Conservative prevention and management of pelvic organ prolapse in women (Review)

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[Intervention Review]

Conservative prevention and management of pelvic organ prolapse in women

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ABSTRACT

Background

Pelvic organ prolapse is common, and some degree of prolapse is seen in 50% of parous women. Women with prolapse can experience a variety of pelvic floor symptoms. Treatments include surgery, mechanical devices and conservative management. Conservative management approaches, such as giving lifestyle advice and delivering pelvic floor muscle training (PFMT), are often used in cases of mild to moderate prolapse. This is an update of a Cochrane review first published in 2004, and previously updated in 2006.

Objectives

To determine the effects of conservative management (physical and lifestyle interventions) for the prevention or treatment of pelvic organ prolapse in comparison with no treatment or other treatment options (such as mechanical devices or surgery).

Search methods

We searched the Cochrane Incontinence Group Specialised Trials Register (searched 6 May 2010), EMBASE (1 January 1996 to 6 May 2010), CINAHL (1 January 1982 to 10 May 2010), PEDro (January 2009), the UK National Research Register (January 2009), ClinicalTrials.gov (April 2009), Current Controlled Trials register (April 2009), CENTRAL (Issue 1, 2009) and ZETOC (January 2009) and the reference lists of relevant articles.

Selection criteria

Randomised and quasi-randomised trials in women with pelvic organ prolapse that included a physical or lifestyle intervention 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 for Systematic Reviews of Interventions.

Main results

Six trials were included; three of these trials are new to this update. Four trials were small (less than 25 women per arm) and two had moderate to high risk of bias. Four trials compared PFMT as a treatment for prolapse against a control group (n = 857 women); two trials included women having surgery for prolapse and compared PFMT as an adjunct to surgery versus surgery alone (n = 118 women).

PFMT versus control

There was a significant risk of bias in two out four trials in this comparison. Prolapse symptoms and women's reports of treatment outcomes (primary outcomes) were measured differently in the three trials where this was reported: all three indicated greater improvement in symptoms in the PFMT group compared to the control group. Pooling data on severity of prolapse from two trials indicated that PFMT increases the chance of an improvement in prolapse stage by 17% compared to no PFMT. The two trials which measured pelvic floor muscle function found better function (or improvement in function) in the PFMT group compared to the control group; measurements were not known to be blinded. Two out of three trials which measured urinary outcomes (urodynamics, frequency and bother of symptoms, or symptom score) reported differences between groups in favour of the PFMT group. One trial reported bowel outcomes, showing less frequency and bother with symptoms in the PFMT group compared to the control group.

PFMT supplementing surgery versus surgery alone

Both trials were small and neither measured prolapse-specific outcomes. Pelvic floor muscle function findings differed between the trials: one found no difference between trial groups in muscle strength, whilst the other found a benefit for the PFMT group in terms of stronger muscles. Similarly findings relating to urinary outcomes were contradictory: one trial found no difference in symptom score change between groups, whilst the other found more improvement in urinary symptoms and a reduction in diurnal frequency in the PFMT group compared to the control group.

Authors' conclusions

There is now some evidence available indicating a positive effect of PFMT for prolapse symptoms and severity. The largest most rigorous trial to date suggests that six months of supervised PFMT has benefits in terms of anatomical and symptom improvement (if symptomatic) immediately post-intervention. Further evidence relating to effectiveness and cost-effectiveness of PFMT, of different intensities, for symptomatic prolapse in the medium and long term is needed. A large trial of PFMT supplementing surgery is needed to give clear evidence about the usefulness of combining these treatments. Other comparisons which have not been addressed in trials to date and warrant consideration include those involving lifestyle change interventions, and trials aimed at prolapse prevention.

PLAIN LANGUAGE SUMMARY

Conservative management of pelvic organ prolapse in women

Pelvic organs, such as the uterus, cervix, bladder or bowel, may protrude into the vagina because of weakness in the tissues that normally support them. The symptoms that they cause vary, depending on the type of prolapse. Conservative methods, such as pelvic floor muscle training (exercises to improve the pelvic floor muscles) or lifestyle changes (for example, avoiding lifting or losing weight), are commonly recommended for prolapse. The review looked for randomised trials of conservative methods, either to prevent or treat prolapse, from which to judge their effects.

Six trials were included. Four trials compared pelvic floor muscle training (PFMT) with no intervention, and two trials compared pelvic floor muscle training plus surgery to surgery alone. PFMT compared to no intervention was found in individual trials to improve prolapse symptoms, but data could not be combined. Data on prolapse severity was combined from two trials and results indicated that PFMT increases the chance of improvement in prolapse stage by 17% compared to no treatment. Pelvic floor muscle function appeared to be improved in women who received PFMT in the two trials which measured this. Bladder symptoms were improved with PFMT in two out of three trials measuring this; bowel symptoms were measured in one trial, and an improvement with PFMT was found.

The two trials which looked at the benefit of PFMT in addition to surgery, were small but of good quality. Findings were contradictory: women benefited from PFMT, in terms of urinary symptoms and pelvic floor muscle strength, in one trial but not the other.

The evidence from the trials suggests there is some benefit from conservative treatment of prolapse, specifically for PFMT as compared to no intervention. More randomised controlled trials are still needed to look at different regimens of PFMT, the cost in relation to

benefit, and the long-term effects. The combination of PFMT and surgery requires to be evaluated in a large randomised trial. There is a dearth of trials addressing lifestyle changes as a treatment for prolapse, and trials aimed at prevention of prolapse. Trials of one type of conservative intervention versus another, and combinations of conservative interventions, are also lacking.

BACKGROUND

Description of the condition

Pelvic organ prolapse is common and is seen in 50% of parous women (Beck 1991). One community survey found that 40% of the general female population aged 45 to 85 years had evidence of pelvic organ prolapse of at least POP-Q stage II (within 1 cm above or below the hymen) (Slieker-ten Hove 2004). Around 10% of women in the community undergo surgery at some time in their lives for the management of prolapse or urinary incontinence (Olsen 1997). Pelvic organ prolapse includes anterior vaginal wall prolapse (urethrocele, cystocele), posterior vaginal wall prolapse (enterocele, rectocele) and prolapse of the apical segment of the vagina (cervix/cuff, uterine or vault prolapse) (Bump 1996). A woman can present with prolapse of one or more of these compartments. A problematic issue in prolapse research to date is the different ways in which prolapse is defined. For example, prolapse may be identified based on anatomical measurements, presence of symptoms or the fact that prolapse surgery has been performed. This hampers comparisons across studies. Systems such as the POP-Q which provide a severity grading based on the anatomy of the vagina compared to nulliparous anatomy, do not take into account what is normal for multiparous women, nor do they consider whether symptoms are present.

The aetiology of pelvic organ prolapse is complex and multi-factorial. Risk factors include pregnancy, childbirth, congenital or acquired connective tissue abnormalities, denervation or weakness of the pelvic floor, ageing, menopause and factors associated with chronically raised intra-abdominal pressure (e.g. heavy lifting) (Bump 1998; Gill 1998; MacLennan 2000).

Women with prolapse commonly have a variety of pelvic floor symptoms including pelvic heaviness; dragging sensation in the vagina; bulge, lump or protrusion coming down from the vagina; and backache. Bladder and bowel symptoms, and sexual dysfunction are also frequently present.

Choice of treatment for prolapse depends on the severity of prolapse and its symptoms, and the woman's general health and preference. Options available for treatment can be categorised as conservative, mechanical and surgical. Conservative or mechanical management is generally considered for women with a mild degree of prolapse, those who wish to have more children, and the frail or those unwilling to undergo surgery. Separate Cochrane reviews of surgical (Maher 2010) and mechanical interventions (Adams 2004), and the effects of oestrogen (Ismail 2010) have been undertaken.

Description of the intervention

Conservative prevention or treatment of prolapse is defined here as physical or lifestyle interventions.

Physical interventions include pelvic floor muscle assessment, pelvic floor exercises and pelvic floor muscle bracing against increased intra-abdominal pressure (e.g. lifting, coughing). The term "pelvic floor muscle training" (PFMT) is used in this review to encompass these components of treatment which are normally used together. (For consistency, when describing studies, if authors have used the term "pelvic floor exercises" or "pelvic floor exercise programme" we have referred to pelvic floor muscle training instead.) PFMT involves the contraction of the pelvic floor muscles, to improve strength, endurance and timing of contractions and ultimately to better support the pelvic organs. Through assessment and prescription of daily exercises, women begin to lengthen contractions, increase repetitions and reduce rest periods. Electrical stimulation and biofeedback, which are often used as adjuncts to PFMT, are also included under the heading of physical interventions in this review.

Lifestyle interventions include weight loss, reducing exacerbating activities (e.g. lifting, coughing) and treating constipation.

How the intervention might work

Biological rationale for PFMT for POP

The pelvic floor muscles play a critical role in giving structural support to the pelvic organs and pelvic openings (DeLancey 1993). Pelvic floor muscle activity adjusts to variations in posture and intra-abdominal pressure (Morgan 2005). It is hypothesised that improving pelvic floor muscle function (strength, endurance and coordination) may improve this structural support for the pelvic organs.

There are two main hypotheses for PFMT being an effective treatment for POP. Firstly, intensive strength training for the pelvic

floor muscles may build up pelvic structural support by increasing muscle volume and elevating the levator plate (pelvic floor muscles and pelvic organs) to a higher position inside the pelvis. This increased strength may hypertrophy and improve stiffness of the pelvic floor muscles (Bo 2004; Bo 2006). The hypothesis of improving pelvic floor muscle strength is supported for treatment of urinary incontinence where the anatomical position of the pelvic floor muscles has been shown to be different in continent and incontinent women (Hoyte 2001; Peschers 2001) and increased urethral stability at rest and during effort following 14 weeks of supervised PFMT has been shown (Balmforth 2004). DeLancey demonstrated that women with POP generated less vaginal closure force during a maximal voluntary contraction than controls (DeLancey 2007). Improving pelvic floor muscle strength in women with POP may have an important role to play in the treatment of POP.

Secondly, an intentional, effective pelvic floor muscle contraction prior to and during effort (cough) has been shown to reduce leakage from stress urinary incontinence - the Knack (Miller 1998). Bladder neck descent has been shown to be significantly less when women were asked to contract the pelvic floor prior to a cough than when coughing without contraction (Peschers 2001). Thus the Knack/pelvic floor muscle pre-contraction has become a standard element of PFMT for urinary incontinence (Dumoulin 2010). There are no studies looking at the effectiveness of such a technique on the effect of POP. Carrière 2006 recommends pre-contracting the pelvic floor muscles not only during a cough but for any daily task that results in increased intra-abdominal pressure (Carrière 2006). Activities involving raised intra-abdominal pressure (heavy lifting, chronic coughing) have been cited in the aetiology of POP (Gill 1998) so it is logical to find a way to help women with POP to counteract intra-abdominal pressure increases. Thus, it is possible to apply this principle of the Knack or pre-contracting the pelvic floor muscles with any rise in intra-abdominal pressure to many activities such as coughing, sneezing and lifting to prevent descent of the bladder neck and possibly other pelvic organ structures for the treatment of POP.

The aims of PFMT for treating POP are, therefore, to improve pelvic floor muscle strength (to improve structural support to the pelvic organs), co-ordination and timing (to improve pelvic organ support during increases in intra abdominal pressure).

The aims of conservative treatment in the management of pelvic organ prolapse include:

- to increase strength and endurance of the pelvic floor muscles to better support the pelvic organs;
- to decrease the frequency or severity of symptoms associated with prolapse (vaginal, bladder, bowel and sexual symptoms, and backache);
- to prevent the severity of the prolapse from becoming worse;
- to avert or delay the need for surgery.

Why it is important to do this review

Pelvic floor muscle training appears to be effective compared to no treatment or inactive control in the treatment of urinary stress, urge and mixed incontinence (Dumoulin 2010). However, its role in managing prolapse is not established (Poma 2000). The extent to which any of the lifestyle interventions are effective in managing prolapse is also unknown (Bump 1998). The importance of clarifying the place of conservative treatment in the prevention and management of prolapse, particularly in relation to the role of PFMT, has been highlighted (Thakar 2002).

OBJECTIVES

To determine the effects of specified conservative interventions on symptoms of pelvic organ prolapse and prolapse severity.

The following comparisons were made.

A conservative intervention versus no intervention

1. Physical interventions versus control/waiting list/no active treatment.
2. Lifestyle interventions versus control/waiting list/no active treatment.

One conservative intervention versus another conservative intervention, or another intervention type

3. Physical intervention versus another physical intervention.
4. Physical interventions versus lifestyle interventions.
5. Physical interventions versus surgery.
6. Lifestyle interventions versus surgery.
7. Physical interventions versus mechanical devices.
8. Lifestyle interventions versus mechanical devices.

A combination of conservative interventions versus a conservative intervention alone

9. Combination of physical and lifestyle interventions versus lifestyle interventions alone.
10. Combination of physical and lifestyle interventions versus physical interventions alone.

A combination of conservative interventions versus another type of intervention or no intervention

11. Combination of physical and lifestyle interventions versus surgery.
12. Combination of physical and lifestyle interventions versus mechanical devices.
13. Combination of physical and lifestyle interventions versus control/waiting list/no active treatment.

A combination of conservative intervention and another type of intervention versus the other intervention alone

14. Physical and/or lifestyle interventions supplementing surgery versus surgery alone.
15. Physical and/or lifestyle interventions supplementing mechanical device versus mechanical device alone.

A combination of conservative intervention and another type of intervention versus the conservative intervention alone

16. Physical and/or lifestyle interventions supplementing surgery versus physical and/or lifestyle intervention alone.
17. Physical and/or lifestyle interventions supplementing mechanical device versus physical and/or lifestyle intervention alone.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled trials in which at least one arm was a conservative intervention for treatment or prevention of pelvic organ prolapse.

Types of participants

Adult women with any severity of pelvic organ prolapse. Prolapse included one or more of the following types:

- anterior vaginal wall prolapse;
- posterior vaginal wall prolapse;
- prolapse of the apical segment of the vagina (uterus or vault).

Women at risk of prolapse were included in trials aimed at preventing prolapse occurrence or progression.

Types of interventions

One arm of the trial was allocation to a physical or lifestyle intervention, or combination including such interventions. Comparison interventions were to include no treatment, surgery or a mechanical device, or physical or lifestyle intervention if appropriate. The conservative interventions being considered were as follows:

1. Physical interventions:

- pelvic floor muscle training;
- pelvic floor muscle training with biofeedback;
- learning to brace pelvic floor muscles against increased intra-abdominal pressure (e.g. lifting, coughing) also known as "the Knack";
- electrical stimulation.

2. Lifestyle interventions:

- weight reduction;
- reduction of exacerbating activities (e.g. lifting, coughing);
- treatment of constipation.

Types of outcome measures

The range of outcome measures to be reviewed included:

Primary outcomes

1) Prolapse symptoms (reported as number of women with prolapse symptoms);
2) Failure to improve prolapse symptoms (reported by the woman);
3) Prolapse symptom scores and prolapse-specific quality of life assessment (e.g. PQoL, ICIQ-VS, POP-SS, POPDI (PFDI subscale));
4) Global assessment of treatment outcome (e.g. PGI-I).

Secondary outcomes

5) Severity of prolapse (clinician measures e.g. POP-Q stage or individual measurements, ultrasound measurements of pelvic floor);
6) Measures of pelvic floor muscle function (e.g. electromyography, vaginal squeeze pressure, digital assessment (modified Oxford scale));
7) Urinary outcomes (e.g. number of leakage episodes, pad and paper towel testing, flow and voiding cystometry, urinary symptom questionnaire);
8) Bowel outcomes (e.g. evacuating proctography, bowel symptom questionnaire);

9) Sexual outcomes (e.g. Prolapse and Incontinence Sexual Questionnaire - PISQ);
10) Generic quality of life measures (e.g. SF-36);
11) Psychological outcome measures (e.g. Hospital Anxiety and Depression Score);
12) Economic analysis (e.g. cost effectiveness, cost utility).

Other outcomes

13) Treatment adherence;
14) Adverse events (e.g. associated with pelvic floor muscle training: discomfort, worsening of prolapse; associated with use of biofeedback, electrical stimulation, surgery: vaginal irritation, vaginal infection, urinary tract infection, pain, intolerance, surgical complications, sexual dysfunction);
15) Any other outcome measures of perceived response to treatment;
16) Any other outcome not pre-specified, but judged important when performing the review.

Search methods for identification of studies

We did not impose any language or other restrictions on any of the searches.

Electronic searches

This review has drawn on the search strategy developed for the Cochrane Incontinence Review Group. Relevant trials were identified from the Group's Specialised Register of controlled trials which is described under the Incontinence Group's module in *The Cochrane Library*. The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, CINAHL and handsearching of journals and conference proceedings. Date of the most recent search of the trials register for this review: 6 May 2010. The trials in the Incontinence Group Specialised Register are also contained in CENTRAL. The terms used to search the Incontinence Group Trials Register are given in Appendix 1.
For this review extra specific searches were performed by the review authors. These are listed below and the search strategies used are detailed in Appendix 1.

- EMBASE: We searched the years 1 January 1980 to week 17 2010. Date of last search: 6 May 2010
- CINAHL: We searched the years 1 January 1982 to 30 April 2010 inclusive. Date of last search: 10 May 2010
- PEDro (the Physiotherapy Evidence Database) was last searched on 27 January 2009
- UK National Research Register was last searched on 27 January 2009
- ClinicalTrials.gov (9 April 2009)
- Current Controlled Trials register (9 April 2009)
- CENTRAL (Issue 1 2009)
- ZETOC database of conference abstracts (January 2009)

Searching other resources

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

Data collection and analysis

Reports of all possibly eligible studies were assessed for their methodological quality and relevance to the review objectives.

Screening for eligibility

Two reviewers (SH, DS) assessed each study independently in terms of whether the subjects were women with, or at risk of, pelvic organ prolapse, comparisons included a conservative intervention and design was a randomised or quasi-randomised controlled trial, and came to an agreement on whether it should be included or excluded. Excluded studies were listed with the reasons for their exclusion.

Assessment of methodological quality

Methodological quality was assessed on the basis of:

- provision of clear inclusion/exclusion criteria;
- quality of random allocation (sequence generation and concealment of randomisation);
- baseline similarity of randomised groups;
- use of blinding (participants, carers, outcome assessors);
- potential for selection bias in analysis (based on assessment of withdrawals and dropouts (incomplete data; use of an intention to treat analysis);
- selective reporting;
- other sources of bias.

Data extraction

Data extraction was undertaken independently by two reviewers (SH, DS) and comparisons made to ensure accuracy. Where trial data were not reported adequately, attempts were made to acquire the necessary information from the authors. Data were processed as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009).

Analysis

For categorical outcomes the numbers reporting an outcome were related to the numbers at risk in each group to derive a risk ratio. For continuous variables, means and standard deviations were used to derive a mean difference, or a standardised mean difference.

A fixed- effect model was used for calculation of pooled estimates and associated 95% confidence intervals. Differences between trials were further investigated if significant heterogeneity existed or appeared obvious from visual inspection of results. Meta-analysis was possible for the prolapse severity outcomes of three trials. Outcomes were not measured in the same way across trials, however in some cases meta-analysis was possible using the standardised mean difference.

Physical interventions and lifestyle interventions were to be analysed as separate subgroups within the same analyses, if sufficient trials existed.

RESULTS

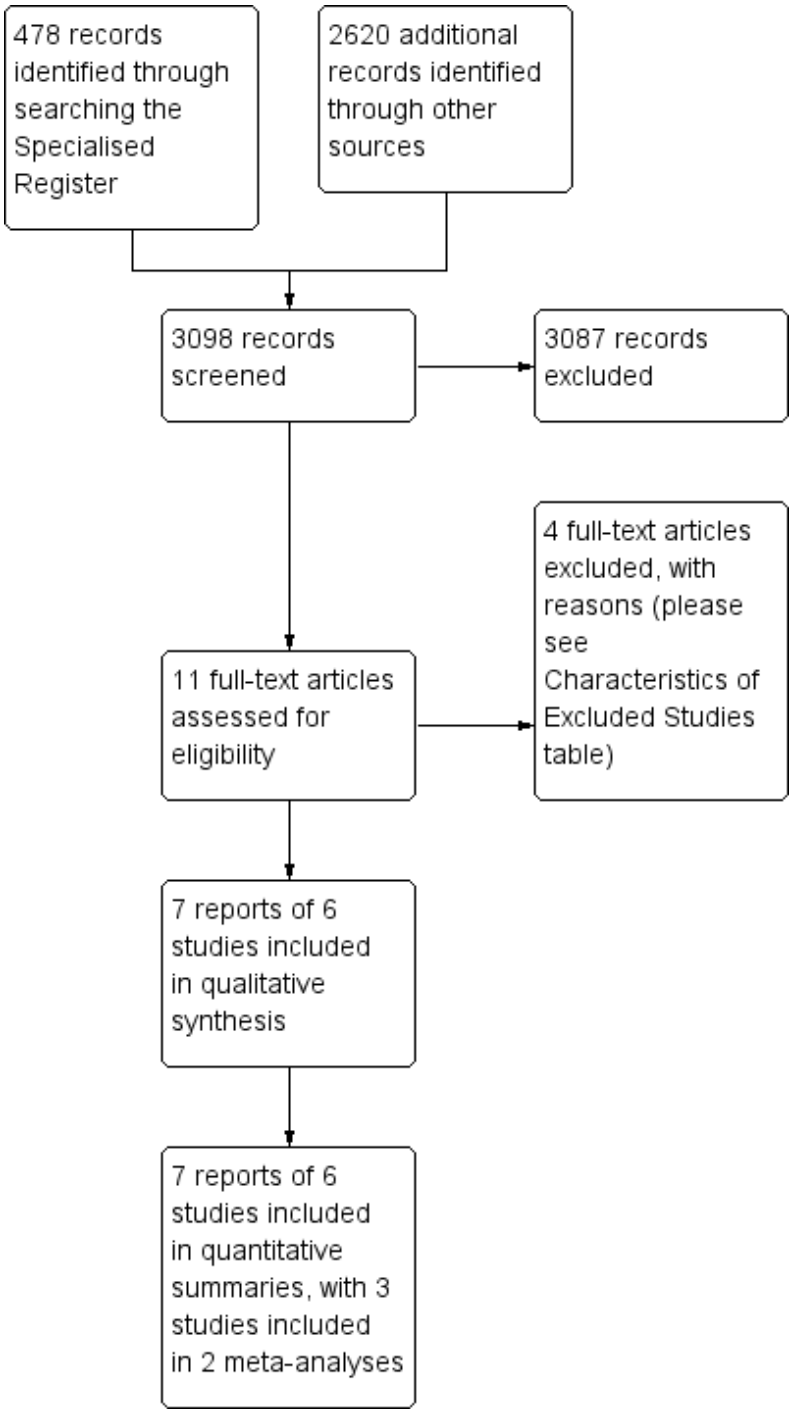
Description of studies

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

Results of the search

A total of 3098 records, found by the literature search, were screened for this review. Six randomised controlled trials relevant to the review objectives, reported in seven articles, were identified (Braekken 2010; Frawley 2010; Ghroubi 2008; Hagen 2009; Jarvis 2005; Piya-Anant 2003). The trial by Frawley 2010 was ongoing in the previous version of this review. The trial by Hagen 2009 had previously been included in this review but with unpublished data only: this trial has now been published. There are three relevant trials which are ongoing (Barber 2009; Hagen 2010; Hagen 2011). Four studies were excluded (Adamkiewicz 2001; Aguirre 2005; Culligan 2010; Mimura 2000). The flow of literature through the searching and screening process is shown in the PRISMA flow diagram Figure 1. Details of the information requested from the authors of included trials, and whether this was obtained, are given in the Characteristics of included studies table.

Figure 1. PRISMA study flow diagram.



Included studies

Braekken 2010 undertook a trial where they randomised 109 women (59 intervention, 50 control), the results of which were reported in two articles. Women had stage I, II or III prolapse of any type (determined by POP-Q), and 63% were reporting symptoms of prolapse. Randomisation was stated as stratified by severity of prolapse. The intervention group women were instructed in PFMT for six months (weekly physiotherapy appointments for three months then fortnightly visits) with home exercise (three sets of eight to 12 close to maximal contractions daily). Both groups were given lifestyle advice and taught "the Knack". Prolapse stage (POP-Q), prolapse, bladder and bowel symptoms, pelvic floor muscle manometry and ultrasound measurements were taken at six months (women in the control group were offered PFMT after this).

Frawley 2010 compared physiotherapist-led pre- and post-operative PFMT versus usual care in 58 women (30 intervention, 28 control) undergoing prolapse repair surgery, with or without hysterectomy. Intervention comprised one pre-operative PFMT instruction session, and seven post-operative appointments, and a final appointment at nine months post-operatively. Outcomes measured at four time points (pre-operatively prior to randomisation, and three, six and 12 months post-operatively) included urinary symptoms and associated impact (UDI-19, IIQ-7), 3-day bladder diary, 48-hour pad test, bowel symptoms, general exercise participation and blinded pelvic floor muscle strength (manometry and modified Oxford grading scale). No prolapse-specific outcomes were measured.

Ghroubi 2008 reported on a trial carried out in Tunisia which was published in French with an English abstract. The translation of this paper proved difficult but there was a reasonable amount of information obtainable. The trial involved 47 women with stage I or II cystocele (with or without additional stage I rectocele), randomised to PFMT plus healthy living advice (n = 27) or a non treated group (n = 20). There was no description of the randomisation or blinding. The intervention included 24 clinic-based sessions (containing pelvic floor exercises, electrical stimulation and digital biofeedback) and lifestyle advice. Women were asked to perform 20 pelvic floor muscle contractions at home each day after the 10^{th} session. Outcome measures included pelvic heaviness, urinary symptoms, pelvic floor muscle strength, quality of life, urodynamics and patient satisfaction.

Hagen 2009 described a feasibility study designed to inform the development of a larger multi-centre trial to assess the use of PFMT in the management of pelvic organ prolapse. The feasibility study included a small (n = 47: 23 intervention, 24 control) randomised controlled single blind trial. Women with stage I or II prolapse were eligible. The intervention group had 5 physiotherapy appointments over 16 weeks and were advised to do up to six sets of exercises daily, and the control group were sent a lifestyle advice leaflet only. Prolapse was assessed by vaginal examination (POP-Q) at baseline and at 20 weeks post-randomisation by a gynaecologist blinded to group allocation. A postal questionnaire, including assessment of prolapse, urinary, bowel and vaginal symptoms, prolapse-related quality or life and general health status, was completed by women at baseline, 20 and 26 week post-randomisation.

Jarvis 2005 described a trial to assess the effectiveness of PFMT as an adjunct to surgery. Women who were booked to have surgery to correct pelvic organ prolapse and/or incontinence were randomised to an intervention (a pre-operative and two post-operative physiotherapy appointments) or a control group (no physiotherapy appointments). Intervention women were advised to do four sets of exercises per day. Sixty women were randomised (30 intervention, 30 control). Two of those women were not having surgery to correct prolapse. Outcome measures included urinary diaries and paper towel test (to measure volume of urine leakage), pelvic floor muscle strength (modified Oxford scale and manometry), bladder symptoms and continence-related quality of life. There were no prolapse-specific outcomes measured.

Piya-Anant 2003 described a trial of PFMT, and advice on reducing constipation, in an elderly Thai population. All women over 60 years of age and living within 10 km of the hospital where the trial was conducted were originally assessed for the presence of anterior wall pelvic organ prolapse (the authors refer to this as "genital prolapse"). Clusters of women defined by post-code area were then randomised to an intervention (PFMT and advice to reduce constipation) or control group. There were 654 women included in this cluster randomised controlled trial. Follow-up was conducted at six, 12 and 24 months. Outcomes were assessed in terms of the success of the intervention in preventing the worsening of anterior wall prolapse. This was assessed via clinical examination using a non-standard method of assessment.

Excluded studies

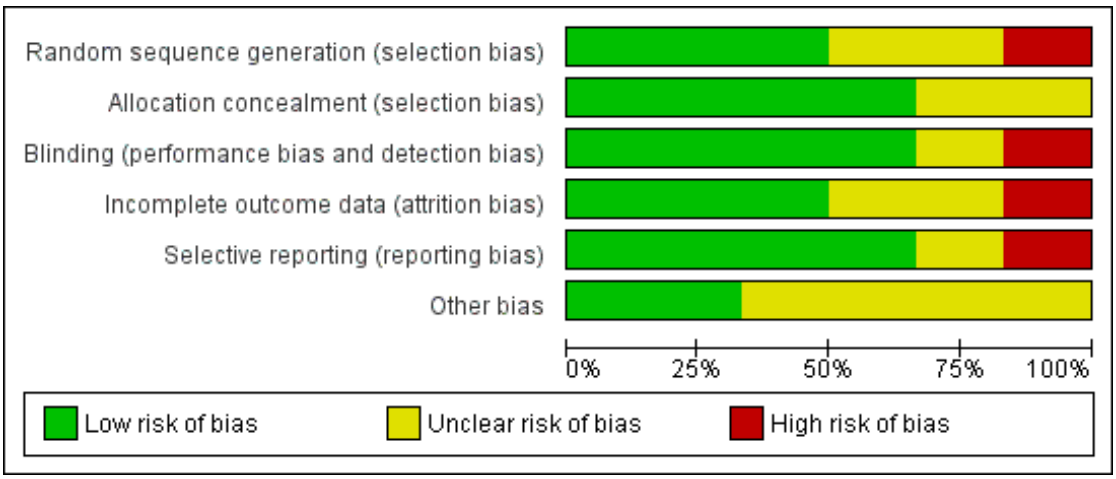
Three studies were excluded because they were not comparative trials (Adamkiewicz 2001; Aguirre 2005; Mimura 2000). A feasibility trial comparing PFMT with a Pilates program was excluded as the women included were recruited from the community and did not necessarily have prolapse and the primary outcome was pelvic floor muscle strength (Culligan 2010). See Characteristics of excluded studies.

Risk of bias in included studies

Overall the risk of bias from included studies was medium, and there was uncertainty about some sources of bias due to a lack of information being reported (Figure 2). Four of the six included

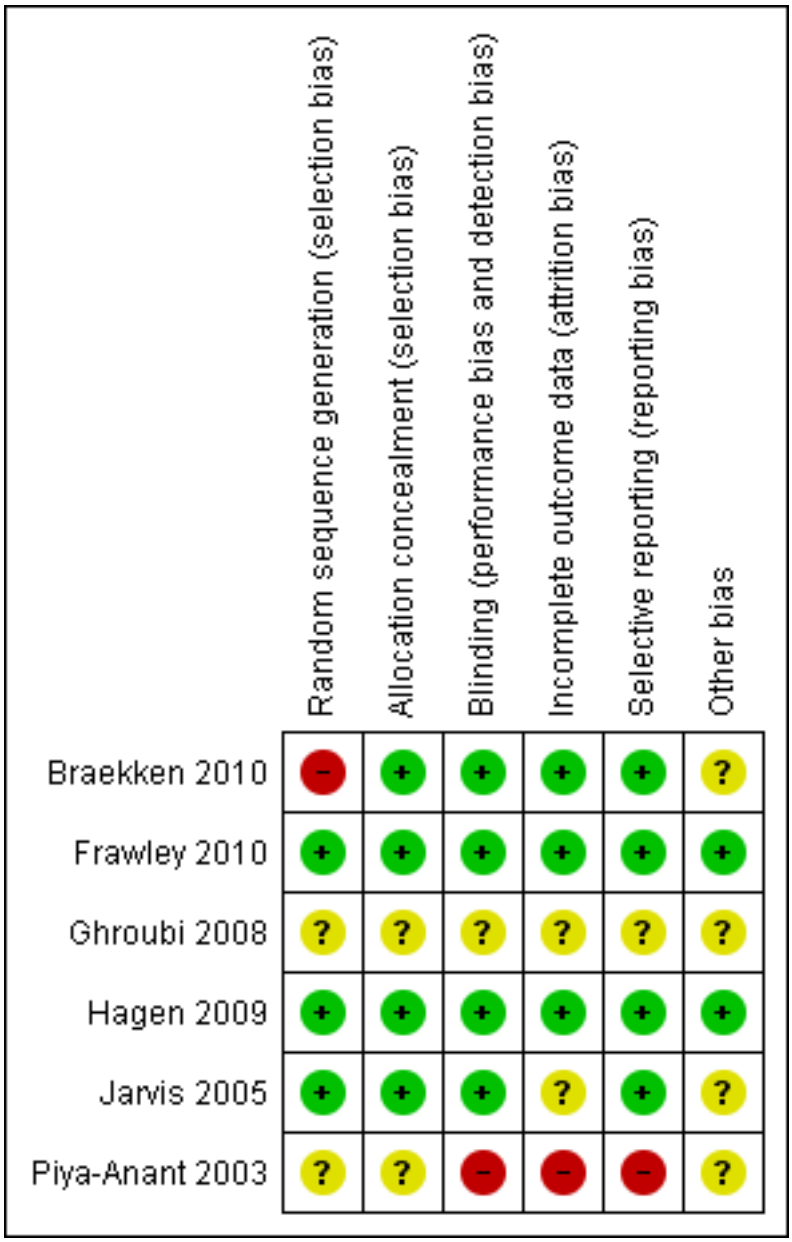
trials were small, with less than 25 women randomised to each comparison arm (Frawley 2010; Ghroubi 2008; Hagen 2009; Jarvis 2005). The remaining two trials had more than 50 women randomised per arm (Braekken 2010; Piya-Anant 2003), and the latter had a substantially larger sample size, in excess of 300 women per arm.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Risk of bias was judged to be low in four trials (Braekken 2010; Frawley 2010; Hagen 2009; Jarvis 2005) and uncertain or high in two trials (Ghroubi 2008; Piya-Anant 2003) (Figure 3).

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Random allocation and allocation concealment

In three trials, random allocation was generated either by computer or random number tables and concealed in envelopes, either stored off site or distributed by someone other than the staff providing the intervention (Braekken 2010; Frawley 2010; Jarvis 2005). In Hagen 2009 women were randomised using a telephone system which was accessed by researchers in the study office who notified the participant of her group allocation by letter. Two trials gave no detail of the randomisation method (Ghroubi 2008; Piya-Anant 2003).

Two trials reported differences between randomised groups in baseline demographic variables or outcome measures (Braekken 2010; Frawley 2010), suggesting the random allocation process had not been successful in producing similar groups. In addition, the numbers randomised to the two arms differed somewhat in Braekken 2010 (59 intervention versus 50 control) and Ghroubi 2008 (27 intervention versus 20 control). Braekken 2010 also described randomising women within strata defined according to whether they had prolapse beyond the hymen or not. However of the 40 women with prolapse beyond the hymen 25 were randomised to intervention and 15 to control suggesting there had been no stratification.

Blinding during treatment and at outcome assessment

In general women and their treating clinician could not be blinded to women's group allocation as they were required to participate in or deliver the PFMT. Blinding of outcome assessment was attempted where possible in five trials (Braekken 2010; Frawley 2010; Hagen 2009; Jarvis 2005; Piya-Anant 2003), although the methods of blinding were not always described. One trial did not describe any blinding (Ghroubi 2008).

Pelvic floor ultrasounds were taken and assessed blinded to women's group in the Braekken 2010 trial, but pelvic floor assessments were not blinded. In Frawley 2010, assessment of the pelvic floor was undertaken by a physiotherapist blind to group allocation, although the method of blinding was not stated; the operating surgeon was not blinded. In Hagen 2009, at follow-up, prolapse severity (POP-Q) was assessed by the woman's gynaecologist who was blind to the group allocation of the woman. Blinding was achieved by reminding the woman and the gynaecologist prior to assessment not to discuss group allocation, and providing a chaperone at the examination to enforce this. In Jarvis 2005 it was stated that assessment of the women at follow-up, both pelvic floor muscle assessment and paper towel test, was blind to their group allocation, although no detail was given. Piya-Anant 2003 stated that the assessor was blinded both to the previous assessment results of the participant and to their group status, however the method of blinding was not reported.

Description of dropout and withdrawal

In four out of six trials the dropouts and withdrawals were adequately reported (Braekken 2010; Frawley 2010; Hagen 2009; Jarvis 2005). In the remaining two trials there was insufficient detail (Ghroubi 2008; Piya-Anant 2003). A very low dropout rate of 2% was reported in one trial (Braekken 2010). In other trials (where dropouts were adequately reported) the range was between 10% (Jarvis 2005) and 15% (Hagen 2009).

Analysis by intention-to-treat

All trials except one reported undertaking an intention to treat analysis. In Piya-Anant 2003 it was unclear whether an intention to treat analysis had been undertaken or not. Neither was it clear from the report that clustering had been taken into account in the analyses of this trial.

Effects of interventions

Trial results are reported under the appropriate comparison heading.

1. Physical interventions versus control/waiting list/no active treatment.

Four trials compared PFMT with no active treatment (Braekken 2010; Ghroubi 2008; Hagen 2009; Piya-Anant 2003), providing a total of 439 women randomised to PFMT and 418 women randomised to no active treatment.

Primary outcomes

Prolapse symptoms

Three of the four trials specifically measured prolapse symptoms, but the questionnaires used differed. Braekken 2010 used a questionnaire by Mouritsen et al (Mouritsen 2003). Ghroubi 2008 reported the single symptom of 'pelvic heaviness'. Hagen 2009 used the Pelvic Organ Prolapse Symptom Score, developed and validated by the research team (Hagen 2009b). In the Piya-Anant 2003 trial, symptoms were not measured; only severity was reported.

In Braekken 2010, in those women who had prolapse symptoms at baseline (69/109), those in the PFMT group compared to the control group were significantly more likely to have reduced frequency (74% versus 31%) (RR 0.37, 95% CI 0.21 to 0.65) and reduced

bother (67% versus 42%) (RR 0.56, CI 0.33 to 0.97) with these symptoms (Analysis 1.1, Analysis 1.2). Ghroubi 2008 reported significantly less pelvic heaviness in the PFMT group compared with the control group immediately post-treatment (19% versus 70%) (RR 0.26, 95% CI 0.11 to 0.61) (Analysis 1.3). There was a significantly greater improvement in prolapse symptom score (range 0 to 28, higher indicating more frequent symptoms) from baseline to 26 week follow-up in the intervention group compared to the control group in Hagen 2009 (MD -3.37, 95% CI -6.23 to -0.51, Analysis 1.4).

Global assessment of treatment outcome

In relation to women's perception of their prolapse, Hagen 2009 found that the percentage of women reporting their prolapse was the same or worse was significantly less at follow-up in the intervention group (37%) than in the control group (76%) (RR 0.48, 95% CI 0.26 to 0.91, Analysis 1.5). However on a 10-point Likert scale they found no significant difference between groups in the interference of prolapse on everyday life (standardised mean difference (SMD) -0.05, 95% CI -0.67 to 0.57, Analysis 1.6.1; Hagen 2009). Condition specific quality of life (measured using the Ditrovie scale, adapted for prolapse) was significantly better (lower score) in the intervention group compared to the control group at follow-up (SMD -0.95, 95% CI -1.57 to -0.34, Analysis 1.6.2, Ghroubi 2008). Pooling the quality of life results from these two trials gave a standardised mean difference of -0.51, 95% CI -0.94 to -0.07 (Analysis 1.6): however, there was some heterogeneity between the trials.

Ghroubi 2008 also reported on women's satisfaction with treatment (0 to 10 cm visual analogue scale) and found significantly higher satisfaction in the intervention group (MD -3.22, 95% CI -3.79 to -2.65, Analysis 1.7).

Secondary outcomes

Prolapse severity

Severity of prolapse was measured in all four studies: in two studies the POP-Q method of measurement was used (Braekken 2010; Hagen 2009); in one trial a non-standard measure of measuring the area/volume of prolapse visible was used (Piya-Anant 2003); and in the final trial it was unclear from the description the method used and no results on severity were presented (Ghroubi 2008).

Braekken 2010 reported that fewer women in the PFMT group than the control group had no improvement in POP-Q stage (81% versus 92%). They reported no significant difference in the subgroup of women with prolapse beyond the hymen (80% versus 80%). Hagen 2009 found the percentage of women who had no improvement in their POP-Q stage from baseline to 20 weeks was significantly less in the intervention group (55%) than in the control group (100%). The pooled risk ratio of 0.83, (95% CI 0.71 to 0.96, Analysis 1.8) indicates that PFMT decreases the risk of no improvement (or increases the risk of improvement) in prolapse stage by 17% compared to no PFMT.

Hagen 2009 also reported on the change in individual POP-Q measurements and found that change in point Ba (most distal position of the upper anterior vaginal wall) for the intervention group (-1.09 cm SD 1.22) indicated significantly more improvement than for the control group (0.56 cm SD 1.01) (MD -1.65, 95% CI -2.63 to -0.67 Analysis 1.9.2).

Piya-Anant 2003 reported at six, 12 and 24 months the percentage of women with worse prolapse compared to baseline in both the intervention and control groups (results were only presented graphically with P values). Results were presented separately for those women who initially had mild prolapse and those who initially had severe prolapse. For the mild group there was a significant difference between intervention and control group at 12 months only; in the severe group there was a significant difference between intervention and control group at 24 months only (28% versus 72% had worse prolapse).

Braekken 2010 also used ultrasound to measure the position of the bladder and rectum within the pelvis, and the dimensions of the muscles and hiatal area, to indicate the severity of prolapse. They found the change in resting position in standing of the bladder and rectum, compared to baseline, were significantly greater (both were higher) in the intervention group than the control group; and changes in measures of the muscles and hiatal area were also significantly in favour of the intervention group. See Characteristics of included studies for details of ultrasound results.

Pelvic floor muscle function

Two studies (Braekken 2010; Ghroubi 2008) compared pelvic floor muscle strength in the trial arms: Braekken 2010 used manometry (unblinded) to measure contraction strength and endurance, whilst Ghroubi 2008 did not state the measurement method used and whether this was blinded.

Braekken 2010 found the improvement in strength and endurance were significantly greater in the intervention group compared to the control group (strength MD -12.00, 95% CI -14.90 to -0.10; endurance MD -99.00, 95% CI -131.47 to -66.53) (Analysis 1.10). Ghroubi 2008 reported a significant difference between groups in muscle strength after three months in favour of the intervention group:-2.37 SD 0.83 intervention group versus -1.25 SD 0.78 control group (MD -1.12, 95% CI -1.58 to -0.66, Analysis 1.10).

Urinary outcomes

Braekken 2010 reported better urinary outcomes for women in the intervention group in their trial (Analysis 1.11). The percentage with improved frequency and bother of stress and urge symptoms was reported, with sample size ranging from 12 to 39 per group

as not all women had bladder symptoms to start with. There was a significant difference in favour of the intervention group for less increase in frequency of stress symptoms (26% versus 70%) (RR 0.36, 95% CI 0.20 to 0.66, Analysis 1.11.1) and bother of stress symptoms (31% versus 70%) (RR 0.44, 95% CI 0.26 to 0.74, Analysis 1.11.2).

Ghroubi 2008 reported that the urodynamic outcome measures favoured the PFMT group: in particular, after treatment the post-void residual (MD -21.28, 95% CI -32.75 to -9.81) and flow rate (MD -3.23, 95% CI -5.16 to -1.30) were significantly better in the intervention group compared to the control group (Analysis 1.14 to Analysis 1.16). In addition, after treatment the percentage of women reporting urinary pain (19% vs 60%) (RR 0.31, 95% CI 0.13 to 0.74), stress (7% versus 45%) (RR 0.16, 95% CI 0.04 to 0.68), urge (4% versus 35%) (RR 0.11, 95% CI 0.01 to 0.79) and frequency symptoms (15% versus 55%) (RR 0.27, 95% CI 0.10 to 0.72) was significantly less in the intervention group compared to the control group (Analysis 1.17 to Analysis 1.20).

Hagen 2009 reported no significant difference in change from baseline in the ICIQ urinary incontinence short form score between the intervention (-1.79 SD 3.2) and control groups (0.00 SD 2.8) (MD -1.79, 95% CI -3.68 to 0.10, Analysis 1.12). Braekken 2010 also reported ICIQ urinary incontinence short form results favouring the intervention group (n = 102; effect size of 0.62; difference: 2.40; 95% CI 0.90 to 3.80; P = 0.002), however the data presented were insufficient to allow pooling of results with Hagen 2009.

Bowel outcomes

One trial, Braekken 2010, reported on four bowel symptoms: problems with emptying, flatus, loose faecal incontinence and solid faecal incontinence. There was a significant difference in favour of the intervention group for less increase in frequency (47% versus 78%) (RR 0.60, 95% CI 0.40 to 0.91) and bother (53% versus 78%) (RR 0.68, 95% CI 0.46 to 0.99) associated with flatus and less increase in frequency (54% versus 90%) (RR 0.60, 95% CI 0.39 to 0.92) and bother (36% versus 100%) (RR 0.38, 95% CI 0.20 to 0.76) with loose faecal incontinence (Analysis 1.21).

Other outcomes

Data on sexual function, generic quality of life, psychological outcomes or economic measures were not reported.

2. Lifestyle interventions versus control/waiting list/no active treatment.

No trials identified.

3. Physical intervention versus another physical intervention.

No trials identified.

4. Physical interventions versus lifestyle interventions.

No trials identified.

5. Physical interventions versus surgery.

No trials identified.

6. Lifestyle interventions versus surgery.

No trials identified.

7. Physical interventions versus mechanical devices.

No trials identified.

8. Lifestyle interventions versus mechanical devices.

No trials identified.

9. Combination of physical and lifestyle interventions versus lifestyle interventions alone.

No trials identified.

10. Combination of physical and lifestyle interventions versus physical interventions alone.

No trials identified.

11. Combination of physical and lifestyle interventions versus surgery.

No trials identified.

12. Combination of physical and lifestyle interventions versus mechanical devices.

No trials identified.

13. Combination of physical and lifestyle interventions versus control/waiting list/no active treatment.

No trials identified.

14. Physical and/or lifestyle interventions supplementing surgery versus surgery alone.

Two trials addressed this comparison, comparing surgery plus PFMT with surgery alone (Frawley 2010; Jarvis 2005), providing a total of 54 women randomised to surgery plus PFMT and 56 to surgery alone.

Primary outcome

Prolapse symptoms and severity

Prolapse symptoms were not measured specifically in either trial.

Secondary outcomes

Prolapse severity

Prolapse severity was not measured in either trial.

Pelvic floor muscle function

Both trials included blinded measurement of pelvic floor muscle function, using both digital assessment (modified Oxford score) and manometry (Frawley 2010; Jarvis 2005).

Frawley 2010 reported that despite the tendency towards improvement in the PFMT group over time, there were no significant differences in manometry scores between the controls and those who received PFMT: the change from baseline in the vaginal resting pressure, the peak maximum vaginal squeeze pressure and the area maximum vaginal squeeze pressure did not differ between groups (Analysis 14.1). However change in the muscle strength measured digitally (modified Oxford scale) did differ between groups: 0.69 SD 0.64 PFMT versus 0.21 SD 0.66 control (MD -0.48, 95% CI -0.84 to -0.12, Analysis 14.2). Jarvis 2005 reported that improvement in mean maximum pelvic floor muscle squeeze was significantly greater in the intervention group (mean change 2.7 cm H_2O) than the control group (mean change -1.8 cm H_2O).

Urinary outcomes

Both trials focused on urinary function. Frawley 2010 reported that neither the change scores nor the repeated measures analyses demonstrated significant differences between groups in any UDI or IIQ scores (Analysis 14.3 to Analysis 14.10). There were no differences between groups on bladder diary nor pad test weights as assessed by change scores: data were not presented. Jarvis 2005 reported a significant improvement in urine leakage (measured via a pad volume test) for both the intervention and control groups, but no significant difference in improvement between the groups. Both groups had an improvement in urinary symptoms but the improvement for the intervention group was reported to be significantly greater than for the control group (between group difference in mean reduction 3.8; P = 0.017; 95% CI 0.7 to 6.9). Reduction in diurnal frequency was significantly greater in the intervention group (mean reduction 1.5) than in the control group (mean reduction 0.4) (P = 0.024).

Other outcomes

In Frawley 2010, differences between trial groups were not significant for the bowel (Wexner scale or Constipation Scoring System) or AQoL scores. There was a difference in favour of the intervention group in terms of increased frequency of general physical activity (mean 1.8 sessions per week SD 2.97 intervention versus 0.27 sessions SD 1.99 control).

15. Physical and/or lifestyle interventions supplementing mechanical device versus mechanical device alone.

No trials identified.

16. Physical and/or lifestyle interventions supplementing surgery versus physical and/or lifestyle intervention alone.

No trials identified.

17. Physical and/or lifestyle interventions supplementing mechanical device versus physical and/or lifestyle intervention alone.

No trials identified.

DISCUSSION

This is the second update of this review, which considers whether conservative interventions are effective for the management of pelvic organ prolapse. The scope of the review has now been broadened to include prevention trials. Reviews relating to other forms of treatment for prolapse also exist and are covered in other Cochrane reviews: surgery (Maher 2010), mechanical devices (Adams 2004) and oestrogen (Ismail 2010).

Summary of the results

Six trials of relevance to this review were identified; three of these are new to this update. The trials relate to either PFMT as a treatment for prolapse (Braekken 2010; Ghroubi 2008; Hagen 2009; Piya-Anant 2003), or a treatment adjunct (Frawley 2010; Jarvis

2005) for prolapse. The results of two large ongoing treatment trials (Hagen 2010 (ISRCTN 35911035), Barber 2009) are awaited which will add significantly to future updates of this review. No trials were found of lifestyle interventions. No prevention trials were found either although a trial of PFMT for the prevention of prolapse is ongoing (Hagen 2011).

There was limited data which could be pooled across studies, therefore synthesis was mainly of a qualitative nature for most outcomes.

Physical interventions versus control/waiting list/no active treatment (four trials)

Primary outcomes

Prolapse symptoms were significantly improved in three out of three trials that measured this (Braekken 2010; Ghroubi 2008; Hagen 2009). There was evidence from each trial separately that prolapse symptoms improved as a result of PFMT. The largest of these trials (Braekken 2010) found in the intervention group significantly more improvement in prolapse symptom frequency and bother in a subgroup analysis of symptomatic women.

Secondary outcomes

Prolapse severity was reported to be significantly improved in three out of three trials that measured this (Braekken 2010; Hagen 2009; Piya-Anant 2003). Two trials measured severity using the POP-Q system, allowing results to be pooled. The pooled risk ratio of 0.83 indicated that having PFMT increased the chance of improvement in prolapse stage by 17% compared to no PFMT.

Unfortunately the largest of these three included trials, which considered the effect of PFMT in preventing anterior prolapse from worsening, had serious limitations which affected the generalisability and rigor of the findings (Piya-Anant 2003). Prolapse severity was measured using a non-standardised methods; denominators and numerators were not clearly reported and analyses did not take into account clustering effects. For these reasons, the authors' conclusion that the pelvic floor muscle programme was effective in preventing worsening of severe prolapse should be treated cautiously.

Other outcomes

Pelvic floor muscle strength was measured in two trials and results favoured the intervention groups. However in one trial the measurement was not blinded (Braekken 2010) and in the other there was no information on blinding so it is suspected measurement was unblinded also (Ghroubi 2008). Urinary outcomes were considered in three trials. Braekken 2010 found better urinary outcomes, both in terms of prevalence of symptom improvement and symptom summary score, in the PFMT compared to the control group. Urodynamic and symptom prevalence outcomes were more favourable in the PFMT group than the control group in Ghroubi 2008, although these measures may not have been blinded. Hagen 2009 however found no difference between groups in urinary symptom score in their small feasibility trial. Braekken 2010 reported that the frequency and bother associated with bowel problems (loose faecal and flatus incontinence) was less in the group receiving PFMT.

Physical and/or lifestyle interventions supplementing surgery versus surgery alone (two trials)

There was no prolapse-specific data available from either trial. Both trials reported on pelvic floor muscle strength and urinary outcomes but findings were contradictory. Frawley 2010 had a more intensive intervention yet found little difference between groups on either type of outcome, whilst Jarvis 2005 found significant benefit of PFMT for both.

Overall completeness and applicability of evidence

There is still relatively little evidence from large, well-conducted trials to inform this review, and a lack of data on long-term outcomes. Only one comparison (**Physical interventions versus control/waiting list/no active treatment)** had sufficient, high quality data to allow any conclusions to be drawn. A limited amount of pooling of results across trials was possible due to different measures being used by different research teams.

AUTHORS' CONCLUSIONS

Implications for practice

There are now some rigorous trial findings to support the use of PFMT as a treatment for women with prolapse, however the evidence remains limited. There was insufficient evidence about other interventions or combinations of interventions to inform practice.

Implications for research

There remains a need for more trials of PFMT, with longer follow-up and different intensities of intervention. These might also explore the effects of electrical stimulation and biofeedback as these have not been formally included in trials to date. No trials of lifestyle changes (either on their own or in combination with other treatments) were found. Generally lifestyle advice is often given alongside PFMT, and Piya-Anant 2003 and Hagen 2009 reported an element of lifestyle advice within their interventions, although the main focus of these trials was PFMT. A trial that looks at the effects of, for example, weight loss or reducing constipation,

specifically in women with prolapse, may be beneficial. A large trial of PFMT as an adjunct to prolapse surgery is still required, with prolapse-specific outcomes, to assess any added benefit of PFMT alongside prolapse surgery. A 2 x 2 factorial trial of two types of surgery for apical prolapse with or without PFMT is underway, due to complete in 2012 (Barber 2009).

Standardisation of the use of validated outcome measures, both anatomical and symptom-based, is needed to ensure data from future prolapse trials are relevant and have the potential for appropriate data pooling.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Braekken 2010

Methods	**Treatment arms:** 2 groups, PFMT and control **Randomisation**: a statistician generated and stored the allocation envelopes. Immediately after a woman's initial gynaecologist examination the 1st author gave the next numbered envelope to the woman at the University hospital. The woman opened the opaque sealed envelope herself. Random permuted blocks were not used which resulted in unequal group sizes. There was a significant difference at baseline between the randomised groups in the prevalence of prolapse symptoms (43/59 PFMT group, 26/50 control group) **Stratification**: States 2 strata, maximum descent at or above the hymen, below the hymen. However when analyses were reported the number of women was not equal within the "below the hymen" strata: 25 intervention, 15 control. This suggests women were not randomised within strata **Blinding**: the ultrasound films were assessed by an assessor blind to the women's group, clinical and background information. POP-Q assessment was also blinded in this way. Pelvic floor assessment was not blinded: carried out by the 1st author who was also involved in delivering the intervention **Power calculation**: sample size based on effect size of 0.6 (from study of PFMT for stress urinary incontinence), alpha=0.5, power 80%. Suggested 45 women per group was needed **Intention to treat analysis:** was performed. Did not perform "per protocol" analysis as there were very few drop-outs. Baseline values carried forward for 2 women who dropped out **Follow-up**: women were followed up at 6 months.
Participants	**Study population**: 109 out of possible 145 women were randomised (36 excluded, 59 PFMT, 50 control). The trial included: women attending for a routine check-up, women attending with POP symptoms and women interested to know if they might have prolapse **Number/type of centres:** recruitment was by multiple community gynaecologists in Oslo and Akershus. 14 gynaecologists recruited women to the trial. Women were also recruited via newspaper adverts. POP-Qs and ultrasounds were carried out at a University Hospital. Pelvic floor assessments were carried out at a physical therapy centre by the 1st author. The intervention was delivered either at a physical therapist centre or at a University Hospital **Withdrawals**: 1 woman in each group withdrew. **Diagnosis**: POP-Q method. Type of prolapse: • Anterior prolapse: 54/59 PFMT, 49/50 control • Posterior prolapse: 46/59 PFMT, 42/50 control • Apical prolapse: 47/59 PFMT, 41/50 control Severity of prolapse: • Stage I: 19/108 • Stage II: 65/108 • Stage III: 24/108

	• Not classified: 1 **Urinary incontinence present**: 51/59 PFMT and 36/50 control women had bladder symptoms at baseline. Urinary incontinence not mentioned specifically **Inclusion criteria**: • POP-Q Stage I, II, III • >= 1 year postpartum • no prolapse symptoms necessary **Exclusion criteria**: • Cannot contract PFMs • breastfeeding • previous POP surgery • radiating back pain • pelvic cancer • neurological condition • psychiatric disorder • untreated UTI • planned pregnancy within 6 months • planned holiday for > 4 weeks out of the intervention period. **Baseline comparison of treatment groups:** • numbers unequal (59 PFMT vs 50 control) in randomised groups • significant difference in presence of prolapse symptoms. More PFMT group women had prolapse symptoms (vaginal bulging/pelvic heaviness): 43/59 vs 26/50. i.e. 37% of women were asymptomatic • no other significant differences. **Characteristics of population:** • Age: 49.4 +/- 12.2 PFMT; 48.3 +/- 11.4 control • Parity: 2.4 +/- 0.8 PFMT; 2.4 +/- 0.7 control • BMI: 25.8 +/- 3.8 PFMT; 26.2 +/- 5.33 control
Interventions	**Comparisons**: • PFMT vs control • PFMT pre vs post • sub-group analysis of symptomatic women, PFMT versus control **Description**: • Both groups taught the Knack. • PFMT group: 1 visit per week for 3 months, followed by 1 visit every 2 weeks for 3 months. These were supervised sessions with a physiotherapist. Sessions included 3 sets of 8-12 maximal contractions in lying, sitting and standing. Daily exercises prescribed 3 sets of 8-12 close to maximal contractions. Exercise booklet, DVD and diary. • Control group: told not to start (or stop) PFMT and to avoid straining. **Therapists**: 3 women's health physiotherapists (including 1st author) delivered the intervention. **Compliance**: • 89% of women adhered to home exercise • 86% of women adhered to physiotherapy sessions.
Outcomes	**Definition of cure**: Improvement of morphological and functional change. Improvement in symptoms: less frequent symptoms, less bother with symptoms **Outcomes**:

	Pre to post change in ultrasound measures (mean change, 95% CI): *intervention control* • Thickness of pubovisceral muscle (mm) 1.4 (0.8, 2.0) -0.5 (-1.0, 0.0) • Levator hiatus area at rest ($cm^{2)}$ -1.5 (-2.4, -0.6) 0.3 (-0.7, 1.2) • Levator hiatus area at Valsalva ($cm^{2)}$ -2.3 (-4.0, -0.5) 0.1 (-1.7, 1.8) • Pubovisceral muscle length at rest (mm) -5.1 (-8.0, -2.3) 1.0 (-2.7, 4.7) • Pubovisceral muscle length at Valsalva (mm) -7.8 (-13.3, -2.3) 3.2 (-2.2, 8.5) • Position of bladder at rest in standing (mm)* 4.2 (2.8, 5.6) -0.1 (-1.9, 1.6) • Position of rectum at rest in standing (mm)* 3.6 (-0.3, 7.4) -3.4 (-6.4, -0.3) *NB. results for bladder and rectum positions differ in the American Journal of Obstetrics and Gynecology paper as different measurement method was used POP-Q: • % improved 1 stage: 11/58 (19%) PFMT; 4/50 (8%) control (P = 0.035). *The authors were contacted and they indicated a Mann-Whitney U test had been used with the change in POP-Q stage (1 = improved one stage, 0 = no change, -1 = worsening one stage)* • No significant difference between groups in % improved 1 stage for subgroup below the hymen (n = 40, 25 intervention, 15 control): 5/25 vs 3/15. Improvement in frequency and bother of prolapse symptoms: vaginal bulging and/or heaviness • reduced frequency: 32/43 PFMT 8/26 control • reduced bother: 29/43 PFMT 11/26 control Improvement in frequency and bother of bladder symptoms (Analysis 1.11): Percentage with improved frequency and bother of stress and urge symptoms reported. Sample size ranged from 12 to 39 per group as not all women had bladder symptoms to start with. Significant difference in favour of the intervention group for improvement in frequency and bother of stress symptoms, and frequency of urge symptoms ICIQ-UI short form: Difference between groups 2.40; 95% CI [0.90, 3.80], P = 0.002. It is not clear whether this is based on the change in score. The means for each group are not reported Improvement in frequency and bother of bowel symptoms (Analysis 1.21): Percentage with improved frequency and bother of: difficulty emptying, of flatus leakage, of loose faecal incontinence and of solid faecal incontinence reported. Sample size ranged from 2 to 34 per group as not all women had bowel symptoms to start with. Significant difference in favour of the intervention group for improvement in frequency and bother of flatus, and frequency and bother of loose faecal incontinence Pelvic floor muscle assessment (mean change, 95% CI) (Analysis 1.10): • strength (manometry cmH_2O): 13.1 [10.6, 15.5] PFMT; 1.1 [-0.4, 2.7] control, P <0.001 • endurance (manometry cmH_2O sec): 107 [77, 136.4] PFMT; 8 [-7.4, 24.1] control, P <0.001
Notes	• The results from the trial were published in 2 separate papers: ultrasound measure outcomes in one, and symptom and severity in the other. The information on methods and findings have been pooled from these two papers for the purposes of this review. • Sample size smaller for some outcomes e.g. position of rectum at rest n = 35 vs n = 37. • Difference between groups in levator hiatus area at Valsalva was reported to be significant but confidence intervals in table 3 contradict this. • PFM function is described as an independent variable rather than an outcome

	measure as the assessor was not blinded to women's group allocation. • 12/44 postmenopausal women received hormone/oestrogen replacement therapy. • 10% of control group women reported doing more PFMT than before baseline. • Data entered into Review Manager for relevant outcomes.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Randomisation: computer generated random number system with concealed envelopes
Allocation concealment (selection bias)	Low risk	Allocation concealment: participants open the envelope.
Blinding (performance bias and detection bias) All outcomes	Low risk	Blinding: not possible to blind the women. Women were community dwelling therefore no caregiver. Ultrasounds were taken and assessed blinded to women's group. Pelvic floor muscle strength (not an outcome measure) assessor not blind to group status as also delivered the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 woman in each group dropped out: motivation problems (PFMT woman), offered UI surgery (control woman)
Selective reporting (reporting bias)	Low risk	
Other bias	Unclear risk	Not discussed why the numbers are unequal in the randomised groups, and why there are differences in baseline characteristics. May suggest problems with the randomisation process

Frawley 2010

Methods	**Randomisation**: A simple random numbers table was used to generate the sequence. The allocation process was controlled by a researcher not involved in the recruitment, who notified the treating physiotherapist of a woman's group allocation **Stratification:** No stratification was used. **Treatment arms:** Comparisons: The trial had 2 arms: 1) physiotherapy-supervised PFMT intervention (treatment appointment pre-operatively (n = 1) and post-operatively (n = 7)) 2) usual care provided by the surgeon **Blinding:** It was not possible to blind patient to group allocation. The surgeon performing the woman's operation was not blinded. Assessment of the pelvic floor was undertaken by physiotherapist (first author) blind to the woman's group. Not stated how the assessor remained blinded. The first author also undertook the analysis and was unblinded at that stage. Treatment physiotherapist delivering the intervention was not blinded **Power calculation**: Sample size calculation was based on published prevalence relating to overactive bladder. To detect a 20% difference between groups with 80% power at 5% level of significance, 22 women per group were needed. A target of 58 in total was set to allow for drop-outs **Intention to treat:** It is stated that an intention to treat analysis was undertaken. However those women who did not receive the allocated intervention and those who discontinued the intervention are not included in analysis (figure 1). Last observation carried forward method was used to handle missing observations **Follow-up:** Assessment was carried out pre-operatively and at 3, 6 and 12 months post-operatively, with 12 months as the primary outcome
Participants	**Study population**: Women having vaginal or laparoscopic assisted vaginal surgery for repair of prolapse (primary or recurrent), and/or hysterectomy **Diagnosis**: Women were entered to trial by fact that they were having surgery irrespective of diagnosis **Number/type of centres:** Recruitment took place in 6 metropolitan private hospitals in Melbourne. It was not clear how many gynaecologists were involved in recruiting **Exclusion criteria**: Excluded were women who were having surgery for cancer, or concomitant surgery for urinary incontinence **Characteristics of population:** The type and severity of prolapse were not stated. Not all women had prolapse (3 women had hysterectomy for reasons other than prolapse) Types of surgery (% in control group/% in PFMT group): • POP repair with hysterectomy: 56%/50% • POP repair: 26%/38% • Hysterectomy for POP: 4%/8% • Hysterectomy not for POP: 11%/0% • Conversion to abdominal repair: 4%/4% **Baseline comparison of treatment groups:** • Age: 57.4 (10.3) control; 55.8 (10.7) PFMT • Weight: 72.7 (12.5) kg control; 68.2 (12.5) kg PFMT • BMI: 27.6 (4.4) control; 25 (3.5) PFMT • Vaginal deliveries: 2.4 (1.2) control; 3.2 (1.1) PFMT Baseline characteristics were similar in each group except the control group had higher BMI (27.6 v 25) and fewer vaginal deliveries (2.4 v 3.2) **Urinary incontinence present**: Women self reported the presence of UI: controls were less likely to report incontinence (8/27 control v 18/24 PFMT). Average UDI total score:

	41.0 control group and 82.5 treatment group (because of these differences at baseline, time 1 score was used as a covariate in further analyses) **Withdrawals:** • Number who did not receive allocated intervention (withdrew post-operatively): 1 in the control group, 6 in the PFMT group • Number who discontinued intervention: 4 in control group (3 had some data for analysis), 3 in PFMT group (2 had some data for analysis)
Interventions	**Comparisons**: Control (usual care) v Treatment (Physiotherapist supervised PFMT intervention) **Descriptions:** PFMT: 1 pre-operative appointment and 7 post-operative appointments. Increase in effort to maximum voluntary contraction, set of 6-8 second contractions, with rest in between, repeated 8-12 times, 3 times per day, variety of positions progressing from lying to upright. Early post-op gradual increase to pre-op intensity by 6 weeks. Maintenance of intense level for 3-6 months, then reduction to 1-2 sets per day by 12 months. At all sessions counterbracing (the Knack) is taught, PFMT is varied according to the individual woman's needs and adjunctive therapy (biofeedback with pressure manometry, electrical stimulation for absent/very weak contraction or OAB) used at the discretion of the physiotherapist All participants: receive usual care from surgeon and nursing staff. In some cases this might include information about pelvic floor exercises and encouragement to perform them, and advice on bladder and bowel function, and general advice on returning to normal activities **Therapists:** No detail was given of the therapists providing the intervention **Compliance:** Adherence with intervention was measured using a training diary in treatment group. There was 89% attendance at physiotherapy appointments, 47% successful receipt of telephone calls, 71% return of home exercise diaries, 89% adherence with the prescribed exercise dose
Outcomes	**Definition of cure**: None stated specifically. Sample size calculation suggests a 20% improvement in OAB score from the UDI is considered a clinically reasonable improvement **Outcomes:** Primary outcome: • UDI-19 (including irritative, stress and obstructive subscales) • IIQ-7 • 3-day bladder diary • 48-hour pad test Secondary outcome: • Modified Wexner Score for faecal incontinence • Constipation Scoring System • AQoL • General exercise participation and perceived level of intensity • PFM strength (digital palpation, pressure manometry) Results: • There were no significant differences in the change (baseline to 12 month post-op) in UDI-19 subscores or IIQ total score between groups. • There were no significant differences in change scores for bladder diary or pad

	tests (data not presented in article). • There were significant differences in change in general exercise frequency and intensity of exercise in favour of the treatment group. There were no significant differences in the other secondary outcome measures. • Differences between groups were not significant for the bowel or AQoL scores. • There were no significant differences in the manometry scores between groups. • Improvement in modified Oxford grade was significantly greater in the intervention group (PFMT: 0.69 SD 0.64 n = 24 vs Control: 0.21 SD 0.66 n = 26, P = 0.01)
Notes	• No note of type of repairs used and no sub-group analysis of women with POP repair only. • Time 1 scores included as covariate in analyses to offset baseline differences (e.g. treatment group had higher scores on the three UDI-19 subscales and the IIQ-7 at baseline). • The IIQ-7 mean change from baseline to 12 months post-op was summarised as median and 95% confidence interval: control group 0.0 (0, 14), treatment group 10.0 (5, 19) • 67% of controls stated they performed PFMT throughout the course of the trial. • Data entered into Review Manager for relevant outcomes.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	A simple random numbers table was used to generate the sequence
Allocation concealment (selection bias)	Low risk	This was controlled by a researcher not involved in the recruitment, who notified the treating physiotherapist of a woman's group allocation
Blinding (performance bias and detection bias) All outcomes	Low risk	Assessment of the pelvic floor was undertaken by physiotherapist blind to group. Not stated how blinding achieved. Treatment physiotherapist not blinded. Not possible to blind patient. Surgeon not blinded. Blinding of caregiver not relevant.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Withdrawals adequately reported.
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Ghroubi 2008

Methods	**Randomisation**: No description of the randomisation process. No detail of allocation concealment **Stratification:** No stratification was described **Treatment arms:** 2 arms in the trial: conservative treatment group; non-treated group **Blinding:** no detail **Power calculation**: no detail **Intention to treat:** no detail **Follow-up:** Follow-up was immediate post-treatment for the treatment group and 3 months after first consultation for the control group. A 2 year follow-up was carried out for the treatment group only
Participants	**Study population**: Total study population was 47 women; 27 randomised to the treatment group; 20 to the control group **Diagnosis**: Diagnosis of prolapse was made using the ICS classification (unsure whether this refers to POP-Q, the reference given, Cosson et al, could not be obtained). Stage was assessed by gynaecologists **Number/type of centres:** No detail was given about the number or type of centres included in the trial **Inclusion criteria**: Women with Stage I or II cystocele, with or without stage I rectocele, were eligible **Exclusion criteria**: Advanced prolapse, previous pelvic surgery, having other treatment with potential effect on bladder and sphincter function, neurological condition **Characteristics of population:** Average age 53.42 (SD 11.01), duration of symptoms 26.53 months (SD 6.65), pelvic heaviness 85%, dysuria 76.59%, frequency 40.42%, urgency 14.81%, stress incontinence 40.42% **Baseline comparison of treatment groups:** Groups were comparable in terms of number of pregnancies, parity and obstetric factors, and chronic bronchitis, constipation and menopausal status **Urinary incontinence present**: Urinary incontinence was present in 40.42% of participants **Withdrawals:** No detail of withdrawals was given
Interventions	**Comparisons**: 1) Pelvic floor exercises+healthy living advice vs 2) no treatment **Descriptions:** PFMT: • anatomical explanation given and women taught consciousness of PFMs, taught PFEs (stretch reflex technique) + electrical stimulation + digital biofeedback. 24 sessions, 30 minutes per session. • From 10^{th} session women practice every day - 20 contractions per day with "self control on the fourchette/perineum". Lifestyle advice give e.g. re heavy lifting, avoiding constipation and chronic cough. • Compliance checked at each session. **Therapists:** No detail of who delivered the intervention, nor the total duration **Compliance:**
Outcomes	**Definition of cure**: Definition of cure appears to be absence of pelvic heaviness **Outcomes:** • Report of pelvic heaviness: 5/27 intervention; 14/20 control • Clinical exam to assess severity: not reported • Prevalence of urinary symptoms:

	○ dysuria (pain): 5/27 intervention; 12/20 control ○ urgency: 1/27 intervention; 7/20 control ○ stress incontinence: 2/27 intervention; 7/20 control ○ frequency: 4/27 intervention; 11/20 control • Measurement of urinary handicap (MUH) scale ○ total score: 6.48 (2.63) intervention; 15.7 (2.43) control ○ urge subscore: 2.18 (1.38) intervention; 5.25 (1.91) control ○ stress UI subscore: 1.88 (1.47) intervention; 3.45 (1.31) control ○ frequency subscore: 1.77 (1.25) intervention; 5.2 (1.67) control ○ dysuria subscore: 0.59 (0.57) intervention; 1.8 (0.95) control • Levator ani strength: 2.37 (0.83) intervention; 1.25 (0.78) control • Urodynamic tests: ○ closure pressure: 57.81 (12.8) intervention; 52.95 (12.18) control ○ flow: 16.33 (2.51) intervention; 13.1 (3.83) control ○ post-void residual: 57.81 (12.8) intervention; 79.09 (23.75) control • Ditrovie QoL scale: 2.07 (0.57) intervention; 2.57 (0.43) control • Patient satisfaction on VAS (have you felt an improvement and how do you rate it?): 6.77 (1.12) intervention; 3.55 (0.88) control Immediately post-treatment, pelvic heaviness persisted in five women (19%) from the treatment group compared with fourteen (70%) in the control group (P < 0.001). There were also significant differences in other outcomes, including quality of life and urodynamic measures. It was reported that 20 women from the intervention group retained benefits two years after the treatment had ceased
Notes	• Article in French (trial took place in Tunisia) with English abstract. Two partial translations obtained. Authors emailed but no reply received. • The sample size is not given for each of the outcomes reported, and there is no information about withdrawals or the numbers available for treatment. It is assumed in this review for the purposes of data analysis that the treatment group sample size is 27, and the control group sample size is 20 throughout. • The Ditrovie scale measures QoL associated with urinary symptoms. The authors may have altered the scale to assess QoL associate with prolapse. • 20/27 in the treatment group attended and were reviewed 2 years after they stopped the intervention. Data are presented on symptoms, flow, QoL and satisfaction. • Compliance was graded "good" if woman complete 20 contractions every day, medium if she completed 3 times a week, bad if she completed 0 or 1 times a week. • Data entered into Review Manager for relevant outcomes.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no description given
Allocation concealment (selection bias)	Unclear risk	no description given

Ghroubi 2008 (*Continued*)

Blinding (performance bias and detection bias) All outcomes	Unclear risk	no description given
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	no description given
Selective reporting (reporting bias)	Unclear risk	no description given
Other bias	Unclear risk	no description given

Hagen 2009

Methods	**Randomisation**: Randomised controlled trial, single blind. Automated telephone randomisation system for group allocation **Stratification:** Stratified by number of deliveries and centre. **Treatment arms:** PFMT versus control (lifestyle leaflet) **Blinding:** Women and therapist not blind to group allocation. Gynaecologist undertaking POP-Q assessment blind to group allocation (women asked not to reveal their group and chaperone at assessment to enforce this) **Power calculation**: feasibility study therefore no power calculation carried out **Intention to treat:** women analysed in the group they were randomised to. **Follow-up:** questionnaire follow-up at 20 weeks and 26 weeks post-randomisation; gynaecology review appointment (including POP-Q) at 20 weeks post-randomisation
Participants	**Study population**: 47 women with stage I or II prolapse of any type identified at their first appointment at gynaecology outpatient clinics at two centres in Scotland; 23 intervention, 24 control **Diagnosis**: prolapse of any type diagnosed using the POP-Q assessment carried out by a gynaecologist at the first appointment **Number/type of centres:** 2 centres, both large teaching hospitals **Exclusion criteria**: stage 0, III or IV prolapse; main presenting problem not prolapse **Characteristics of population:** • Age: mean 56 years (SD 9) • Vaginal deliveries: all women had had at least 1 vaginal delivery and 40% (the largest group) had had 2 vaginal deliveries; 45% reported at least 1 forceps delivery; no caesarean sections were reported. **Baseline comparison of treatment groups:** There were no significant differences between the groups with respect to age, parity, method of delivery, type or duration of prolapse, or prevalence of symptoms **Withdrawals:** intervention group 4, control group 3; questionnaire response rate at 20 weeks was 87% and at 26 weeks was 85%; 89% of women attended their 20-week follow-up gynaecology review appointment when POP-Q reassessment was undertaken
Interventions	**Comparisons**: PFMT group versus control group. **Descriptions:** PFMT: Women in the intervention group attended 5 physiotherapy sessions over 16 weeks (weeks 0, 2, 6, 11 and 16) where pelvic floor exercise techniques were taught and

	advice on modifying lifestyle was given. An individually tailored exercise programme was provided by the physiotherapist which was performed by the women at home. 6 sets of exercises per day was recommended. One set consisted of up to 10 maximum voluntary contractions held for up to 10 seconds, with 4 seconds rest between each contraction and, after a 1 minute rest, 10 or more fast contractions in a row Control: The control group were sent a lifestyle advice leaflet containing things they might try to help prolapse (weight loss, and avoidance of constipation, heavy lifting, coughing and high impact exercise) All participants: Both groups of women had a review appointment with a gynaecologist at 20 weeks post-randomisation **Therapists:** local physiotherapists, who were specialists in women's health, delivered the PFMT intervention. There were 2 intervention physiotherapists at each centre **Compliance:** 91% of intervention women attended 3 or more PFMT appointments, 74% attended 4 appointments, and 65% attended 5 appointments. 61% of women in the intervention group were rated as good or moderate exercise compliers
Outcomes	**Definition of cure**: improved prolapse symptoms. **Outcomes:** outcomes measured were POP-Q (baseline and 20 weeks), symptom and quality of life questionnaires relating to prolapse, urinary symptoms, bowel symptoms and sexual function (baseline, 20 and 26 weeks), general health status Primary outcome: prolapse symptom severity measured using the Prolapse Symptom Score (POP-SS) and prolapse related quality of life (visual analogue scale) Secondary outcome: prolapse severity (POP-Q), urinary leakage (ICIQ-UI SF), bowel symptoms (ICIQ bowel), sexual symptoms (ICIQ vaginal symptoms), general health status (SF-12) Results: • Prolapse symptom score: mean change score from baseline to 2 weeks -3.5 (SD 5. 4) intervention (n = 17), mean change score -0.1 (SD 2.9) control (n = 20); 95% CI for difference in change score between groups [0.53, 6.21]. • Prolapse QoL score: mean score 2.0 (SD 1.5) intervention, mean score 2.1 (SD 2. 3) control (mean difference -0.10 95% CI [-1.29, 1.09]). • Change in POP-Q severity by 20 weeks: no change or worse stage 6/11 intervention, 9/9 control (RR 0.55 CI [0.32, 0.94]). • Change (cm) in POP-Q measurement by 20 weeks: mean change in Aa -0.36 (SD 1.86) intervention, 0.67 (SD 0.71) control (mean difference -1.03 CI [-2.22, 0.16]); mean change in Ba -1.09 (SD 1.22) intervention, 0.56 (SD 1.01) control (mean difference -1.65 CI [-2.63, -0.67]). No significant differences were found for other POP-Q points. • Self-reported change in prolapse at 26 weeks: number same or worse 7/19 intervention, 16/21 control (RR 0.48 CI [0.26, 0.91]).
Notes	• This trial was a feasibility study intended to test the methods for a larger multi-centre trial. • Pelvic floor muscle strength, measured using the modified Oxford scale in the intervention group women only, increased significantly (mean increase 0.5, SD 0.6, t = -3.09, df 14, P = 0.008, 95% CI [0.2, 0.8]). • Data entered into Review Manager for relevant outcomes.
Risk of bias	

Hagen 2009 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	computer generated allocations
Allocation concealment (selection bias)	Low risk	remote system with telephone access
Blinding (performance bias and detection bias) All outcomes	Low risk	not possible for questionnaires, attempted for POP-Q assessment (achieved in 37 out of 42 follow-up POP-Q assessments)
Incomplete outcome data (attrition bias) All outcomes	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Jarvis 2005

Methods	**Randomisation**: randomised controlled, single blind trial. Randomisation in blocks of size 20. Allocation by computer-generated random numbers. Information on group allocation was stored in a separate location, concealed in opaque envelopes. The treating physiotherapist opened the envelope after a woman was recruited **Stratification:** none mentioned **Treatment arms:** PFMT versus standard care **Blinding:** pelvic floor muscle assessment and paper towel test at 12 weeks were blinded **Power calculation**: used a clinically significant difference between the groups of 30% from other quality of life studies. Based on this assumption, a sample size of 60 was required with 30 in each group **Intention to treat:** not mentioned. No details of numbers in the analysis in order to judge **Follow-up:** Women were followed up for 3 months.
Participants	**Study population**: 60 women who were scheduled to undergo surgery to correct prolapse and/or incontinence. 30 intervention, 30 control. Recruitment April 2000 to December 2003 **Diagnosis**: prolapse and/or urinary incontinence. **Number/type of centres:** endo-gynaecology department at 1 hospital. Recruitment involved women having surgery with 23 gynaecologists at the hospital **Exclusion criteria**: women with neuromuscular disorders or other significant medical problems, or those who had pelvic floor muscle intervention as a routine part of their presurgical assessment. Women undergoing tension-free vaginal tape as the sole intervention were also excluded due to short length of their hospital stay **Characteristics of population:** **Baseline comparison of treatment groups:** Demographics and type of surgery for the two groups were similar. There were no differences in the type of surgery undertaken between the groups

	• Age: intervention mean 62.6 (SD 10.5) range [40-76], control mean 62.8 (SD 11.1) range [47-78] • Weight - not reported • Bmi: intervention mean 27, range 20-40, SD 4.2; control mean 27.4, range 21-32, SD 2.8 • Parity: intervention mean 2.5, range 0-5, SD 1.1; control mean 2.6, range 1-7, SD 1.2 • type of surgery: prolapse surgery alone 17/30 intervention group, 23/30 control group **Urinary incontinence present**: not known as baseline urinary measures not presented. **Withdrawals:** Surgery was cancelled for 3/30 intervention women and 1/30 control woman. States 4 intervention women and 2 control women dropped out. Authors state there were a number of missed appointments and women lost to follow-up, but the details are not given. It is not known how many women are therefore included in the data analysis
Interventions	**Comparisons**: PFMT versus control. **Descriptions:** PFMT: Instructions were given by a physiotherapist on the performance of pelvic floor muscle exercises, and an individually tailored programme of pelvic floor muscle exercises was provided. Women were advised to do 4 sets of exercises a day. Information and advice on pelvic bracing, voiding postures and defaecation techniques. Intervention women saw the physiotherapist on the second post-operative day to reinforce the exercise program, and had a 6-week post-operative visit Control: Received standard care. Did not receive the PFMT intervention All participants: Women in both the intervention and control group underwent surgical procedures for prolapse and/or incontinence and received standard care **Therapists:** no detail **Compliance:** not reported
Outcomes	**Definition of cure**: **Outcomes:** No prolapse-specific outcomes were measured. At baseline (pre-admission) and 12 weeks post-operatively all women had: • pelvic floor muscle assessment (Oxford scale and manometry) • paper towel test, • standardised urinary symptom-specific health and quality of life questionnaire (Kelleher 1997) 48-hour urinary frequency/volume diary Primary outcome: no primary outcome specified although sample size based on difference in quality of life Secondary outcome: not specified Results: • There was a significant improvement in urine leakage for the intervention (mean reduction 62 cm^3) and control group (mean reduction 32cm^3), but there was no significant difference in improvement between the groups (95% CI -11.4 to 72.3 cm^3; P = 0.150). • Both groups had an improvement in urinary symptoms but the improvement for the intervention group (mean reduction 6.3) was significantly greater than for the control group (mean reduction 2.4) (between group difference in mean reduction 3.8;

	P = 0.017; 95% CI 0.7 to 6.9). • Reduction in diurnal frequency was significantly greater in the intervention group (mean reduction 1.5) than in the control group (mean reduction 0.4) (P = 0.024). • Improvement in mean maximum squeeze was significantly greater in the intervention group (mean change 2.7 cm H_2O) than the control group (mean change -1.8 cm H_2O). The difference in mean maximum squeeze pressure between groups was reported to be significant: P = 0.022; 95% CI -9.92 to -0.81.
Notes	• 2 women in the trial were to have incontinence surgery without concurrent prolapse surgery, both were in the intervention group. No subgroup analysis of those women who only had prolapse surgery. • the authors did not report the number of women in each analysis or the standard deviations, thus the data were not entered in this review. • unclear when the baseline assessments took place. Women were approached about the trial 2-4 weeks before surgery at a pre-admissions clinic. Not clear if they were consented, randomised and baseline measures taken at this point also. • Data not entered into Review Manager as no standard deviations or numbers (n) reported, only mean values for each group.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	opaque envelopes stored in a location away from the clinic
Blinding (performance bias and detection bias) All outcomes	Low risk	physiotherapist undertaking the 12 week assessments was blind to group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	details of missing data, other that number of women who withdrew, not given
Selective reporting (reporting bias)	Low risk	
Other bias	Unclear risk	not clear what the sample sizes were for the outcomes reported as no details of missing values given

Piya-Anant 2003

Methods	**Randomisation**: Cluster randomised controlled, single blind trial. No detail of randomisation method. Clustering by post code area **Stratification:** none mentioned **Treatment arms:** pelvic floor muscle training versus non treated control **Blinding:** doctor assessing prolapse at follow-up was blinded to the woman's previous assessment. No mention of blinding of group allocation **Power calculation**: no power calculation was described **Intention to treat:** no mention of whether an intention to treat analysis was used **Follow-up:** Follow-up was conducted at 6, 12 and 24 months. 18-month follow-up planned but was not possible
Participants	**Study population**: 654 community-dwelling Thai women, over 60 years of age and living within 10 km of the hospital where the trial was conducted, with or without anterior wall pelvic organ prolapse. Intervention: n = 330, control: n = 324 **Diagnosis**: vaginal examination before and during Valsalva. No prolapse: anterior wall did not protrude during Valsalva; mild prolapse: protrusion of anterior wall during Valsalva which could be measured by area; severe prolapse: protrusion of anterior vaginal wall during Valsalva which could be by volume **Number/type of centres:** women were recruited via 1 hospital **Exclusion criteria**: • chronic cough • needing gynaecological surgery • using HRT • previous A-P repair or conization • abnormal smear • difficulty communicating **Characteristics of population:** 69.9% of the 682 women examined had anterior prolapse, of whom 30.4% had severe prolapse and 39.6% had mild prolapse. 654/682 women were eligible for the trial. Age range 60 to 88 years, 50% age 60 to 65 years, 25% 66 to 70 years, 25% >70 years. The largest group, 41.6%, had had between 4 and 6 births **Baseline comparison of treatment groups:** There were no significant differences between groups in the baseline characteristics • Age, mean (SD): 67.0 (5.6) intervention group, 67.7 (5.7) control group • Age at menarche, mean (SD): 15.7 (1.9) intervention, 15.8 (2.0) control • Age at menopause, mean (SD): 48.5 (4.5) intervention, 47.8 (4.7) control: • Total number of deliveries: 1631 intervention group, 1598 control group • Total number of caesarean sections: 15 intervention, 10 control **Urinary incontinence present**: no detail given **Withdrawals:** based on information about attendance at follow-up appointments it appears that 88 intervention group women and 91 control group women did not attend for any follow-up
Interventions	**Comparisons**: PFMT versus control **Descriptions:** PFMT: instruction in the performance of pelvic floor muscle exercises. It appears that this happened on one occasion but if a woman could not perform them correctly, she attended monthly until she could do so. 30 exercises "after one meal every day" (note: personal communication with the lead author suggested it was exercise after EACH

	meal). In addition, advice on diet regarding alleviating constipation (to eat more fruit, vegetables and boiled rice, and to drink at least 2 litres of water a day) Control: no treatment. **Therapists:** No indication of who delivered the intervention. **Compliance:** All the women were eventually able to perform the exercises satisfactorily. No details of compliance
Outcomes	**Definition of cure**: The success of the intervention in preventing the worsening of anterior wall prolapse was assessed **Outcomes:** Primary outcome: The main outcome recorded was the severity of prolapse, assessed using a study-defined (i.e. non-standardised) system: on Valsalva, no prolapse (no protrusion of the anterior vaginal wall), mild (protrusion of anterior wall seen and measured as an area) or severe (protrusion measured as a volume) • It was reported that at a 6 month follow-up, there were no significant differences in the number of women with worse prolapse between the treatment and control groups, either for women classified initially with mild or severe prolapse. • For women with mild prolapse at the outset, those in the intervention group were reported to be significantly less likely to have worse prolapse at 12 month follow-up than those in the control group. By the 24 month follow-up, however this difference between the groups was no longer evident. • For women initially classified with severe prolapse, there was no difference between the treatment and control groups at the 12 month follow-up. However, women in the intervention group were less likely to have worse prolapse at 24 month follow-up (28%) than those in the control group (72%) ($P < 0.05$). These two percentages were the only outcome data reported. It is not clear whether or not clustering was allowed for in the analysis. Secondary outcome: There were no outcome measures relating to symptoms of prolapse or to constipation, other bowel or urinary symptoms. It was reported however that some women did not need to use laxatives
Notes	• Initially 682 women were examined for prolapse: 477 were found to have either "mild" or "severe" prolapse and 205 had no prolapse. 654 of the 682 women were eligible for the trial thus implying that some women with no prolapse were included. However trial results were only presented for women who originally had mild and severe prolapse. • The actual numbers of women who became worse, and the numbers of women assessed at each follow up were not always presented. Requests for additional data with more detailed breakdown were unsuccessful. • It is not clear who delivered the intervention, only that women attended a clinic. • The duration of hold of the pelvic floor muscle contractions was not reported. • No data entered into Review Manager due to insufficient reporting. • The lead author was contacted by letter and then telephone and some clarification regarding methods was obtained, although language was a barrier to communications. It was agreed with the author that a further request for greater detail regarding the results was to be faxed. A response to this request was not received.
Risk of bias	

Piya-Anant 2003 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No detail of randomisation process.
Allocation concealment (selection bias)	Unclear risk	No detail of allocation process.
Blinding (performance bias and detection bias) All outcomes	High risk	Doctor assessing prolapse at follow-up was blinded to the woman's previous assessment, but no mention of whether blind to group allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	No information given about attrition.
Selective reporting (reporting bias)	High risk	Seems that data only reported for a subgroup of the women randomise: those with mild or severe prolapse at the start, excluding those with no prolapse. Numerical information presented was limited
Other bias	Unclear risk	no description given

BMI = body mass index; ICS = International Continence Society; OAB = overactive bladder; POP = pelvic organ prolapse; POP-Q = Pelvic Organ Prolapse Quantification system; PFM = pelvic floor muscles; PFMT = pelvic floor muscle training; QoL = quality of life; SD = standard deviation; UDI = Urogenital Distress Inventory.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Adamkiewicz 2001	Not an RCT. Women with pelvic organ prolapse stage I to III (ICS classification) were included in the study. Intervention includes pelvic floor exercises combines with an intravaginal device (Kolpexin). No control group. Outcomes assessed at initial visit and at 6 weeks. The distance between the introitus and the cervix increased (from 6.7 ± 0.9 to 9.0 ± 1.4 cm) as did the distance between the introitus and levator ani (from 0.69 ± 0.88 to 2.07 ± 1.41 cm). The width of the genital hiatus decreased (from 4.12 ± 0.27 to 3.78 ± 0.30 cm). The separate effects of pelvic floor exercises and Kolpexin could not be elucidated
Aguirre 2005	Not an RCT. Thirty-nine women with stage three or higher vaginal prolapse were included in the study. Intervention includes pelvic floor exercises combines with an intravaginal device (Colpexin®). No control group. At sixteen weeks follow up, 63% showed increased muscle function, Incontinence Impact Questionnaire scores showed no change, however Urogenitary Distress Inventory ratings demonstrated a significant improvement

(*Continued*)

Culligan 2010	This was a feasibility trial comparing traditional PFMT with a Pilates program, however the women were recruited from the community and did not necessarily have pelvic floor dysfunction. Therefore the findings do not contain information about treatment. The only outcome measured was pelvic floor muscle strength
Mimura 2000	Not an RCT. Intervention includes defaecatory behavioural therapy, counselling, health education, biofeedback (EMG), and coordination exercises (details in Storrie JB, British Journal of Nursing, 1997, Vol. 6, No. 3). No control group. Patients were 32 women with rectocele of 2 cm or more. At 10 months follow-up, 12% were cured of bowel symptoms, 88% still experiencing some bowel symptoms. Outcome for prolapse not measured. Three women went on to have a prolapse repair, one a colostomy

EMG = Electromyography; RCT = randomised control trial; PFMT = pelvic floor muscle training.

Characteristics of ongoing studies *[ordered by study ID]*

Barber 2009

Trial name or title	Operations and Pelvic Muscle Training in the Management of Apical Support Loss: The OPTIMAL Trial: A randomized trial of sacrospinous ligament fixation (SSLF) versus uterosacral ligament suspension (ULS) with and without perioperative behavioral therapy/pelvic muscle training
Methods	2 x 2 factorial randomised controlled trial
Participants	Women having surgical repair for apical or uterine pelvic organ prolapse of stage 2 or greater, who also have stress urinary incontinence Required sample size is 340 women
Interventions	Women are randomised to both surgery type and behavioural intervention: surgery: 1) sacrospinous ligament fixation, or 2) uterosacral vaginal vault suspension perioperative behavioural intervention: 1) individualised behavioural and pelvic floor muscle training (1 pre-operative visit and 4 post-operative visits with behavioural interventionist for progressive PFMT and exercise and education in behavioural strategies), or 2) usual care (usual peri-operative teaching and post-operative instructions)
Outcomes	endpoints for the behavioural intervention: short term (6 months) improvement in urinary symptoms (UDI subscale of PFDI) and long term (2 years) improvement in anatomic outcomes and prolapse symptoms (POPDI subscale of the UDI)
Starting date	February 2008
Contact information	Matthew D Barber, Obstetrics, Gynecology and Women's Health Institute, Cleveland, USA
Notes	Interventionists included physical therapists, registered nurses and certified registered nurse practitioners who had standardised training Estimated trial completion date is February 2012. ClinicalTrials.gov identifier NCT00597935

Hagen 2010

Trial name or title	A multi-centre randomised controlled trial of a pelvic floor muscle training intervention for women with pelvic organ prolapse (POPPY Trial)
Methods	Parallel group RCT of PFMT versus control
Participants	women with stage I, II or III prolapse of any type
Interventions	individualised PFMT:16 week duration, 5 appointments with specialist physiotherapist
Outcomes	prolapse symptoms and QoL at 12 months, POP-Q at 6 months, need for further treatment at 6 months, bladder, bowel and sexual symptoms
Starting date	April 2007
Contact information	Suzanne Hagen, NMAHP Research Unit, s.hagen@gcu.ac.uk
Notes	Recruitment complete, 12 month follow-up complete April 2011 ISRCTN 35911035

Hagen 2011

Trial name or title	A Study of the Effects of Physiotherapy to Prevent Pelvic Organ Prolapse (PREVPROL)
Methods	A Multicentre Randomised Controlled Trial of Pelvic Floor Muscle Training to Prevent Pelvic Organ Prolapse in Women
Participants	Women involved in the ProLong cohort study who: • have some evidence of vaginal laxity in any compartment (POP-Q stage I, II or III) • have had no previous treatment for prolapse (surgery, pessary, PFMT) Women must be willing to participate in the Trial and to comply with their group allocation Exclusion Criteria: Women: • with stage 0 or IV prolapse • who have had previous incontinence surgery (except mid-urethral sling operation) • who have had previous formal instruction in PFMT for any diagnosis in preceding five years • who are pregnant, or delivered a baby within the last six months • who are unable to comply with PFMT treatment • who are unable to give informed consent
Interventions	Women allocated to the intervention group will have five appointments with a specialist women's health physiotherapist (intervention physiotherapist) over 16 weeks who will prescribe a daily exercise programme and provide a Lifestyle Advice Sheet (focusing on weight loss, constipation, avoidance of heavy lifting, coughing and high-impact exercise) and relevant tailored advice (phase 1) Thereafter women in the intervention group will be offered Pilates-based classes, including PFMT, as maintenance (phase 2). Classes will be led by a physiotherapist who has undertaken Pilates training and will take place in six week blocks; each woman will be offered two six week blocks over a year. An exercise DVD will be provided for home use. Each woman will be offered a one-to-one review physiotherapy appointment at one and two years after randomisation

Hagen 2011 (*Continued*)

	Women allocated to the Control group will only receive, by post, the same Lifestyle Advice Sheet as the intervention group
Outcomes	Prolapse symptoms, severity and quality of life; urinary symptoms bowel symptoms; sexual symptoms; general health status
Starting date	Recruitment started 12/10/10
Contact information	Suzanne Hagen (s.hagen@gcu.ac.uk)
Notes	

PFDI = Pelvic Floor Distress Inventory; POPDI = Pelvic Organ Prolapse Distress Inventory; UDI = Urogenital Distress Inventory.

DATA AND ANALYSES

Comparison 1. PFMT versus no treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 number with increased frequency of prolapse symptoms	1	69	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.21, 0.65]
2 number with increased bother of prolapse symptoms	1	69	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.33, 0.97]
3 number with pelvic heaviness	1	47	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.11, 0.61]
4 prolapse symptom score: mean change from baseline	1	37	Mean Difference (IV, Fixed, 95% CI)	-3.37 [-6.23, -0.51]
5 self-report of no improvement in prolapse	1	40	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.26, 0.91]
6 prolapse QoL score	2	87	Std. Mean Difference (IV, Fixed, 95% CI)	-0.51 [-0.94, -0.07]
6.1 mean score for prolapse interference with everyday life	1	40	Std. Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.67, 0.57]
6.2 Ditrovie quality of life score	1	47	Std. Mean Difference (IV, Fixed, 95% CI)	-0.95 [-1.57, -0.34]
7 Satisfaction with treatment (visual analogue scale 0-10)	1	47	Mean Difference (IV, Fixed, 95% CI)	-3.22 [-3.79, -2.65]
8 number with POP-Q stage not improved	2	128	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.71, 0.96]
9 POP-Q measurements	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
9.1 mean post - pre POP-Q Ba measurement	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.2 mean post - pre POP-Q Aa measurement	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 mean pelvic floor muscle measures	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
10.1 manometry strength improvement (cm H2O)	1	109	Mean Difference (IV, Fixed, 95% CI)	-12.00 [-14.90, -9.10]
10.2 manometry endurance improvement (cm H2O sec)	1	109	Mean Difference (IV, Fixed, 95% CI)	-99.0 [-131.47, -66.53]
10.3 other strength measure	1	47	Mean Difference (IV, Fixed, 95% CI)	1.12 [0.66, 1.58]
11 number with worse bladder symptoms	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
11.1 SUI: number with increased frequency	1	66	Risk Ratio (M-H, Fixed, 95% CI)	0.36 [0.20, 0.66]
11.2 SUI: number with increased bother	1	66	Risk Ratio (M-H, Fixed, 95% CI)	0.44 [0.26, 0.74]
11.3 UUI: number with increased frequency	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.61 [0.33, 1.12]
11.4 UUI: number with increased bother	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.59 [0.35, 1.01]
12 change in ICIQ UI-SF	1	39	Mean Difference (IV, Fixed, 95% CI)	-1.79 [-3.68, 0.10]
13 mean bladder symptom score	1	47	Mean Difference (IV, Fixed, 95% CI)	-9.22 [-10.68, -7.76]

14 urodynamics: post void residual (mL)	1	47	Mean Difference (IV, Fixed, 95% CI)	-21.28 [-32.75, -9.81]
15 urodynamics: flow rate (mL/s)	1	47	Mean Difference (IV, Fixed, 95% CI)	-3.23 [-5.16, -1.30]
16 urodynamics: closure pressure (cm H2O)	1	47	Mean Difference (IV, Fixed, 95% CI)	-4.86 [-12.06, 2.34]
17 number with dysuria	1	47	Risk Ratio (M-H, Fixed, 95% CI)	0.31 [0.13, 0.74]
18 number with stress incontinence	1	47	Risk Ratio (M-H, Fixed, 95% CI)	0.16 [0.04, 0.68]
19 number with urgency	1	47	Risk Ratio (M-H, Fixed, 95% CI)	0.11 [0.01, 0.79]
20 number with frequency	1	47	Risk Ratio (M-H, Fixed, 95% CI)	0.27 [0.10, 0.72]
21 number with worse bowel symptoms	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
21.1 Emptying difficulty: number with increased frequency	1	40	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.35, 1.26]
21.2 Emptying difficulty: number with increased bother	1	40	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.47, 1.90]
21.3 Flatus leakage: number with increased frequency	1	57	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.40, 0.91]
21.4 Flatus leakage: number with increased bother	1	57	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.46, 0.99]
21.5 Loose FI: number with increased frequency	1	34	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.39, 0.92]
21.6 Loose FI: number with increased bother	1	24	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.20, 0.76]
21.7 Solid FI: number with increased frequency	1	5	Risk Ratio (M-H, Fixed, 95% CI)	2.25 [0.13, 38.09]
21.8 Solid FI: number with increased bother	1	5	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.08, 5.54]

Comparison 14. PFMT and/or lifestyle plus surgery versus surgery

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in manometry measures (cm H2O)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 vaginal resting pressure	1	31	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-3.67, 3.27]
1.2 vaginal squeeze pressure: peak maximum	1	41	Mean Difference (IV, Fixed, 95% CI)	2.9 [-2.06, 7.86]
1.3 vaginal squeeze pressure: area maximum	1	41	Mean Difference (IV, Fixed, 95% CI)	8.2 [-5.79, 22.19]
2 Digital muscle test (modified Oxford)	1	50	Mean Difference (IV, Fixed, 95% CI)	0.48 [0.12, 0.84]
3 Change in UDI total score (12 months post-op - baseline)	1	49	Mean Difference (IV, Fixed, 95% CI)	-9.90 [-24.46, 4.66]
4 Change in UDI irritative score (12 months post-op - baseline)	1	49	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-5.53, 4.73]

5 Change in UDI stress score (12 months post-op - baseline)	1	49	Mean Difference (IV, Fixed, 95% CI)	-5.5 [-15.76, 4.76]
6 Change in UDI obstructive score (12 months post-op - baseline)	1	49	Mean Difference (IV, Fixed, 95% CI)	-0.60 [-4.07, 2.87]
7 Number with irritative bladder symptoms at 12 months (UDI-19)	1	49	Risk Ratio (M-H, Fixed, 95% CI)	1.36 [0.48, 3.86]
8 Number with stress bladder symptoms at 12 months (UDI-19)	1	49	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.54, 2.36]
9 Number with obstructive bladder symptoms at 12 months (UDI-19)	1	49	Risk Ratio (M-H, Fixed, 95% CI)	5.63 [0.28, 111.43]
10 IIQ-7 at 12 months			Other data	No numeric data

Analysis 1.1. Comparison 1 PFMT versus no treatment, Outcome 1 number with increased frequency of prolapse symptoms.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 1 number with increased frequency of prolapse symptoms

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Braekken 2010	11/43	18/26		100.0 %	0.37 [0.21, 0.65]
Total (95% CI)	**43**	**26**		**100.0 %**	**0.37 [0.21, 0.65]**
Total events: 11 (Treatment), 18 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.42 (P = 0.00063)					
Test for subgroup differences: Not applicable					

Analysis 1.2. Comparison 1 PFMT versus no treatment, Outcome 2 number with increased bother of prolapse symptoms.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 2 number with increased bother of prolapse symptoms

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Braekken 2010	14/43	15/26		100.0 %	0.56 [0.33, 0.97]
Total (95% CI)	**43**	**26**		**100.0 %**	**0.56 [0.33, 0.97]**
Total events: 14 (Treatment), 15 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.07 (P = 0.038)					
Test for subgroup differences: Not applicable					

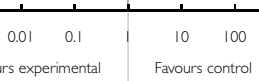
Analysis 1.3. Comparison 1 PFMT versus no treatment, Outcome 3 number with pelvic heaviness.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 3 number with pelvic heaviness

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Ghroubi 2008	5/27	14/20		100.0 %	0.26 [0.11, 0.61]
Total (95% CI)	**27**	**20**		**100.0 %**	**0.26 [0.11, 0.61]**
Total events: 5 (Treatment), 14 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.10 (P = 0.0020)					
Test for subgroup differences: Not applicable					



Analysis 1.4. Comparison 1 PFMT versus no treatment, Outcome 4 prolapse symptom score: mean change from baseline.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 4 prolapse symptom score: mean change from baseline

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Hagen 2009	17	-3.47 (5.4)	20	-0.1 (2.9)		100.0 %	-3.37 [-6.23, -0.51]
Total (95% CI)	**17**		**20**			**100.0 %**	**-3.37 [-6.23, -0.51]**

Heterogeneity: not applicable

Test for overall effect: Z = 2.31 (P = 0.021)

Test for subgroup differences: Not applicable

Analysis 1.5. Comparison 1 PFMT versus no treatment, Outcome 5 self-report of no improvement in prolapse.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 5 self-report of no improvement in prolapse

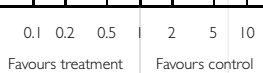
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Hagen 2009	7/19	16/21		100.0 %	0.48 [0.26, 0.91]
Total (95% CI)	**19**	**21**		**100.0 %**	**0.48 [0.26, 0.91]**

Total events: 7 (Treatment), 16 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 2.24 (P = 0.025)

Test for subgroup differences: Not applicable



Analysis 1.6. Comparison 1 PFMT versus no treatment, Outcome 6 prolapse QoL score.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 6 prolapse QoL score

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference IV,Fixed,95% CI	Weight	Std. Mean Difference IV,Fixed,95% CI
1 mean score for prolapse interference with everyday life							
Hagen 2009	19	2 (1.5)	21	2.1 (2.3)		49.3 %	-0.05 [-0.67, 0.57]
Subtotal (95% CI)	**19**		**21**			**49.3 %**	**-0.05 [-0.67, 0.57]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.16 (P = 0.87)							
2 Ditrovie quality of life score							
Ghroubi 2008 (1)	27	2.07 (0.57)	20	2.57 (0.43)		50.7 %	-0.95 [-1.57, -0.34]
Subtotal (95% CI)	**27**		**20**			**50.7 %**	**-0.95 [-1.57, -0.34]**
Heterogeneity: not applicable							
Test for overall effect: Z = 3.05 (P = 0.0023)							
Total (95% CI)	**46**		**41**			**100.0 %**	**-0.51 [-0.94, -0.07]**
Heterogeneity: Chi^2 = 4.13, df = 1 (P = 0.04); I^2 =76%							
Test for overall effect: Z = 2.28 (P = 0.022)							
Test for subgroup differences: Chi^2 = 4.13, df = 1 (P = 0.04), I^2 =76%							

(1) Ditrovie validated as QoL measure for urinary symptoms but authors report it in terms of prolapse

Analysis 1.7. Comparison 1 PFMT versus no treatment, Outcome 7 Satisfaction with treatment (visual analogue scale 0-10).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

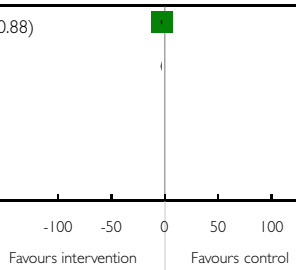
Outcome: 7 Satisfaction with treatment (visual analogue scale 0-10)

Study or subgroup	Treatment N	Mean(SD)[cm]	Control N	Mean(SD)[cm]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Ghroubi 2008	27	-6.77 (1.12)	20	-3.55 (0.88)		100.0 %	-3.22 [-3.79, -2.65]
Total (95% CI)	**27**		**20**			**100.0 %**	**-3.22 [-3.79, -2.65]**

Heterogeneity: not applicable

Test for overall effect: Z = 11.03 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 1.8. Comparison 1 PFMT versus no treatment, Outcome 8 number with POP-Q stage not improved.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 8 number with POP-Q stage not improved

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Braekken 2010	47/58	46/50		82.7 %	0.88 [0.76, 1.02]
Hagen 2009	6/11	9/9		17.3 %	0.57 [0.33, 0.98]
Total (95% CI)	**69**	**59**		**100.0 %**	**0.83 [0.71, 0.96]**

Total events: 53 (Treatment), 55 (Control)

Heterogeneity: Chi^2 = 2.51, df = 1 (P = 0.11); I^2 =60%

Test for overall effect: Z = 2.50 (P = 0.012)

Test for subgroup differences: Not applicable

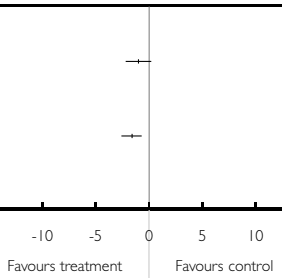
Analysis 1.9. Comparison 1 PFMT versus no treatment, Outcome 9 POP-Q measurements.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 9 POP-Q measurements

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 mean post - pre POP-Q Ba measurement						
Hagen 2009	11	-0.36 (1.86)	9	0.67 (0.71)		-1.03 [-2.22, 0.16]
2 mean post - pre POP-Q Aa measurement						
Hagen 2009	11	-1.09 (1.22)	9	0.56 (1.01)		-1.65 [-2.63, -0.67]



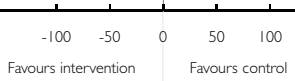
Analysis 1.10. Comparison 1 PFMT versus no treatment, Outcome 10 mean pelvic floor muscle measures.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 10 mean pelvic floor muscle measures

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 manometry strength improvement (cm H2O)							
Braekken 2010	59	-13.1 (9.6)	50	-1.1 (5.6)		100.0 %	-12.00 [-14.90, -9.10]
Subtotal (95% CI)	**59**		**50**			**100.0 %**	**-12.00 [-14.90, -9.10]**
Heterogeneity: not applicable							
Test for overall effect: Z = 8.11 (P < 0.00001)							
2 manometry endurance improvement (cm H2O sec)							
Braekken 2010	59	-107 (112.8)	50	-8 (54.2)		100.0 %	-99.00 [-131.47, -66.53]
Subtotal (95% CI)	**59**		**50**			**100.0 %**	**-99.00 [-131.47, -66.53]**
Heterogeneity: not applicable							
Test for overall effect: Z = 5.98 (P < 0.00001)							
3 other strength measure							
Ghroubi 2008	27	2.37 (0.83)	20	1.25 (0.78)		100.0 %	1.12 [0.66, 1.58]
Subtotal (95% CI)	**27**		**20**			**100.0 %**	**1.12 [0.66, 1.58]**
Heterogeneity: not applicable							
Test for overall effect: Z = 4.74 (P < 0.00001)							
Test for subgroup differences: Chi^2 = 112.95, df = 2 (P = 0.00), I^2 =98%							

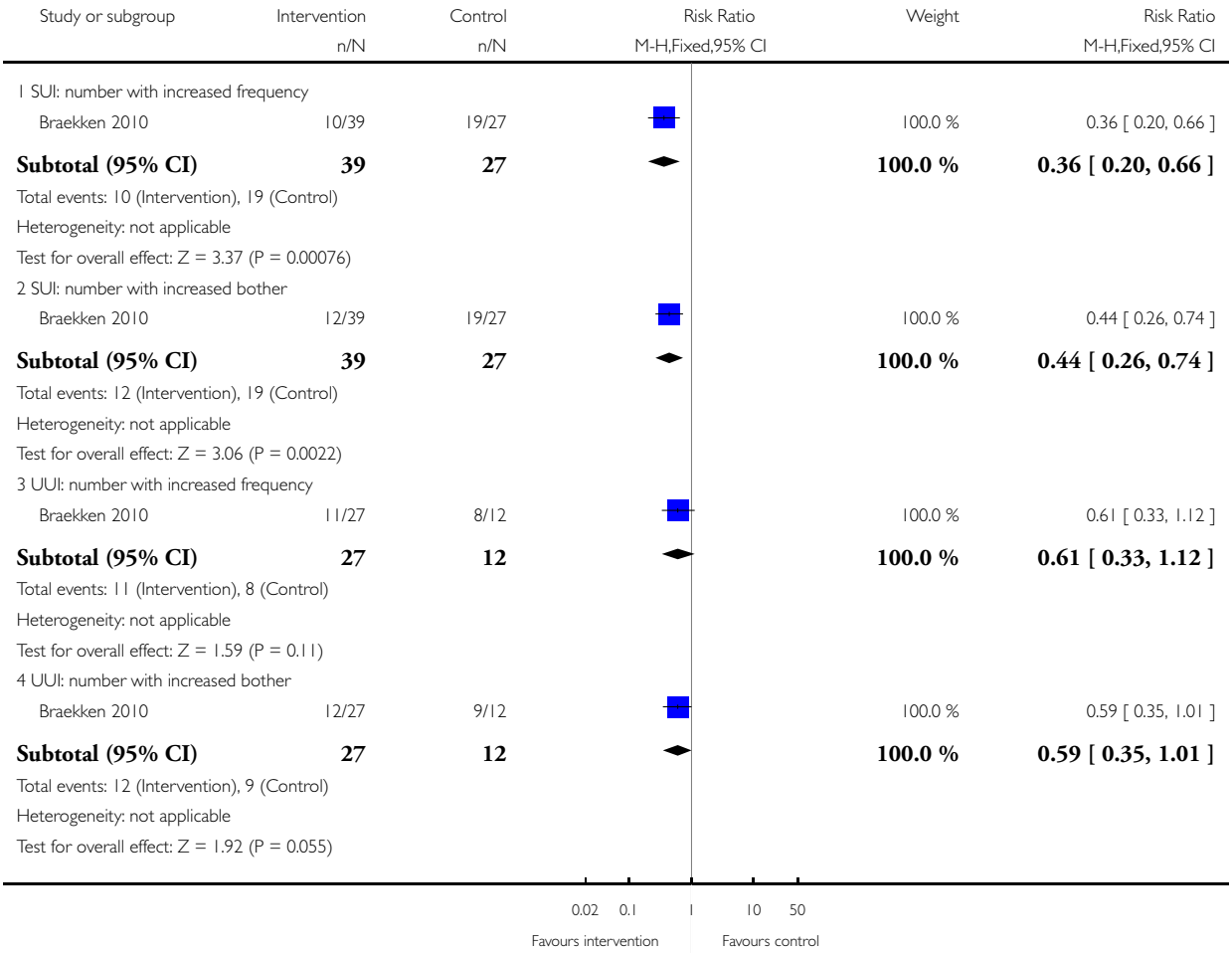


Analysis 1.11. Comparison 1 PFMT versus no treatment, Outcome 11 number with worse bladder symptoms.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 11 number with worse bladder symptoms



Analysis 1.12. Comparison 1 PFMT versus no treatment, Outcome 12 change in ICIQ UI-SF.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 12 change in ICIQ UI-SF

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Hagen 2009	19	-1.79 (3.2)	20	0 (2.8)		100.0 %	-1.79 [-3.68, 0.10]
Total (95% CI)	**19**		**20**			**100.0 %**	**-1.79 [-3.68, 0.10]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.86 (P = 0.064)

Test for subgroup differences: Not applicable

Analysis 1.13. Comparison 1 PFMT versus no treatment, Outcome 13 mean bladder symptom score.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

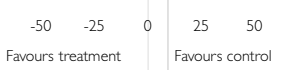
Outcome: 13 mean bladder symptom score

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Ghroubi 2008	27	6.48 (2.63)	20	15.7 (2.43)		100.0 %	-9.22 [-10.68, -7.76]
Total (95% CI)	**27**		**20**			**100.0 %**	**-9.22 [-10.68, -7.76]**

Heterogeneity: not applicable

Test for overall effect: Z = 12.42 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 1.14. Comparison 1 PFMT versus no treatment, Outcome 14 urodynamics: post void residual (mL).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

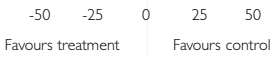
Outcome: 14 urodynamics: post void residual (mL)

Study or subgroup	Treatment N	Mean(SD)[mL]	Control N	Mean(SD)[mL]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Ghroubi 2008	27	57.81 (12.8)	20	79.09 (23.75)		100.0 %	-21.28 [-32.75, -9.81]
Total (95% CI)	**27**		**20**			**100.0 %**	**-21.28 [-32.75, -9.81]**

Heterogeneity: not applicable

Test for overall effect: Z = 3.64 (P = 0.00028)

Test for subgroup differences: Not applicable



Analysis 1.15. Comparison 1 PFMT versus no treatment, Outcome 15 urodynamics: flow rate (mL/s).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

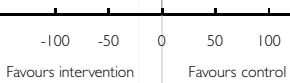
Outcome: 15 urodynamics: flow rate (mL/s)

Study or subgroup	Treatment N	Mean(SD)[mL/s]	Control N	Mean(SD)[mL/s]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Ghroubi 2008	27	-16.33 (2.51)	20	-13.1 (3.83)		100.0 %	-3.23 [-5.16, -1.30]
Total (95% CI)	**27**		**20**			**100.0 %**	**-3.23 [-5.16, -1.30]**

Heterogeneity: not applicable

Test for overall effect: Z = 3.29 (P = 0.0010)

Test for subgroup differences: Not applicable



Analysis 1.16. Comparison 1 PFMT versus no treatment, Outcome 16 urodynamics: closure pressure (cm H2O).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 16 urodynamics: closure pressure (cm H2O)

Study or subgroup	Treatment N	Mean(SD)[cm H2O]	Control N	Mean(SD)[cm H2O]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Ghroubi 2008	27	-57.81 (12.8)	20	-52.95 (12.18)		100.0 %	-4.86 [-12.06, 2.34]
Total (95% CI)	**27**		**20**			**100.0 %**	**-4.86 [-12.06, 2.34]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.32 (P = 0.19)

Test for subgroup differences: Not applicable

Analysis 1.17. Comparison 1 PFMT versus no treatment, Outcome 17 number with dysuria.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 17 number with dysuria

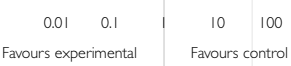
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Ghroubi 2008	5/27	12/20		100.0 %	0.31 [0.13, 0.74]
Total (95% CI)	**27**	**20**		**100.0 %**	**0.31 [0.13, 0.74]**

Total events: 5 (Treatment), 12 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 2.65 (P = 0.0080)

Test for subgroup differences: Not applicable



Analysis 1.18. Comparison 1 PFMT versus no treatment, Outcome 18 number with stress incontinence.

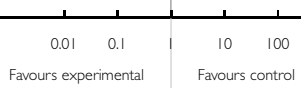
Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 18 number with stress incontinence

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Ghroubi 2008	2/27	9/20		100.0 %	0.16 [0.04, 0.68]
Total (95% CI)	**27**	**20**		**100.0 %**	**0.16 [0.04, 0.68]**

Total events: 2 (Treatment), 9 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 2.49 (P = 0.013)
Test for subgroup differences: Not applicable



Analysis 1.19. Comparison 1 PFMT versus no treatment, Outcome 19 number with urgency.

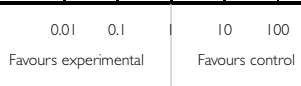
Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 19 number with urgency

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Ghroubi 2008	1/27	7/20		100.0 %	0.11 [0.01, 0.79]
Total (95% CI)	**27**	**20**		**100.0 %**	**0.11 [0.01, 0.79]**

Total events: 1 (Treatment), 7 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 2.19 (P = 0.029)
Test for subgroup differences: Not applicable

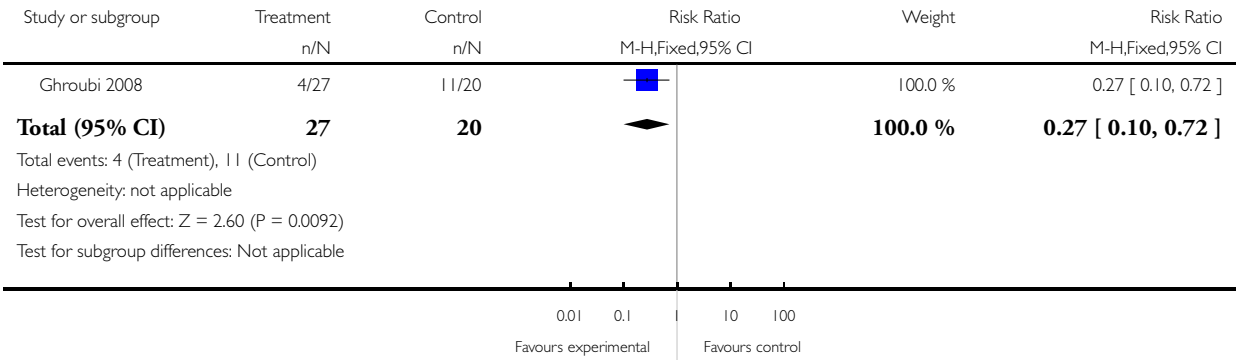


Analysis 1.20. Comparison 1 PFMT versus no treatment, Outcome 20 number with frequency.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 20 number with frequency

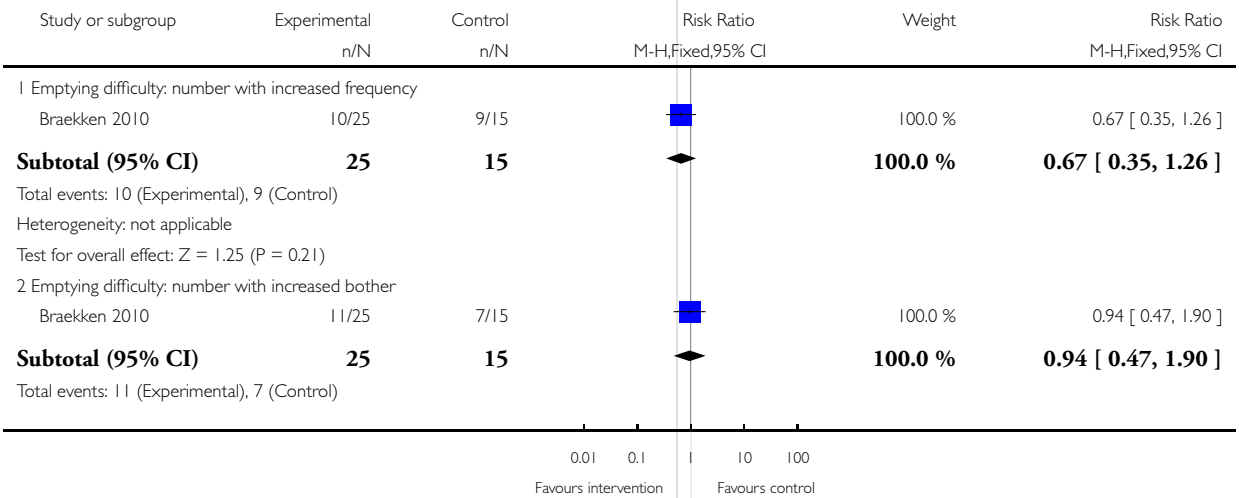


Analysis 1.21. Comparison 1 PFMT versus no treatment, Outcome 21 number with worse bowel symptoms.

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 21 number with worse bowel symptoms



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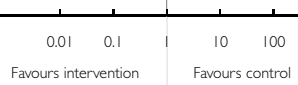
Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Heterogeneity: not applicable					
Test for overall effect: Z = 0.17 (P = 0.87)					
3 Flatus leakage: number with increased frequency					
Braekken 2010	16/34	18/23		100.0 %	0.60 [0.40, 0.91]
Subtotal (95% CI)	**34**	**23**		**100.0 %**	**0.60 [0.40, 0.91]**
Total events: 16 (Experimental), 18 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.39 (P = 0.017)					
4 Flatus leakage: number with increased bother					
Braekken 2010	18/34	18/23		100.0 %	0.68 [0.46, 0.99]
Subtotal (95% CI)	**34**	**23**		**100.0 %**	**0.68 [0.46, 0.99]**
Total events: 18 (Experimental), 18 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.00 (P = 0.046)					
5 Loose FI: number with increased frequency					
Braekken 2010	13/24	9/10		100.0 %	0.60 [0.39, 0.92]
Subtotal (95% CI)	**24**	**10**		**100.0 %**	**0.60 [0.39, 0.92]**
Total events: 13 (Experimental), 9 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.36 (P = 0.018)					
6 Loose FI: number with increased bother					
Braekken 2010	5/14	10/10		100.0 %	0.38 [0.20, 0.76]
Subtotal (95% CI)	**14**	**10**		**100.0 %**	**0.38 [0.20, 0.76]**
Total events: 5 (Experimental), 10 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.77 (P = 0.0056)					
7 Solid FI: number with increased frequency					
Braekken 2010	1/3	0/2		100.0 %	2.25 [0.13, 38.09]
Subtotal (95% CI)	**3**	**2**		**100.0 %**	**2.25 [0.13, 38.09]**
Total events: 1 (Experimental), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.56 (P = 0.57)					
8 Solid FI: number with increased bother					
Braekken 2010	1/3	1/2		100.0 %	0.67 [0.08, 5.54]
Subtotal (95% CI)	**3**	**2**		**100.0 %**	**0.67 [0.08, 5.54]**
Total events: 1 (Experimental), 1 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.38 (P = 0.71)					
Test for subgroup differences: Chi^2 = 4.36, df = 7 (P = 0.74), I^2 =0.0%					



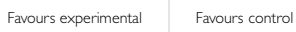
Analysis 14.1. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 1 Change in manometry measures (cm H2O).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 14 PFMT and/or lifestyle plus surgery versus surgery

Outcome: 1 Change in manometry measures (cm H2O)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 vaginal resting pressure							
Frawley 2010	14	2.1 (4.9)	17	2.3 (4.9)		100.0 %	-0.20 [-3.67, 3.27]
Subtotal (95% CI)	**14**		**17**			**100.0 %**	**-0.20 [-3.67, 3.27]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.11 (P = 0.91)							
2 vaginal squeeze pressure: peak maximum							
Frawley 2010	20	4.8 (8)	21	1.9 (8.2)		100.0 %	2.90 [-2.06, 7.86]
Subtotal (95% CI)	**20**		**21**			**100.0 %**	**2.90 [-2.06, 7.86]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.15 (P = 0.25)							
3 vaginal squeeze pressure: area maximum							
Frawley 2010	20	11.2 (22.8)	21	3 (22.9)		100.0 %	8.20 [-5.79, 22.19]
Subtotal (95% CI)	**20**		**21**			**100.0 %**	**8.20 [-5.79, 22.19]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.15 (P = 0.25)							
Test for subgroup differences: Chi^2 = 2.04, df = 2 (P = 0.36), I^2 =2%							



Analysis 14.2. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 2 Digital muscle test (modified Oxford).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 14 PFMT and/or lifestyle plus surgery versus surgery

Outcome: 2 Digital muscle test (modified Oxford)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Frawley 2010	24	0.69 (0.64)	26	0.21 (0.66)		100.0 %	0.48 [0.12, 0.84]
Total (95% CI)	**24**		**26**			**100.0 %**	**0.48 [0.12, 0.84]**

Heterogeneity: not applicable

Test for overall effect: Z = 2.61 (P = 0.00911)

Test for subgroup differences: Not applicable

Analysis 14.3. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 3 Change in UDI total score (12 months post-op - baseline).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 14 PFMT and/or lifestyle plus surgery versus surgery

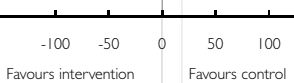
Outcome: 3 Change in UDI total score (12 months post-op - baseline)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Frawley 2010	23	-54 (25.9)	26	-44.1 (26)		100.0 %	-9.90 [-24.46, 4.66]
Total (95% CI)	**23**		**26**			**100.0 %**	**-9.90 [-24.46, 4.66]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.33 (P = 0.18)

Test for subgroup differences: Not applicable



Analysis 14.4. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 4 Change in UDI irritative score (12 months post-op - baseline).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 14 PFMT and/or lifestyle plus surgery versus surgery

Outcome: 4 Change in UDI irritative score (12 months post-op - baseline)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Frawley 2010	23	-12.9 (9.11)	26	-12.5 (9.18)		100.0 %	-0.40 [-5.53, 4.73]
Total (95% CI)	**23**		**26**			**100.0 %**	**-0.40 [-5.53, 4.73]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.15 (P = 0.88)

Test for subgroup differences: Not applicable

Analysis 14.5. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 5 Change in UDI stress score (12 months post-op - baseline).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 14 PFMT and/or lifestyle plus surgery versus surgery

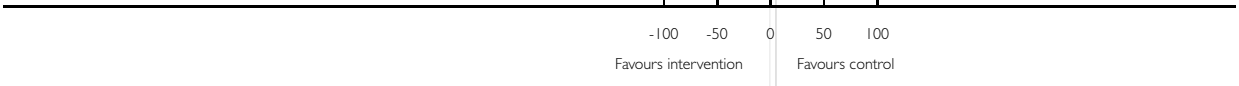
Outcome: 5 Change in UDI stress score (12 months post-op - baseline)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Frawley 2010	23	-15.1 (18.224)	26	-9.6 (18.356)		100.0 %	-5.50 [-15.76, 4.76]
Total (95% CI)	**23**		**26**			**100.0 %**	**-5.50 [-15.76, 4.76]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.05 (P = 0.29)

Test for subgroup differences: Not applicable



Analysis 14.6. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 6 Change in UDI obstructive score (12 months post-op - baseline).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 14 PFMT and/or lifestyle plus surgery versus surgery

Outcome: 6 Change in UDI obstructive score (12 months post-op - baseline)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Frawley 2010	23	-24 (6.2345)	26	-23.4 (6.1188)		100.0 %	-0.60 [-4.07, 2.87]
Total (95% CI)	**23**		**26**			**100.0 %**	**-0.60 [-4.07, 2.87]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.34 (P = 0.73)

Test for subgroup differences: Not applicable

Analysis 14.7. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 7 Number with irritative bladder symptoms at 12 months (UDI-19).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 14 PFMT and/or lifestyle plus surgery versus surgery

Outcome: 7 Number with irritative bladder symptoms at 12 months (UDI-19)

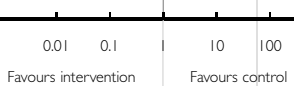
Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Frawley 2010	6/23	5/26		100.0 %	1.36 [0.48, 3.86]
Total (95% CI)	**23**	**26**		**100.0 %**	**1.36 [0.48, 3.86]**

Total events: 6 (Experimental), 5 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.57 (P = 0.57)

Test for subgroup differences: Not applicable



Analysis 14.8. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 8 Number with stress bladder symptoms at 12 months (UDI-19).

Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 14 PFMT and/or lifestyle plus surgery versus surgery

Outcome: 8 Number with stress bladder symptoms at 12 months (UDI-19)

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Frawley 2010	9/23	9/26		100.0 %	1.13 [0.54, 2.36]
Total (95% CI)	**23**	**26**		**100.0 %**	**1.13 [0.54, 2.36]**

Total events: 9 (Experimental), 9 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.33 (P = 0.74)
Test for subgroup differences: Not applicable

Analysis 14.9. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 9 Number with obstructive bladder symptoms at 12 months (UDI-19).

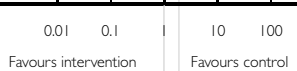
Review: Conservative prevention and management of pelvic organ prolapse in women

Comparison: 14 PFMT and/or lifestyle plus surgery versus surgery

Outcome: 9 Number with obstructive bladder symptoms at 12 months (UDI-19)

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Frawley 2010	2/23	0/26		100.0 %	5.63 [0.28, 111.43]
Total (95% CI)	**23**	**26**		**100.0 %**	**5.63 [0.28, 111.43]**

Total events: 2 (Experimental), 0 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 1.13 (P = 0.26)
Test for subgroup differences: Not applicable



Analysis 14.10. Comparison 14 PFMT and/or lifestyle plus surgery versus surgery, Outcome 10 IIQ-7 at 12 months.

IIQ-7 at 12 months

Study	median change from baseline intervention	95% CI	median change from baseline control	95% CI	Heading 5
Frawley 2010	0.0	0, 14	10.0	5, 19	

APPENDICES

Appendix 1. Search strategies

Incontinence Group Specialised Register

The terms used to search the Incontinence Group Trials Register are given below. Date of the most recent search of the trials register for this review: 6 May 2010.

({design.cct*} OR (design.rct*})

AND

{topic.prolapse*}

(All searches were of the keywords field of Reference Manager 12, Thomson Reuters).

MEDLINE

The Specialised Register now includes searches for pelvic organ prolapse for the search strategy used in MEDLINE for previous versions of this review please '*Older searches for previous versions of this review*' see below.

EMBASE

We searched the years 1 January 1980 to week 17 2010. Date of last search: 6 May 2010. The database was searched on OVID, using the following search terms:

1.pelvic adj5 prolaps$.tw.
2.uterus prolapse/
3.rectocele/
4.vagina prolapse/
5.cystocele/
6.or/1-5
7.randomised controlled trial/
8.controlled study/
9.clinical study/
10.major clinical study/
11.prospective study/
12.meta analysis/
13.exp clinical trial/
14.randomisation/
15.crossover procedure/ or double blind procedure/ or parallel design/ or single blind procedure/
16.placebo/
17.latin square design/
18.exp comparative study/
19.follow up/

20.pilot study/
21.family study/ or feasibility study/ or study/
22.placebo$.tw.
23.random$.tw.
24.(clin$ adj25 trial$).tw.
25.((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
26.factorial.tw.
27.crossover.tw.
28.latin square.tw.
29.(balance$ adj2 block$).tw.
30.or/7-29
31.(nonhuman not human).sh.
32.30 not 31
33.6 and 32
(Earlier versions of this review searched: EMBASE (1996 to Week 2 2003) was searched on 20 January 2003. For the 2005 update EMBASE (2003 to Week 43 2005) was searched on 25 October 2005. The same search strategy was used.)

CINAHL

CINAHL on EBSCO: We searched the years 1 January 1982 to 30 April 2010 inclusive. Date of last search: 10 May 2010.

Search Terms	Search Options
S88	S83 and S87
S87	S84 or S85 or S86
S86	ZD 20081*
S85	ZD 2009*
S84	ZD 2010*
S83	S24 and S82
S82	S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43 or S44 or S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52 or S53 or S54 or S55 or S56 or S57 or S58 or S59 or S60 or S61 or S62 or S63 or S64 or S65 or S66 or S67 or S68 or S69 or S70 or S71 or S72 or S73 or S74 or S75 or S76 or S77 or S78 or S79 or S80 or S81
S81	TI hysteropex* or AB hysteropex*
S80	TI viscer* N2 prolap* or AB viscer* N2 prolap*
S79	TI bladder* N2 protru* or AB bladder* N2 protru*
S78	TI hernia* N2 vesico* or AB hernia* N2 vesico*
S77	TI hernia* N2 cystic* or AB hernia* N2 cystic*
S76	TI hernia* N2 bladder* or AB hernia* N2 bladder*
S75	TI vagin* N2 evert* or AB vagin* N2 evert*

(*Continued*)

S74	TI vagin* N2 eversion* or AB vagin* N2 eversion*
S73	TI procident* or AB procident*
S72	TI descen* N2 pelvi* or AB descen* N2 pelvi*
S71	TI descen* N2 genit* or AB descen* N2 genit*
S70	TI descen* N2 uter* or AB descen* N2 uter*
S69	TI cervi* N5 prolaps* or AB cervi* N5 prolaps*
S68	TI urogenital N5 prolaps* or AB urogenital N5 prolaps*
S67	TI vagin* N3 defect* or AB vagin* N3 defect*
S66	TI pelvi* N3 relax* or AB pelvi* N3 relax*
S65	TI pelvi* N3 disorder* or AB pelvi* N3 disorder*
S64	TI pelvi* N3 dysfunct* or AB pelvi* N3 dysfunct*
S63	TI sigmoidocoele* OR AB sigmoidocoele*
S62	TI sigmoidocoele* OR AB sigmoidocoele*
S61	TI sigmoidocele* OR AB sigmoidocele*
S60	TI proctocele* OR AB proctocele*
S59	TI proctocele* OR AB proctocele*
S58	TI proctocoele* OR AB proctocoele*
S57	TI proctocoele* OR AB proctocoele*
S56	TI enterocoele* OR AB enterocoele*
S55	TI enterocoele* OR AB enterocoele*
S54	TI enterocele* OR AB enterocele*
S53	TI urethrocele* OR AB urethrocele*
S52	TI urethrocoele* OR AB urethrocoele*
S51	TI cystocoele* OR AB cystocoele*

(*Continued*)

S50	TI cystocele* OR AB cystocele*
S49	TI rectocoele* OR AB rectocoele*
S48	TI rectocele* OR AB rectocele*
S47	AB prolaps* N5 pelvi*
S46	AB prolaps* N5 vagin*
S45	AB prolaps* N5 genit*
S44	AB prolaps* N5 uter*
S43	AB prolaps* N5 vault*
S42	AB prolaps* N5 apical*
S41	AB prolaps* N5 urethr*
S40	AB prolaps* N5 segment*
S39	AB prolaps* N5 wall*
S38	TI prolaps* N5 wall*
S37	TI prolaps* N5 segment*
S36	TI prolaps* N5 urethr*
S35	TI prolaps* N5 apical*
S34	TI prolaps* N5 vault*
S33	TI prolaps* N5 uter*
S32	TI prolaps* N5 genit*
S31	TI prolaps* N5 vagin*
S30	TI prolaps* N5 pelvi*
S29	MH rectocele
S28	MH uterine prolapse
S27	(MH "Pelvic Organ Prolapse+")

(*Continued*)

S26	MH genital diseases, female
S25	MH prolapse
S24	(S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23)
S23	AB singl$ OR doubl* OR trebl* OR tripl* N25 blind* OR mask*
S22	TI singl$ OR doubl* OR trebl* OR tripl* N25 blind* OR mask*
S21	(MH "Comparative Studies")
S20	(MH "Clinical Research+")
S19	(MH "Static Group Comparison")
S18	(MH "Quantitative Studies")
S17	(MH "Crossover Design") or (MH "Solomon Four-Group Design")
S16	(MH "Factorial Design")
S15	(MH "Community Trials")
S14	(MH "Random Sample")
S13	TI balance* N2 block* or AB balance* N2 block*
S12	TI "latin square" or AB "latin square"
S11	TI factorial or AB factorial
S10	TI clin* N25 trial* or AB clin* N25 trial*
S9	(MH "Study Design")
S8	(AB random*) OR (TI random*)
S7	(AB placebo*) OR (TI placebo*)
S6	(MH "Placebos")
S5	PT Clinical Trial
S4	(MH "Clinical Trials+")

(*Continued*)

S3	MH (random assignment) OR (crossover design)
S2	cross-over
S1	crossover

Last search conducted on CINAHL on OVID covered 1 January 1982 to Week 3 November 2008, and was performed on 1 December 2008 using the following search terms:
1.exp pelvic organ prolapse/
2.genital diseases, female/
3.prolapse/
4.uterine prolapse/
5.Rectocele/
6.(prolaps$ adj5 (pelvi$ or vagin$ or genit$ or uter$ or vault$ or apical or urethr$ or segment$ or wall$)).tw.
7.cystoc?ele$.tw.
8.rectoc?ele$.tw.
9.urethroc?ele$.tw.
10.enteroc?ele$.tw.
11.proctoc?ele$.tw.
12.sigmoidoc?ele$.tw.
13.(pelvi$ adj3 dysfunct$).tw.
14.(pelvi$ adj3 (disorder$ or relax$)).tw.
15.(vagin$ adj3 defect$).tw.
16.(urogenital adj5 prolaps$).tw.
17.(cervi$ adj5 prolaps$).tw.
18.((descen$ adj2 (uter$ or genit$ or pelv$)).tw.
19.procident$.tw.
20.(vagin$ adj2 (eversion$ or evert$)).tw.
21.(hernia$ adj2 (bladder$ or cystic or vesico$)).tw.
22.(bladder$ adj2 protru$).tw.
23.(viscer$ adj2 prolap$).tw.
24.hysteropex$.tw.
25.or/1-24
26.placebo$.tw.
27.random$.tw.
28.(clin$ adj25 trial$).tw.
29.((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
30.factorial.tw.
31.crossover.tw.
32.latin square.tw.
33.(balance$ adj2 block$).tw.
34.or/26-33
35.25 and 34

Other databases

The following databases were all searched using the search terms: cystocele, urethrocele, rectocele, vault prolapse, uterine prolapse, vaginal prolapse, pelvic organ prolapse, pelvic floor.

- PEDro (the Physiotherapy Evidence Database) (www.pedro.fhs.usyd.edu.au) produced by the Centre for Evidence-Based Physiotherapy (CEBP), University of Sydney, Australia was searched on 13 October 2003, 30 September 2005 and 27 January 2009, using the search term "prolapse".

- UK National Research Register (Issue 3, 2003, Issue 3, 2005 and 27 January 2009),
- ClinicalTrials.gov (5 October 2005, 9 April 2009),
- Current Controlled Trials register (5 October 2005 and 9 April 2009),
- Cochrane Central Register of Controlled Trials (CENTRAL) (April 2003, September 2005 and January 2009) and
- ZETOC database of conference abstracts (April 2003, September 2005 and January 2009)

Older searches for previous versions of this review

MEDLINE

Previous versions of this review (up to and including 2005) searched MEDLINE and preMEDLINE separately, this search is now included within the Specialised Register search and is not run separately. Details of the searches are given below.

MEDLINE (January 1966 to Week 2 January 2003) was searched on 3 February 2003 and PREMEDLINE (15 January 2003) was searched on 16 January 2003. For the 2005 update MEDLINE (January 2003 to Week 5 August 2005) was searched on 14 September 2005 and MEDLINE In Process & Other Citations (15 September 2005) was searched on 19 September 2005. All databases were searched on OVID, using the following search terms:

1.prolapse/
2.uterine prolapse/
3.Rectocele/
4.(prolaps$ adj5 (pelvi$ or vagin$ or genit$ or uter$ or vault$ or apical or urethr$ or segment$ or wall$)).tw.
5.cystoc?ele$.tw.
6.rectoc?ele$.tw.
7.urethroc?ele$.tw.
8.enteroc?ele$.tw.
9.proctoc?ele$.tw.
10.sigmoidoc?ele$.tw.
11.(pelvi$ adj3 dysfunct$).tw.
12.(pelvi$ adj3 (disorder$ or relax$)).tw.
13.(vagin$ adj3 defect$).tw.
14.(urogenital adj5 prolaps$).tw.
15.(cervi$ adj5 prolaps$).tw.
16.or/1-15

This set of terms was combined with the first two parts of the Cochrane Highly Sensitive Search Strategy for randomised controlled trials (Appendix 5b.2, Cochrane Handbook, version 4.2, March 2003) using the Boolean operator 'AND'.

CINAHL

The previous versions of this review used the same search terms to search CINAHL on OVID as shown in CINAHL section above (January 1982 to February Week 4 2003) searched on 13 March 2003, and CINAHL (January 2003 to October Week 1 2005) was searched on 5 October 2005 for the updated review.

WHAT'S NEW

Last assessed as up-to-date: 6 May 2010.

Date	Event	Description
27 June 2011	New citation required and conclusions have changed	Three new trials have been added
27 June 2011	New search has been performed	Three new trials have been added

HISTORY

Protocol first published: Issue 4, 2002

Review first published: Issue 2, 2004

Date	Event	Description
23 April 2008	New citation required and conclusions have changed	Updated submitted.
23 August 2006	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Suzanne Hagen carried out searching, reviewed studies and produced the final review. Diane Stark reviewed studies and contributed to the writing of the final review.

DECLARATIONS OF INTEREST

Suzanne Hagen was the Chief Investigator of one of the included studies (Hagen 2009), and was one of the reviewers who carried out the study quality assessment and data extraction.

SOURCES OF SUPPORT

Internal sources

- Chief Scientist Office, Scottish Executive Health Department, UK.

External sources

- National Health Service Research and Development Programme, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Muscle Strength; Exercise Therapy [methods]; Pelvic Floor; Pelvic Floor Disorders [complications; *therapy]; Pelvic Organ Prolapse [etiology; *therapy]; Randomized Controlled Trials as Topic

MeSH check words

Adult; Female; Humans