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

A Cochrane systematic review

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

Objectives. **The aim of this paper was to determine the effects of pelvic floor muscle training for women with urinary incontinence in comparison to no treatment, placebo or sham treatments, or other inactive control treatments.**

Method. **The Cochrane Incontinence Group Specialized Trials Register was searched up until December 1, 2004. The review included randomized or quasi-randomized trials in women with stress, urge or mixed urinary incontinence. One arm of the trial comprised pelvic floor muscle training, the other comprised either no treatment, placebo, sham, or other inactive control treatment. The trials were independently assessed for eligibility and methodological quality. Data were extracted then cross-checked by the two authors. Disagreements were resolved by discussion. The data were processed as described in the Cochrane Handbook. The trials were sub-grouped by diagnosis. Formal meta-analysis was not undertaken because of study heterogeneity.**

Results. **Thirteen trials involving 714 women met the inclusion criteria; however, only six trials (403 women) contributed to data analysis.**

Conclusion. **Overall, the review provides support for the widespread recommendation that pelvic floor muscle training be included in first-line conservative management programs for women with stress, urge or mixed urinary incontinence.**

KEY WORDS: Pelvic floor - Muscle, skeletal - Physical therapy modalities - Urinary incontinence, stress - Urinary incontinence, urge.

Urinary incontinence is defined as "the complaint of any involuntary leakage of urine".[1] It is a common condition in women, with estimates of prevalence varying between 10% to 40% in most studies [2] and showing a gradual increase with age, to an early peak prevalence around mid-life (50 to 54 years), followed by a slight decline or a stabilization until about 70 years of age when prevalence steadily increases.[2] Urinary incontinence is a serious medical condition in that it can lead to urinary tract infections, pressure ulcers and perineal dermatoses.[3] Moreover,

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it is an undeniable social problem, as it creates embarrassment and negative self-perception.[4, 5] Urinary incontinence has been found to reduce social interactions and physical activities [4] and is associated with poor self-rated health,[5] impaired emotional and psychological well-being [4] and impaired sexual relationships.[6] Women with urinary incontinence, particularly older women, often find themselves, in the medium or longer term, isolated and relatively inactive.[7]

Type of urinary incontinence

Urinary incontinence can be subdivided into three types according to symptoms, signs and urodynamic studies (a physiological test): stress urinary incontinence, urge urinary incontinence and mixed urinary incontinence.[1] If a woman reports involuntary urine leakage with physical exertion (symptom) or a clinician observes urine leakage at the same time as the exertion (sign) this is called stress urinary incontinence (SUI).[1] Urodynamic SUI is the demonstration of involuntary loss of urine during increase abdominal pressure, in the absence of detrusor muscle contraction.[1] SUI is associated with anatomical defects in the structures that support the bladder and urethra, resulting in sub-optimal position of these structures at rest or on exertion, and/or dysfunction of the neuromuscular components that help control urethral pressure.[8] As a result, the urethra is not closed off properly during exertion and this results in urine leakage.[8]

If a woman reports involuntary leakage associated with a sudden, strong desire to void or urgency (symptom) this is called urge urinary incontinence (UUI).[1] UUI usually results from an increase in bladder pressure due to overactivity of the detrusor muscle. When urodynamic investigations show this, it is called detrusor overactivity incontinence.[1] Many women have symptoms or signs of both stress and UUI, and urodynamic studies sometimes reveal that urine leakage results from a combination of urodynamic stress incontinence and detrusor overactivity incontinence. When women have both conditions, this is called mixed urinary incontinence (MUI).[1]

Treatment of women's urinary incontinence

A wide range of treatments has been used in the management of women's urinary incontinence, including conservative interventions, pharmaceutical interventions, and surgery. This review focuses on the most commonly used conservative intervention, pelvic floor muscle training (PFMT).

PFMT has been recommended for stress and mixed urinary incontinence principally but has increasingly become part of the conservative treatment offered to women with urge urinary incontinence.[9] The use of PFMT in the management of urinary incontinence is based on two functions of pelvic floor muscle, namely support of the pelvic organs and a contribution to the sphincteric closure mechanism of the urethra. For stress urinary incontinence, the aims of PFMT are twofold. First, to teach women to pre-contract the pelvic floor muscle before and during efforts when intra-abdominal pressure increases [10] (this stabilizes the bladder neck during increased abdominal pressure such as coughing, which prevents UI leakage through a muscle timing process). Second, to improve pelvic floor muscle strength in order to build up long-lasting structural support for the pelvis by elevating the levator plate within the pelvis and by enhancing hypertrophy and stiffness of the pelvic floor muscle and connective tissues, thereby improving pelvic organ support during exertion.[11] The biological rationale for the use of PFMT for the management of urge urinary incontinence is less clear but a reflex inhibition of detrusor contraction has been demonstrated with an electrically stimulated contraction of the pelvic floor muscles.[12] It has also been suggested that reflex inhibition of detrusor contraction may accompany repeated voluntary pelvic floor muscle contractions.[13]

Objectives

The objective of this review was to determine the effects of PFMT in comparison to no treatment, placebo, sham treatments or other inactive control treatments in women with urinary incontinence (stress, urge, mixed). The review tested the hypothesis that in women with urinary incontinence, PFMT is better than no treatment, placebo, sham, or any other form of inactive control treatment. The present review is a shorter adapted version of the Cochrane review published in the Cochrane Library 2006, Issue 1, Art. No.: CD005654. DOI: 10.1002/14651858.CD005654.[14] Cochrane reviews are regularly updated as new evidence emerges and in response to feedback, *The Cochrane Library* should therefore be consulted for more complete information and most recent version of the review.

Materials and methods

Criteria for considering studies for this review

To be eligible for inclusion in the review, studies had to meet the following *a priori* criteria:

— To be randomized or quasi-randomized (*i.e.* allocation by alternation) controlled trials. Other forms of controlled clinical trial were excluded.

— To include women with urinary incontinence diagnosed as having stress, urge, or mixed, urinary incontinence on the basis of symptoms, signs or urodynamic evaluation. Excluded were studies of women with urinary incontinence related to significant factors outside the urinary tract (*e.g.* neurological disorders, cognitive impairment, lack of independent mobility). Studies investigating nocturnal enuresis in women were also excluded as were studies that specifically recruited antenatal or postnatal women (up to three months from delivery). Given the physiological changes of pregnancy and postpartum period there is a possibility that the effect of PFMT might differ in this group.

— To compare the use of a PFMT program with no treatment, a placebo treatment, a sham treatment (*e.g.* sham electrical stimulation), or an inactive control (*e.g.* advice on use of pads) in the treatment of women's urinary incontinence. PFMT was defined as a program of repeated voluntary pelvic floor muscle contractions taught and supervised by a health care professional. Trials in which PFMT was combined with a single episode of biofeedback (for the purpose of teaching a pelvic floor muscle contraction) or advice on strategies for symptoms of urge and/or frequency (but without a scheduled voiding regimen characteristic of bladder training) were eligible for inclusion. Trials in which PFMT was combined with another conservative therapy (*e.g.* bladder training, vaginal cones, electrical stimulation) or drug therapy (*e.g.* anticholinergic) were excluded.

Although study eligibility was not determined by the outcomes measured, the *a priori* primary outcomes of interest were: a) patient-reported symptomatic cure or improvement and b) symptoms and incontinence-specific quality-of-life assessment. Secondary outcomes of interest included the number of leakage episodes, number of micturitions, measurements of the pelvic floor muscle function, other quality-of-life measures (not UI-specific *e.g.* Short Form 36) and formal economic analysis. Other outcomes of interest were treatment adherence, any of the primary or secondary outcomes in the longer term (*i.e.* 12 months or more), and adverse events.

Search strategy for identification of studies

This review used the search strategy developed for the Cochrane Incontinence Review Group. Relevant trials were identified from searching the Cochrane Incontinence Group Specialized trial register. The register contains trials identified from The Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, CINAHL and searching of journals and conference proceedings. There was no restriction on the language of the publication. The date of the last search was December 2004.

Methods of the review

All potentially eligible studies were evaluated for inclusion by two reviewers, without prior consideration of the results. Similarly, assessment of the methodological quality was undertaken by the two reviewers using the Cochrane Incontinence Group's criteria which include assessment of quality of random allocation and concealment, description of dropout and withdrawal, analysis by intention to treat, and blinding during treatment and at outcome assessment. Data extraction was undertaken independently by two reviewers and then cross checked. Any differences of opinion arising in this process were resolved by discussion. All trial data included were finally processed as described in the Cochrane Collaboration Hand-book.[14]

Analysis

For categorical outcomes, the numbers reporting an outcome were related to the numbers at risk in each group to derive a relative risk. For continuous variables, means and standard deviations were used to derive a mean difference. The extent of the heterogeneity among the studies was assessed in three ways: visual inspection of data plots, χ^2 test for heterogeneity and the I^2 statistic. A meta-analysis was planned but was not performed because of heterogeneity amongst the studies.

Subgroup analysis was used to address the effect of the type of incontinence on outcome. Since the rationale for PFMT is different for the two main types of urinary incontinence (stress and urge), it is plausible to expect a difference in the outcome of PFMT on the basis of the type of incontinence. It is commonly

believed that PFMT is most effective for women with stress urinary incontinence, and may be effective in combination with behavioral interventions (*e.g.* bladder training) for women with mixed urinary incontinence. In the past, PFMT has rarely been the first-choice treatment for women with urge urinary incontinence alone. The four pre-specified diagnostic subgroups were: a) trials that recruit only women with stress urinary incontinence; b) trials that recruit only women with urge urinary incontinence; c) trials that recruit only women with mixed urinary incontinence; d) trials that recruit women with a range of diagnoses.

Description of included studies

Sixteen trials were identified of which three were excluded.[15-30] Two were excluded because they compared two approaches of PFMT.[28, 29] The third trial was reported only as a conference abstract and was excluded because it was not clear if it was a randomized control trial and furthermore contained no data.[30]

The 13 included trials are summarized in Table I. All are cited using the first author of the trial publication. Of the 13 trials, ten studies recruited women with SUI only.[15-24] One included women with SUI with or without urge incontinence, but the proportion with mixed UI was small (9%) and therefore it was analyzed with the SUI studies.[25] The two remaining studies recruited women with a range of diagnoses.[26, 27]

The PFMT programs used in the 13 trials are described in Table II. Unfortunately, four studies gave no details of the PFMT program used.[16, 19, 20, 24] Interestingly, of the nine remaining trials, five stated that a correct voluntary pelvic floor muscle contraction was confirmed prior to training.[15, 17, 18, 22, 26] PFMT was taught by specialist nurses or physiotherapists in six studies and by a family doctor in the seventh. Based on the description of training, three trials had PFMT programs that clearly and predominantly targeted coordination [22] or strength training.[17, 23] It was more difficult to categorize the other PFMT programs, because they were either a mixed (*e.g.* strength and endurance) program or did not give enough information about key training parameters such as the amount of voluntary effort during contraction to confirm the purpose of the endeavor.

The comparison groups were no treatment,[15, 16, 25, 18, 19, 22, 28] placebo drug,[26] sham electrical stimulation,[20] sham PFMT,[23] imitation PFMT with placebo drug [24] or a non-active control intervention such as use of anti-incontinence device [17] and advice on incontinence pads.[21] More details of the PFMT programs or alternate treatment are available in Table II.

Overall, there was no consistency in the choice of outcome measures by the trialists. Disappointedly, half of the eligible trials did not contribute any data to the main analysis because they did not measure any of the pre specified outcomes of interest or did not report their outcome data in a usable way (*e.g.* mean without a measure of dispersion). This limited the possibilities for considering results from individual studies together.

Methodological quality

The brevity of the reporting made it difficult to assess the methodological quality in four trials that were published as conference abstracts.[16, 19, 23, 24]

Results

Thirteen randomized or quasi-randomized trials, involving 714 women, compared PFMT (375 women) with no treatment, placebo, sham or other non-active control treatments (339 women). In the six trials contributing data, the two comparison groups comprised 197 and 206 women respectively.

Primary outcome measure

PATIENT-REPORTED "CURE" OR "IMPROVEMENT"

Many different scales, including Likert scales, visual analog scales and percent reduction in symptoms, were used to measure the patient response to treatment. Whatever the scale, data were included in the formal comparison when the trialists stated the number of women who perceived they were cured or improved after treatment.

Two trials reported data on cure: women reported "100% perceived improvement (that is dry)",[26] or that the incontinence was now "unproblematic".[17] Both trials found that PFMT women were statistically significantly more likely to report they were cured. The estimated size of treatment effect was quite different in the two trials; PFMT women were about 17 times more likely to report cure than controls in Bø *et al.* ,[17] but only about two and half times as likely in Burgio *et al.*[26] The confidence intervals in both trials were wide (Table III).

Four trials contributed data to the patient perceived "cure or improvement" comparison; women reported

TABLE I.—*Description of included studies.*

Study	Method	Participants	Interventions	Outcomes	Notes
Aksac *et al.* 2003 [15]	3 arm RCT, parallel design Not clear if adequate allocation concealment Not clear if blinded outcome assessment	50 women with urodynamic SUI No further inclusion or exclusion criteria stated Median age, years: PFMT 52.5 (SD7.9), control 54.7 (SD7.8) Single centre, Turkey	1) PFMT (n=20). Use of digital palpation to teach VPFMC with abdominal and buttock muscle relaxation. Weekly clinic visits for 8 weeks. Details of PFMT programme in Data Table 2 2. Control (n=10). No PFMT 3. PFMT with biofeedback (n=20)	Primary outcome: not stated Other outcomes: pad test cure (weight gain of 1g or less), pad test improvement (50% or greater reduction in pad weight), vaginal squeeze pressure, digital palpation score, incontinence frequency (four point ordinal scale), Social Activity Index	Post-treatment evaluation at 8 weeks, no lon-ger-term follow up Dropouts: not stated
Bidmead *et al.* 2002 [16]	4 arm RCT, parallel design (after treatment period control patients crossed over into group 3) Not clear if adequate random allocation concealment Blinded outcome assessment Primary analysis by intention to treat	Women with urodynamic SUI (number recruited not clear, 170 or 173?) Inclusion: new diagnosis of SUI or no treatment for SUI in previous 6 months Exclusion: not further criteria reported Mean age, years: PFMT 46.2 (SD 8.5), control 47.5 (SD 11.5) Single centre, UK	1. PFMT (n=40). Conventional PFMT supervised by physiotherapist. Individually tailored lifestyle advice. Five clinic visits in 14 weeks (weeks 1, 3, 6, 10 and 14) 2. Control (n=20). No treatment for 14 weeks. Thereafter crossed over into group 3 3. PFMT with electrical stimulation (n=?) 4. PFMT with sham electrical stimulation (n=42)	Primary outcome measure: not stated Other outcome measures: pad test, King's Health Questionnaire	Post-treatment evaluation at 14 weeks, no longer-term follow up Dropouts: 10/40 PFMT, 7/20 control, 15/? PFMT + electrical stimulation, 12/42 PFMT + sham stimulation
Burgio *et al.* 1998 [26]	3-arm RCT, parallel design Stratified by type (UUI, MUI) and severity of incontinence (number of leakage episodes) Not clear if adequate allocation concealment Blinded outcome assessment Primary analysis by intention-to-treat	197 women, with DO with or without urodynamic SUI Inclusion: community dwelling women aged 55 years or more, 2 or more urge accidents per week, urge incontinence predominant pattern Exclusion: continual leakage, uterine prolapse past introitus, unstable angina, decompensated heart failure, history of malignant arhythmias, impaired mental status (MMSE<20) Mean age, years: PFMT 67.3 (SD 7.6), control 67.6 (SD 7.6) Mean duration symptoms, years: 9.4 (10.8), control 12.7 (15.9) More than 10 leakage episodes per week: PFMT 52%, control 54% Diagnosis: 96 UUI only (49%), 101 MUI (51%) Single centre, USA	1. PFMT (n=65). Use of anorectal biofeedback to teach VPFMC with abdominal muscle relaxation. Response to urge (pause, sit, relax, repeated VPFMC to suppress urge). Use of bladder-sphincter biofeedback at third visit for those with <50% reduction in leakage episodes to teach VPFMC against increasing fluid volume and urge. Fortnightly clinic visit with nurse practitioner, 8 weeks. Details of PFMT programme in Data Table 2 2. Controls (n=65). Placebo drug, three times a day, for 8 weeks. Capsule contained 500 mg riboflavin phosphate marker. Fortnightly clinic visit with nurse practitioner 3. Drug (n=67)	Primary outcome: change in leakage frequency (2 week urinary diary) Secondary outcomes: Hopkins Symptom checklist for psychological distress, self report (worse to much better), satisfaction with pro-gress (not at all to completely), perceived impro-vement (none or 0% to dry or 100%), willingness to continue PFMT, desire for other treatment, leakage episodes (2 week urinary diary), cystometry (for 105/ 197)	Post-treatment evaluation at 10 weeks, no longer-term follow up Dropouts: 4/65 PFMT, 12/65 control, 12/67 drug ITTA: for primary outcome, most recent urinary diary data carried forward

Table I to be continued

Table I (continued)—Description of included studies.

Study	Method	Participants	Interventions	Outcomes	Notes
Burns *et al.* 1993 [25]	3 arm RCT, parallel design Not clear if adequate allocation concealment Blinded outcome assessment	135 women, with urodynamic SUI with or without DO Inclusion: women with SUI or MUI, 55 years or older, minimum of 3 leakage epi-sodes per week, demonstrates leakage with stress manoeuvres during physical examination, MMSE>23, absence of glycosuria or pyuria, post void residual <50 ml, maximum uroflow >15 ml/s Exclusion: no additional criteria reported Mean age, years: PFMT 63 (SD 6), control 63 (5) Mean leakage episodes 24 hours: PFMT 2.6 (SD 2.1), control 2.6 (2.6) Diagnosis: 123 urodynamic SUI (91%), 12 (9%) Single centre, USA	1. PFMT (n=43, after dropouts). Booklet explaining anatomy, PFMT, and completion of exercise and urinary diaries. Videotape describing exercise protocol. Weekly exercise reminder cards mailed between visits. Weekly clinic visits with nurse, 8 weeks. Details of PFMT programme in Data Table 2 2. Control (n=40, after dropouts). No treatment 3. PFMT with weekly clinic biofeedback (n=40, after dropouts)	Primary outcome: leakage episodes (2-week urinary diary) Secondary outcomes: incontinence severity (based on number of leakage episo-des from diary), pelvic floor muscle EMG, cystometry	Post-treatment evaluation at 8 weeks, with longer term follow up at 12 weeks and 6 months Dropouts: 10/135 and 2/135 excluded from analysis (no urinary diary); group not specified
Bø *et al.* 1999 [17]	4 arm RCT, parallel design Stratified by severity of leakage on pad test Adequate allocation concealment Blinded outcome assessment Secondary analysis by intention to treat A priori power calculation	122 women, with urodynamic SUI Inclusion: women with a history of SUI, waiting for surgery or recruited through advertising, >4g leakage on pad test with standardised bladder volume Exclusion: other types of incontinence, DO on urodynamics, residual urine >50 ml, maximum uroflow <15 ml/s, previous surgery for urodynamic SUI, neurological or psychiatric disease, ongoing urinary tract infection, other disease that could interfere with participation, use of concomitant treatments during trial, inability to understand instructions given in Norwegian Mean age, years: PFMT 49.6 (SD 10.0), control 51.7 (SD 8.8) Mean duration symptoms, years: PFMT 10.2 (SD 7.7), control 9.9 (SD 7.8) Mean leakage episodes 24 hours: PFMT 0.9 (SD 0.6), control 1.0 (SD 1.0) Diagnosis: 122 urodynamic SUI (100%) 5 centres, Norway	1. PFMT (n=29). Explanation of anatomy, physiology, and continence mechanism by physiotherapist. Audiotape of home training programme. Weekly 45 minute exercise class to urodynamic SUI with PFMT in a variety of body positions, and back, abdominal, buttock and thigh muscle exercises. Monthly clinic visit with physiotherapist, 6 months. Details of PFMT programme in Table 2 2. Controls (n=32). Explanation of anatomy, physiology, and continence mechanism. Correct VPFMC confirmed by palpation. No clinic visits. Offered instruction in use of the Continence Guard (14 accepted) 3. Electrical stimulation (n= 32) 4. Vaginal cones (n=29)	Primary outcomes: 60 second pad test with standardised bladder volume, self-report (very problematic to unproblematic) Secondary outcomes: Norwe-gian Quality of Life Scale, Bristol Female Lower Urinary Tract Symptoms Questionnaire, Leakage Index, Social Activity Index, leakage episodes (3 day urinary diary), 24 hour pad test, vaginal squeeze pressure	Post-treatment evaluation at 6 months, no longer-term follow up Dropouts: 4/29 PFMT, 2/32 controls, 7/32 electrical stimulation, 2/29 vaginal cones ITTA: baseline values used for losses to follow up

Table I to be continued

Table I (continued)—Description of included studies.

Study	Method	Participants	Interventions	Outcomes	Notes
Henalla *et al.* 1989 [18]	4-arm RCT, parallel design Not clear if adequate random allocation concealment Not clear if blinded outcome assessment	100 women with urodynamic SUI Exclusion: fistula, more than one surgical procedure for incontinence, major degree of prolapse, absolute contraindication to oestrogens Single centre, UK	1. PFMT (n=26). Correct VPFMC taught by physiotherapist. Weekly clinic visit for 12 weeks. Details of PFMT programme in Data Table 2 2. Control (n=25). No treatment 3. Electrical stimulation (n=25) 4. Drug (n=24). Oestrogen	Primary outcome measure: not stated Other outcome measures: pad test cure (negative following positive result), pad test improvement (50% or greater reduction in pad weight), cystometry	Post-treatment evaluation at 12 weeks, with longer-term follow up at 9 months (questionnaire) Dropouts: none at 12 weeks?
Henalla *et al.* 1990 [19]	3 arm RCT, parallel design Not clear if adequate random allocation concealment Not clear if blinded outcome assessment	26 women with urodynamic SUI Inclusion: postmenopausal Exclusion: no further criteria stated Mean age, years: 54 (range 49-64) Single centre, UK	1. PFMT (n=8). No detail given 2. Control (n=7). No treatment 3. Drug (n=11). Oestrogen	Primary outcome: not stated Other outcome measures: pad test cure or improved (not defined), vaginal pH, vaginal cytology, anal EMG	Post-treatment evaluation at 6 weeks, no longer-term follow up Dropouts: none?
Hofbauer *et al.* 1990 [20]	4 arm RCT, parallel design Not clear if adequate random allocation concealment Not clear if blinded outcome assessment	43 women with urodynamic SUI Exclusion: urge incontinence. Mean age, years: 57.5 (SD 12) Grade 3 incontinence: 4 PFMT, 2 control	1. PFMT (n=11). Exercise programme including PFMT, abdominal and hip adductor exercise, twice a week for 20 minutes with therapist, and daily home programme 2. Control (n=10) Sham electrical stimulation 3. PFMT + electrical stimulation (n=11) 4. Electrical stimulation (n=11)	Primary outcome: not stated Other outcome measures: incontinence scale (? symptom scale, not defined), leakage episodes (urinary diary), cystometry	Not clear when post-treatment evaluation performed Further follow-up at 6 months Dropouts: none?
Lagro-Janssen *et al.* 1991 [21]	2 arm RCT, parallel design Stratified by type and severity of incontinence Inadequate allocation concealment Blinded outcome assessment	110 women, with urodynamic SUI with or without DO Inclusion: women between 20 and 65 years of age reporting 2 or more leakage episodes per month Exclusion: previous incontinence surgery, neurological causes of incontinence, urinary tract infection, temporary cause of incontinence Mean age, years: PFMT 46.1 (SD 10.1), controls 44.6 (SD 8.2) Symptoms for more than 5 years: PFMT 55%, control 33% Mean leakage episodes 24 hours: PFMT 2.5 (SD 2.0), control 3.3 (SD 2.2) Diagnosis: 66 urodynamic SUI (60%), 20 MUI (18%),	1. PFMT (n=54, but 33 with urodynamic SUI only). Advice about incontinence pads from practice assistant. Information on PFM function and how to contract by family doctor. PFMT for 12 weeks. Details of PFMT programme in Data Table 2 2. Control (n=56, but 33 with urodynamic SUI only). Advice about incontinence pads only. Offered treatment after 12 weeks	Primary outcome: not stated Other outcomes: incontinence severity (12 point score), subjective assessment, health locus of control questionnaire, general health questionnaire, leakage episodes (7 day diary), self-reported treatment adherence	Post-treatment evaluation at 12 weeks, with longer term follow up at 6 months, 12 months and 5 years Dropouts: 1/54 PFMT, 3/56 control

Table I to be continued

Table I (continued)—Description of included studies.

Study	Method	Participants	Interventions	Outcomes	Notes
		18 UUI (16%), 6 other (6%). NB: only data from urodynamic SUI women are included in the review, because women with other diagnoses also had bladder training 13 general practices, The Netherlands			
Miller *et al.* 1998 [22]	2 arm RCT, parallel design (after one month controls cross over into treatment group) Not clear if adequate allocation concealment Blinded outcome assessment	27 women with symptoms and signs of SUI Inclusion: community dwelling women, mild to moderate SUI (at least one and up to 5 leaks per day), 60 years or more, direct visualisation of urine loss on cough with 100ml or more voided after stress test Exclusion: systemic neuromuscular disease, previous bladder surgery, active urinary tract infection, delayed leakage after cough, more than moderate leakage with cough, inability to do a VPFMC, prolapse below hymenal ring Mean age, years: 68.4 (SD 5.5) Mean number leakage episodes per day: 1.4 (SD 1.4) Single centre, USA	1. PFMT (n=13). Education on basic physiology and function of pelvic floor muscles, digital palpation to teach VPFMC. Taught 'The Knack', i.e. VPFMC prior to hard cough maintained throughout cough until abdominal wall relaxed. Practice at home for one week 2. Control (n=14). No treatment for one week, then cross over to treatment group at one month	Primary outcome measure: Paper towel test Secondary outcome measures: digital palpation	Post-treatment evaluation: one week, no longer-term follow-up Dropouts: none
Ramsay *et al.* 1990 [23]	2 arm RCT, parallel design Not clear if adequate allocation concealment Blinded participants	44 women, with symptoms of SUI Inclusion: women whose only symptom was SUI Exclusion: no additional criteria reported Diagnosis: 44 SUI (100%) Single centre, Scotland	1. PFMT (n=22). Taught by physiotherapist. PFMT for 2 weeks. Details of PFMT programme in Data Table 2 2. Controls (n=22). As above, but with sham PFMT programme comprising hip abductor muscle contraction with feet crossed at the ankles	Primary outcome: not stated Other outcomes: self-reported severity (worse to improved), pad test, vaginal squeeze pressure	Post-treatment evaluation at 12 weeks, with no longer-term follow up Dropouts: none ITTA: data for all participants
Schagen van Leeuwen *et al.* 2004 [24]	RCT, 2×2 design Not clear if adequate random allocation concealment Blinded for drug but not PFMT components of intervention? Intention to treat analysis	201 women with urodynamic SUI or positive cough test Inclusion: women aged 18-75 years with two or more stress leakage episodes per day and normal voiding frequency Exclusion: enuresis, urge incontinence Five centres, 3 countries (The Netherlands, UK, USA)	1. PFMT+placebo drug (n=50) 2. Control (n=47). Imitation PFMT (not defined) and placebo drug 3. PFMT + drug (n=52). Duloxetine 4. Imitation PFMT+drug (n=52)	Primary outcome: percent change in incontinence episode frequency Secondary outcomes: change in Incontinence Quality of Life (I-QoL), percent chan-ge in pad use	Post-treatment evaluation at 12 weeks, no longer term follow up Dropouts: yes, but no data given

Table I to be continued

Table I (continued)—Description of included studies.

Study	Method	Participants	Interventions	Outcomes	Notes
Yoon *et al.* 2003 [27]	3-arm RCT, parallel design Not clear if adequate allocation concealment Blinded outcome assessment	50 women with urinary incontinence Inclusion: urine loss >1g on 30 minute pad test, 14 voids or more in 48 hours Exclusion: women under 35 and over 55 years of age, urinary tract infection, previous surgery for urinary incontinence, hormonal or other drug therapy for incontinence Mean voids per day: PFMT 15.1 (SD 1.6), control 16.3 (1.8) Diagnosis: urinary incontinence (100%) Single centre, Korea	1. PFMT (n=15). 20 minutes weekly session of EMG biofeedback with nurse, 8 weeks. Details of PFMT programme in Data Table 2 2. Control (n=14). No treatment or clinic contact	Primary outcome: not stated Other outcomes: urinary incontinence score (severity based on leakage with 18 activities), leakage episo-des and frequency (2 day diary), 30 minute pad test, vaginal squeeze pressure	Post-treatment evaluation at 8 weeks, with no longer-term follow-up Dropouts: 2/15 PFMT, 2/21 Bladder training, 2/14 controls

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

they were "improved",[23] had "75% or more perceived improvement",[26] were "dry" or "improved",[21] or were "continent" or "almost continent".[17] Visual inspection of the plot showed that the trial by Ramsay and Thow [23] differed from the other three studies (Table IV). This trial by Ramsay and Thow might be confounded by the choice of sham PFMT, which consisted of strong isometric hip adductor contractions that may have facilitated synergistic contractions in the muscles of the pelvic floor with a PFMT effect. Adherence rates in both groups were also very low. Assuming that PFMT has an effect, if exercise levels are sub optimal, then the size of effect might be diminished to the point where it is not detected. It is possible that women in the PFMT group were doing insufficient training to demonstrate an effect on the pelvic floor muscles. In the three remaining trials, the two in women with urodynamic stress urinary incontinence [17, 21] suggested a higher likelihood of cure or improvement than the single study in women with urge urinary incontinence with or without urodynamic stress urinary incontinence.[26]

Symptom and condition specific quality of life assessment

Two trials used psychometrically robust questionnaires for assessment of incontinence symptoms, the impact of these symptoms on quality of life, or both.[17, 24] Bø *et al.* [17] used the Bristol Female Lower Urinary Tract Symptoms Questionnaire (B-FLUTS), which has established validity, reliability and responsiveness to change for evaluation of urinary incontinence symptoms in women.[31] Only two parts of the questionnaire were reported, the lifestyle and sex-life questions. Data were reported as frequencies, rather than mean scores. Fewer women in the PFMT group reported that urinary incontinence symptoms interfered with activity, or were problematic (Table V). Schagen van Leeuwen *et al.*[24] reported a mean change in incontinence quality of life using the (I-QoL) score; I-QoL has established validity, reliability and responsiveness to change for assessing quality of life impact of urinary incontinence.[31] Although the quality of life was better in the PFMT group, it was not clear if there were important differences between PFMT and control groups because the means were presented without a measure of dispersion.

Secondary outcome measures

Number of leakage episodes in 24 hours

Five studies used urinary diaries to count leakage episodes[17, 21, 25, 26 27] although one of them, that of Yoon *et al.*,[27] did not report these data. Meanwhile,

TABLE II.—*Description of PFMT programs.*

Study	VPFMC confirmed	Description	VPFMC per day	Training	Supervision
Aksac *et al.* 2003 [15]	Voluntary pelvic floor muscle contraction (VPFMC) confirmed by palpation. Relaxation of abdominal and buttock muscles	Set: 10 VPFMC, with 5 second hold and 10 second rest. Progressed at 2 weeks to 10 second hold and 20 second rest. Sets per day:3	30	8 weeks	Weekly clinic visits
Burgio *et al.* 1998 [26]	Anorectal biofeedback for teaching selective contraction and relaxation of pelvic floor muscles, while keeping abdominal muscles relaxed	Set: 15 VPFMC, with 10 seconds hold. Sets per day: 3. Body position: lying, sitting, standing. Use of VPFMC to prevent leakage (the Knack), and to suppress urge. Interrupt urine stream once per day. 45.8 weeks. Fortnightly clinic visit with nurse practitioner	45	8 weeks	Fortnightly clinic visit with nurse practitioner
Burns *et al.* 1993 [25]	—	Set: 10 VPFMC with 3 second hold, and 10 VPFMC with 10 second hold. Progressed by 10 per set to daily maximum of 200. Sets per day:4. Videotape describing exercise protocol	200	8 weeks	Weekly exercise reminder cards mailed between visits. Weekly clinic visits with nurse
Bø *et al.* 1999 [17]	VPFMC confirmed by palpation	Set: 8 to 12 high intensity (close to maximal) VPFMC, with 6 to 8 second hold and 3 to 4 fast contractions added at the end of each hold, 6 second rest between contractions. Sets per day: 3. Body position: included lying, kneeling, sitting, standing; all with legs apart. Women used preferred position. Audiotape of home training programme. Weekly 45 minute exercise class to music, with PFMT in a variety of body positions, and back, abdominal, buttock and thigh muscle exercises	136	6 months	Weekly 45 minute exercise class. Monthly clinic visit with physiotherapist
Henalla *et al.* 1989 [18]	Correct VPFMC taught by physiotherapist	Set: 5 VPFMC, with 5 second hold. Sets per day: 1 set per hour	Approximately 80	12 weeks	Weekly clinic visit.
Lagro-Janssen *et al.* 1991	Teaching from family doctor	Set: 10 VPFMC, with 6 seconds hold. Sets per day: 5 to 10	50-100	12 weeks	—
Ramsay *et al.* 1990 [23]	Taught by physiotherapist	Set: 4 maximum isometric VPFMC, with 4 second hold and 10 second rest. Sets per day: 1 set every waking hour	Approximately 64	12 weeks	—
Yoon *et al.* 2003 [27]	Weekly surface electromyography biofeedback with nurse	Set: not stated. Sets per day: 30 VPFMC for strength and endurance per day (not clear if 30 total or 30 each), taking 15 to 20 minutes per day. Strength: burst of intense activity lasting a few seconds. Endurance: 6 second holds progressed by 1 second per week to 12 seconds	Not clear if 30 or 60	8 weeks	Weekly clinic visit with nurse

the 3-day diary was adopted by Bø *et al.*,[17] the 7-day diary, by Lagro-Janssen *et al*.[21] and the 14-day diary by Burns *et al*.[25] and Burgio *et al*.[26] (Table VI). To enable comparison between trials, the data were presented as the number of leakage episodes in 24 hours. Visual inspection of the forest plot suggested the effect size might be greater in the trial by Lagro-Janssen *et al*.,[21] while the effect size appeared similar in the three remaining trials.[17, 25, 26] It was not clear why the data from Lagro-Janssen *et al*. might be different from the two other trials in stress urinary incontinent women or the trials overall. A possible reason

TABLE III.—*Patient reported cure.*

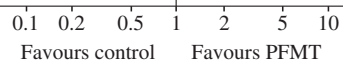
Review: Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women
Comparison: 01 PFMT versus no treatment, placebo or control
Outcome: 01 Patient perceived 'cure'

Study or sub-category	PFMT n/N	Control n/N	RR (fixed) 95% CI	RR (fixed) 95% CI
01 stress urinary incontinence				
Bo 1999	14/25	1/30		16.80 [2.37, -19.04]
02 urge urinary incontinence				
03 mixed urinary incontinence				
04 urinary incontinence (all types)				
Burgio 1998	19/63	8/62		2.34 [1.11, 4.94]

TABLE IV.—*Patient reported cure or improvement.*

Review: Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women
Comparison: 01 PFMT versus no treatment, placebo or control
Outcome: 02 Patient perceived 'cure'

Study or sub-category	PFMT n/N	Control n/N	RR (fixed) 95% CI	RR (fixed) 95% CI
01 stress urinary incontinence				
Ramsay 1990	14/22	14/22		1.00 [0.64, 1.56]
Largo-Janssen 1991	20/33	1/33		20.00 [2.85, 140.51]
Bo 1999	12/25	1/30		14.40 [2.01, 103.23]
02 urge urinary incontinence				
03 mixed urinary incontinence				
04 urinary incontinence (all types)				
Burgio 1998	46/63	20/62		2.34 [1.11, 4.94]



was inadequate random allocation concealment, with an overestimate of treatment effect. The point estimates in the other three trials[17, 25, 26] were similar, all were statistically significant. PFMT women experienced about one less leakage episode per 24 hours compared to controls.

NUMBER OF VOIDS PER DAY AND PER NIGHT

A single study reported data on frequency of voids per day.[27] PFMT women reported about three less voids per day than controls but with wide confidence intervals that included no difference (MD-3.1, 95% CI –4.7 to 1.5). Data from the same study [27] showed no statistically significant difference in the number of night-time voids between PFMT and control groups.

MEASURES OF PELVIC FLOOR MUSCLE FUNCTION

Four studies used perineometry (pressure measurements) to measure pelvic floor muscle squeeze pressure.[15, 17, 23, 27] Other methods of assessing pelvic floor muscle function were pelvic floor muscle EMG recording [25] and digital palpation.[15, 22] Of the six studies undertaken, one did not report the data in a way that made it possible to calculate the mean difference

TABLE V.—*Incontinence specific quality of life.*

Study	Outcome	Measure	PFMT	Control	Difference
Bø *et al.* 1999 [17]	Bristol Female Lower Urinary Tract Symptoms Questionnaire (BFLUTS). For analysis positive findings ('a little", "somewhat" and "a lot", or "a bit of a problem", "quite a problem" and "a serious problem") were grouped together and reported as frequencies. Only the lifestyle questions (28-31, 33) and sex-life questions (21-24) were reported	Number with positive findings	Avoiding places and situations: 7, n=25 Interference with social life: 1, n=25 Interference with physical activity: 11, n=25 Overall interference with life: 14, n=25 Unsatisfied if had to spend rest of life as now: 10, n=25 Sex-life spoilt by urinary symptoms: 3, n=20 Problem with sex-life being spoilt: 2, n=20 Problem with painful intercourse, 2, n=20 Urinary incontinence with intercourse: 2, n=20	Avoiding places and situations: 10, n=30 Interference with social life: 12, n=30 Interference with physical activity: 24, n=30 Overall interference with life: 25, n=30 Unsatisfied if had to spend rest of life as now: 11, n=30 Sex-life spoilt by urinary symptoms: 13, n=25 Problem with sex-life being spoilt: 13, n=25 Problem with painful intercourse: 10, n=25 Urinary incontinence with intercourse: 10, n=25	Avoiding places and situations: relative risk (RR) 0.84, 95% confidence interval (CI) 0.37 to 1.88 Interference with social life: RR 0.10, 95% CI 0.01 to 0.72 Interference with physical activity: RR 0.55, 95% CI 0.34 to 0.89 Overall interference with life: RR 0.67, 95% CI 0.46 to 0.99 Unsatisfied if had to spend rest of life as now: RR 0.11, 95% CI 0.02 to 0.79 Sex-life spoilt by urinary symptoms: RR 0.29, 95% CI 0.10 to 0.87 Problem with sex-life being spoilt: RR 0.19, 95% CI 0.05 to 0.76 Problem with painful intercourse: RR 0.25, 95% CI 0.06 to 1.01 Urinary incontinence with intercourse: RR 0.25, 95% CI 0.06 to 1.01
	Social Activity Index	Mean (standard deviation)	9.3 (1.0), n=25	7.9 (2.2), n=30	Mean difference (MD) 1.4, 95% CI 0.4 to 2.4
Shangen van Leeuwen *et al.* 2004 [24]	Incontinence Quality of Life (I-QoL) score	Mean change (standard deviation)	7.8 (?), n=?	4.8 (?), n=?	4.8 (?), n=?

between pelvic floor muscle squeeze pressure or digital palpation score.[15]

Two studies out of the three that measured pelvic floor muscle squeeze pressure found greater pressure in the PFMT than the control group, in one study the difference was statistically significant while in the other it was not.[17, 27] The third study by Ramsay and Thow did not report data, but stated that there were no statistically significant differences between the groups.[23] In the single trial that used EMG, Burns *et al.*[25] did not find any statistically significant difference between the groups for fast and sustained contraction and the mean scores were very similar in both groups. Finally, the findings for digital palpation in the study by Miller *et al.* showed no statistically significant difference between the two groups.[22] However, there were reasonable explanations for this lack of difference. Miller *et al.* reassessed muscle function after just one week of coordination training. It is not clear what changes in muscle function might have occurred after such a short training period or if these would have been picked up with digital palpation.

OTHER QUALITY- OF-LIFE-MEASUREMENT

Validated measures were used to evaluate generic quality-of-life [17] and psychological distress.[26] Neither study found any statistically significant differences between PFMT and control groups.

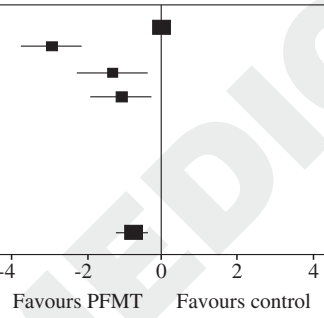
FORMAL ECONOMIC ANALYSIS

None of the included trials reported a formal economic analysis or any economic data.

TABLE VI.—*Leakage episodes.*

Review: Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women
Comparison: 01 PFMT versus no treatment, placebo or control
Outcome: 04 Number of leakage=episodes in 24 hours

Study or sub-category	PFMT Mean (SD)	PFMT n/N	Control n/N	RR (fixed) 95% CI	RR (fixed) 95% CI
01 stress urinary incontinence					
Largo-Janssen 1991	0.69 (0.84)	33	3.61:2.26>		-2.92 [-3.74, -2.10]
Burns 1993	1.14 (1.43)	39	2.43:2,71>		-1.29 [-2.24, -0.34]
Bo 1999	0.27 (0.70)	30	1.07:2.11>		-0.80 [-1.60, 0.001]
02 urge urinary incontinence					
03 mixed urinary incontinence					
04 urinary incontinence (all types)					
Burgio 1998		46/63	20/62		-0.77 [-1.22, -0.32]



Other outcome of interests

LONGER-TERM FOLLOW-UP

Few trials had longer-term follow-up after cessation of supervised training. In all trials, supervised PFMT stopped at the end of the treatment period, except in trials where the controls were then offered a period of supervised training. Because of this "crossover" of controls to training, follow up data were usually presented for all women in the trial, rather than by group allocation. Three trials have published longer-term follow up, at the three and six month,[25] nine months,[18] and 12 months and five years.[21]

Burns *et al*. found that those with mild leakage were more likely to have a return of the symptoms in contrast with those with moderate to severe leakage, who were more likely to continue to improve with PFMT.[25] Henalla *et al.* reported that only three of the 17 women who returned the nine-month questionnaire (from the 25 originally allocated to the treatment group) had recurrent symptoms.[18] Lagro-Janssen and van Weel [21] contacted 101 of the 110 women included in their original trial five-years later. Seven women had received surgery at that time, one had become pregnant, and five women did not wish to participate in the follow-up. Data from the 88 women who consented showed that the number of continent women was the same after five years (25%), but the number with severe incontinence increased from 3% to 18%. The number of leakage episodes per week had also increased significantly (P=0.009), with a mean increase of 2.7 episodes (95%; CI 0.7 to 4.6). Two thirds of the women (67%) remained satisfied with the outcome and did not want further treatment. Women with urge or mixed incontinence were less likely to be satisfied with outcome at five years, and stress urinary incontinent women were less likely to report their condition had worsened.

Nearly half of the women (43%) who had received PFMT were no longer training at all, while 39% were training daily or "when needed". The relationship between age, parity, anxiety, incontinence severity adherence and treatment success at five years was investigated in a logistic regression. For stress urinary incontinent women, the only significant factor significantly associated with better outcome at five years was continued PFMT (P=0.04).

TREATMENT ADHERENCE

Five trials attempted to measure treatment adherence using exercise diaries [15, 17, 23, 25] and self-report.[21] Bø *et al.*[17] reported the highest rate of adherence to PFMT (95%). Bidmead *et al.*[16] found 75% of women allocated to PFMT had excellent (daily) or good (training more than three times a week) adherence to exercise. Women in the study by Lagro-Janssen *et al.*[21] rated their adherence as excellent or good (62%), reasonable (20%), or poor or none (18%). Ramsay and Thow [23] stated that adherence was poor, with PFMT occurring at "15% of the requested level", with simi-

lar rates of exercise between PFMT and sham PFMT groups. Burns *et al.*[25] did not present any data.

ADVERSE EVENTS

Three trials specifically mentioned adverse events, and two did not report any in the PFMT group.[17, 26] Lagro-Janssen *et al.* were the only trial to report adverse events with PFMT.[21] These were, pain (1 participant), uncomfortable feeling during exercise (3 participants), and not wanting to be continuously bothered with the problem (2 participants).[21]

OTHER OUTCOMES - OTHER MEASURES OF THE PATIENT'S PERCEIVED RESPONSE TO TREATMENT

Other outcomes, not pre-specified, but judged important when performing the review were all measures of patient-perceived response to treatment. Two of these were symptom scales, the Leakage Index [17] and a urinary incontinence score.[27] Participants were also asked about their perceptions in frequency and amount of leakage [26] and their desire for further treatment.[17, 26]

The symptom scores used by Bø *et al.*[17] and Yoon *et al.*[27] both evaluated leakage severity with specified activities, but the former addressed leakage frequency and the latter leakage amount. Bø *et al.* found PFMT women had less perceived leakage frequency than controls; this was an average of 1.2 points difference, on a scale with a maximum score of 35 points and a minimum of 5.[17] Yoon *et al.* also found lower scores in the PFMT group, but the difference was not statistically significant.[27] Burgio *et al.* found PFMT women were about one and a half times more likely to report a reduction in frequency, and amount of leakage with each leakage episode, than controls.[26] Bø *et al.* and Burgio *et al.* asked if women wanted further treatment or not; in both trials, PFMT women were significantly more likely say they did not (RR 12.6;95% CI 3.3 – 48.6; RR3.5, 95% CI 2.1 to 5.8, respectively).

Although the review authors had concerns about the comparability and interpretation of findings from pad and paper towel tests, these were used in nine of the 13 included studies, so the data were extracted and examined for consistency with other findings.[15, 16, 20, 22, 23, 27]In all trials the number cured or improved on pad test, or the mean or median pad test scores, were in favor of the PFMT group. The one trial that did not find a statistically significant difference in the pad test cure, or cure or improvement, was very small (less than 10 participants per group) and had no cases of cure or improvement in the control group.[19]

Discussion

Of the 13 trials that addressed the review question "*Is PFMT better than no treatment, placebo or control treatment?"* only six reported data (suitable for analysis) for the primary outcomes of interest. Of these six, one was probably confounded by the choice of sham PFMT program [23] which consisted of strong isometric hip adductors, and another was at high risk of bias based on reported inadequate allocation concealment.[21] No more than four studies contributed data to each of the formal comparisons, and heterogeneity was observed in each comparison.

Primary outcome measure

Patient perceived *cure* was more likely after PFMT than control. The trial with the greater effect size included women with urodynamic SUI only, while the other recruited women with detrusor overactivity incontinence with or without urodynamic stress incontinence. Of the two diagnoses, and based on a biological rationale, it is reasonable to expect that PFMT might have more effect on SUI than urge or mixed incontinence. However, other factors might also contribute to the difference between the two trials. For example, the trial with the greater effect size defined "cure" as "unproblematic"[17] incontinence, whereas, in the other, women reported they were "dry".[26] These descriptors might measure different things. "Cure" was also more likely in the trial where women trained for a longer period (six months *versus* eight weeks),[17] and were younger on average (mean age around 50 compared to 67 years).

Four studies grouped "cure and improvement". The data from Ramsay and Thow [23] were presented (Table IV), but were thought to be confounded. The other three studies [17, 21, 26] all found statistically significant differences in favor of PFMT, although the estimated size of treatment effect varied considerably. The two trials in women with urodynamic stress incontinence observed similarly large treatment effects,[17, 21] while the suggested effect was much less in the single study in women with urge incontinence with or without urodynamic stress incontinence.[26] As with patient-reported cure, the trials with larger effect sizes recruited noticeably younger women.[17, 21] Finally, although

there was some similarity in the exercise content of the PFMT programs, the two trials with greater effects had the longer treatment durations (three and six months, *versus* eight weeks).[17, 21]

Overall, the differences in likelihood of cure or improvement after PFMT compared to control suggested by the review are sufficient to be of interest to women. As discussed above, the proportion of women who are cured or improved might be larger if women have SUI rather than urge or mixed urinary incontinence and train for a longer time. When interpreting these data, it is worth noting that there is a relationship between age and diagnosis; younger women being more likely to have SUI, and older women, urge or mixed incontinence.[32] Without an individual patient data analysis, it was not possible to tell if diagnosis, age, duration of training, or all these factors might be associated with greater treatment effect. The association between these factors and treatment outcome is a hypothesis that requires further testing.

Additionally, it seems there might be improved incontinence -specific quality of life (lifestyle and sex-life) in women treated with PFMT compared to controls [17] but there might be less or no effect on generic quality of life.[17, 26] Incontinence-specific quality-of-life measures have only recently been developed. Some of the included trials predated the development of these instruments. It is interesting that, although generic measures of quality of life have been available longer, they were not used in incontinence research. The inclusion of validated, reliable and responsive condition-specific and generic quality-of-life instruments in future studies of PFMT is imperative.

Secondary outcome measures

For leakage episodes, there was a statistically significant reduction in leakage episodes with PFMT in all four studies contributing to the forest plot (Table VI); one had a noticeably larger treatment effect.[21] This trial was at high risk of bias (inadequate random allocation) and might have overestimated the treatment effect.[21] Apart from the quality of the method, it is not clear why this trial might have been different from the others. If the data from the other three studies are considered together, the difference between PFMT and control is about one less leakage episode per day.[17, 25, 26] It is not clear how important this difference might be for women; it might well depend on how often they leak. If they are leaking frequently, then this difference might not seem so important. Leakage frequency was similar between two trials in urodynamic stress incontinent women [17, 25] and the single study in women with urge incontinence with or without urodynamic stress incontinence,[26] although the likelihood of self-reported cure and improvement appeared quite different in these diagnostic groups. It is possible that the effect of treatment on leakage episodes is similar, but women with detrusor overactivity urinary incontinence (with or without urodynamic stress incontinence) probably also experience urgency and frequency in addition to urge incontinence. PFMT might be less effective in addressing urgency and frequency than incontinence. If so, then women with urge urinary incontinence will be less likely to report that PFMT has cured or improved their condition, because two of their symptoms might still be bothersome.

A single study presented data on the number of voids in a sample of women with urinary incontinence (stress, urge, mixed).[27] It is surprising that no other included trial presented data on frequency, as this is a common problem for women with urinary incontinence. Even if there is no physiological reason for frequency, many women who fear leakage void often to keep their bladder volume low. In the single study with data, PFMT women reported fewer voids per day than controls, but there was no difference in the average number of night-time voids between groups.[27]

Pelvic floor muscle function was measured with different instruments so that it was difficult to compare the data from these tests. Interestingly, three of the studies reporting measures of pelvic floor muscle function also reported data on self reported cure or cure and improvement. While none of the trials found any statistically significant difference between PFMT and control groups for pelvic floor muscle squeeze pressure [17, 23] or EMG,[25] two found PFMT women were more likely to report cure or cure and improvement.[17, 25] The trial that did not find a difference in cure rates was potentially confounded [23] (see results section, primary outcome measures). This suggests that change in pelvic floor muscle function is not, or perhaps not, the only explanation for the effect of PFMT. It is also possible that other aspects of muscle function that were not measured in these two trials, such as timing, coordination, endurance and rapidity of contraction, might contribute to the perception of improvement in urinary incontinence.

Other outcome of interests

Treatment adherence is likely to have an impact on the size and direction of treatment effect, because adherence affects the exercise 'dose'. Although adherence data might be useful in interpreting trial results, treatment adherence is difficult to measure. It is interesting to note that the two trials that reported good to excellent rates of training adherence were also the two trials that demonstrated the greatest treatment effects for cure and improvement.[17, 21] Because these two trials also recruited young, urodynamic stress incontinence women, there are other potential explanations for this observation. Nevertheless, it is possible that treatment adherence contributed.

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

Finally, none of the included studies was accompanied by a cost description, cost analysis or cost effectiveness study. Although the review suggested PFMT is better than control treatment, in the absence of economic data it was impossible to estimate the cost at which these gains are made.

Conclusions

Implications for practice

Based on the data available, PFMT is better than no treatment, placebo drug or inactive control treatment for women with stress, urge, or mixed incontinence. Women treated with PFMT were more likely to report cure or improvement, and have fewer leakage episodes per day than controls. Condition-specific quality of life might also be better after PFMT, but this finding needs confirmation from further studies. The trials suggested treatment effect might be greater in women with stress urinary incontinence who tended to be younger (in their 40s and 50s) and participating in a supervised PFMT program for at least 3 months. These hypotheses need further testing. Overall, there is support for the widespread recommendation that PFMT be included in first treatment line conservative management programs for women with stress, urge or mixed incontinence. However, the limited nature of follow-up beyond the end of treatment means that the long-term outcomes of use of PFMT are less clear.

Implication for research

In essence, there is a need for at least one large, pragmatic, well-conducted, and explicitly reported trial comparing PFMT with control to investigate its longer-term clinical effectiveness. The trial would recruit women with symptoms of stress, urge, or mixed urinary incontinence based on clinical history and physical examination; and with a sample size based on a clinically important difference in condition-specific quality of life, and sufficient for subgroup analysis on the basis of diagnosis and age. Random allocation to groups should be hidden and stratification or minimisation procedures would ensure an even distribution of women with different diagnoses across both arms of the trial. One arm of the study would comprise a supervised PFMT program derived from sound exercise science, confirmation of a correct voluntary pelvic floor muscle contraction, and incorporate appropriate adherence measures. The choice of program would have to be set against the resource implications of intensively supervised individual programs and the opportunity cost this represents. Careful clinical judgement is needed about what sort of program could actually be applied in everyday practice and in different countries with their different health care delivery systems. The other arm of the trial would be a control treatment, *e.g.* explanation of anatomy and physiology of the bladder and pelvic floor, advice on good bladder habits, with the same explanation and advice given in both arms. The outcome should be measured at an appropriate time, and also some time after the treatment has stopped. Such a trial would require substantial funding and multiple recruitment centres.

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