation concealment	B

Study	Wyman 1998b
Methods	As Wyman 1998
Participants	Used to differentiate women with detrusor instability or mixed incontinence
Interventions	As Wyman 1998

Characteristics of included studies

Outcomes	As Wyman 1998
Notes	As Wyman 1998
Allocation concealment	B

Footnotes:
BF = biofeedback, BT = bladder training, DI = detrusor instability, EMG = electromyography, ES = electrical stimulation, ex = exercise, gd = grade, gp = group, GSI = genuine stress incontinence, hr = hour, HRT = hormone replacement therapy, IVRD = intravaginal resistance device, kn = kneeling, ly = lying, max = maximum, min(s) = minutes(s), MMSE = mini mental state examination, PFM = pelvic floor muscle(s), PFMT = pelvic floor muscle training, pr kn = prone kneeling (crawling position), RCT = randomised controlled trial, rx = treatment, sd = standard deviation, sd ly = side lying, sec = second(s), sitt = sitting, st = standing, std = standard, sup ly = supine lying, se = standard error of the mean, VC = weighted vaginal cones, VPFMC = voluntary pelvic floor muscle contraction(s), wk(s) = week(s), yr(s) = year(s),

Characteristics of excluded studies

Study	Reason for exclusion
Blowman 1991	Essentially a comparison of electrical stimulation and sham stimulation. A randomised trial in women with genuine stress incontinence that compared PFMT and electrical stimulation versus PFMT and sham stimulation.
Borrie 1992	Not all participants received PFMT? Randomised trial of conservative management versus control (no treatment) in men and women with incontinent of urine >1 per week. Conservative management included any combination of the following interventions as appropriate - PFMT, bladder training, urge suppression techniques, and counselling regarding fluids, caffeine, and weight loss.
Bourcier 1994	Unable to distinguish effect of PFMT. Randomised trial comparing intensive PFMT and vaginal cones versus electrical stimulation and biofeedback (presumably biofeedback of voluntary pelvic floor muscle contractions but this is not stated).
Burgio 1986	Not a randomised trial. A controlled trial that compared PFMT with biofeedback versus PFMT alone. Non-random allocation confirmed by authors.
Fonda 1994	Not all participants received PFMT? Randomised trial of conservative management versus control (no treatment) for older men and women with urinary incontinence. Conservative treatment included any combination of the following interventions as appropriate - PFMT, advice, individualised bladder training, post voiding urethral massage, therapy for associated conditions (e.g. poor mobility), incontinence aids if needed, and oestrogen cream.
Haig 1995	Not a randomised trial. A controlled trial that compared PFMT versus PFMT with electrical stimulation versus PFMT with sham stimulation in women with genuine stress incontinence. Alternate assignment to groups.
Holtedahl 1998	Not all participants received PFMT? A randomised trial of conservative management versus control (no treatment) for women with symptoms of urinary incontinence. Conservative management included any combination of the following interventions as appropriate - PFMT, oestrogen, bladder training, electrical stimulation, incontinence aids.
Mayne 1988	Investigated the effect of two forms of biofeedback. A randomised trial in which women with genuine stress incontinence all received the same programme of PFMT but were randomised to receive biofeedback from urethral conductance or perineometry.

Characteristics of excluded studies

Olah 1990	Essentially a comparison of vaginal cones and electrical stimulation. A randomised trial in women with symptoms of urinary incontinence that compared PFMT and vaginal cones versus PFMT and electrical stimulation. Both arms received the same PFMT programme.
Shepherd 1984	Essentially a comparison of electrical stimulation and sham stimulation. A randomised trial in women with symptoms of urinary incontinence that compared PFMT and electrical stimulation versus PFMT and sham stimulation. The ES was maximal perineal stimulation under general anaesthetic. Both women received the same PFMT programme.
Voigt 1996	Not a randomised trial. A controlled trial that compared PFMT versus electrical stimulation in women with stress incontinence.
Wang 1997	Not a randomised trial (for intervention of interest) Women with symptoms of urgency were randomised to receive oxybutynin chloride or no treatment. Treatment failures from the oxybutynin group were then "assigned" to biofeedback or PFMT.
Wilson 1987	Not a randomised trial. A controlled trial that compared PFMT with biofeedback (clinic visits with physiotherapist) versus PFMT with electrical stimulation (faradism) versus PFMT with electrical stimulation (interferential) versus PFMT (home programme only). Alternate assignment to group.

Characteristics of ongoing studies

Study	Demain MRC
Trial name or title	A randomised controlled trial of educational group sessions and conventional individual management in the physiotherapeutic treatment of female urinary incontinence.
Participants	60 women with clinical diagnosis of stress and/or urge incontinence. Excluded if pregnant, pelvic surgery in last 3 months, history of pelvic malignancy, neurological disease, acute mental illness, dementia, severe prolapse, faecal incontinence, urinary tract infection, physiotherapy within last 12 months.
Interventions	1. Individual treatment. 2. Group treatment with 4-12 per group.
Outcomes	Not known.
Starting date	Start date 01/10.96. Expected completion 01/10/97.
Contact information	Mrs S Demain. Physiotherapy Dept., St Michael's Hospital, Trent Valley Road, Lichfield WS13 6EF, England.
Notes	"Pilot study". Does not specifically state if treatment includes PFMT. Details not confirmed by named lead researcher.

Study	Leics MRC
Trial name or title	The evaluation of pelvic floor therapies in women with genuine stress incontinence: A randomised controlled trial in primary care.
Participants	360 women with GSI following failure of nurse led conservative management (pelvic floor awareness - leaflet and instructions. No pelvic examination).

Characteristics of ongoing studies

Interventions	1. PFMT = vaginal palpation of correct VPFMC, perineometry, 4 clinic visits over 12 wks. 2. Vaginal cones 3. Placebo = pelvic floor awareness.
Outcomes	Urinary diary. 1 hr pad test. 24 hr pad test. Perineometry. Palpation of PFM strength. Urodynamics.
Starting date	Trial began 01/06/97. Anticipated completion 01/04/01.
Contact information	Dr P Assassa Senior Clinical Research Fellow. University of Leicester.
Notes	Details confirmed by lead researcher.

Footnotes:
MRC = Medical Research Council (UK), PFM = pelvic floor muscle(s), PFMT = pelvic floor muscle training, VPFMC = voluntary pelvic floor muscle contraction,

COVER SHEET

Title	**Pelvic floor muscle training for urinary incontinence in women**
Reviewer(s)	**Hay-Smith EJC, Bø K, Berghmans LCM, Hendriks HJM, de Bie RA, van Waalwijk van Doorn ESC**
Contribution of reviewer(s)	Conception of the review was a collective effort but the particular contributions of Bary Berghmans and Kari Bø are recognised. They were the principal authors of previous systematic reviews investigating the efficacy of physical therapies for female stress incontinence. Jean Hay-Smith has taken the principal role in all aspects of this review. Kari Bø assisted in screening all trials for eligibility, quality assessment and cross checking data extraction except where she was an author of a study being considered for inclusion. All reviewers commented on the interpretation of the results and discussion.
Issue protocol first published	1999/1
Issue review first published	2001/1
Date of most recent amendment	28 April 2000
Date of most recent SUBSTANTIVE amendment	20 November 2000
Most recent changes	Information not supplied by reviewer
Date new studies sought but none found	Information not supplied by reviewer

Date new studies found but not yet included/excluded	Information not supplied by reviewer
Date new studies found and included/excluded	Information not supplied by reviewer
Date reviewers' conclusions section amended	Information not supplied by reviewer
Contact address	Jean Hay-Smith HRC Training Fellow Department of Women's and Children's Health Dunedin School of Medicine, University of Otago PO Box 913 Dunedin NEW ZEALAND Telephone: +64 3 474 0999 E-mail: jean.hay-smith@stonebow.otago.ac.nz Facsimile: +64 3 474 7620
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SUMMARY TABLES

01 PFMT versus no treatment				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	3	216	Relative Risk [Fixed] [95% CI]	7.25 [1.99, 26.49]
02 self reported cure or improvement post treatment	3	164	Relative Risk [Fixed] [95% CI]	23.04 [7.56, 70.22]
03 number of leakage episodes in 24 hours	4	325	WMD [Fixed] [95% CI]	-1.246 [-1.565, -0.927]

02 PFMT versus placebo treatments				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	3	167	Relative Risk [Fixed] [95% CI]	3.12 [1.56, 6.23]
02 self reported cure or improvement post treatment	4	211	Relative Risk [Fixed] [95% CI]	1.53 [1.26, 1.87]
03 number of leakage episodes in 24 hours	1	125	WMD [Fixed] [95% CI]	-0.770 [-1.215, -0.325]

03 Comparisons of PFMT

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	4	672	Relative Risk [Fixed] [95% CI]	1.47 [1.17, 1.84]
02 self reported cure or improvement post treatment	1	52	Relative Risk [Fixed] [95% CI]	1.46 [1.11, 1.93]
03 number of leakage episodes in 24 hours			No numerical data	

04 PFMT versus electrical stimulation

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	4	132	Relative Risk [Fixed] [95% CI]	2.94 [0.99, 8.67]
02 self reported cure or improvement post treatment	4	132	Relative Risk [Fixed] [95% CI]	1.23 [0.97, 1.57]
03 number of leakage episodes in 24 hours	1	50	WMD [Fixed] [95% CI]	-0.290 [-0.588, 0.008]

05 PFMT versus vaginal cones

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	3	204	Relative Risk [Fixed] [95% CI]	0.74 [0.50, 1.09]
02 self reported cure or improvement post treatment	3	145	Relative Risk [Fixed] [95% CI]	1.12 [0.88, 1.41]
03 number of leakage episodes in 24 hours	2	112	WMD [Fixed] [95% CI]	-0.683 [-1.180, -0.185]

06 PFMT versus bladder training

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment			No numerical data	
02 self reported cure or improvement post treatment	1	132	Relative Risk [Fixed] [95% CI]	1.19 [0.94, 1.49]
03 number of leakage episodes in 24 hours	2	131	WMD [Fixed] [95% CI]	0.810 [-0.210, 1.830]

07 PFMT versus medication (anticholinergic)

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	1	128	Relative Risk [Fixed] [95% CI]	1.31 [0.73, 2.34]

07 PFMT versus medication (anticholinergic)				
02 self reported cure or improvement post treatment	1	128	Relative Risk [Fixed] [95% CI]	1.18 [1.01, 1.37]
03 number of leakage episodes in 24 hours	1	128	WMD [Fixed] [95% CI]	-0.410 [-0.788, -0.032]

08 PFMT versus medication (oestrogen)				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment			No numerical data	
02 self reported cure or improvement post treatment			No numerical data	
03 number of leakage episodes in 24 hours			No numerical data	

09 PFMT versus medication (alpha adrenergic)				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment			No numerical data	
02 self reported cure or improvement post treatment	1	118	Relative Risk [Fixed] [95% CI]	0.92 [0.77, 1.10]
03 number of leakage episodes in 24 hours	1	113	WMD [Fixed] [95% CI]	0.080 [0.020, 0.140]

10 PFMT versus incontinence surgery				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	1	50	Relative Risk [Fixed] [95% CI]	0.20 [0.07, 0.61]
02 self reported cure or improvement post treatment	1	50	Relative Risk [Fixed] [95% CI]	0.80 [0.60, 1.07]
03 number of leakage episodes in 24 hours			No numerical data	

11 PFMT with electrical stimulation versus electrical stimulation				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	1	22	Relative Risk [Fixed] [95% CI]	3.00 [0.37, 24.58]
02 self reported cure or improvement post treatment	1	22	Relative Risk [Fixed] [95% CI]	2.33 [0.81, 6.76]
03 number of leakage episodes in 24 hours			No numerical data	

12 PFMT with vaginal cones versus vaginal cones				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment			No numerical data	
02 self reported cure or improvement post treatment			No numerical data	
03 number of leakage episodes in 24 hours			No numerical data	

13 PFMT with bladder training versus bladder training				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment			No numerical data	
02 self reported cure or improvement post treatment	1	129	Relative Risk [Fixed] [95% CI]	1.43 [1.17, 1.74]
03 number of leakage episodes in 24 hours	2	125	WMD [Fixed] [95% CI]	-0.540 [-1.037, -0.044]

14 PFMT with incontinence device versus device alone				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment			No numerical data	
02 self reported cure or improvement post treatment			No numerical data	
03 number of leakage episodes in 24 hours			No numerical data	

15 PFMT versus PFMT with biofeedback				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	2	105	Relative Risk [Fixed] [95% CI]	0.56 [0.29, 1.10]
02 self reported cure or improvement post treatment	2	63	Relative Risk [Fixed] [95% CI]	0.90 [0.75, 1.08]
03 number of leakage episodes in 24 hours	3	161	WMD [Fixed] [95% CI]	0.149 [-0.066, 0.365]

16 PFMT versus PFMT with intravaginal resistance device				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	1	22	Relative Risk [Fixed] [95% CI]	0.38 [0.13, 1.05]

16 PFMT versus PFMT with intravaginal resistance device				
02 self reported cure or improvement post treatment	2	63	Relative Risk [Fixed] [95% CI]	0.90 [0.75, 1.08]
03 number of leakage episodes in 24 hours			No numerical data	

17 PFMT versus PFMT with electrical stimulation				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	1	22	Relative Risk [Fixed] [95% CI]	2.00 [0.66, 6.04]
02 self reported cure or improvement post treatment	3	113	Relative Risk [Fixed] [95% CI]	0.95 [0.67, 1.35]
03 number of leakage episodes in 24 hours			No numerical data	

18 PFMT versus PFMT with vaginal cones				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment	2	138	Relative Risk [Fixed] [95% CI]	0.83 [0.50, 1.37]
02 self reported cure or improvement post treatment	1	46	Relative Risk [Fixed] [95% CI]	1.96 [0.92, 4.19]
03 number of leakage episodes in 24 hours			No numerical data	

19 PFMT versus PFMT with bladder training				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 self reported cure post treatment			No numerical data	
02 self reported cure or improvement post treatment	1	125	Relative Risk [Fixed] [95% CI]	0.83 [0.71, 0.98]
03 number of leakage episodes in 24 hours	2	122	WMD [Fixed] [95% CI]	0.870 [-0.199, 1.939]

Fig. 01 PFMT versus no treatment

01.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 01 PFMT versus no treatment
Outcome: 01 self reported cure post treatment

Study	PFMT	Control	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Burns 1993a	7 / 43	1 / 39		41.7	6.35 [0.82, 49.32]
Burns 1993b	9 / 40	1 / 39		40.2	8.78 [1.17, 66.04]
Bø 1999	2 / 25	0 / 30		18.1	5.96 [0.30, 118.71]
Total (95% CI)	18 / 108	2 / 108		100.0	7.25 [1.99, 26.49]

Test for heterogeneity chi-square=0.07 df=2 p=0.9671
Test for overall effect Z=3.00 p=0.00

0.01   0.1   1   10   100
Favours control   Favours PFMT

01.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 01 PFMT versus no treatment
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	Control	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Bø 1999	23 / 25	1 / 30		32.0	27.60 [4.00, 190.25]
Lagro-Janssen 1992a	20 / 33	1 / 33		35.2	20.00 [2.85, 140.51]
Lagro-Janssen 1992b	19 / 20	1 / 23		32.8	21.85 [3.20, 148.97]
Total (95% CI)	62 / 78	3 / 86		100.0	23.04 [7.56, 70.22]

Test for heterogeneity chi-square=0.06 df=2 p=0.9720
Test for overall effect Z=5.52 p=0.00

0.01   0.1   1   10   100
Favours control   Favours PFMT

01.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 01 PFMT versus no treatment
Outcome: 03 number of leakage episodes in 24 hours

Study	PFMT N	PFMT Mean (SD)	Control N	Control Mean (SD)	WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
Burns 1993a	43	1.14 (1.43)	39	2.43 (2.71)		11.2	-1.290 [-2.242, -0.338]
Burns 1993b	40	0.71 (0.86)	39	2.43 (2.71)		12.8	-1.720 [-2.611, -0.829]
Bø 1999	25	0.27 (0.34)	30	1.07 (1.12)		57.0	-0.800 [-1.222, -0.378]
Lagro-Janssen 1992	53	1.03 (1.70)	56	3.27 (2.18)		19.0	-2.240 [-2.972, -1.508]
Total (95% CI)	161		164			100.0	-1.246 [-1.565, -0.927]

Test for heterogeneity chi-square=12.47 df=3 p=0.0059
Test for overall effect Z=-7.66 p=0.00

-10   -5   0   5   10
Favours PFMT   Favours control

Fig. 02 PFMT versus placebo treatments

02.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 02 PFMT versus placebo treatments
Outcome: 01 self reported cure post treatment

Study	PFMT	placebo treatment	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Burgio 1998	19 / 63	8 / 62		88.5	2.34 [1.11, 4.94]
Hofbauer 1990a	6 / 11	0 / 10		5.7	11.92 [0.76, 187.85]
Hofbauer 1990b	3 / 11	0 / 10		5.7	6.42 [0.37, 110.71]
Total (95% CI)	28 / 85	8 / 82		100.0	3.12 [1.56, 6.23]

Test for heterogeneity chi-square=1.73 df=2 p=0.4219
Test for overall effect Z=3.22 p=0.00

0.01 0.1 1 10 100
Favours placebo   Favours PFMT
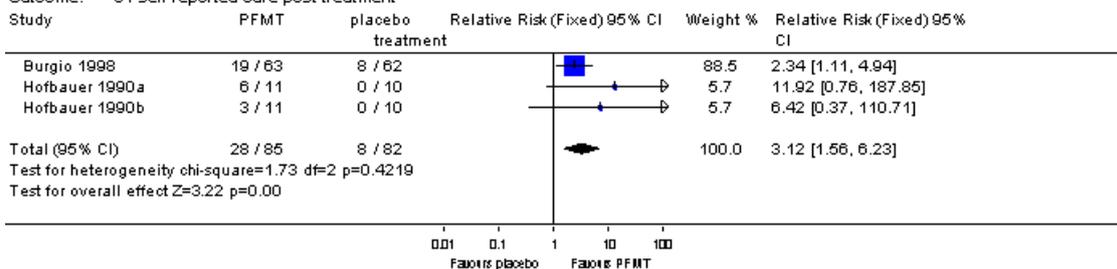
02.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 02 PFMT versus placebo treatments
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	placebo treatment	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Burgio 1998	57 / 63	40 / 62		72.8	1.40 [1.15, 1.71]
Hofbauer 1990a	7 / 11	0 / 10		0.9	13.75 [0.88, 213.66]
Hofbauer 1990b	7 / 11	0 / 10		0.9	13.75 [0.88, 213.66]
Ramsay 1990	14 / 22	14 / 22		25.3	1.00 [0.64, 1.56]
Total (95% CI)	85 / 107	54 / 104		100.0	1.53 [1.26, 1.87]

Test for heterogeneity chi-square=9.19 df=3 p=0.0269
Test for overall effect Z=4.19 p=0.00

0.01 0.1 1 10 100
Favours placebo   Favours PFMT

02.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 02 PFMT versus placebo treatments
Outcome: 03 number of leakage episodes in 24 hours

Study	PFMT N	PFMT Mean (SD)	placebo treatment N	placebo treatment Mean (SD)	WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
Burgio 1998	63	0.40 (0.67)	62	1.17 (1.66)		100.0	-0.770 [-1.215, -0.325]
Total (95% CI)	63		62			100.0	-0.770 [-1.215, -0.325]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=3.39 p=0.00

-10 -5 0 5 10
Favours PFMT   Favours placebo

Fig. 03 Comparisons of PFMT

03.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 03 Comparisons of PFMT
Outcome: 01 self reported cure post treatment

Study	intensive	standard	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Bø 1990	2 / 23	0 / 29		0.5	6.25 [0.31, 124.11]
Wilson 1997a	65 / 156	37 / 124		50.5	1.40 [1.01, 1.94]
Wilson 1997b	45 / 120	31 / 110		39.6	1.33 [0.91, 1.94]
Wilson 1998	10 / 19	22 / 91		9.3	2.18 [1.24, 3.81]
Total (95% CI)	122 / 318	90 / 354		100.0	1.47 [1.17, 1.84]

Test for heterogeneity chi-square=3.15 df=3 p=0.3693
Test for overall effect Z=3.33 p=0.00

0.01 0.1 1 10 100
Favours standard   Favours Intensive

03.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 03 Comparisons of PFMT
Outcome: 02 self reported cure or improvement post treatment

Study	intensive	standard	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Bø 1990	22 / 23	19 / 29		100.0	1.46 [1.11, 1.93]
Total (95% CI)	22 / 23	19 / 29		100.0	1.46 [1.11, 1.93]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=2.67 p=0.01

0.01 0.1 1 10 100
Favours standard   Favours intensive

03.03 number of leakage episodes in 24 hours

No graph or table supplied by reviewer

Fig. 04 PFMT versus electrical stimulation

04.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 04 PFMT versus electrical stimulation
Outcome: 01 self reported cure post treatment

Study	PFMT	stimulation	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Bø 1999	2 / 25	1 / 25		26.0	2.00 [0.19, 20.67]
Hahn 1991	1 / 10	1 / 10		26.0	1.00 [0.07, 13.87]
Hofbauer 1990	6 / 11	1 / 11		26.0	6.00 [0.86, 41.97]
Laycock 1993	2 / 17	1 / 23		22.1	2.71 [0.27, 27.46]
Total (95% CI)	11 / 63	4 / 69		100.0	2.94 [0.99, 8.67]

Test for heterogeneity chi-square=1.27 df=3 p=0.7359
Test for overall effect Z=1.95 p=0.05

0.01 0.1 1 10 100
Favours stimulation   Favours PFMT

04.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 04 PFMT versus electrical stimulation
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	stimulation	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Bø 1999	23 / 25	16 / 25		40.6	1.44 [1.05, 1.97]
Hahn 1991	10 / 10	8 / 10		21.6	1.24 [0.87, 1.75]
Hofbauer 1990	7 / 11	3 / 11		7.6	2.33 [0.81, 6.76]
Laycock 1993	7 / 17	14 / 23		30.2	0.68 [0.35, 1.30]
Total (95% CI)	47 / 63	41 / 69		100.0	1.23 [0.97, 1.57]

Test for heterogeneity chi-square=5.51 df=3 p=0.1380
Test for overall effect Z=1.69 p=0.09

0.01 0.1 1 10 100
Favours stimulation   Favours PFMT

04.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 04 PFMT versus electrical stimulation
Outcome: 03 number of leakage episodes in 24 hours

Study	PFMT N	Mean (SD)	stimulation N	Mean (SD)	WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
Bø 1999	25	0.27 (0.34)	25	0.56 (0.68)		100.0	-0.290 [-0.588, 0.008]
Total (95% CI)	25		25			100.0	-0.290 [-0.588, 0.008]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=-1.91 p=0.06

-10 -5 0 5 10
Favours PFMT   Favours stimulation

Fig. 05 PFMT versus vaginal cones

05.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 05 PFMT versus vaginal cones
Outcome: 01 self reported cure post treatment

Study	PFMT	vaginal cones	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Bø 1999	2 / 25	0 / 27		1.7	5.38 [0.27, 106.98]
Wilson 1998a	22 / 91	11 / 21		62.1	0.46 [0.27, 0.80]
Wilson 1998b	10 / 19	11 / 21		36.3	1.00 [0.56, 1.81]
Total (95% CI)	34 / 135	22 / 69		100.0	0.74 [0.50, 1.09]

Test for heterogeneity chi-square=5.60 df=2 p=0.0609
Test for overall effect Z=-1.51 p=0.13

0.01 0.1 1 10 100
Favours cones   Favours PFMT

05.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 05 PFMT versus vaginal cones
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	vaginal cones	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Bø 1999	23 / 25	17 / 27		36.3	1.46 [1.07, 2.00]
Cammu 1998	16 / 30	17 / 30		37.8	0.94 [0.60, 1.49]
Peattie 1988	10 / 16	12 / 17		25.9	0.89 [0.54, 1.44]
Total (95% CI)	49 / 71	46 / 74		100.0	1.12 [0.88, 1.41]

Test for heterogeneity chi-square=4.27 df=2 p=0.1182
Test for overall effect Z=0.92 p=0.40

0.01 0.1 1 10 100
Favours cones   Favours PFMT

05.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 05 PFMT versus vaginal cones
Outcome: 03 number of leakage episodes in 24 hours

Study	PFMT N	PFMT Mean (SD)	vaginal cones N	vaginal cones Mean (SD)	WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
Bø 1999	25	0.27 (0.34)	27	1.17 (1.78)		52.7	-0.900 [-1.585, -0.215]
Cammu 1998	30	0.80 (0.79)	30	1.24 (1.86)		47.3	-0.440 [-1.163, 0.283]
Total (95% CI)	55		57			100.0	-0.683 [-1.180, -0.185]

Test for heterogeneity chi-square=0.82 df=1 p=0.3652
Test for overall effect Z=-2.69 p=0.01

-10 -5 0 5 10
Favours PFMT   Favours cones

Fig. 06 PFMT versus bladder training

06.01 self reported cure post treatment

No graph or table supplied by reviewer

06.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 06 PFMT versus bladder training
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	behavioural	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Wyman 1998	48 / 64	43 / 68		100.0	1.19 [0.94, 1.49]
Total (95% CI)	48 / 64	43 / 68		100.0	1.19 [0.94, 1.49]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=1.45 p=0.15

0.01 0.1 1 10 100
Favours behavioural   Favours PFMT

06.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 06 PFMT versus bladder training
Outcome: 03 number of leakage episodes in 24 hours

Study	PFMT		behavioural		WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
	N	Mean (SD)	N	Mean (SD)			
× Wyman 1998a	46	1.24 (0.00)	48	1.79 (1.19)		0.0	Not estimable
Wyman 1998b	18	1.70 (1.81)	19	0.89 (1.30)		100.0	0.810 [-0.210, 1.830]
Total (95% CI)	64		67			100.0	0.810 [-0.210, 1.830]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=1.56 p=0.12

-10 -5 0 5 10
Favours PFMT   Favours behavioural
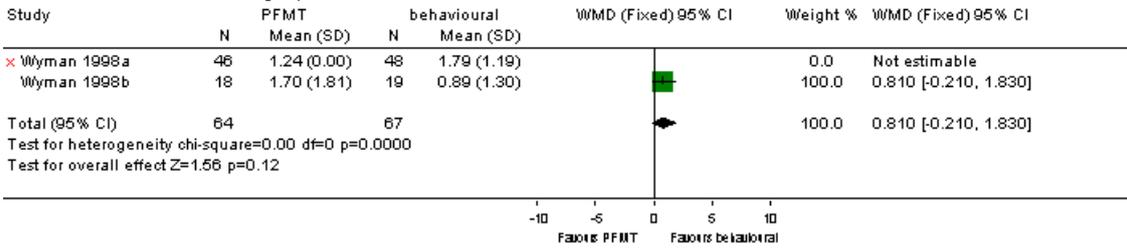
Fig. 07 PFMT versus medication (anticholinergic)

07.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 07 PFMT versus medication (anticholinergic)
Outcome: 01 self reported cure post treatment
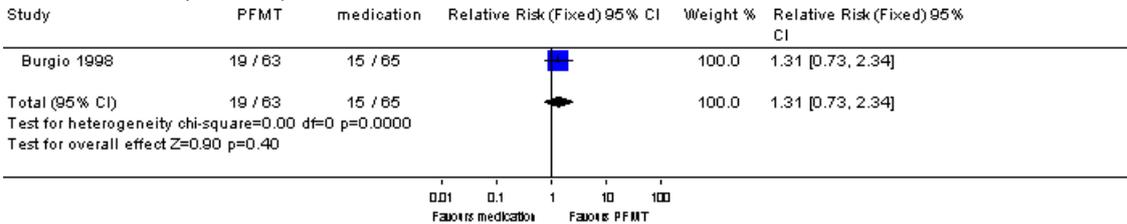
Study	PFMT	medication	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Burgio 1998	19 / 63	15 / 65		100.0	1.31 [0.73, 2.34]
Total (95% CI)	19 / 63	15 / 65		100.0	1.31 [0.73, 2.34]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=0.90 p=0.40

0.01 0.1 1 10 100
Favours medication   Favours PFMT

07.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 07 PFMT versus medication (anticholinergic)
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	medication	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Burgio 1998	57 / 63	50 / 65		100.0	1.18 [1.01, 1.37]
Total (95% CI)	57 / 63	50 / 65		100.0	1.18 [1.01, 1.37]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=2.05 p=0.04

0.01 0.1 1 10 100
Favours medication   Favours PFMT

07.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 07 PFMT versus medication (anticholinergic)
Outcome: 03 number of leakage episodes in 24 hours

Study	PFMT		medication		WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
	N	Mean (SD)	N	Mean (SD)			
Burgio 1998	63	0.40 (0.67)	65	0.81 (1.40)		100.0	-0.410 [-0.788, -0.032]
Total (95% CI)	63		65			100.0	-0.410 [-0.788, -0.032]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=-2.12 p=0.03

-10 -5 0 5 10
Favours PFMT   Favours medication

Fig. 08 PFMT versus medication (oestrogen)

08.01 self reported cure post treatment

No graph or table supplied by reviewer

08.02 self reported cure or improvement post treatment

No graph or table supplied by reviewer

Fig. 09 PFMT versus medication (alpha adrenergic)

09.01 self reported cure post treatment

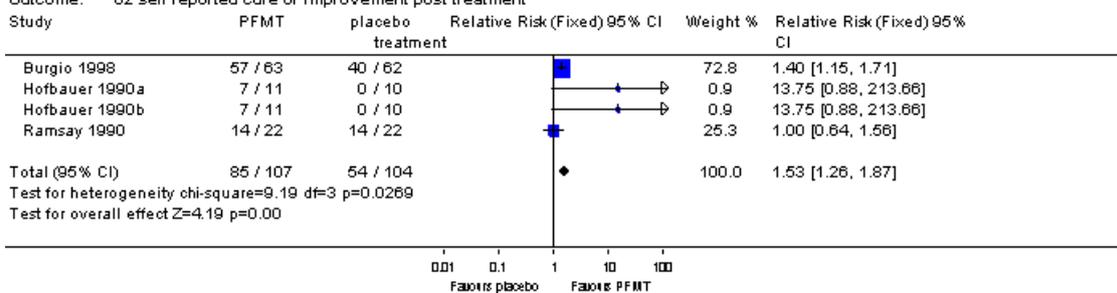No graph or table supplied by reviewer

09.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 09 PFMT versus medication (alpha adrenergic)
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	medication	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Wells 1991	42 / 54	54 / 64		100.0	0.92 [0.77, 1.10]
Total (95% CI)	42 / 54	54 / 64		100.0	0.92 [0.77, 1.10]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=-0.90 p=0.40

```
         0.01   0.1    1    10   100
         Favours medication   Favours PFMT
```

09.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 09 PFMT versus medication (alpha adrenergic)
Outcome: 03 number of leakage episodes in 24 hours

Study	PFMT N	Mean (SD)	medication N	Mean (SD)	WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
Wells 1991	51	0.75 (0.18)	62	0.67 (0.14)		100.0	0.080 [0.020, 0.140]
Total (95% CI)	51		62			100.0	0.080 [0.020, 0.140]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=2.59 p=0.01

```
         -10    -5    0    5    10
         Favours PFMT    Favours medication
```

Fig. 10 PFMT versus incontinence surgery

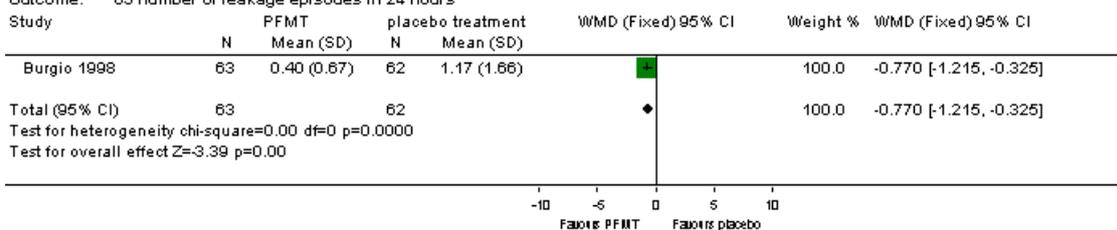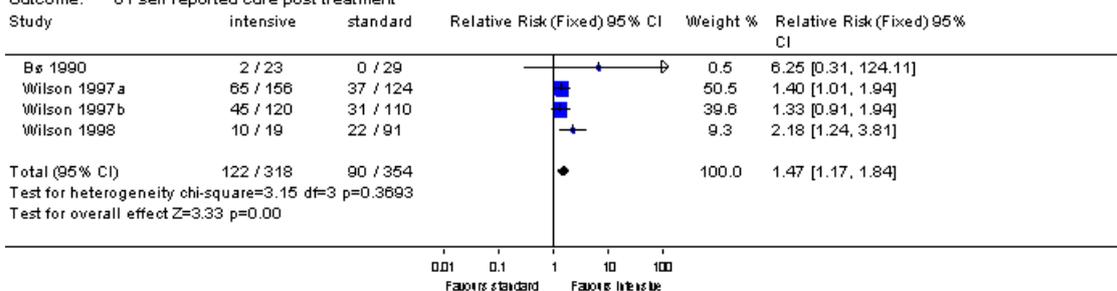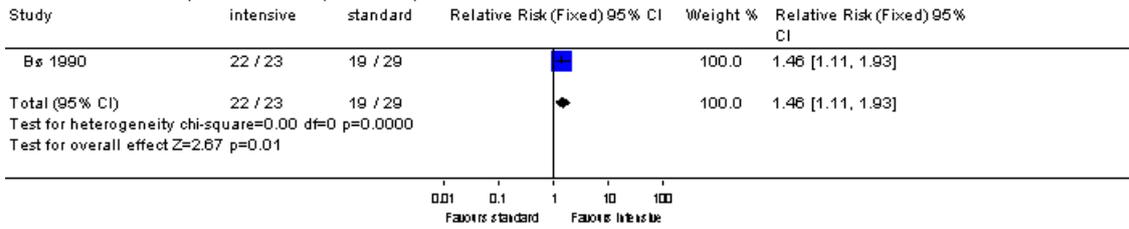### 10.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 10 PFMT versus incontinence surgery
Outcome: 01 self reported cure post treatment

Study	PFMT	surgery	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Klarskov 1986	3 / 24	16 / 26		100.0	0.20 [0.07, 0.61]
Total (95% CI)	3 / 24	16 / 26		100.0	0.20 [0.07, 0.61]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=-2.84 p=0.01

```
         0.01   0.1    1    10   100
         Favours surgery    Favours PFMT
```

10.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 10 PFMT versus incontinence surgery
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	surgery	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Klarskov 1986	17 / 24	23 / 26		100.0	0.80 [0.60, 1.07]
Total (95% CI)	17 / 24	23 / 26		100.0	0.80 [0.60, 1.07]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=-1.49 p=0.14

```
         0.01   0.1    1    10   100
         Favours surgery    Favours PFMT
```

10.03 number of leakage episodes in 24 hours

No graph or table supplied by reviewer
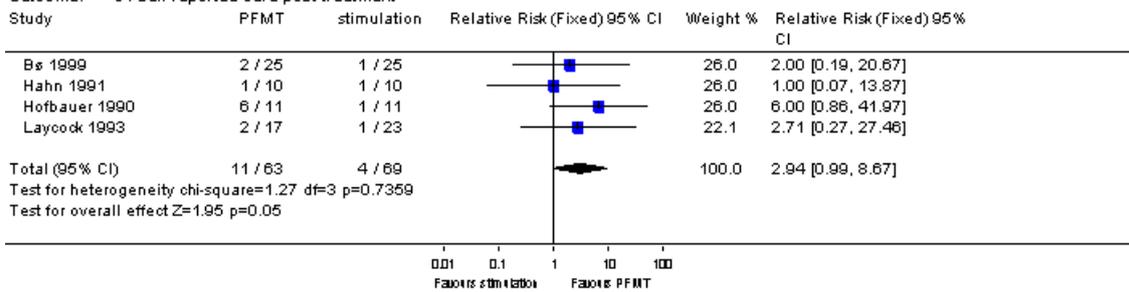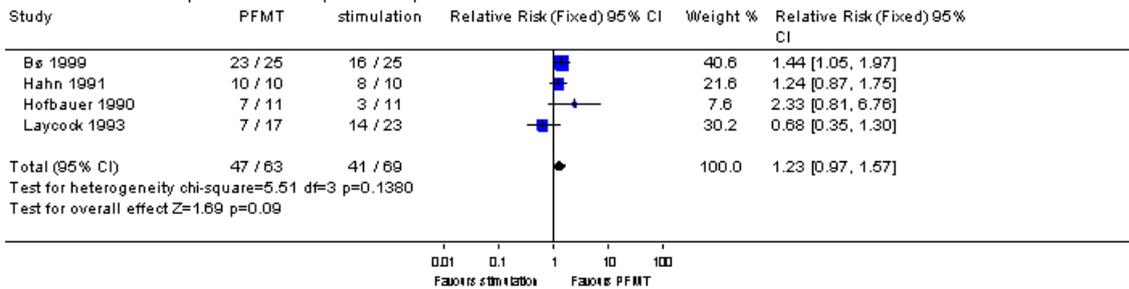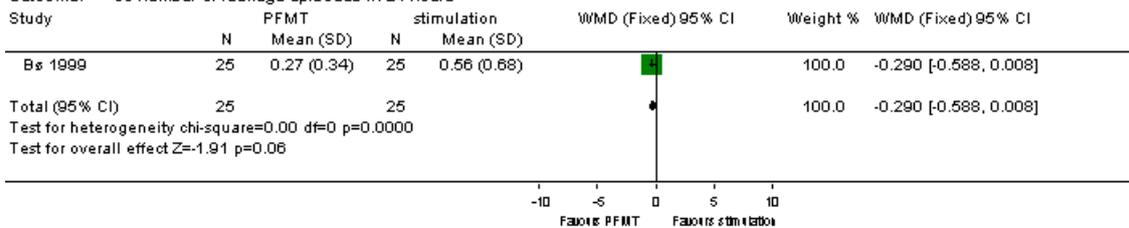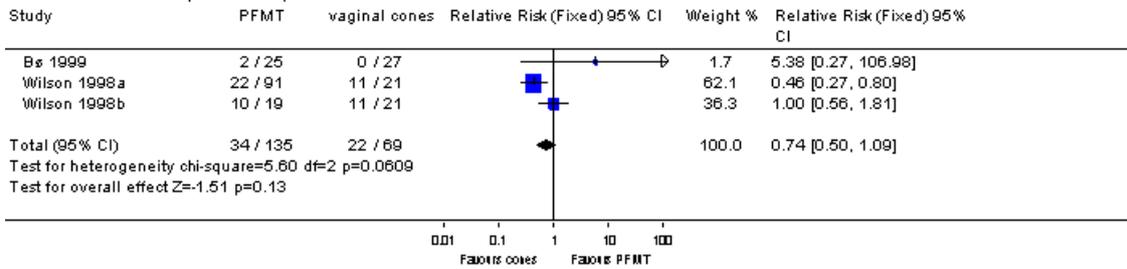
Fig. 11 PFMT with electrical stimulation versus electrical stimulation

11.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 11 PFMT with electrical stimulation versus electrical stimulation
Outcome: 01 self reported cure post treatment

Study	Combination	stimulation	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Hofbauer 1990	3 / 11	1 / 11		100.0	3.00 [0.37, 24.58]
Total (95% CI)	3 / 11	1 / 11		100.0	3.00 [0.37, 24.58]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=1.02 p=0.30

0.01   0.1   1   10   100
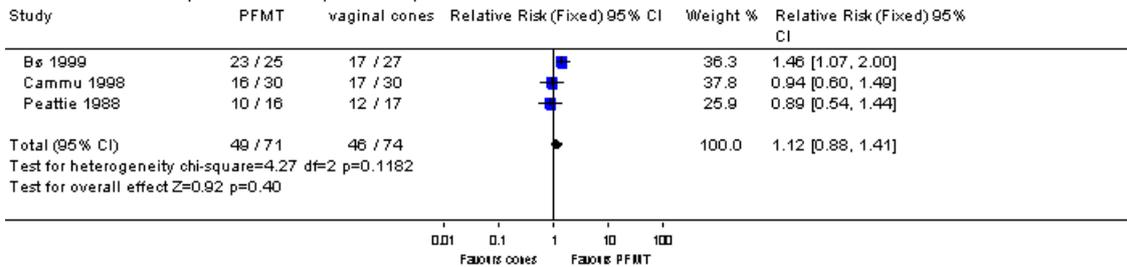Favours stimulation   Favours combination

11.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 11 PFMT with electrical stimulation versus electrical stimulation
Outcome: 02 self reported cure or improvement post treatment

Study	Combination	stimulation	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Hofbauer 1990	7 / 11	3 / 11		100.0	2.33 [0.81, 6.76]
Total (95% CI)	7 / 11	3 / 11		100.0	2.33 [0.81, 6.76]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=1.56 p=0.12

0.01   0.1   1   10   100
Favours stimulation   Favours combination

11.03 number of leakage episodes in 24 hours

No graph or table supplied by reviewer

Fig. 12 PFMT with vaginal cones versus vaginal cones

12.01 self reported cure post treatment

No graph or table supplied by reviewer

12.02 self reported cure or improvement post treatment

No graph or table supplied by reviewer

12.03 number of leakage episodes in 24 hours

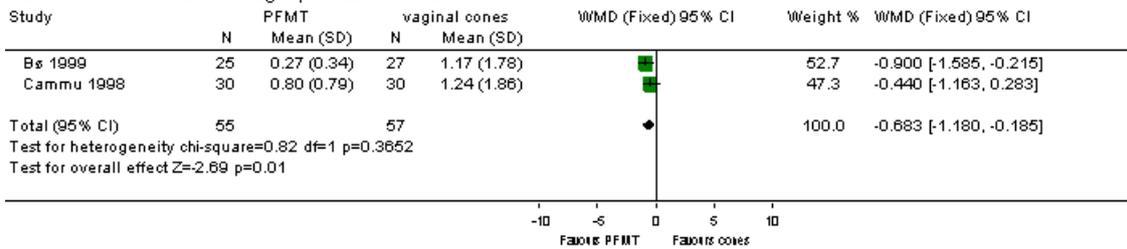No graph or table supplied by reviewer

Fig. 13 PFMT with bladder training versus bladder training
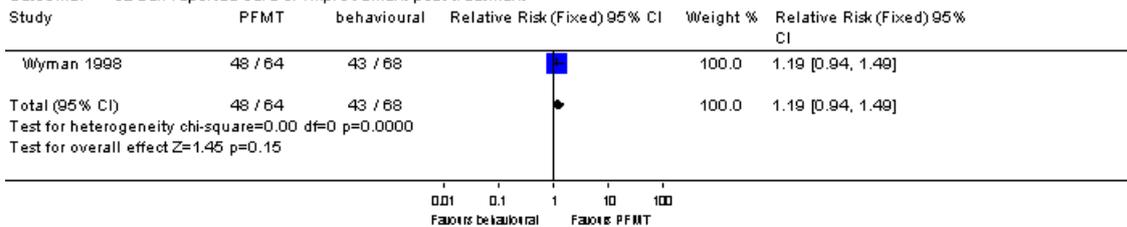
13.01 self reported cure post treatment

No graph or table supplied by reviewer

13.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 13 PFMT with bladder training versus bladder training
Outcome: 02 self reported cure or improvement post treatment

Study	combination	behavioural	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Wyman 1998	55 / 61	43 / 68		100.0	1.43 [1.17, 1.74]
Total (95% CI)	55 / 61	43 / 68		100.0	1.43 [1.17, 1.74]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=3.49 p=0.00

0.01   0.1   1   10   100
Favours behavioural   Favours combination

13.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 13 PFMT with bladder training versus bladder training
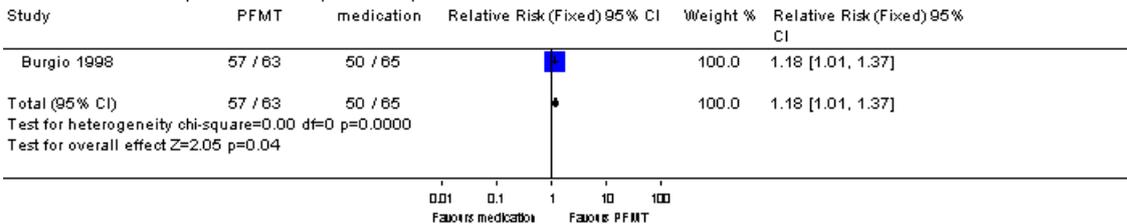Outcome: 03 number of leakage episodes in 24 hours

Study	combination N	Mean (SD)	behavioural N	Mean (SD)	WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
Wyman 1998a	42	1.03 (1.64)	48	1.79 (1.19)		68.6	-0.760 [-1.359, -0.161]
Wyman 1998b	16	0.83 (1.36)	19	0.89 (1.30)		31.4	-0.060 [-0.946, 0.826]
Total (95% CI)	58		67			100.0	-0.540 [-1.037, -0.044]

Test for heterogeneity chi-square=1.64 df=1 p=0.1998
Test for overall effect Z=-2.13 p=0.03

-10 -5 0 5 10
Favours combination   Favours behavioural

Fig. 14 PFMT with incontinence device versus device alone

14.01 self reported cure post treatment

No graph or table supplied by reviewer

14.02 self reported cure or improvement post treatment

No graph or table supplied by reviewer

14.03 number of leakage episodes in 24 hours

No graph or table supplied by reviewer

Fig. 15 PFMT versus PFMT with biofeedback

15.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 15 PFMT versus PFMT with biofeedback
Outcome: 01 self reported cure post treatment

Study	PFMT	combination	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Burns 1993	7 / 43	9 / 40		53.8	0.72 [0.30, 1.76]
Shepherd 1983	3 / 11	8 / 11		46.2	0.38 [0.13, 1.05]
Total (95% CI)	10 / 54	17 / 51		100.0	0.56 [0.29, 1.10]

Test for heterogeneity chi-square=0.90 df=1 p=0.3421
Test for overall effect Z=-1.69 p=0.09

0.01 0.1 1 10 100
Favours combination   Favours PFMT

15.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 15 PFMT versus PFMT with biofeedback
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	combination	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Klingler 1995	21 / 21	19 / 20		66.6	1.05 [0.92, 1.20]
Shepherd 1983	6 / 11	10 / 11		33.4	0.60 [0.34, 1.06]
Total (95% CI)	27 / 32	29 / 31		100.0	0.90 [0.75, 1.08]

Test for heterogeneity chi-square=7.04 df=1 p=0.0080
Test for overall effect Z=-1.11 p=0.30

0.01 0.1 1 10 100
Favours combination   Favours PFMT

15.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 15 PFMT versus PFMT with biofeedback
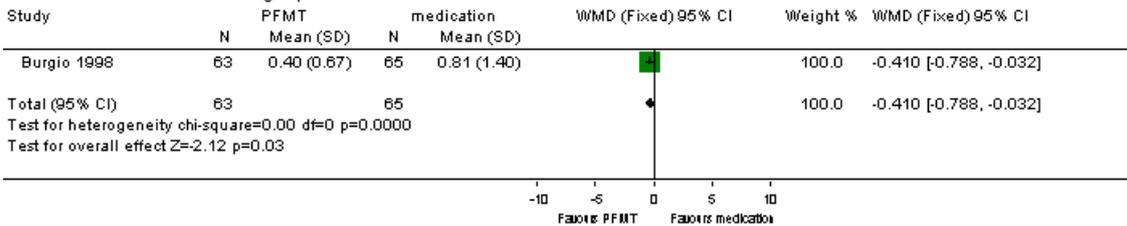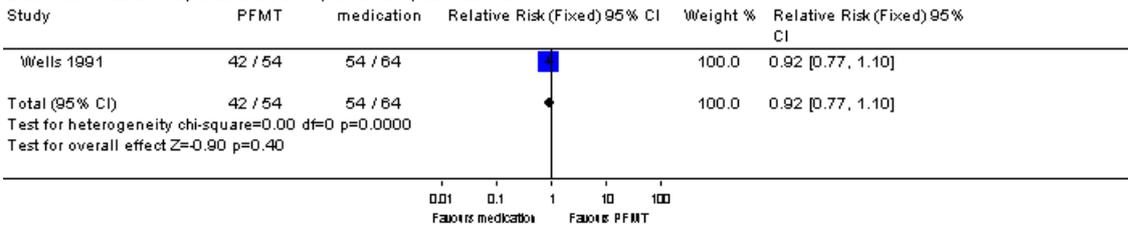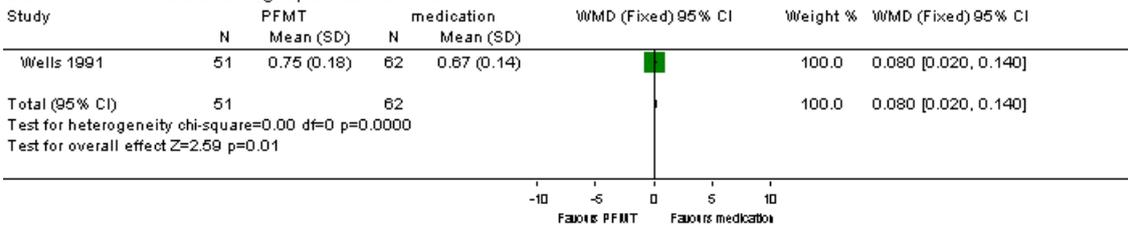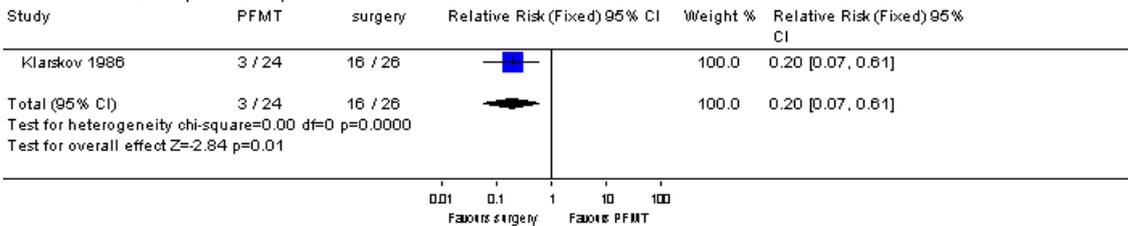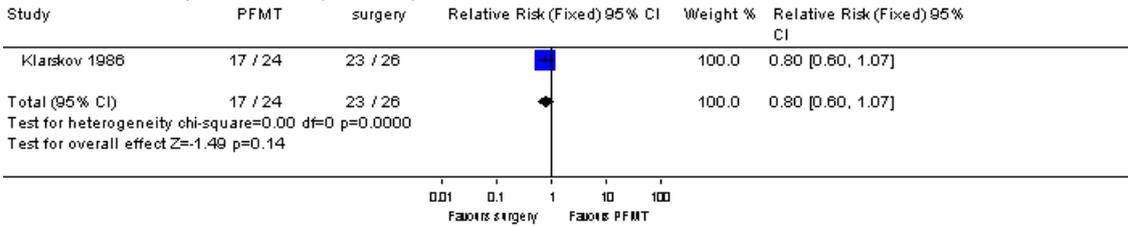Outcome: 03 number of leakage episodes in 24 hours

Study	PFMT N	PFMT Mean (SD)	combination N	combination Mean (SD)	WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
Berghmans 1996	20	0.20 (0.51)	20	0.12 (0.19)		81.5	0.080 [-0.159, 0.319]
Burns 1993	43	1.14 (1.43)	40	0.71 (0.86)		18.3	0.430 [-0.074, 0.934]
Sherman 1997	16	5.25 (7.24)	22	2.90 (6.53)		0.2	2.350 [-2.126, 6.826]
Total (95% CI)	79		82			100.0	0.149 [-0.066, 0.365]

Test for heterogeneity chi-square=2.45 df=2 p=0.2943
Test for overall effect Z=1.36 p=0.17

-10 -5 0 5 10
Favours PFMT   Favours combination

Fig. 16 PFMT versus PFMT with intravaginal resistance device

16.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 16 PFMT versus PFMT with intravaginal resistance device
Outcome: 01 self reported cure post treatment

Study	PFMT	combination	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Shepherd 1983	3 / 11	8 / 11		100.0	0.38 [0.13, 1.05]
Total (95% CI)	3 / 11	8 / 11		100.0	0.38 [0.13, 1.05]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=-1.87 p=0.06

0.01 0.1 1 10 100
Favours combination   Favours PFMT

16.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 16 PFMT versus PFMT with intravaginal resistance device
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	combination	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Klingler 1995	21 / 21	19 / 20		66.6	1.05 [0.92, 1.20]
Shepherd 1983	6 / 11	10 / 11		33.4	0.60 [0.34, 1.06]
Total (95% CI)	27 / 32	29 / 31		100.0	0.90 [0.75, 1.08]

Test for heterogeneity chi-square=7.04 df=1 p=0.0080
Test for overall effect Z=-1.11 p=0.30

0.01 0.1 1 10 100
Favours combination   Favours PFMT
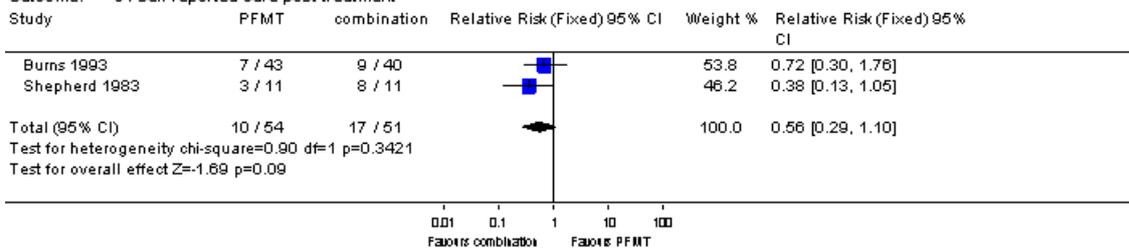
16.03 number of leakage episodes in 24 hours

No graph or table supplied by reviewer

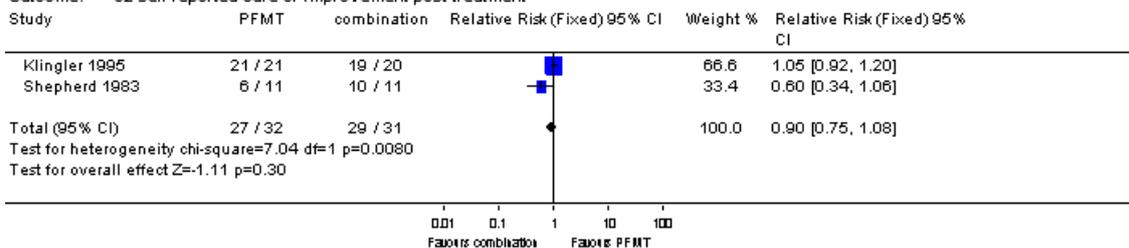## Fig. 17 PFMT versus PFMT with electrical stimulation

17.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 17 PFMT versus PFMT with electrical stimulation
Outcome: 01 self reported cure post treatment

Study	PFMT	combination	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Hofbauer 1990	6 / 11	3 / 11		100.0	2.00 [0.66, 6.04]
Total (95% CI)	6 / 11	3 / 11		100.0	2.00 [0.66, 6.04]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=1.23 p=0.20

0.01 0.1 1 10 100
Favours combination   Favours PFMT

17.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 17 PFMT versus PFMT with electrical stimulation
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	combination	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Hofbauer 1990	7 / 11	7 / 11		23.2	1.00 [0.53, 1.88]
Knight 1998a	10 / 21	9 / 25		27.3	1.32 [0.66, 2.63]
Knight 1998b	10 / 21	16 / 24		49.5	0.71 [0.42, 1.21]
Total (95% CI)	27 / 53	32 / 60		100.0	0.95 [0.67, 1.35]

Test for heterogeneity chi-square=2.02 df=2 p=0.3645
Test for overall effect Z=-0.31 p=0.80

0.01 0.1 1 10 100
Favours combination   Favours PFMT

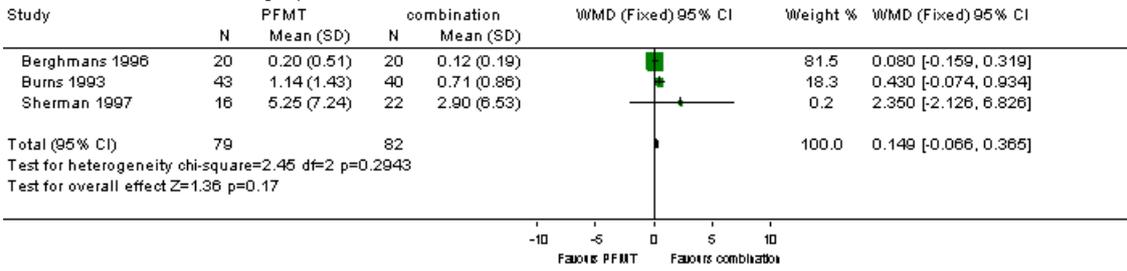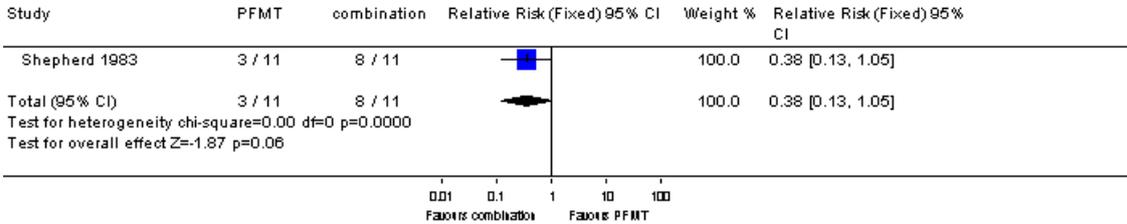## 17.03 number of leakage episodes in 24 hours

No graph or table supplied by reviewer

Fig. 18 PFMT versus PFMT with vaginal cones

18.01 self reported cure post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 18 PFMT versus PFMT with vaginal cones
Outcome: 01 self reported cure post treatment

Study	PFMT	combination	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Wilson 1998a	22 / 91	6 / 14		60.1	0.56 [0.28, 1.14]
Wilson 1998b	10 / 19	6 / 14		39.9	1.23 [0.59, 2.57]
Total (95% CI)	32 / 110	12 / 28		100.0	0.83 [0.50, 1.37]

Test for heterogeneity chi-square=2.23 df=1 p=0.1357
Test for overall effect Z=-0.73 p=0.50

0.01 0.1 1 10 100
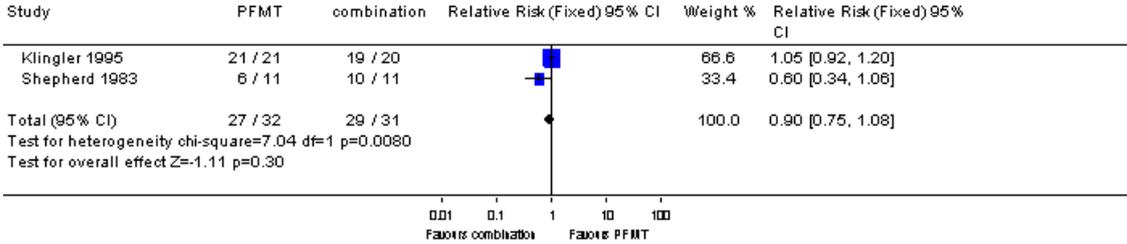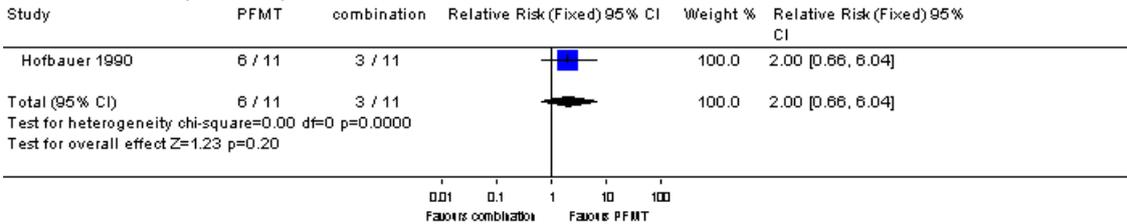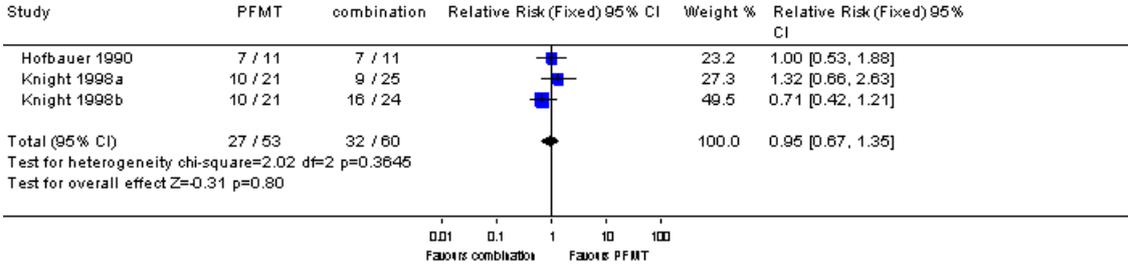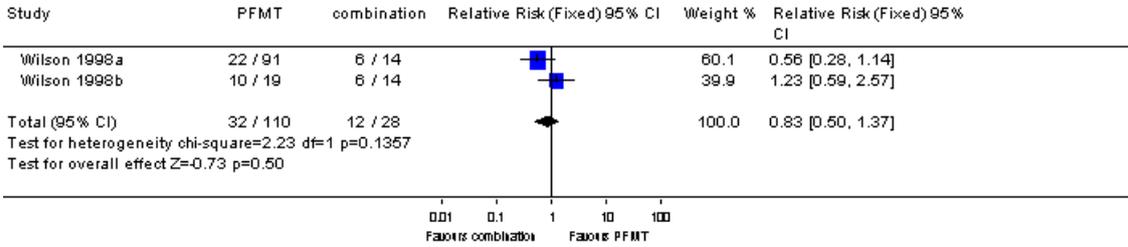Favours combination   Favours PFMT

18.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 18 PFMT versus PFMT with vaginal cones
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	combination	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Pieber 1995	14 / 25	6 / 21		100.0	1.96 [0.92, 4.19]
Total (95% CI)	14 / 25	6 / 21		100.0	1.96 [0.92, 4.19]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=1.73 p=0.08

0.01 0.1 1 10 100
Favours combination   Favours PFMT

18.03 number of leakage episodes in 24 hours

No graph or table supplied by reviewer

Fig. 19 PFMT versus PFMT with bladder training

19.01 self reported cure post treatment

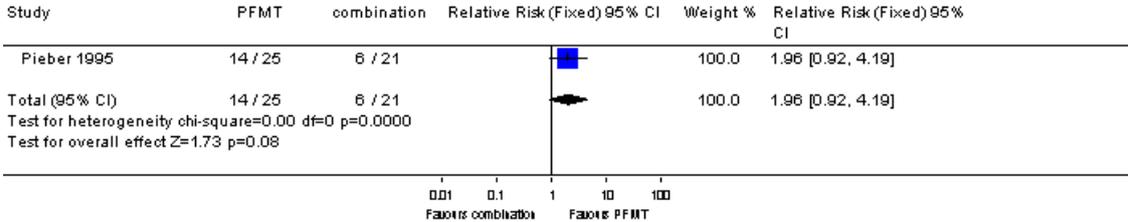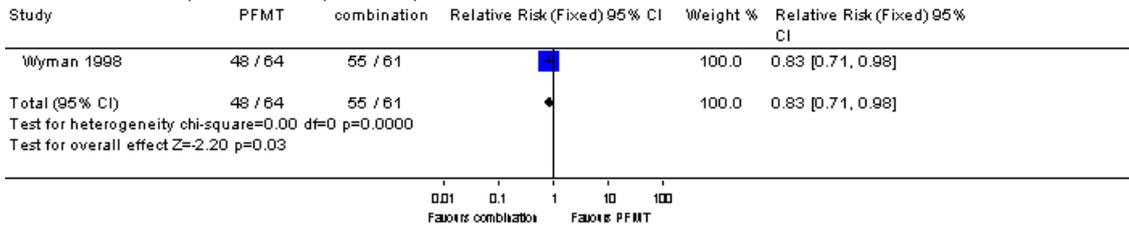No graph or table supplied by reviewer

19.02 self reported cure or improvement post treatment

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 19 PFMT versus PFMT with bladder training
Outcome: 02 self reported cure or improvement post treatment

Study	PFMT	combination	Relative Risk (Fixed) 95% CI	Weight %	Relative Risk (Fixed) 95% CI
Wyman 1998	48 / 64	55 / 61		100.0	0.83 [0.71, 0.98]
Total (95% CI)	48 / 64	55 / 61		100.0	0.83 [0.71, 0.98]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=-2.20 p=0.03

```
        0.01   0.1    1     10    100
      Favours combination   Favours PFMT
```

19.03 number of leakage episodes in 24 hours

Review: Pelvic floor muscle training for urinary incontinence in women
Comparison: 19 PFMT versus PFMT with bladder training
Outcome: 03 number of leakage episodes in 24 hours

Study	PFMT N	PFMT Mean (SD)	combination N	combination Mean (SD)	WMD (Fixed) 95% CI	Weight %	WMD (Fixed) 95% CI
× Wyman 1998a	46	1.24 (0.00)	42	1.03 (1.64)		0.0	Not estimable
Wyman 1998b	18	1.70 (1.81)	16	0.83 (1.36)		100.0	0.870 [-0.199, 1.939]
Total (95% CI)	64		58			100.0	0.870 [-0.199, 1.939]

Test for heterogeneity chi-square=0.00 df=0 p=0.0000
Test for overall effect Z=1.59 p=0.11

```
       -10    -5     0     5     10
      Favours PFMT    Favours combination
```