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Comparisons of approaches to pelvic floor muscle training for urinary incontinence in women: an abridged Cochrane systematic review

J. HAY-SMITH [1], R. HERDERSCHEE [1, 2], C. DUMOULIN [3], P. HERBISON [4]

[1]Rehabilitation Teaching and Research Unit
Department of Medicine
University of Otago, Wellington, New Zealand
[2]Department of Obstetrics and Gynaecology
Academic Medical Centre
University of Amsterdam, Amsterdam, The Netherlands.
[3]School of Rehabilitation, Faculty of Medicine
University of Montreal, Montreal, Canada
[4]Department of Preventive and Social Medicine
Dunedin School of Medicine
University of Otago, Dunedin, New Zealand

COMPARISONS OF APPROACHES TO PELVIC FLOOR MUSCLE TRAINING FOR URINARY INCONTINENCE IN WOMEN

Pelvic floor muscle training (PFMT) is a first-line therapy for women with stress, urgency or mixed urinary incontinence (UI). Supervision and content of PFMT programmes is highly variable. The most effective approach to training is not known. The aim of the review was to compare the effects of different approaches to PFMT for women with UI. This was a systematic review with meta-analysis of randomized or quasi-randomized trials in women with stress, urgency or mixed UI that compared one approach to PFMT with another. The Cochrane Incontinence Group Specialised Trials Register (17 May 2011) was searched. Two reviewers independently assessed trials for eligibility and risk of bias, and extracted data. Data were analyzed as described in the Cochrane Handbook for Systematic Reviews of Interventions (version 5.2.2). From 574 records we included 21 trials (1490 women randomized) that addressed 11 comparisons. Comparisons made included: differences in training supervision (amount, individual versus group), in approach (one versus another, the effect of an additional component) and the exercise training (type of contraction, frequency of training). There were few trials or data in any comparison. In women with stress UI, 10% who received more health professional contact (weekly or twice-weekly group supervision plus individual appointments) did not report improvement compared to 43% who had individual appointments only (risk ratio for no improvement 0.29, 95% confidence interval 0.15 to 0.55, four trials). While women receiving more contact were more likely to report improvement, the confidence interval was wide, and more than half of "controls" reported improvement. This finding, of subjective improvement in both active treatment groups, with more improvement reported by those receiving more health professional contact, was consistent throughout the review. Considerable caution is needed in interpreting the results of the review. Existing evidence is insufficient to make any strong recommendations about the best approach to PFMT. A consistent pattern of more self-reported improvement with more health professional contact was observed; the few data consistently showed that women receiving regular (*e.g.* weekly) supervision were more likely to report improvement than women doing PFMT with little or no supervision. The clinical rehabilitation impact is to offer women reasonably frequent health professional contact during supervised PFMT.

KEY WORDS: Urinary incontinence -Women - Pelvic floor - Exercise therapy.

Corresponding author: E. J. C. Hay-Smith, Rehabilitation Teaching and Research Unit, Department of Medicine, University of Otago, Wellington, Mein Street, Wellington 6242, New Zealand.
E-mail: jean.hay-smith@otago.ac.nz

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

is particularly common amongst those in residential care.[1] For a variety of reasons (such as difference in study populations, definitions and measurement) estimates of UI prevalence differ widely. A recent comprehensive review of 36 epidemiological studies found that most reported a prevalence of "any" UI in the range of 25% to 45% for women; this estimate came from studies in which symptoms of UI were reported as "ever", "any" or "at least once in the past 12 months".[2] UI has a substantive and detrimental impact on quality of life.[3]

The two most common types of UI in women are stress UI and urgency UI.[2] Stress UI is typically experienced as involuntary urine leakage with cough, sneeze and other types of physical exertion, while urgency UI is characterised by involuntary urine leakage associated with urgency (that is, the sudden and compelling need to urinate).[4] Some women experience both stress UI and urgency UI; these women are said to have mixed UI.

The mechanisms underlying involuntary leakage in stress UI and urgency UI are different. In stress UI leakage results from insufficient urethral closure pressure during exertion that raises intra-abdominal pressure. The lack of urethral closure pressure is due to anatomic changes in the bladder and urethra (for instance, the bladder has prolapsed) and muscles (for example, the pelvic floor muscles are weak, do not lift the bladder neck, or generate sufficient urethral closure pressure). In urgency UI the problem is that a bladder (detrusor muscle) contraction generates sufficient bladder pressure to overwhelm the urethral closure pressure resulting in urine leakage; in urgency UI the problem is one of an overactive bladder muscle.

Because the underlying reason for leakage is different the choice of therapy may differ by type of UI. For example, women with urgency UI are commonly offered an anticholinergic drug to reduce overactive detrusor muscle contraction. Women with stress UI might be offered surgery that aims to increase urethral closure pressure. However, PFMT is commonly offered as first line therapy for all three main types of UI. PFMT aims to strengthen the pelvic floor muscles and improve urethral closure pressure (to ameliorate stress UI), and contraction of the pelvic floor muscle may reflexly inhibit a detrusor muscle contraction (to suppress urgency). For a more comprehensive background to the rationale for treatment of UI with PFMT, see Dumoulin and Hay-Smith.[5]

In a prior Cochrane systematic review Dumoulin and Hay-Smith (2010) concluded that there was support for the widespread recommendation that PFMT is offered as first-line conservative management programmes for women with stress, urge or mixed UI.[5] If effective, the corollary is whether one approach to training is more effective than another. The need to identify the optimal frequency and duration of supervised PFMT was recently identified as a priority as an outcome of a study to develop a methodology (using the James Lind criteria process) in which patients and clinicians worked together to identify and prioritise important UI research questions through consensus.[6]

The purpose of our review was to summarise the existing trials comparing different approaches to PFMT for UI in women to inform further research to address the existing uncertainty regarding optimal training. We tested the following hypothesis: there are differences in the effects of alternative approaches to PFMT in the management of urinary (stress, urge, mixed) incontinence in women. In addressing the hypothesis we specifically excluded trials of biofeedback assisted PFMT *versus* PFMT alone; a separate Cochrane review investigated the effect of adding biofeedback to PFMT.[7]

Materials and methods

We conducted the data collection and analysis in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (version 5.2.2).[8] The review methods are fully reported in the unabridged review available in the Cochrane Library.[9] Briefly, the methods are summarized here.

We included randomised and quasi-randomized (*e.g.* allocation by alternation) trials that recruited women with stress, urgency or mixed UI. Studies of antenatal and postnatal women, women with nocturnal enuresis, or women with incontinence associated with significant factors outside the urinary tract (*e.g.* neurological disorders, cognitive impairment, lack of independent mobility) were excluded. At least two arms of all included trials utilized PFMT to treat UI. PFMT was defined as any programme of repeated voluntary pelvic floor muscle contractions, irrespective of variations in purpose and training parameters. We further classified PFMT as "direct" or "indirect" PFMT. In "direct" PFMT woman focussed

specifically on a voluntary contraction of the pelvic floor muscles; in "indirect" PFMT the focus of contraction was "other" muscle group(s) (*e.g.* abdominal, hip or gluteal muscles) in order to facilitate or enhance or substitute for a direct pelvic floor muscle contraction.

The primary outcomes of interest for the review were the woman's observations of change (cure or improvement) in symptoms, and incontinence-specific quality of life; these choices reflected the findings of a recent study of women with UI who identified these as important outcomes to be measured in incontinence research.[10] Secondary outcomes included quantification of symptoms (*e.g.* leakage episodes), clinician measures (*e.g.* pelvic floor muscle function), health status and generic quality of life, socioeconomics, treatment adherence, and adverse events.

We identified relevant trials from the Cochrane Incontinence Group Specialised Trials Register (see the 'Specialized Register' section of the Group's module in the Cochrane Library). The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and CINAHL, and hand-searching of journals and conference proceedings. The date of the last search was: 17 May 2011. We did not impose any restrictions, for example language or publication status, on the searches. Two review authors independently evaluated records of all studies retrieved in the search and immediately excluded, after cross-checking, studies that were ineligible on the basis of title or abstract alone (*e.g.* the trial recruited only men or children). The full text of all remaining records was retrieved.

Two authors independently evaluated eligibility, assessed risk of bias (using the Cochrane "risk of bias" assessment tool) and extracted the study data. Eligibility, risk of bias, and extracted data were cross-checked and all disagreements were resolved through discussion. Data entry was carried out by one author and cross-checked by another. Where one of the review authors was an author of a study identified by the search, that review author had no involvement in deciding eligibility, risk of bias, or extracting data.

For categorical outcomes such as self-reported cure we related the numbers reporting an outcome to the numbers at risk in each group to derive a risk ratio. We dichotomized ordinal data (such as Likert scales for symptom improvement) and managed them as a categorical outcome. For continuous variables such as quality of life score we used means and standard deviations to derive mean differences. We treated count data (such as leakage episodes, which were considered a relatively common event) as continuous data.

If there were enough trials, the results were pooled in meta-analysis using fixed-effect models unless otherwise stated. Data analysis was on an intention-to-treat basis as far as possible, and we made attempts to obtain missing data from the trialists. Statistical heterogeneity was assessed in three ways: visual examination of the forest plots; χ^2 test ($P<0.10$) for heterogeneity and I^2 statistics. An I^2 statistic measurement greater than 50% was taken to indicate substantial heterogeneity. We sought and discussed plausible explanations for statistically significant heterogeneity. If meta-analysis was not considered appropriate we discussed the findings of studies in a narrative synthesis.

Results

The search produced 574 study records from which 55 potentially eligible study reports were identified. We included 40 reports of 21 studies, two studies (three reports) were ongoing, and we excluded 11 studies (12 reports) (Figure 1). One of the 21 included trials had three arms (and two comparisons) eligible for inclusion in the review. The two comparisons were identified separately in the data analysis as Sriboonreung 2011a (daily *versus* three times weekly PFMT), and Sriboonreung 2011b (three times weekly PFMT *versus* three times weekly PFMT with abdominal muscle training).

Summary of included trials

Full details of the 21 included trials and risk of bias assessment are described in the unabridged version of the Cochrane review.[9] Briefly, the 21 trials randomised 1490 women. Fifteen trials recruited women with stress UI only,[11-25] two included women with stress or stress predominant mixed UI,[26, 27] three included stress or mixed UI,[28-30] one mixed UI only.[31] Nine trials set an age limit that excluded older women.[12, 13, 17-19, 21, 24, 28, 29] Based on median or mean age the trials recruited women aged: up to 45 years;[11, 16] 45 to 49 years;[20, 21, 27, 28] 50 to 54 years;[12, 13, 15, 19, 23, 24, 26, 29, 31] 55 years or more.[14, 17, 18, 25, 30]

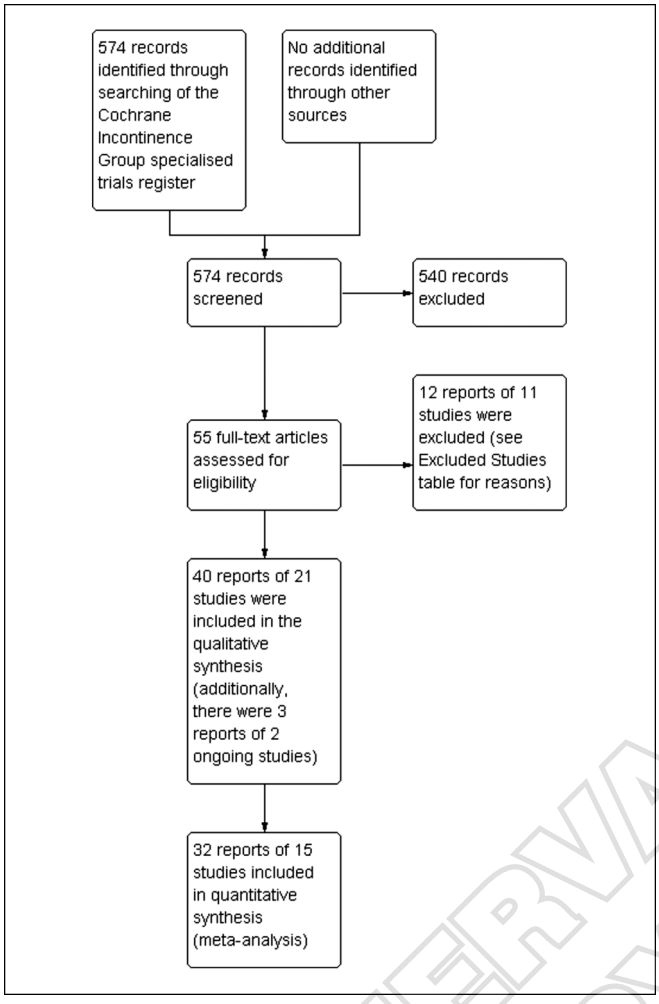

Figure 1.—Search and screening flowchart.

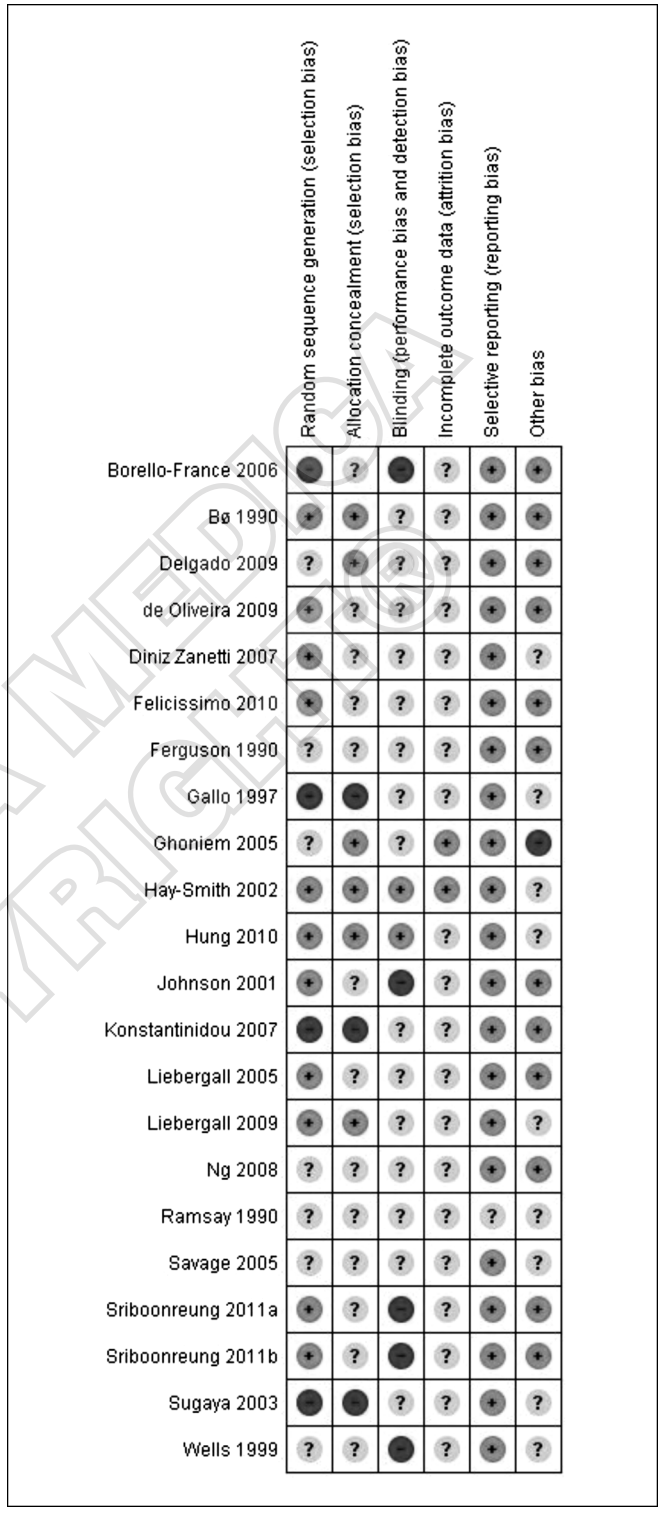

Figure 2.—Risk of bias summary.

About half (12 of 21 trials) reported symptom duration. Wells (1999) stated that 68% of women had symptoms for more than one year. The approximate mean or median duration of symptoms in the other 11 trials was five years [13-15, 26] or up to 10 years.[11, 20, 23, 25, 27, 28] No other demographic characteristics were consistently reported.

Risk of bias assessment is summarised in Figure 2. Overall, with regard to random allocation and concealment, we considered: six trials were at low risk of bias [11, 18, 21, 26-28] because there was sufficient detail reported to be sure the method of generating a random sequence was genuinely random and allocation was concealed; four were at high risk of bias;[12, 17, 20, 25] and for the remainder the risk of bias

was unclear. The rating given for performance and detection bias in Figure 2 is based solely on blinding of outcome assessment (or detection bias) because it is difficult to blind participants to an intervention such as PFMT [although Ghoniem *et al.* (2005) and Ramsay and Thow (1990) attempted this] and we considered that none of the trials could blind treatment providers. All trials could blind outcome assessment of some or all outcomes, although the primary outcomes we selected for the review were self-reported and therefore could not be blinded. Only three trials clearly stated that outcome assessment was blinded for one or more of the outcomes of interest in the review [23, 27, 28] and two trials stated that a lack of blind outcome assessment was a limitation.[24, 30] The proportion of losses to follow up and incomplete outcome data (attrition bias) ranged from 0 to 45%. Aside from the four trials that did not clearly state the number of losses to follow-up by treatment group [13, 18, 19, 26] it seemed there were no substantive differences in the proportion of losses to follow up across the treatment arms. None of the included trials met both criteria (analysed by group assignment and a reasonable method for imputing missing data) for a full intention-to-treat analysis.

Interventions

Seventeen trials made a clear cut ('unconfounded') comparison of interventions. In 13 instances the control group received PFMT and the experimental group had the same PFMT programme with an additional intervention, specifically:

— more health professional contact in the form of an exercise class including PFMT,[11, 15, 20] individual appointments [14] or phone calls;[31]
— an intravaginal resistance device;[16, 26, 30]
— a cue to exercise;[17, 25]
— two more exercise positions;[12]
— a strength training programme;[27]
— an abdominal muscle exercise programme.[24]

In another four studies, the trialists kept all aspects of the intervention the same in all respects except one. These were direct comparisons of:

— "indirect" *versus* "direct" PFMT.[18, 22, 23] In Ghoniem *et al.* (2005) and Ramsay and Thow (1990) the "indirect" training group were asked to cross their ankles and do isometric hip abductor contractions, and in Savage (2005) the "indirect" training group were doing a Pilates exercise programme;
— submaximal *versus* near maximal pelvic floor muscle contractions;[19]
— Daily PFMT *versus* PFMT three times a week.[24]

In the remaining four trials there were multiple differences between the intervention groups, such as differences in both the PFMT programmes and the amount of health professional contact. These trials contributed to more than one comparison in the analysis. It was difficult to be sure how to attribute any differences in outcome between the trial arms because each comparison was potentially confounded by at least one other intervention variable. The four trials compared:

— "indirect" PFMT for 15 to 45 minutes per day with weekly individual supervision *versus* "direct" PFMT of 15 minutes per day with weekly group supervision;[21, 29] the "indirect" PFMT was the "Paula" method;
— "indirect" PFMT and fortnightly clinic visits *versus* "direct" PFMT and no clinic visits;[28] the "indirect" PFMT was a breathing, abdominal and pelvic floor muscle rehabilitation programme;
— "standard" PFMT with twice-weekly group supervision *versus* "individualized" PFMT with twice-weekly individual supervision.[13]

Summary of comparisons

All data from each of the 11 comparisons in the Cochrane review are available in the full version.[9] The 11 comparisons were:

— more *versus* less contact with health professionals;
— group *versus* individual supervision of PFMT;
— direct *versus* indirect methods of PFMT;
— individualized *versus* generic PFMT;
— near maximal *versus* submaximal contractions;
— daily *versus* three times per week PFMT;
— upright and supine *versus* supine exercise positions alone;
— strength and motor learning *versus* motor learning PFMT alone;
— PFMT and abdominal muscle exercise *versus* PFMT alone;
— PFMT with intravaginal resistance device *versus* PFMT alone;
— PFMT with adherence strategy *versus* PFMT alone.

We selected one comparison (more *versus* less contact with health professionals), the one with

most data for meta-analysis to present here. We also report a *post-hoc* comparison performed to investigate our impression that outcomes tended to favour the most intensive intervention within any of the 11 comparisons; the "all in one analysis" of the trials was made according to the degree of contrast in intervention intensity.

Three outcomes had sufficient useable data for meta-analysis (no self-reported cure, no self-reported cure or improvement, leakage episodes in 24 hours). For cure and improvement, trialists reported data in the affirmative; that is, whether participants were better. So long as we could categorise the data into "cured" or "improved" we calculated the inverse (*i.e.* not cured, not improved) and entered these data into the meta-analysis, regardless of what instrument was used. We did not include any data where the definition of cure or improvement was based on something other than the patient's perception of their UI (e.g. pad test cure, or no leakage episodes in a urinary diary, or clinician's perception). Other outcomes were subject to a narrative synthesis.

More versus less health professional contact

Six trials, in three subgroups, contributed to this comparison. The subgroups were "additional group supervision", "additional phone calls", and "individual supervision *versus* no supervision (difference in PFMT)". The interventions are described in more detail in Table I.

Four trials formed the "additional group supervision' subgroup. Three had the same home PFMT programme and individual clinic appointments in both trial arms, and investigated the effect of adding an exercise class that included PFMT (weekly 45-minute exercise class;[11] twice-weekly 50-minute exercise class;[15] weekly group session).[20] A fourth trial also added twice-weekly 45-minute exercise sessions [14] although it was not clear if this was individual or group supervised exercise. We grouped the trial by Dinez Zanetti *et al.* (2007) with those of Bø *et al.* (1990), Felicissimo *et al.* (2010) and Konstantinidou *et al.* (2007) for analysis because of the similarity in the amount and frequency of extra health professional contact. All four trials recruited women with urodynamic stress UI. Bø *et al.* (1990) was the only one of the four trials judged to be at low risk of bias based on reporting of random sequence generation and allocation concealment; Konstantinidou *et al.* (2007) was considered at high risk. The other two trials were categorised as unclear risk of bias.

The second subgroup, "additional phone calls", comprised a single trial that had the same home PFMT programme in both trial arms and investigated the effect of adding twice-weekly phone calls [31] after the initial period of face-to-face contact with a health professional. This trial recruited women with mixed UI. Based on reporting of random sequence generation and allocation concealment, the trial was judged as having an unclear risk of bias.

A single trial comprised the third subgroup, "individual supervision *versus* no supervision (difference in PFMT)"; this trial had differences the amount of health professional contact and also differences in the PFMT programme between groups.[28] The trial recruited women with stress or mixed UI. One treatment group was given advice and instruction in a home PFMT programme ("direct" PFMT), with no further health professional contact. The other treatment group completed a structured 16-week programme of "indirect" PFMT (a combination of diaphragmatic, trans*versus* abdominus and combined trans*versus* abdominus/pelvic floor muscle contraction) with fortnightly clinic visits for four months; the "indirect" group were asked not to perform isolated voluntary pelvic floor muscle contractions during the intervention period. Thus, we categorised the trial as a comparison of both "direct" *versus* "indirect" PFMT, and more *versus* less health professional contact. While the trial was judged at low risk of bias (for random sequence generation and random allocation), the multiple comparisons mean that it is difficult to be sure if the treatment outcome is attributable to one, both, or a combination, of the treatment variables.

The patient's perception of cure or improvement was measured in a variety of ways (Table II). Fewer women were still incontinent in the group that received additional group supervision (risk ratio [RR] for no cure 0.89, 95% confidence interval [CI] 0.78 to 1.03, two trials, Figure 3), although the difference was not statistically significant. Hung *et al.* (2010) did not find any statistically significant difference between the supervised and unsupervised groups (RR for no cure 0.86, 95% CI 0.73 to 1.02, Figure 3). Ng *et al.* (2008) reported the odds ratio (OR) (95% CI) of the difference between groups for their responses to two items from the Bristol Female Lower Urinary Tract Symptoms questionnaire (whether they did or did not have symptoms of stress or urgency UI). For both

TABLE I.—*Interventions in trials comparing more versus less health professional contact.*

Trial	Our categorisation	Intervention	Duration	Supervision
Bø *et al.* 1990 [11]	Less contact	Correct VPFMC confirmed. PFMT: 8 to 12 near maximal contractions (with 6 to 8 sec hold and rests) 3 times daily. Monthly clinic visits for perineometer biofeedback of PFM strength.	6 months	Physiotherapist monthly
	More contact	As above, with addition of weekly 45-min group exercise session which included PFMT, abdominal, gluteal and thigh exercises. The PFMT comprised near maximal contractions for 6 to 8 sec each and 3 to 4 fast contractions, repeated 8 to 12 times, in standing, sitting, lying and kneeling positions.	6 months	As above, plus weekly in a group
Dinez Zanetti *et al.* (2007) [14]	Less contact	PFMT: 10 contractions with 5-sec hold and 5-sec rest, 20 contractions of 1-sec hold and 1-sec rest, 5 contractions of 10-sec hold and 10-sec rest, 5 strong contractions with cough, and 1-minute intervals between sets. Monthly clinic visits for assessment only.	12 weeks	Physiotherapist monthly
	More contact	PFMT as above, with 45-min twice-weekly supervision (no clear if individual or group)	12 weeks	Physiotherapist monthly, plus fortnightly in a group?
Felicissimo *et al.* (2010) [15]	Less contact	Correct VPFMC confirmed. PFMT: 10 contractions with 6-sec hold and 12-sec rest in different positions 9 (?) times per day. Start with 90 contractions in first week, then 180 a day for remaining 7 weeks.	8 weeks	Physiotherapist at initial session
	More contact	As above, with addition of twice-weekly 50-min group exercise session.	8 weeks	As above, plus twice weekly in a group
Hung *et al.* (2010) [28]	Less contact	Correct VPFMC confirmed. Oral instruction in PFMT. No other detail given.	16 weeks	None
	More contact	Correct VPFMC confirmed. 'Indirect' PFMT: weeks 1 to 4 diaphragmatic breathing, weeks 2 to 5 tonic transversus abdominus and PFM activation, weeks 4 to 7 tonic activation with activities of daily living and walking, weeks 6 to 16 muscle strengthening, weeks 8 to 16 functional expiratory patterns, and weeks 10 to 16 impact activities. A very full description of the programme is given in the paper by Hung *et al.* (2010). Participants in this group were "asked not to perform isolated voluntary pelvic floor muscle contraction exercise during the intervention period".	16 weeks	Fortnightly with physiotherapist
Konstantinidou *et al.* (2007) [20]	Less contact	Correct VPFMC confirmed. PFMT: Individualised programme of 3 sets of fast contractions, 3 to 4 sets of slow contractions daily in lying, standing and sitting positions. Individual follow-up in hospital every 4 weeks.	12 weeks	Physiotherapist monthly
	More contact	As above, with addition of weekly exercise group	12 weeks	As above, plus weekly in a group
Ng *et al.* (2008) [31]	Less contact	Not clear if correct VPFMC confirmed. Home PFMT progressing to "50 to 75 contractions three times a day". Taught urgency strategies. One-hour clinic visits twice a week for 4 weeks with nurse.	6 months?	Nurse twice a week for 4 weeks
	More contact	As above, then phone calls twice a week from the nurse after cessation of clinic visits to encourage exercise.	6 months?	Nurse twice a week for 4 weeks, then twice weekly phone calls

Sec: second(s); VPFMC: voluntary pelvic floor muscle contraction

items the group receiving phone calls had reduced odds of stress or urgency UI (OR 0.49, 95% CI 0.31 to 0.76 and OR 0.40, 95% CI 0.24 to 0.66 respectively).

Ten per cent (9 of 87) of those who received weekly or twice-weekly group supervision in addition to individual appointments with the therapist did not report improvement post-treatment compared to 43% (39 of 90) of the group who had individual appointments only (RR for no improvement 0.29, 95% CI 0.15 to 0.55, four trials, Figure 4).

TABLE II.—*Categorization of self-reported cure and improvement.*

Trial	Our categorisation	Trialists' definition	Instrument used
Bø *et al.* (1990) [11]	cure	"continent"	5 point Likert scale (worse to continent)
	improved	"almost continent" and "some improvement"	
Delgado *et al.* (2009) [26]	cure	"never"	5-point Likert scale (never to all of time) for question 11a of the ICIQ-FLUTS (Does urine leak when you are physically active, exert yourself, cough or sneeze?)
	improved	"Improvement" is positive change by two or more points on the scale	
de Oliveira *et al.* (2009) [13]	improved	"Subjective" cure if satisfied	How patient felt after treatment - satisfied or dissatisfied
Dinez Zanetti *et al.* (2007) [14]	improved	"yes"	Satisfied with improvement and did not want further therapy
Felicissimo *et al.* (2010) [15]	cure	"cured"	4 point Likert scale (worse to cured)
	improved	"better"	
Konstantinidou *et al.* (2007) [20]	improved	"yes"	Patient global assessment of improvement
Ghoniem *et al.* (2005) [18]	improved	"a little better", "much better", "very much better"	Patient global assessment of improvement
Hay-Smith (2003) [27]	cure	"cured"	6 point Likert scale (much worse to cured)
	improved	"much better" and "somewhat improved"	
Hung *et al.* (2010) [28]	cure	"cured"	4 point Likert scale (worse to cured)
	improved	"improved"	
Ramsay and Thow (1990) [22]	improved	"improvement"	"Subjective"
Sriboonreung *et al.* (2011) [24]	cure	"continent"	"satisfaction with their incontinence condition" on a 5 point Likert scale (worse to continent)
	improved	"almost continent"	
Sugaya *et al.* (2003) [25]	improved	"delighted", and "pleased" and "mostly satisfied"	"Quality of life index for urination" using a 7 point Likert-type scale for responses (terrible to delighted)
Wells *et al.* (1999) [30]	cure	"cure" is "no post-treatment wetting"	10 point visual analogue scale (a lot of leakage to no leakage)
	improved	"better" is 2 or more point lower	

Looking at this another way, 90% of those who had combined group and individual supervision reported improvement *versus* 57% of women receiving individual supervision only. Thus, women receiving additional group supervision were more likely to report their UI was improved. Similarly, Hung and colleagues (2010) found women in the supervised group were more likely to improve (RR for no improvement 0.10, 95% CI 0.01 to 0.71, Figure 4).

Only one of the four trials investigating the effect of additional group supervision measured leakage episodes.[20] The women receiving additional supervision had fewer leakage episodes per day (mean difference [MD] -1.38, 95% CI -2.04 to -0.72). Because the data came from a single trial, potentially at high risk of bias, we were cautious about the interpretation of this finding. Hung *et al.* (2010) also measured leakage episodes and found no differences between the supervision and no supervision groups (median 0 leaks per day, IQR 0 to 0.3, in both groups).

Two trials used validated measures of incontinence-specific quality of life but chose different measures.[14, 15] Konstantinidou *et al.* (2007) used a single item measure of unknown origin, which we categorised as a measure of symptom impact (a secondary outcome in the review). The difference between the randomised groups could not be statistically evaluated; it was difficult to tell if the higher contact group had better incontinence-specific quality of life. With regard to the secondary outcomes, the pattern was not consistent although the findings were either of no difference between the groups or were in favour of the group with more health professional contact. There were no findings statistically significantly in favour of the group with less health professional contact.

More versus *less intensive PFMT*

The post-hoc, "all in one analysis" of trials, was made according to the "contrast" in intervention intensity. We used three categories (high, moderate

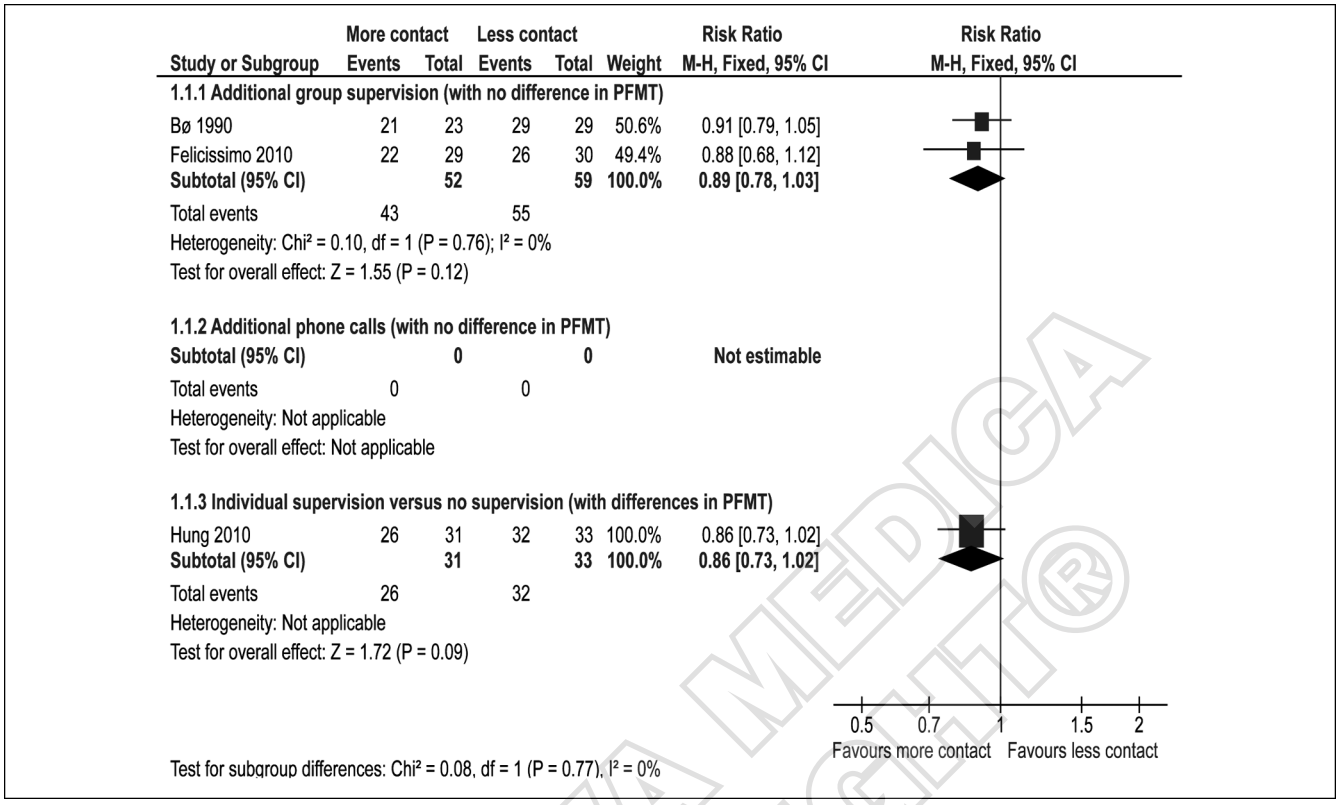

Figure 3.—Meta-analysis of no self reported cure in trials comparing more versus less health professional contact.

and low contrast comparisons), summarized in Table III. Two criteria were used as the basis for categorization the amount of face-to-face health professional contact and the exercise intensity. We used a random-effects model for the pooled data in the "all in one" analysis, as there was considerable heterogeneity in the trials, and a random-effects model gave a more conservative estimate of effect.

To be categorized as a "High" contrast in health professional contact there was at least five times more face-to-face contact in one arm compared to the other. Trials were categorized as "Low" contrast if the number of face-to-face contacts was the same but the type of contact (*e.g.* individual *versus* group) differed. Any other differences in contact were classified as "moderate" contrast.

For exercise intensity, trials that compared a "direct" *versus* "indirect" PFMT were classified as "high" contrast comparisons. "Low" contrasts in exercise intensity were trials in which direct PFMT was used in both arms, with some difference in type of contraction (*e.g.* near maximal *versus* maximal), frequency of exercise (*e.g.* daily *versus* three times a week) or an additional element (such as intravaginal resistance, or adherence strategy). Any other differences in exercise intensity were classified as "moderate" contrast.

Figure 5, the meta-analysis of no cure, contained trials making "High" and "Low" contrast comparisons. In the "High" contrast comparison 83% of women (69 of 83) receiving the most intensive therapy were not cured *versus* 95% of the less intensive therapy group (87 of 92), a difference of 8% statistically significantly in favour of more intensive PFMT (RR for no cure 0.89, 95% CI 0.80 to 0.98, 3 trials, Figure 5). All three trials in this subgroup had substantively more health professional contact in the more 'intensive' treatment arm, with no difference in the PFMT programme. On the contrary, in the "Low" contrast comparison 92% of the more intensive therapy group (148 of 161) were not cured *versus* 88% of the less intensive therapy group (126 of 143), a near to statistically significant difference of 4% in

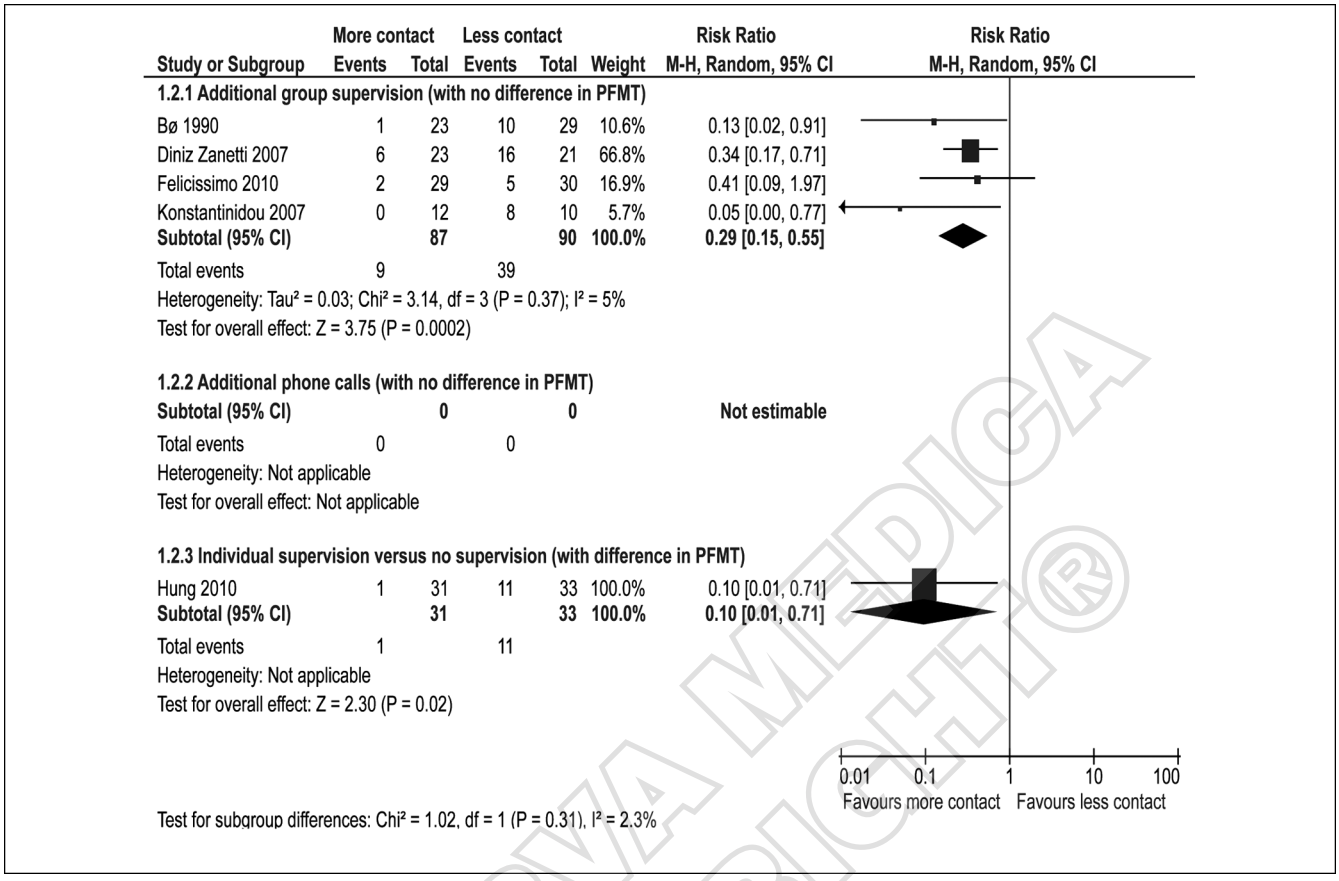

Figure 4.—Meta-analysis of no self reported improvement in trials comparing more versus less health professional contact.

favour of the less intensive intervention (RR for no cure 1.06, 95% CI 1.00 to 1.13, 3 trials, Figure 5).

In the meta-analysis of no self-reported improvement (Figure 6) there was a statistically significant difference in each subgroup (high, moderate and low contrast comparisons) in favour of the more intensive PFMT programmes, with greater treatment effect where there was stronger contrast. Statistically significant heterogeneity (I^2=61%) was observed in the "High" contrast subgroup. Visual inspection suggested the trials by Ghoniem *et al.* (2005) and Ramsay and Thow (1990) contributed to the observed heterogeneity. Both trials compared PFMT with sham PFMT (with the same health professional contact in both groups) whereas the other trials had a high contrast in the amount of health professional contact between the trial arms. When the two trials by Ghoniem *et al.*, and Ramsay and Thow, are removed from the subgroup analysis the likelihood of improvement increased and there was no statistically significant heterogeneity (RR for no improvement 0.17, 95% CI 0.06 to 0.44, I^2=0%).

Fewer trials contributed data to the meta-analysis of number of leakage episodes in 24 hours (Figure 7) and all but one trial was a "Low" contrast comparison. The single "High" contrast trial found the intensive intervention group had, on average, four fewer leakage episodes every three days compared to the less intensive therapy group (MD -1.38, 95% CI -2.04 to -0.72). No statistically significant difference was seen in the "Low" contrast subgroup (MD -0.03, 95% CI -0.19 to 0.14, 6 trials).

Discussion

The primary objective of this review was to consider whether one approach to PFMT was better

TABLE III.—*Categorisation of included trials into high, moderate and low contrast interventions.*

Our categorisation	Trial	Contact intensity	Exercise intensity
"High" contrast	Bø *et al.* (1990) [11]	High contrast: 6 individual and 24 group contacts versus 6 individual contacts	No contrast: same PFMT
	Felicissimo *et al.* (2010) [15]	High contrast: 1 individual and 16 group contacts versus 1 individual contact	No contrast: same PFMT
	Ghoniem *et al.* (2005) [18]	No contrast: same amount of contact	High contrast: 'indirect' PFMT (sham PFMT) versus 'direct' PFMT
	Hung *et al.* (2010) [28]	High contrast: 8 individual versus no contacts	Moderate contrast: 'indirect' PFMT (transversus abdominus initiated PFMT) versus 'direct' PFMT
	Konstantinidou *et al.* (2007) [20]	High contrast: 3 individual and 12 group contacts versus 3 individual contacts	No contrast: same PFMT
	Ramsay and Thow (1990) [22]	No contrast: same amount of contact	High contrast: 'indirect' PFMT (sham PFMT) versus 'direct' PFMT
	Savage (2005) [23]	No contrast: same amount of contact	High contrast: 'indirect' PFMT (Pilates) versus 'direct' PFMT
"Moderate" contrast	Dinez Zanetti *et al.* (2007) [14]	Moderate contrast: 3 individual and 6 group contacts versus 3 individual contacts	No contrast: same PFMT
	Liebergall-Wischnitzer *et al.* (2005) [29]	Moderate contrast: 12 individual versus 4 group contacts	Moderate contrast: 'indirect' PFMT (Paula method) versus 'direct' PFMT
	Liebergall-Wischnitzer *et al.* (2009) [21]	Moderate contrast: 12 individual versus 6 group contacts	Moderate contrast: 'indirect' PFMT (Paula method) versus 'direct' PFMT
	Ng *et al.* (2008) [31]	Moderate contrast: 8 individual and 40 phone contacts	No contrast: same PFMT
"Low" contrast	Borello-France *et al.* (2006) [12]	No contrast: same amount of contact	Low contrast: upright and supine PFMT versus supine PFMT
	Delgado *et al.* (2009) [26]	No contrast: same amount of contact	Low contrast: PFMT plus intravaginal resistance device versus PFMT
	de Oliveira *et al.* (2009) [13]	Low contrast: 12 individual versus 12 group contacts	Low contrast: individualised versus generic PFMT
	Ferguson *et al.* (1990) [16]	No contrast: same amount of contact	Low contrast: PFMT plus intravaginal resistance device versus PFMT
	Gallo and Staskin (1997) [17]	No contrast: same amount of contact	Low contrast: PFMT plus adherence strategy versus PFMT
	Hay-Smith (2003) [27]	No contrast: same amount of contact	Low contrast: strengthening with motor relearning PFMT versus motor relearning alone
	Johnson (2001) [19]	No contrast: same amount of contact	Low contrast: near maximal versus submaximal PFM contractions
	Sriboonreung 2011a [24]	No contrast: same amount of contact	Low contrast: daily PFMT versus 3x weekly PFMT
	Sriboonreung 2011b [24]	No contrast: same amount of contact	Low contrast: PFMT plus abdominal muscle exercises versus PFMT
	Sugaya *et al.* (2003) [25]	No contrast: same amount of contact	Low contrast: PFMT plus adherence strategy versus PFMT
	Wells *et al.* (1999) [30]	No contrast: same amount of contact	Low contrast: PFMT plus intravaginal resistance device versus PFMT

than another. Overall, there were few data from 21 studies, spread over 11 primary comparisons. The maximum number of trials in any comparison was six. Further, the design of some trials meant that more than one treatment variable differed between the comparison groups; these trials were interpreted cautiously because we were not sure which of the experimental variables contributed to the observed effects. A 12th comparison, that pooled the data from the 11 primary comparisons, was a post hoc subgroup analysis. The heterogeneity of interventions in the "all in one analysis" was considerable; we considered this analysis was exploratory and was most useful for generating hypotheses or assisting

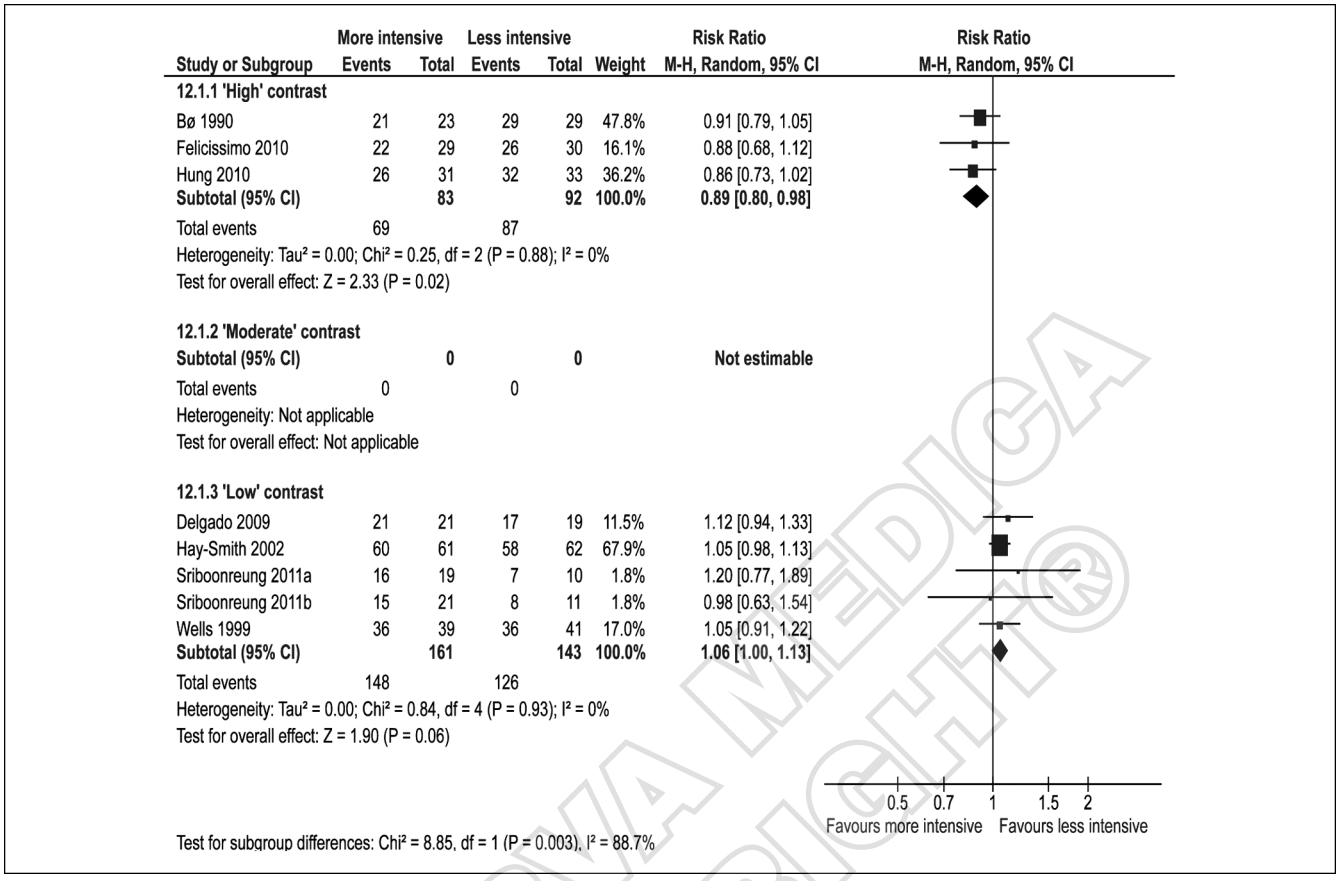

Figure 5.—Meta-analysis of no self reported cure in "all in one" analysis.

with trial design for further research. With these cautions in mind, the review conclusions are tentative rather than strong.

Amount of health professional contact during PFMT

In the comparison of more *versus* less contact with health professionals, (six trials, three subgroups) the trial arms with more contact were consistently more likely to report cure and improvement although there was insufficient evidence to be sure that the self reported improvement was echoed in incontinence-specific quality of life or more "objective" incontinence measures such as leakage episodes. Credible explanations for the effect include improved adherence or effort with more attention (*e.g.* women may be prompted to exercise more often and work harder, increasing the exercise dose), and a class environment could provide social benefits that are reflected in how women feel about UI and PFMT.

An alternative plausible explanation is that the observed benefit is 'experimenter effect' (32), because the potential for experimenter effect is perhaps greatest in those trials where one group receives substantively more health professional contact than the other. Further, none of the trials could feasibly blind women or treatment providers to treatment assignment so those getting more attention knew it. The two outcomes for which there were most data (no self-reported cure or improvement) could be influenced by attention; women receiving more attention may over-estimate their improvement to please the treatment provider.

Imamura *et al.* (2010) in a large and robust systematic review of all conservative treatments for stress

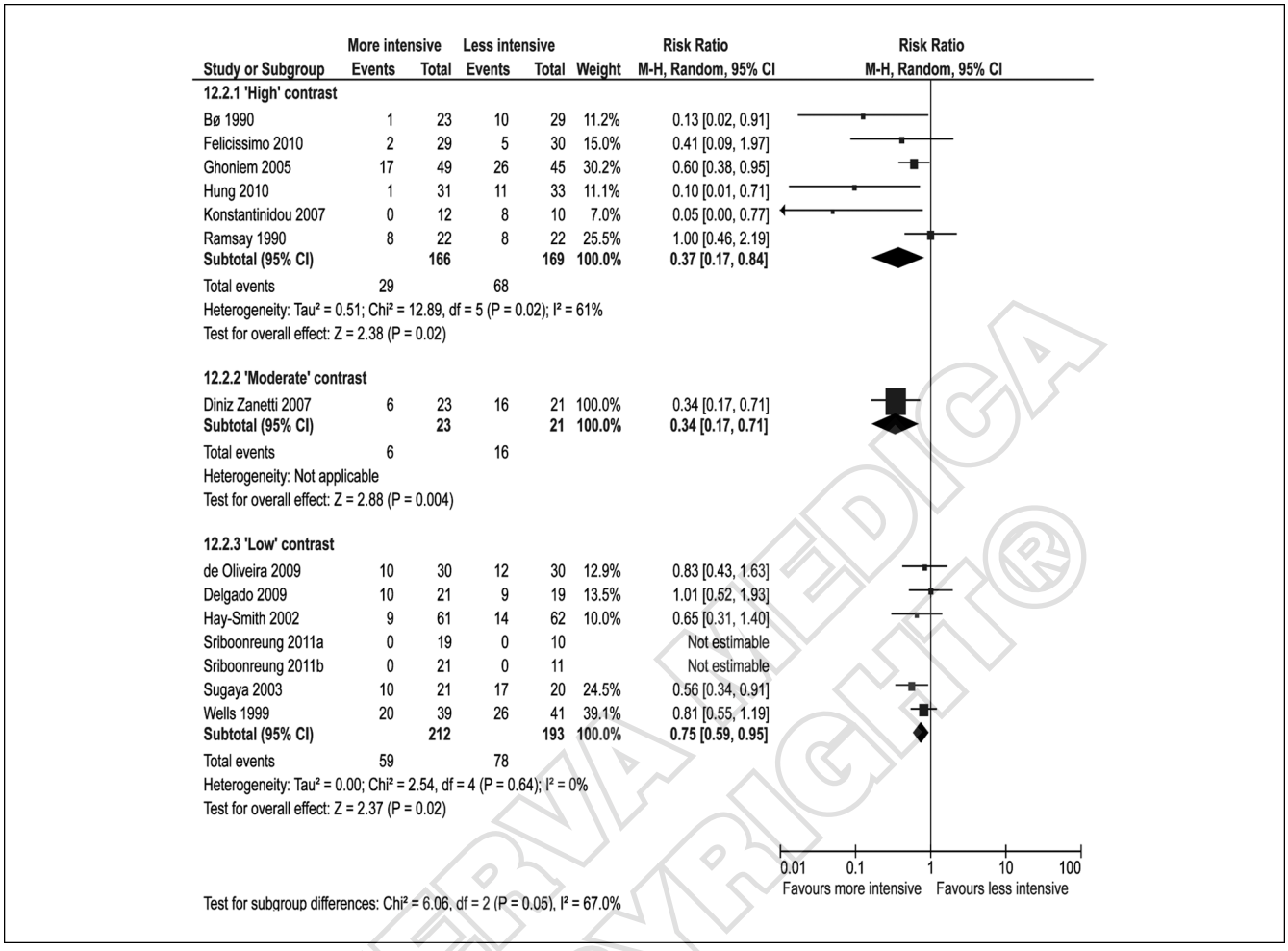

Figure 6.—Meta-analysis of no self reported improvement in "all in one" analysis.

UI in women found that more intensive PFMT intervention (either extra sessions with a health professional or the addition of biofeedback) was the most effective non-surgical treatment.[33] Thus, the findings of Imamura *et al.* (2010) and the present review appear congruent regarding more health professional contact. The more detailed analysis of the trials that was possible (because of the more limited scope) in our review has highlighted the difficulty with interpreting this finding about the benefit of more health professional contact, including the plausibility of experimenter effects and potential confounding by differences in PFMT over and above differences in contact.

Probably the only way to tease out the effect of attention is, where there is some difference in the amount of health professional contact between trial arms, for the trial to include attention control. For example, in a study of pelvic floor muscle rehabilitation in women with persistent postnatal UI, Dumoulin *et al.* (2004) provided attention control by providing relaxation massage in one arm (which was unlikely to affect self-reported incontinence); incidentally, Dumoulin *et al.* (2004) demonstrated a statistically significant difference in self-reported improvement in favour of PFM rehabilitation (compared with attentional controls).[34] Essentially, researchers who want to find out if

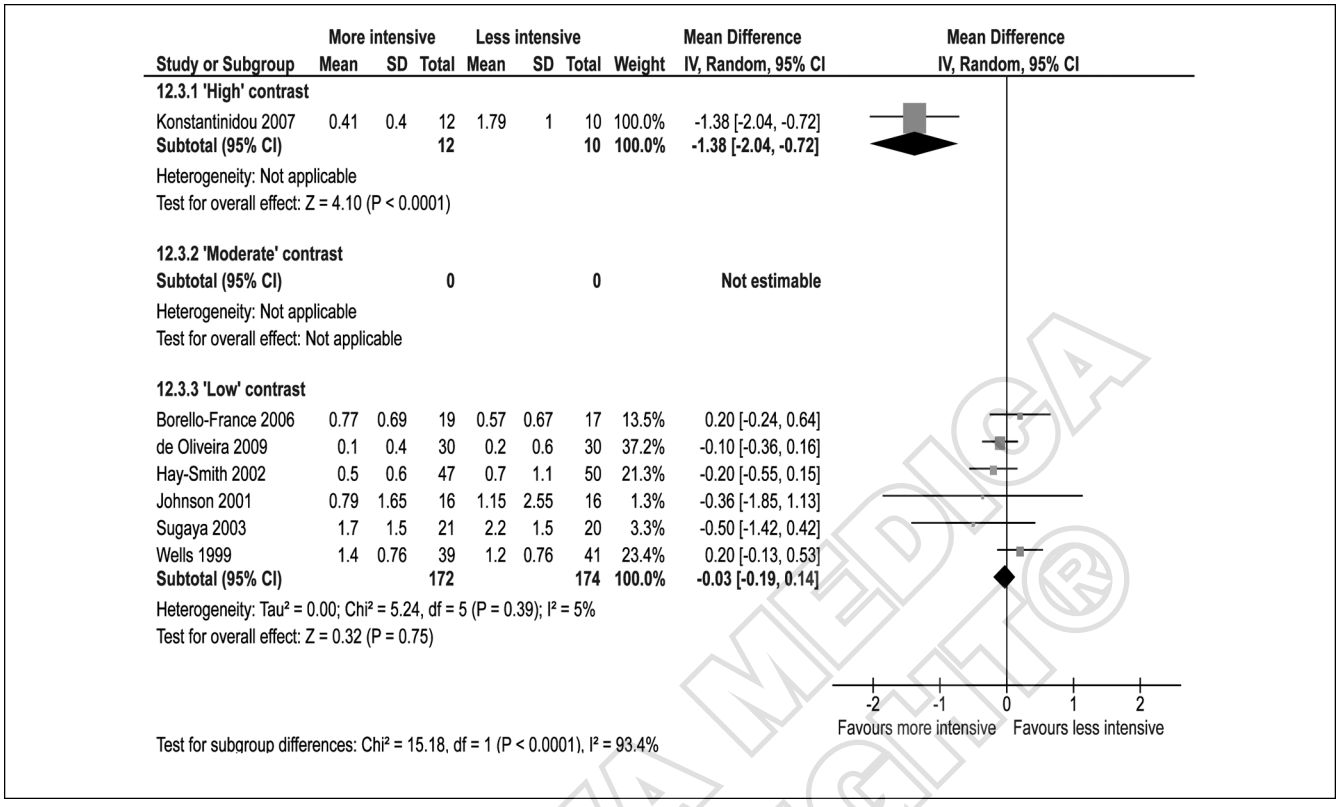

Figure 7.—Meta-analysis of number of leakage episodes in 24 hours in "all in one" analysis.

a new or experimental approach to PFMT is better than an existing or standard approach need to carefully consider the potential for confounding study outcome if the comparison also includes differences in health professional contact between trial arms.

Comment on "all in one" analysis

The consistent pattern in the "all in one analysis" was that the higher the contrast in intervention intensity the more likely it was that there was a statistically significant difference in favour of the more intensive therapy group. The summary statistics from the "High" contrast subgroups were statistically significantly in favour of the more 'intensive' interventions for all three outcomes. Finding more difference in outcome when there is greater contrast in intensity of intervention seems logical. Interpreting the meaning of this difference is less straightforward. For example, we have already raised the possibility that the lack of attentional control means "experimenter" effect cannot be excluded in unblinded outcomes such as self reported cure and improvement.

The summary statistics for the "Low" contrast subgroups were in favour of the more intensive interventions for self reported improvement, but were consistent with no benefit for self reported cure (although this was very close to statistical significance in favour of the less intensive intervention) or for leakage episodes in 24 hours. The close to statistically significant difference in favour of the less intensive intervention for self reported cure was interesting. It is possible that those women who concentrated on a more "basic" PFMT programme benefited from putting their full efforts into this, and were less distracted by additional elements (such as using adjuncts like intravaginal resistance devices or rotating their exercises through multiple body positions). However, the finding for self reported improvement was just in favour of the more intensive intervention, so the inconsistency in the cure and

improvement outcomes means we remain uncertain about the importance of the possible difference in the former.

Most of the trials in the review recruited only women with stress UI or predominant stress UI who were on average about 50 years of age, and a mean duration of symptoms of at least five years. This distribution of mean or median age is congruent with stress UI as the most common diagnostic category for the included trials. Urgency and urgency UI become more prevalent in older age. Therefore, we consider the review findings are most applicable to women with stress UI as their only or predominant symptom, and suggest the review findings cannot be assumed to apply to women with urgency UI as their only or predominant symptom. Trials are needed to address questions about the effectiveness of different approaches to PFMT in women with urgency UI or mixed symptoms.

The outcome that matters most to women with UI is probably incontinence-specific quality of life.[10] Unfortunately the few data for this outcome were not reported in ways that could be used in meta-analysis. If data from psychometrically robust incontinence-specific quality of life measures was also consistent with the findings discussed above (more effect in more intensive contact arm), we would feel more confident that any differences were clinically important. We would also feel more confident if there were more supporting data for more "objective" outcomes (such as leakage episodes). So far, the pattern appears similar from the few data on leakage episodes but more data are needed.

Finally, the "all in one" analysis highlighted that at least half of women receiving a 'less intensive' but active PFMT intervention (that is, the 'control' conditions) were likely to report improvement post-treatment. Interventions with more health professional contact increased the proportion of women reporting improvement, but there might be a trade-off between the resource implications of an intensively supervised programme and the opportunity cost this represents if at least half of women do improve with less intensive supervision. However, we do not have sufficient evidence from follow-up studies to know if there is a difference in medium to longer-term outcomes between more and less intensively supervised groups, which might change estimates of cost/benefit.

Trials that compare two approaches to PFMT are comparisons of two active treatments; it seems differences between treatments might only be observed if there is a high contrast in intervention intensity. Therefore, it might be difficult to find out which approaches to PFMT are best unless: 1) the differences in outcome are large; 2) a trial is powered to find small to moderate differences in outcome which would probably mean large or very large trials are needed; or 3) a trial is powered to establish equivalence, which again would probably need a large trial. Further, because there are so many potential differences in PFMT programmes it would take many trials to investigate every possible difference using direct comparisons. Considerable thought is needed to choose important comparisons to test in trials, and approaches other than randomised trials may also need to be considered (see for example, Whiteneck *et al.* (2009).[35]

Substantiating the most effective PFMT programme was identified as a high priority by Buckley *et al.* (2009), in a process that involved patient groups and clinicians. This review found that the existing evidence is insufficient to make any robust recommendations about the best approach to PFMT, other than it appeared women were more likely to report they were improved if they received more attention from a health professional.

Conclusions

Based on the limited data available it seemed that PFMT with regular (*e.g.* weekly) health professional contact was better than PFMT with little or no contact. Although finding the best approach to PFMT was identified as high priority in recent research involving clinicians and patients, large costly trials may not be the best use of research funds when the difference in outcome between two active PFMT treatments is expected to be small, unless there are likely to be significant economic benefits (such as much lower costs for one treatment).

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