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Pelvic floor muscle training for women with lumbopelvic pain: a systematic review and meta-analysis

Running Head: Pelvic floor muscle training for lumbopelvic pain

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Significance: This study summarises the current knowledge about the efficacy of PFMT for women with lumbopelvic pain. PFMT appear to result in significant but small clinical benefits compared to other conservative interventions. Results are based on small studies with methodological limitations.

ABSTRACT

BACKGROUND AND OBJECTIVE: It has been suggested that pelvic floor dysfunction may contribute to the development of lumbopelvic pain as a result of changes in trunk muscle control. However, there is limited evidence that pelvic floor muscle training (PFMT) can improve clinical outcomes in women with lumbopelvic pain.

DATABASES AND DATA TREATMENT: Six databases were searched for randomised controlled trials (RCTs) comparing the effectiveness of PFMT to other conservative interventions (usual physiotherapy care or minimal intervention), no treatment, or placebo interventions on pain and disability in women with lumbopelvic pain.

RESULTS: We included eight RCTs totalling 469 participants. PFMT were more effective than minimal intervention for lumbopelvic pain [Mean Difference (MD) 15.9/100 (95% Confidential Interval (CI), 8.2 to 23.6; p=0.00; I^2=3.92%)] and disability [Standardized Mean Difference (SMD) 0.5 (95% CI, 0.1 to 0.9; p=0.00; I^2=0%)] during pregnancy. PFMT were more effective than usual physiotherapy care for pain [MD 11.7/100 (95% CI, 7.5 to 15.9; p=0.00; I^2=94.14%)] and disability [SMD 0.3 (95% CI, 0.0 to 0.6; p=0.01; I^2=82.54%)] in non-pregnant women. Effect sizes were in general of arguable clinical relevance.

CONCLUSIONS: Overall, the certainty of the evidence was very low-to low. There is no conclusive evidence that the addition of PFMT to usual physiotherapy care or minimal intervention is superior to minimal intervention and usual care alone given the small number of studies and high levels of heterogeneity of included studies. Further well-design trials are needed to establish the effectiveness of PFMT for lumbopelvic pain in women.

INTRODUCTION

During pregnancy, lumbopelvic pain (i.e., low back pain (LBP) and/or pelvic pain) (Wu et al., 2004) is a common problem with worsening of symptoms as pregnancy advances (Borg-Stein & Dugan, 2007; Casagrande, Gugala, Clark, & Lindsey, 2015). The prevalence of lumbopelvic pain has been estimated to affect more than half of pregnant women (Vermani, Mittal, & Weeks, 2010). Moreover, women continue to experience moderate to severe lumbopelvic pain after delivery (Wu et al., 2004) with significant burden on women's quality of life and activities of daily living (Elden, Gutke, Kjellby-Wendt, Fagevik-Olsen, & Ostgaard, 2016).

Tissue health is influenced by loading (Ashton-Miller & Schultz, 1988), among other factors. Abnormal or excessive loading of the lumbar spine and pelvis is one factor understood to be associated with the initial development of LBP for most with the

condition (Marras, Davis, Ferguson, Lucas, & Gupta, 2001). As trunk loading is controlled by trunk muscle activity, past studies have investigated a potential relationship between modified trunk muscle activation and pain (Radebold, Cholewicki, Panjabi, & Patel, 2000). A key observation is that activation of deep anterior and posterior muscles of the trunk is delayed or reduced in many individuals with pain (P. H. Ferreira, Ferreira, & Hodges, 2004; Hodges & Richardson, 1996; MacDonald, Moseley, & Hodges, 2009; Radebold, Cholewicki, Polzhofer, & Greene, 2001). These muscles influence spine control via direct muscle forces, but also via modulation of intra-abdominal pressure (Hodges & Richardson, 1996; Stokes, Gardner-Morse, & Henry, 2010) and fascial tension (which also depends on intra-abdominal pressure) (Barker et al., 2006). Pelvic floor muscles (PFM) have been proposed to contribute to control of the lumbar spine via their essential contribution to intra-abdominal pressure (and thus fascial tension) and to pelvic control via stiffening of the sacroiliac joints through compression (A. Pool-Goudzwaard et al., 2004). The hypothesised role of the PFM in control of the lumbar spine and pelvic has been supported by recordings of activity of these muscles in tasks that challenge lumbopelvic stability (Hemborg, Moritz, & Lowing, 1985; Sapsford et al., 2001; Sapsford, Richardson, & Stanton, 2006). Based on the contribution of PFM to lumbopelvic control, it has been proposed that deficits in activation of these muscles might compromise control of loading, and enhancement of this function could be a target for intervention to aid in the management of LBP.

Pelvic floor dysfunction refers to compromised active (muscle and neural input) and passive (connective tissue) support by pelvic floor that may result in symptoms such as urinary/faecal incontinence, pelvic organ prolapse and sexual dysfunction (Bo et al.,

2017). Epidemiological studies have identified a relationship between symptoms of pelvic floor dysfunction such as urinary incontinence (UI) and current (Smith, Russell, & Hodges, 2014) or future development of LBP (Smith, Russell, & Hodges, 2009). The association between UI and LBP prevalence was three times higher for parous women (Eliasson, Elfving, Nordgren, & Mattsson, 2008). Although these studies have not identified a causal link, it is plausible to speculate that pelvic floor dysfunction might lead to compromised control of lumbopelvic loading, or that pelvic floor dysfunction and LBP may have a common underlying basis from factors such as hormonal effects (Smith, Coppieters, & Hodges, 2007b).

On the basis of the plausible biomechanical link between pelvic floor dysfunction and LBP, pelvic floor muscle training (PFMT) has been proposed as a possible treatment for lumbopelvic pain. PFMT can take many forms, but strengthening is most common. This type of training has been argued to increase pelvic support by elevating its structures, increasing muscle tone, increasing connective tissues stiffness, and providing stability to the lumbopelvic system (Smith, Coppieters, & Hodges, 2007a; Smith et al., 2007b). PFM training is considered the first line of prevention and treatment for pelvic floor dysfunction (Dumoulin, Hay-Smith, & Mac Habee-Seguin, 2014; Hagen et al., 2014; Woodley, Boyle, Cody, Morkved, & Hay-Smith, 2017). Whether PFMT is efficacious for the management of lumbopelvic pain requires consideration.

This study aimed to systematically review and appraise the literature investigating the efficacy of PFMT to reduce pain and disability associated with lumbopelvic pain in women.

METHODS

This review was registered at PROSPERO - International Prospective Register of Systematic Reviews (record number: CRD42017079920, http:// www.crd.york.ac.uk/prospero/index.asp). Our reporting adheres to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement (Liberati et al., 2009), and to the methods described in the Cochrane Handbook for Intervention Reviews (Higgins JPT, 2011).

Eligibility criteria

Participants

Studies were included if they investigated adult women (age >18 years) with non-specific LBP (i.e., pain between the gluteal folds and the 12th rib) (Airaksinen et al., 2006) or pelvic pain (pain in between the posterior iliac crest and the gluteal region, particularly in the region of the sacroiliac joints) (Vleeming, Albert, Ostgaard, Sturesson, & Stuge, 2008) of any duration. For pregnant participants we considered studies that included women with pregnancy-related lumbopelvic (i.e., pain that started during the current pregnancy). In addition, women with LBP in combination with pelvic pain (combined pain) were also included. The term lumbopelvic pain is used when there is no distinction between pelvic pain and LBP (Wu et al., 2004). Studies that included patients with cognitive impairment, lack of independent mobility, neurological disorders or serious spinal pathology (such as tumor, cauda equina syndrome, osteoporosis, or infection) were excluded.

Type of study

We included only randomised controlled clinical trials (RCT) written in English that investigated the effects of PFMT as a component of the management program for lumbopelvic pain. Other forms of clinical trials, conference abstracts and studies that were not published in peer reviewed journals were excluded.

Intervention

The intervention of interest was exercises that promote the voluntary contraction, strength, endurance, power and relaxation of PFM (Bo et al., 2017) with any frequency, intensity, duration and time session. Exercises could be supervised or unsupervised. To be included, trials needed to compare PFMT alone or PFMT in combination with other types of exercise or treatments (e.g., transcutaneous electrical nerve stimulation, manual therapy, therapeutic ultrasound, back strengthening exercises or pilates) to any other conservative (i.e. non-operative) intervention, no treatment or placebo. Trials had to include exercise regimens aiming to promote the contraction and strengthening of PFM with and without use of devices to aid training, such as biofeedback, electrical stimulation or vaginal cones (weights).

Outcomes

Outcomes of interest included pain measured by visual analogue scales (range 0–100) or numerical rating scales (range 0–10) and disability measured by Roland-Morris Disability Questionnaire (range 0–24), Oswestry Disability Index (range 0–100) and Likert-modified Roland–Morris Disability Questionnaire scores (range 0-144).

Data source and searches

Using Medical Subject Headings (MeSH) based on the terms “low back pain”, “pelvic floor muscle”, “exercise”, “training” and “randomized controlled trials”, we ran the search strategy for MEDLINE (Ovid), EMBASE, CENTRAL (Cochrane Central Register of Controlled Trials), PEDro, CINAHL, and Web of Science databases were searched from their inception to 13 June 2019. The complete search strategy is shown in Appendix Table 1.

Selection of studies

Two reviewers (GV and JP) independently screened all titles and abstracts, and finally full texts. The reviewers worked independently, and if they were in conflict a third reviewer (MF) would resolve any disagreement.

Data extraction

Two independent reviewers (GV and JP) extracted the relevant study characteristics including participant demographics, interventions and outcome data, using a standardized data extraction form. Disagreements were resolved by a third author (MF). Means, standard deviations, and sample sizes for our outcome measures were extracted. When medians, interquartile range or standard error were reported, we used recommendations in the Cochrane Handbook to calculate the effect size (Higgins JPT, 2011). Reviewers resolved disagreement by discussion.

Outcome data were extracted for the immediate-term (post-treatment to ≤3 months), follow-up and medium-term (>3 months to 1-year follow-up) follow-ups. None of the included trials reported long-term follow up data (i.e. >12 months). When insufficient data were reported in a paper, authors were contacted for further

information. When authors were unavailable we estimated data from figures using a public available Web-based program (WebPlotDigitizer® (v. 4.1) (Burda, O'Connor, Webber, Redmond, & Perdue, 2017)), which is recommended by the Cochrane Collaboration (Higgins JPT, 2011) and has been demonstrated to be more convenient and accurate than visual estimation or use of a ruler (Jelicic Kadic, Vucic, Dosenovic, Sapunar, & Puljak, 2016).

Data analysis

Meta-analyses were performed using random-effects models. Trials that were assumed to be clinically homogeneous were grouped according to outcome, time points of assessment (i.e., immediate- and medium-term), and duration of LBP symptoms (i.e., acute or chronic). Moreover, the following separate analyses were pre-planned: i) stratification in pregnant and non-pregnant women: the effect of PFMT might differ between these groups of women, given the physiological and biomechanical changes that occur during pregnancy and the peripartum period (Ashton-Miller & Delancey, 2009); ii) PFMT intervention: studies that explicitly stated that the intervention promoted contraction of PFM as an isolated intervention or in association with other interventions (e.g., Pilates).

Pain outcome data were converted to a 0–100 scale and pooled results presented as mean differences (MD) with 95% confidence intervals (CI). Disability data were pooled as standardized mean difference (SMD) along with the respective CI of 95%. We considered treatment effects of 20 points (on a 0–100 scale) for pain as the smallest worthwhile effect of intervention (M. L. Ferreira et al., 2013). A SMD of 0.2 or greater was considered clinically important (Ferguson, 2009; J, 1988). When data

reported in the paper were insufficient, we contacted the authors for further information. When authors were unavailable, we imputed data using the recommendations of The Cochrane Collaboration (Higgins JPT, 2011). Between-trial heterogeneity was calculated using I^2. An I^2 <25% was considered to represent small between-trial heterogeneity; 25% <I^2< 75%: moderate heterogeneity; and I^2> 75%: large heterogeneity. All analyses were conducted with Comprehensive Meta-Analysis software version 3.3.070 (Comprehensive Meta-Analysis, Englewood, NJ).

We planned to use funnel plots to assess publication bias, however given the small number of included studies (<10) this could not be undertakent (Sterne et al., 2011).

Methodological quality assessment

Scoring of methodological quality of each RCT included was performed using the PEDro (Physiotherapy Evidence Base Database) scale. Scores were applied to the following 11 items: eligibility criteria specified, random allocation of participants, concealed allocation, groups similar at baseline, participant blinding, therapist blinding, assessor blinding, follow-up >85%, use of intention-to-treat analysis, between-group statistical comparison, report of point estimates and variability. The total score ranges between 0-10 points and was extracted from the PEDro database (www.pedro.org.au). A higher score indicates higher methodological quality. Trials with scores of 7 or higher are classified as high quality (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003).

Certainty of evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology was used to appraise the certainty of the evidence from high,

moderate, low, or very low and was based upon four main domains (Guyatt et al., 2008). For each domain that was not met we reduced the certainty by one level according to the following criteria: risk of bias (downgraded if >25% of participants came from studies with a low-quality methods [PEDro score <7 points]) (Guyatt, Oxman, Vist, et al., 2011); inconsistency of results (Guyatt, Oxman, Kunz, Woodcock, Brozek, Helfand, Alonso-Coello, Glasziou, et al., 2011); and imprecision (downgraded if the number of events are <400) (Guyatt, Oxman, Kunz, Brozek, et al., 2011). The indirectness criterion was not relevant in the context of the current study, given we have included a specific population with specific outcome measures and direct comparisons (Guyatt, Oxman, Kunz, Woodcock, Brozek, Helfand, Alonso-Coello, Falck-Ytter, et al., 2011).

RESULTS

Description of included studies

The electronic search identified 5,360 studies. After removing 1,748 duplicates, 3,612 individual records were screened and excluded based on keywords, titles and abstracts resulting in 99 potentially eligible articles. After full-text examination, nine articles were included that met the eligibility criteria (Cruz-Diaz et al., 2015; Cruz-Diaz, Martinez-Amat, Osuna-Perez, De la Torre-Cruz, & Hita-Contreras, 2016; Ghaderi, Mohammadi, Amir Sasan, Niko Kheslat, & Oskouei, 2016; Gutke, Sjodahl, & Oberg, 2010; Kluge, Hall, Louw, Theron, & Grove, 2011; Kordi et al., 2013; Mohseni-Bandpei, Rahmani, Behtash, & Karimloo, 2011; Naqaish, Rizvi, & Ambreen, 2013), with two publications reporting data from the same trial (Cruz-Diaz et al., 2015; Cruz-Diaz et al., 2016). Thus, eight original RCTs were included with data from 469 participants with

lumbopelvic pain. The flow diagram of studies through the review and the reasons for exclusion of studies are presented in Figure 1.

All articles were published in 2010 or later (Cruz-Diaz et al., 2016; Ghaderi et al., 2016; Gutke et al., 2010; Kluge et al., 2011; Kordi et al., 2013; Mohseni-Bandpei et al., 2011; Naqaish et al., 2013). Included studies reported data from five different countries: Iran, (Ghaderi et al., 2016; Kordi et al., 2013; Mohseni-Bandpei et al., 2011; Teymuri, Hosseinifar, & Sirousi, 2018) Pakistan, (Naqaish et al., 2013) South Africa, (Kluge et al., 2011) Spain (Cruz-Diaz et al., 2016) and Sweden (Gutke et al., 2010). A summary of each study is presented in Table 1.

Characteristics of the included studies

Among the eight original trials that were included, two trials included pregnant women (Kluge et al., 2011; Kordi et al., 2013), six investigated non-pregnant participants (Cruz-Diaz et al., 2016; Ghaderi et al., 2016; Gutke et al., 2010; Mohseni-Bandpei et al., 2011; Naqaish et al., 2013; Teymuri et al., 2018), including two studies during the post-partum period (Gutke et al., 2010; Teymuri et al., 2018). Age of participants ranged from 20 to 72 years. With the exception of two studies in which symptom duration was not defined (Gutke et al., 2010; Naqaish et al., 2013), studies included participants with chronic lumbopelvic pain (Cruz-Diaz et al., 2016; Ghaderi et al., 2016; Mohseni-Bandpei et al., 2011) and pregnancy-related lumbopelvic pain (Kluge et al., 2011; Kordi et al., 2013) (Table 1).

Two trials recruited women with pelvic floor dysfunction and lumbopelvic pain (Ghaderi et al., 2016; Naqaish et al., 2013). Four studies included in the qualitative synthesis reported specific data on PFM activity and strength among the participants.

Studies used a wide range of PFM contraction assessment tools, including: perineometer (Mohseni-Bandpei et al., 2011), vaginal examination (Ghaderi et al., 2016), surface electromyography (Gutke et al., 2010) and ultrasonography (Teymuri et al., 2018). Because of differences in PFM contraction measurement, a meta-analysis was not feasible. From these studies, only one study reported data on UI symptoms (Ghaderi et al., 2016) (Table 1).

Methodological quality of the included studies

The overall quality of included studies ranged from four to eight with a mean score of 5.5 (SD: 1.42; 0–10 PEDro score) (Appendix Table 2). The control and intervention groups did not differ at baseline, except for one study (Naqaish et al., 2013). Four studies (44.4%) had inadequate retention of participants (<85%) at follow-up (Ghaderi et al., 2016; Gutke et al., 2010; Mohseni-Bandpei et al., 2011; Teymuri et al., 2018), and two studies (22.2%) conducted an intention-to-treat analysis (Cruz-Diaz et al., 2016; Kluge et al., 2011). The most common methodological limitation was lack of blinding of assessors (4 of 9; 44.4%), participants (0 of 9; 0%), and therapists (0 of 0; 0%), as is common for trials of exercise.

Efficacy of pelvic floor muscle training to reduce pain

Pooling of data was possible for five trials that investigated the effect of PFMT on pain reduction (Cruz-Diaz et al., 2016; Ghaderi et al., 2016; Kluge et al., 2011; Kordi et al., 2013; Mohseni-Bandpei et al., 2011) (Figure 2). Control groups consisted predominantly of usual physiotherapy care (i.e., transcutaneous electrical nerve stimulation (Cruz-Diaz et al., 2016; Ghaderi et al., 2016; Mohseni-Bandpei et al., 2011), manual therapy (Cruz-Diaz et al., 2016), infra-red (Mohseni-Bandpei et al., 2011),

therapeutic ultrasound (Ghaderi et al., 2016; Mohseni-Bandpei et al., 2011) and back strengthening exercises (Ghaderi et al., 2016)) or minimal intervention (i.e., basic education about LBP care (Kluge et al., 2011; Kordi et al., 2013), body posture (Kluge et al., 2011; Kordi et al., 2013) and ergonomic advices (Kluge et al., 2011; Kordi et al., 2013)) in women with lumbopelvic pain. The PFMT interventions followed different training protocols in terms of duration of training period, follow-up, training intensity and frequency. Individual trial effect sizes are summarised in Table 1.

The results showed there is low certainty evidence provided by two trials (Kluge et al., 2011; Kordi et al., 2013) that PFME is more effective than minimal intervention in improving pain in pregnant women with lumbopelvic pain (Table 3). Pooled analysis revealed a statistically significant difference at immediate-term with a MD of 15.9 on a 100-point scale (95% CI: 8.2 to 23.6; p=0.000; I^2=3.92%), favouring PFME intervention. Although the point estimate did not reach clinical significance, which was defined *a priori* as treatment effects >20 points (Figure 2), a clinically significant effect cannot be ruled out, given the upper limit of the 95% confidence interval surpasses the clinical significance threshold. For non-pregnant women, the results showed there is very-low certainty evidence provided by three trials (Cruz-Diaz et al., 2016; Ghaderi et al., 2016; Mohseni-Bandpei et al., 2011) that PFME associated with usual physiotherapy care is more effective than usual physiotherapy care alone to improve pain (Table 3). The pooled analysis demonstrated statistically significant difference at immediate-term (MD: 11.7; 95% CI: 7.5 to 15.9 on a 100-point scale; p=0.000; I^2=94.14%), but the difference was too small to be considered clinically significant (Figure 2).

One trial that could not be included in the pooled analyses because of differences in follow-up duration, showed that PFMT associated with usual physiotherapy care was not superior to usual physiotherapy care alone to improve pain at medium-term in non-pregnant women (Naqaish et al., 2013). A second trial that could not be pooled as it included women with postpartum LBP only, (Teymuri et al., 2018) demonstrated that PFMT delivered in combination with usual physiotherapy care, clearly reduced pain in women with postpartum lumbopelvic pain at immediate-term compared to usual physiotherapy care (MD: 31.1; 95% CI: 19.3 to 42.8).

Efficacy of pelvic floor muscle exercises to reduce disability

Pooling of data was possible for five trials that investigated the effect of PFME on disability reduction (Cruz-Diaz et al., 2016; Ghaderi et al., 2016; Kluge et al., 2011; Kordi et al., 2013; Mohseni-Bandpei et al., 2011) (Figure 3). The results showed there is low certainty evidence provided by two trials (Kluge et al., 2011; Kordi et al., 2013) that PFMT is more effective than minimal intervention in pregnant women with lumbopelvic pain (Table 3). Pooled analyses revealed clinically and statistically significant difference at immediate-term (SMD:0.5; 95% CI: 0.1 to 0.9; p=0.005; I^2=0%) in pregnant women. For non-pregnant women, the results showed there is very-low certainty evidence provided by three trials (Cruz-Diaz et al., 2016; Ghaderi et al., 2016; Mohseni-Bandpei et al., 2011) that PFME in conjunction with usual physiotherapy care is more effective than usual physiotherapy care alone to improve disability (Table 3). The pooled analysis demonstrated a clinically and statistically significant difference at immediate-term the SMD was 0.3 (95% CI: 0.0 to 0.6; p=0.016; I^2=82.54%), (Figure 2). When PFMT is performed in conjunction with Pilates exercises only, the results were clinically

significant (SMD: 0.9; 95% CI: 0.5 to 1.3) (Cruz-Diaz et al., 2016). Due to differences in follow-up duration and comparator group two trials could not be pooled with the remaining trials (Gutke et al., 2010; Teymuri et al., 2018). Gutke et al (Gutke et al., 2010) showed that PFME was not superior to minimal intervention in improving disability at immediate and medium-term in women with postpartum pelvic pain and LBP (SMD: 0.3; 95% CI:-0.1 to 0.8) (Table 1). Teymuri et al (Teymuri et al., 2018) reported that PFMT combined with usual physiotherapy care were superior to usual physiotherapy care alone in improving disability for women with postpartum lumbopelvic pain at immediate-term (SMD: 1.4; 95% CI:0.6 to 2.1) (Table 1).

DISCUSSION

Main findings

This systematic review of the effectiveness of strengthening-based PFMT to reduce pain and disability in women with lumbopelvic pain identified eight RCTs suggesting 'very low' to 'low' certainty of evidence on reducing pain and disability in pregnant and non-pregnant women. Meta-analysis of data from two studies that assessed the effects in pregnant women with lumbopelvic pain provide evidence that PFMT is efficacious in reducing pain and disability in the immediate-term. Three studies that assessed the effects in non-pregnant women with chronic LBP, provide evidence that PFMT is not superior to minimally interventions in reducing pain and disability in the immediate-term. When PFMT was used in addition to Pilates exercises, there was 'very low' certainty evidence that it reduced pain in patients with chronic LBP, compared to usual physiotherapy care. In terms of pain, PFMT demonstrated no effects that

reached the pre-defined threshold for clinical important effect sizes in pregnant and non-pregnant women. In terms of disability, PFMT produced clinically important effect sizes for both pregnant or non-pregnant women with lumbopelvic pain. Although pain was measured in the same way in all included studies, functional disability was measured in a variety of ways. Disability from LBP is highest during working age worldwide (Disease, Injury, & Prevalence, 2016). Given the number of women that participate in the workforce and the consequences of lumbopelvic pain in basic activities of daily living (Morino et al., 2017) strategies that improve disability in women with lumbopelvic pain should be addressed in future studies. Despite the evidence for a plausible relationship between pelvic floor dysfunction and lumbopelvic pain, we lack high quality evidence supporting the endorsement of PFMT as treatment for women with lumbopelvic pain (Dufour et al., 2018). The results of the systematic review suggest that evidence supporting the use of PFMT in the management of lumbopelvic pain in women is limited due to the small number and low quality of trials.

Implications

Current guidelines endorse the use of exercise therapy for patients with lumbopelvic pain (Airaksinen et al., 2006; Gutke, Ostgaard, & Oberg, 2008) but without recommendation regarding which type of exercise is the best among the different exercise programmes (Foster et al., 2018). Other systematic reviews have shown favourable outcomes of exercises for lumbopelvic pain during pregnancy (Davenport et al., 2019; Liddle & Pennick, 2015). However, they included a variety types of prenatal exercises (i.e., water-based, land-based, or combination of different types of exercises)

that could mask the results of PFMT. In contrast, we only included studies where the contrast between groups was the presence of PFMT.

The rationale of PFMT for women with lumbopelvic pain is related to an association between pelvic floor dysfunction and LBP (Arab, Behbahani, Lorestani, & Azari, 2010; Dufour, Vandyken, Forget, & Vandyken, 2018; Eliasson et al., 2008; MD, A, & PW, 2006), that may be present for some individuals, but would not be expected to be relevant for all with LBP. Although the biological basis for this relationship is not yet completely understood, it has been suggested that it might be associated with the contribution of PFM to lumbopelvic stability (Hodges, Sapsford, & Pengel, 2007). Activation of PFM has also been reported to differ between women with and without pelvic pain (Dufour et al., 2018; Sjodahl, Gutke, Ghaffari, Stromberg, & Oberg, 2016). Similar findings have been reported by digital vaginal palpation of the PFM (Dufour et al., 2018) which showed a high correlation between pelvic girdle pain and pelvic floor dysfunction (95.3%) - 71% of the participants had PFM tenderness, 66% had pelvic floor weakness and 41% had pelvic organ prolapse of the total population studied. Furthermore, PFM tenderness has been correlated with scores on the Central Sensitization Inventory (Keizer et al., 2019). Recent clinical trials (Ghaderi, Bastani, Hajebrahimi, Jafarabadi, & Berghmans, 2019; Schvartzman et al., 2019) have shown that PFM strengthening-based protocols are effective for the treatment of pelvic floor dysfunctions that causes muscle tenderness. Women with sensitiveness to palpation usually present with decreased ability to achieve and sustain a PFM contraction and to relax the PFM after activation (McLean & Brooks, 2017). PFMT can contribute to improve PFM function by an increase in the number of capillaries in trained muscle,

improving blood flow and reducing muscle tone (Mercier et al., 2020; Naess & Bo, 2018).

PFMT appears not to be an effective treatment compared to usual physiotherapy care in women with chronic LBP. This may not be surprising as the prevalence of pelvic floor dysfunction (i.e. that target for this intervention) would be expected to be less in a non-specific LBP group, than in individuals with a specific challenge to PFM (e.g., pregnancy). However, when compared to minimal intervention in pregnant women, PFMT seems to have a significant effect on pain reduction and function improvement. Although the aetiology of lumbopelvic is multifactorial, it is plausible that biomechanical factors may be involved in LBP in pregnancy. Biomechanical factors may include increased lumbar lordosis in association with the increasing anterior weight of the abdomen (Sandler, 1996), laxity of the sacroiliac joints as a result of hormonal effects (Borg-Stein, Dugan, & Gruber, 2005), or injury to the PFM due to weight of the abdominal contents and vaginal delivery (A. L. Pool-Goudzwaard et al., 2005). Furthermore, pregnancy-related hormonal changes promote weakening of the PFM (Sangsawang & Sangsawang, 2013) and altered control of muscles in the lumbopelvic region (A. L. Pool-Goudzwaard et al., 2005). Increased strength and endurance of the PFM may augment spine control via enhanced capacity to regulate intra-abdominal pressure, and augment pelvic control (Lee et al., 2016) via increased stiffness of the sacroiliac joints (A. Pool-Goudzwaard et al., 2004). Severe consequences of lumbopelvic pain during pregnancy has been found up to 11 years postpartum (Elden et al., 2016). This emphasises the importance of identification of evidence-based therapy that can best contribute to lumbopelvic pain management. PFMT used as an adjunct treatment,

could potentially optimize the effects of current treatments for lumbopelvic pain and may offer low-cost option that can be utilized by health care providers.

In this systematic review, two studies (Gutke et al., 2010; Teymuri et al., 2018) assessed the efficacy of PFMT in post-partum women, but were too heterogeneous to be combined in a meta-analysis, and the results comparing the trials were inconsistent. Although one study found no effect in lumbopelvic pain and disability (Gutke et al., 2010) the other study did find significant differences between groups (Teymuri et al., 2018). Variation in results may be explained by the differences in the effect of the interventions. For instance, the trial that showed no effect for pain and disability also did not show improvement in the of PFM function in the intervention group (Gutke et al., 2010). This is surprising as we expected an increase in strength and endurance of PFM as a result of the intervention and that could potentially improve lumbopelvic pain.

Strengths and limitations

Some limitations of this review must be considered. First, the high between-trial heterogeneity in the results may be due to the influence of different PFMT programs and the inclusion of women with and without known pelvic floor dysfunction (i.e. urinary incontinence and pelvic organ prolapse). It would be reasonable to speculate that PFM training may have potential to impact LBP in those with PFM dysfunction, but not in those without PFM dysfunction. The majority of the included trials fail to report information about the level of adherence to PFMT. It was not possible to ensure that the PFM were correctly contracted in all studies, with widely different treatment combinations and the divergent duration, intensity, frequency and types of intervention. Guidance from a specialized professional on how to properly contract PFM may improve

the results from this kind of treatment. However, to assess optimal contraction of PFM, such interventions are dependent on the training and skills of an experienced physiotherapist in the comprehensive evaluation and management of PFM, which might not be the case of physiotherapists that provide treatment for lumbopelvic pain. Only a small number of studies were identified, and all had a modest number of participants. The PEDro rating scale is considered a valid method to assess the methodological quality of exercise intervention trials and scores higher than 7 of 10 are considered to reflect high quality trials (Maher et al., 2003). The most common limitations in the included studies were lack of blinding of participants and therapists. However, blinding of participants and therapists is almost impossible in pragmatic trials (Morkved & Bo, 2014).

Despite these limitations, this is the first review to synthesize the findings and quantify the effectiveness of PFMT in lumbopelvic pain. We included a comprehensive search strategy across different databases, and a rigorous approach to screening titles, a pre-registered protocol, data extraction with independent reviewers and used well-established methodologies to assess trial risk of bias and certainty of evidence.

CONCLUSION

This systematic review provides no conclusive evidence that the addition of strength-based, not exclusively individualized or supervised, PFMT to usual physiotherapy care or minimal intervention is superior to minimal intervention and usual care alone for the management of lumbopelvic pain. There is low to very low certainty evidence that PFMT improves pain and function in pregnant and non-pregnant

women with lumbopelvic pain, respectively. Future larger, high-quality trials with longer follow-ups are needed to establish the effectiveness of PFMT, given current evidence relies on few and small studies and with high levels of heterogeneity.

Author Contributions

G. Vesentini: review inception, designed protocol, searched databases, identified eligible studies, extracted relevant data and conducted quality assessments, synthesised results, wrote the original draft. J. Prior: duplicate eligibility screening, duplicate data extraction and quality assessment. P. H. Ferreira: review inception, protocol development, interpretation of results. P. W. Hodges: review inception, protocol development, interpretation of results. M. Rudge: review inception. M. L. Ferreira: review inception, protocol development, interpretation of results. All authors critically reviewed earlier drafts of the article and contributed significantly to the final version. All authors discussed the results and commented on the manuscript.

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Table 1. Summary of the characteristics in the included studies.

Study and Country	Sample size	Age (y)	Population and condition	Intervention	Intervention frequency	Comparator	Outcome measures	Results	Effect size	Time points	PED scor
					Non-pregnant women						
Mohseni-Bandpei et al. (2011) Iran	Total: 20 C: 10 PFMT: 10	C: 34.91 (6.29) PFMT: 34.71 (5.03)	Women with CLBP	Usual physiotherapy care + PFMT	6 times/day during 8 weeks	Usual physiotherapy care[1]	Pain, disability, and PFM strength, abdominal muscles endurance	Both groups improved LBP and disability. The PFMT group had similar effect and not superior to usual care.	Immediate-term Pain: *MD -0.6 (-5.9 to 4.7) $MD -1.0 (-3.3 to 1.3) Disability *SMD 0.0 (-0.9 to 0.8) $SMD 0.1 (-1.2 to 0.8)	Baseline, 8 weeks and 3 months	4
Cruz-Diaz et al. (2015b) Spain	Total: 101 C: 48 PFMT: 53	C: 72.69 (3.53) PFMT: 69.57 (2.18)	Women with CLBP	Usual physiotherapy care + Pilates with PFMT	2 times/week during 6 weeks	Usual physiotherapy care[1]	Pain and disability	Both groups improved LBP and disability. Between groups comparison showed significant improvement in	Immediate-term Pain: MD 18.8 (13.2 to 24.3) Disability SMD 0.9 (0.5 to 1.3) Medium-term	Baseline, 6 weeks and 1 year	8

								PFMT group.	Pain: MD 20.4 (14.3 to 26.4) Disability SMD 3.3 (2.7 to 3.0)		
Ghaderi et al. (2016) Iran	Total: 60 C: 30 PFMT: 30	C: 52.6 (1.06) PFMT: 53.2 (1.1)	Women with CLBP and UI	Usual physiotherapy care + PFMT	3 times/week during 12 weeks	Usual physiotherapy care[1]	Pain, disability, UI symptoms, PFM strength and endurance and TrA strength	Both groups improved LBP and disability. The PFMT group had similar effect and not superior to the usual care.	Immediate-term Pain: MD 7.9 (3.0 to 12.7) Disability SMD -0.3 (-0.8 to 0.1)	Baseline and 3 months	4
Naqaish et al. (2013) Pakistan	Total: 50 C: 25 PFMT: 25	Between 20 - 40	Women with LBP and POP	Usual physiotherapy care + PFMT	Daily during 4 months	Usual physiotherapy care[1]	Pain	Both groups improved LBP. The PFMT group had similar effect and not superior to the usual care.	Medium-term Pain: MD 2.0 (-0.6 to 4.6)	Baseline and 4 months	4

Gutke et al. (2010) Sweden	Total: 60 C: 36 PFMT: 24	C: 30 (4) PFMT: 32 (4)	Women with postpartum lumbopelvic pain	Core stability[2] + PFMT	10 woman trained ≥ 1.5 times/day and 15 woman trained < 1.5 times/day	Minimal intervention[3]	Pain, disability, quality of life, wellbeing and PFM function	Both groups were effective in the improvement of LBP and disability. The PFMT group had similar effect and not superior to the minimal intervention.	Immediate-term Disability SMD 0.3 (-0.1 to 0.8) Medium-term Disability SMD 0.2 (-0.2 to 0.7)	Baseline, 3 months and 6 months	6
Teymuri et al. (2018) Iran	Total: 36 C: 18 PFMT: 18	C: 36.77 (9.21) PFMT: 33.55 (6.86)	Women with postpartum lumbopelvic pain	Usual physiotherapy care + PFMT	3 times/week during 6 weeks	Usual physiotherapy care[1]	Pain, disability and PFM function	Both groups were effective in the improvement of LBP and disability. Between groups comparison showed significant improvement in the PFMT group.	Immediate-term Pain: MD 31.1 (19.3 to 42.8) Disability SMD 1.4 (0.6 to 2.1)	Baseline and 6 weeks	6

Pregnant women

Kordi et al. (2013) Iran	Total: 96 C: 31 Belt: 34 PFMT: 31	C: 25.45 (5.59) Belt: 28.26 (4.82) PFMT: 26.45 (5.37)	Pregnant women with PP (Gestational age 20-32 weeks)	Minimal intervention + PFMT	3 times/week for 6 weeks	Control Group: Minimal intervention[3] Belt group: Education + non-rigid lumbopelvic belt[4]	Disability, Pain and Quality of Life	Both groups were effective in the improvement of LBP and disability. Between groups comparison showed significant improvement in PFMT group.	Immediate-term Pain: MD 14.1 (6.0 to 22.1) Disability SMD 0.4 (0.0 to 0.9)	Baseline, 3 weeks and 6 weeks	5
Kluge et al. (2011) South Africa	Total: 46 C: 22 PFMT: 24	C: 29 (21-39) PFMT: 27 (20-32)	Pregnant women with LBP and PP (Gestational age 16-20 weeks)	Minimal intervention + TrA and PFMT	Daily exercise at home and classes every 2 weeks during 10 weeks	Minimal intervention[3]	Pain, disability and fetal outcomes	Significant decrease in pain intensity and disability for PFMT group.	Immediate-term Pain: MD 24.1 (6.5 to 41.7) Disability SMD 0.6 (0.6 to 1.2)	Baseline and 10 weeks	7

C, control; PFMT, pelvic floor muscle training; y, years; CLBP, chronic low back pain; LBP, low back pain; PP, pelvic pain; UI, urinary incontinence; PP, pelvic pain; ABD, abdominal; TrA, transversus abdominis; MD, mean difference; SMD, standardized mean difference.

[1]Usual physiotherapy care was considered any of the following: transcutaneous electrical nerve stimulation, manual therapy, infra-red, therapeutic ultrasound and back strengthening exercises.

[2]Core stability refers to the ability of the trunk and pelvis muscles (i.e. core musculature) to control the position and motion of the trunk to stabilise the spine.

[3]Minimal intervention was considered basic education about LBP care, body posture and ergonomic advices.

[4]Belt group was not considered in the analysis.

*8 weeks intervention.

[$]3 months after randomization.

Table 2. Summary of the GRADE scale evidence of recommendation.

Quality assessment							Summary of findings			
No. of studies	Design	Risk of bias[a]	Inconsistency[b]	Imprecision[c]	Indirectness[d]	Publication Bias[e]	No. of patients		Effect (95% CI)	Certainty of evidence
							Control	PFMT		
Pain										
Pregnant/Immediate-term*, two studies[62,63]	Randomised controlled trials	Serious limitation	Not serious limitation	Serious limitation	Not detectable	Not detectable	53	55	MD 15.9 (8.2 to 23.6)	⊕⊕OO LOW
Non-pregnant/Immediate-term*, three studies[64,66,68]	Randomised controlled trials	Serious limitation	Serious limitation	Serious limitation	Not detectable		95	101	MD 11.7 (7.5 to 15.9)	⊕OOO VERY LOW
Disability										
Pregnant/Immediate-term*, two studies[62,63]	Randomised controlled trials	Serious limitation	Not serious limitation	Serious limitation	Not detectable	Not detectable	53	55	SMD 0.5 (0.1 to 0.9)	⊕⊕OO LOW
Non-pregnant/Immediate-term*, three studies[64,66,68]	Randomised controlled trials	Serious limitation	Serious limitation	Serious limitation	Not detectable		95	101	SMD 0.3 (0.0 to 0.6)	⊕OOO VERY LOW

MD, mean difference; SMD, standard mean difference; CI, confidence intervals; No., sample size; PFMT, pelvic floor muscle training.

*Immediate-term: immediate effect post-treatment to ≤3 months' follow-up.

[a]Risk of bias: more than 25 % of participants came from studies with low methodological quality (PEDro score <7 points).

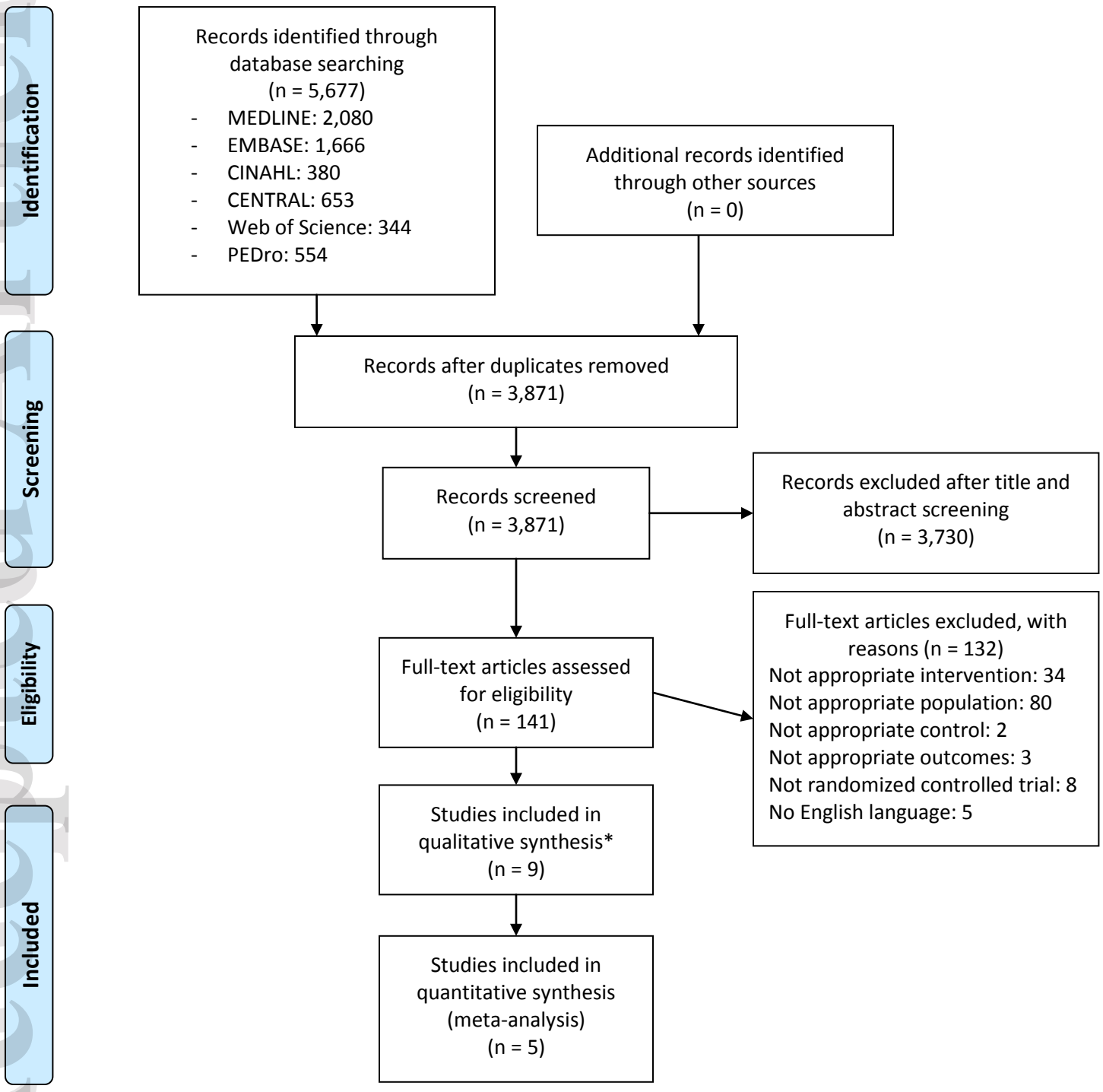
[b]Inconsistency: similarity of estimates of effect across studies (considerable heterogeneity = I^2 <50%)

[c]Imprecision: 95% CI of absolute effects include clinically important significance and no significance.

[d]Indirectness: not detecble because the included a specific population with relevant outcomes and direct comparisons.

[e]Publication bias: not detectble given the small number of included studies (<10).

PRISMA 2009 Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

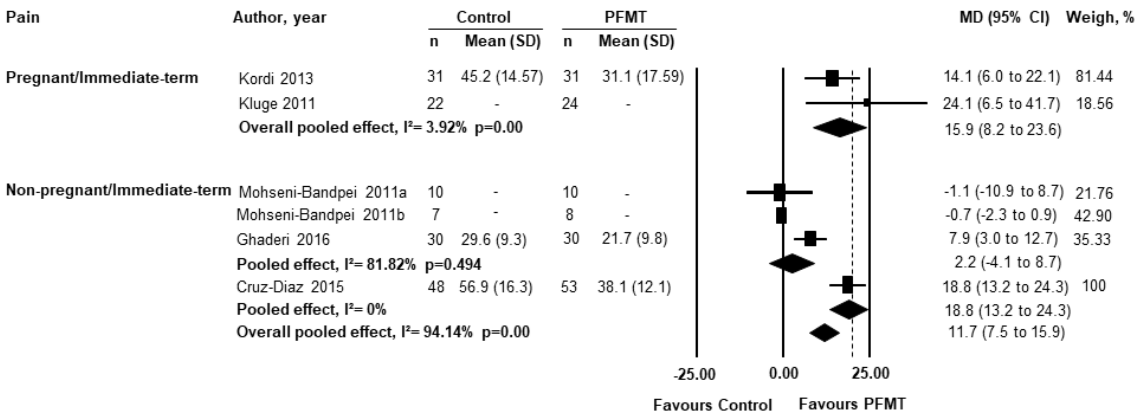


Figure 2. Pooled effect of randomised controlled trials on efficacy of pelvic floor muscle training on pain for pregnant and non-pregnant women with lumbopelvic pain. Results from meta-analysis of included studies presented as mean difference of pain scores (0–100 scale). Immediate-term=immediate effect post-treatment to ≤3 months follow-up.

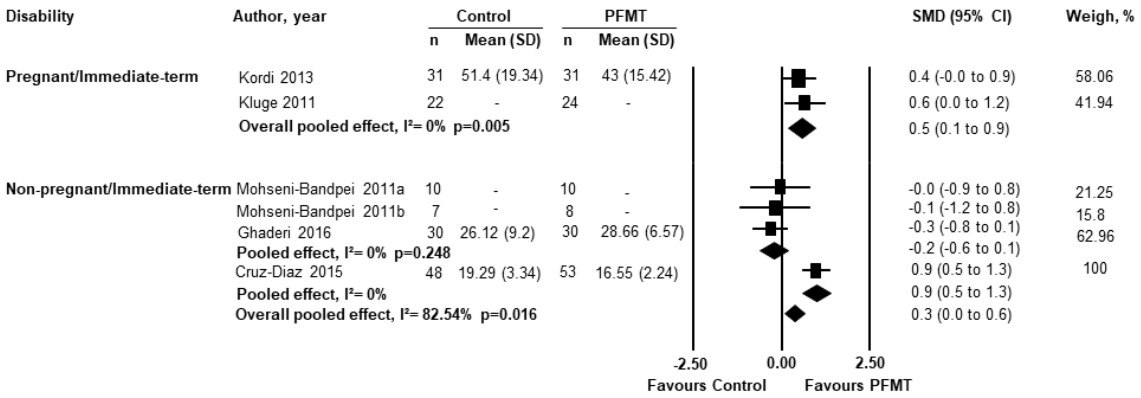


Figure 3. Pooled effect of randomised controlled trials on efficacy of pelvic floor muscle training on disability for pregnant and non-pregnant women with lumbopelvic pain. Results from meta-analysis of included studies presented as standardized mean differences of disability scores. Immediate-term=immediate effect post-treatment to ≤3 months follow-up.