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Review Article

Efficacy of pelvic floor muscle training in the treatment of female pelvic organ prolapse: a meta-analysis of randomized controlled trials

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Abstract: This study was to evaluate the efficacy of pelvic floor muscle training (PFMT) as a treatment for females with pelvic organ prolapse (POP). PubMed, Cochrane, Embase, Wanfang, China National Knowledge Infrastructure (CNKI), and Weipu (VIP) databases were searched using the index words to identify qualified randomized controlled trials (RCTs), and relevant literature sources were also searched. The latest research was performed in February 2017. Relative risk (RR), mean difference (MD) along with 95% confidence interval (CI) were used to analyze the main outcomes. Eight RCTs were involved in the meta-analysis with 919 patients in the treatment group and 903 patients in the control group. The results indicated that females receiving PFMT decreased the POP-Q stage (OR: 1.76, 95% CI: 1.24-2.48), as compared with the control group. There was no statistical difference in adding one or more POP-Q stage (OR: 0.98, 95% CI: 0.74-1.29), no change of POP-Q stage (OR: 0.97, 95% CI: 0.77-1.23), the overall POP-Q stage change (OR: 1.11, 95% CI: 0.95-1.30), PFDI-20 (SMD: 0.13, 95% CI: -0.14-0.40), POPDI-6 (SMD: 0.14, 95% CI: -0.15-0.42), CRADI-8 (SMD: 0.03, 95% CI: -0.11-0.16), UDI-6 (SMD: 0.17, 95% CI: -0.10-0.43), PFIQ-7 (SMD: 0.05, 95% CI: -0.09-0.18) after the PMFT treatment, as compared with the control group. In conclusion, females receiving PFMT showed an advantage in decreasing the POP-Q stage. However, more high quality RCTs are still needed to confirm PFMT is a better treatment for POP.

Keywords: Pelvic floor muscle training (PFMT), pelvic organ prolapse (POP), meta-analysis, randomized controlled trial (RCT)

Introduction

The American College of Obstetricians and Gynecologists has defined pelvic organ prolapse (POP) as the prolapses of organs in pelvis into the vaginal canal and downwards outside the canal. POP includes prolapse of anterior vaginal wall (urethrocele, cystocele), posterior vaginal wall (enterocele, rectocele) and apical segment of the vagina [1]. According to the severity level, POP has been classified by 5 stages of 0, 1, 2, 3, 4 [2]. About 40% of women older than 50 years have different degrees of POP [3], and the prevalence of typical symptoms of prolapse is reported to be about 3-12% [4, 5]. Typical POP symptoms emerge when the prolapse reaches to or beyond the hymen. Women with 2 or above stage POP more often experience such as concurrent bladder, bowel symptoms, sexual symptoms, or pelvic pressure/heaviness. Treatment options include pelvic floor muscle training, pessary treatment and surgical correction. Only 11% of women undergo surgery for urinary incontinence or prolapse in their lifetime, and 7% for prolapse alone [6]. However, surgery could cause several problems and complications, comorbidity and frailty make surgery undesirable. Studies have shown that pelvic floor muscle training (PFMT) is effective in the treatment of POP in stage 1 and/or 2. However, the efficacy of PFMT still needs to be identified by more high quality studies.

Based on these considerations, the present meta-analysis of all available literatures was performed to obtain accuracy evidences on the efficacy of PFMT for females with POP.

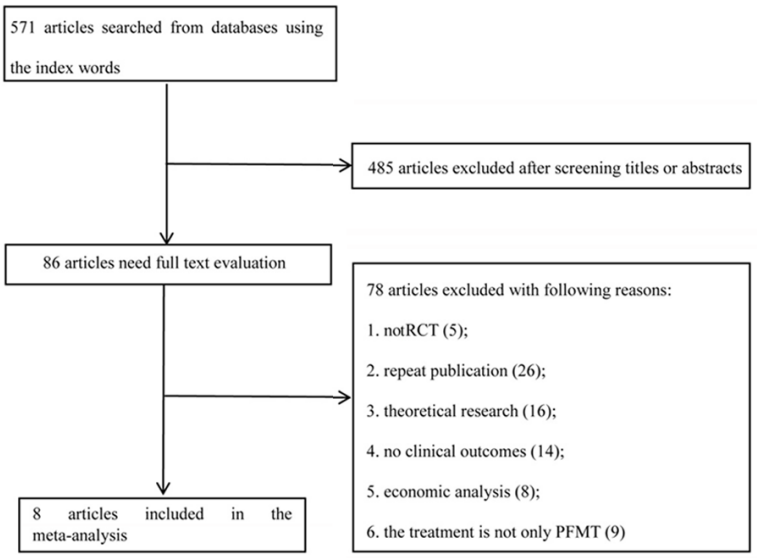

Figure 1. Flow diagram of selection process and results of literature search.

Methods

Search strategy

The Cochrane, Pubmed, Embase, CNKI (China National Knowledge Infrastructure), Wanfang and Weipu (VIP) databases were searched for all the randomized controlled trials (RCTs) about the efficacy of PFMT in the treatment of females with POP. Other related articles and reference materials were also searched. The latest research was performed in February 2017. Two authors independently performed the literature search and a third author was involved when a disagreement occurred.

Inclusion and exclusion criteria

A study was included if: (1) it is a randomized control trial (RCT); (2) the research subjects are females with POP and don't have other serious diseases; (3) the treatment group is PFMT, the control group is standard treatment or other relative medicine; (4) only published in English and Chinese.

A study was excluded if: (1) it is a repeat published article, or the content and result are same; (2) data have obvious mistake; (3) case report, theoretical research, conference report, systematic review, meta-analysis, expert comment, economic analysis; (4) the outcomes are erroneous.

All the studies were independently screened by two authors to determine whether they met the inclusion and exclusion criteria. Discrepancies were resolved by discussion with an independent third author.

Data extraction and quality assessment

The data were extracted from all the included studies and consisted of two parts: basic information and main outcomes. The following demographic basic information was extracted: the author name, the interventions of treatment group and control group, the sample size, the percentage of male, the main age, the relative information of Jadad. The second part was the clinical outcomes: pelvic organ prolapse quantification (POP-Q) stages improvement, pelvic floor distress inventory-20 (PFDI-20), pelvic organ prolapse distress inventory-6 (POPDI-6), colorectal anal distress inventory-8 (CRADI-8), urinary distress inventory-6 (UDI-6), pelvic floor impact questionnaire-7 (PFIQ-7). The Jadad scoring checklist was used to appraise the quality of involved studies. We evaluated all the RCTs from the five items: statement of randomization; appropriateness of generating randomized sequence; use of double blind; description of double blinding method; detail of withdrawals and dropouts. Studies with a score of less than 3 represented a low-quality and high bias risks, studies got a score exceed 3 were considered as high-quality trials. All the above processes were independently performed by two authors. Disagreements between these two authors were resolved by discussion with an independent third author until a consensus was reached.

Statistical analysis

All statistical analyses were performed in the STATA 10.0 (TX, USA). Chi-squared and I^2 tests were used to assess the heterogeneity of clinical trial results and decide the analysis model (fixed-effect model or random-effect model). When the Chi-squared test *P*-value of ≤ 0.05 and I^2 tests-value > 50%, it was defined as acceptable heterogeneity and assessed by random-effect model. When the Chi-squared test *P*-value of > 0.05 and I^2 tests-value $\leq 50\%$, it

Table 1. Basic characteristic information of the included studies

Study	Therapy		No. of patients		Age		BMI		Parity		Jadad score
	T	C	T	C	T	C	T	C	T	C	
Marian Wiegersma	PFMT	Watchful waiting	145	142	64.5	64.0	27.0	26.6	2.4 1.2	2.4 1.1	3
Suzanne Hagen	PFMT	Lifestyle advice	225	222	56.2	57.5	27.2	27.4	2 (2-3)	2 (2-3)	3
Hagen S	PFMT	Lifestyle advice	224	222	56.8		-	-	2.0		3
Ulla Due	PFMT	Lifestyle advice	56	53	58.0	60.0	25.0	24.0	2.0	2.0	4
Boudewijn J Kollen	PFMT	Pessary treatment	80	82	65.6 (6.4)	64.9 (7.4)	26.6 (4.3)	26.1 (3.8)	2.6 (1.1)	2.4 (0.9)	3
Liliana Stupp	PFMT	Lifestyle advice	21	16	52.95 (6.4)	58.12 (9)	29.9 (3.5)	29.7 (2.7)	3.2 (2.2)	4 (3.2)	3
Suzanne Hagen	PFMT	Lifestyle advice	23	24	56 (9)		-	-	-	-	3
CMCR Panman	PFMT	Watchful waiting	145	142	64.5 (6.8)	64.0 (6.5)	27.0 (4.7)	26.6 (4.8)	2.4 (1.2)	2.4 (1.1)	4

T: Treatment group; C: Control group; BMI: Body Mass Index; PFMT: Pelvic Floor Muscle Training; -: Not Applicable.

was defined as homogeneous data and assessed by fixed-effect model. The continuous variables were presented as the mean ± standard deviation (SD) and analyzed by mean difference (MD). The categorical data were presented as percentages and analyzed by relative risk (RR) or odds ratio (OR). POP-Q stages improvement were analyzed by OR and 95% CI. MD along with 95% CI were used to analyze PFDI-20, POPDI-6, CRADI-8, UDI-6, PFIQ-7.

Results

Study selection and characteristics of the included studies

Five hundred and seventy one articles were searched using the index words, and 485 articles were excluded after screening the titles or abstracts. 86 remaining articles were for further evaluation. After obtaining and thorough reviewing the full text, 78 articles were eliminated for not meeting the inclusion criteria: not RCT (n = 5), repeat publication (n = 26), theoretical research (n = 16), no clinical outcomes (n = 14), economic analysis (n = 8), the treatment is not only PFMT (n = 9). Finally, 8 RCTs [7-14] were included in the meta-analysis with 919 patients in the treatment group and 903 patients in the control group. The flow diagram of selection process and results of literature search were displayed in **Figure 1**.

The main characteristics of the included studies were summarized in **Table 1**. All the included studies adopted PFMT in the treatment group and in the placebo group. Five studies adopted lifestyle advice, two studies adopted watchful waiting and one study adopted pessary treatment. The basic characteristic information included age, body mass index (BMI) and parity. Six studies got a score of 3 and two studies got a score of 4. The main Jadad score of the included studies was 3.2, indicating that the 8 included RCTs were with high-quality.

Synthesis of results

Eight studies with 1822 patients (PFMT group = 919, control group = 903) reported the POP-Q stages change after the PFMT intervention. Based on the Chi-squared test *P*-value (P-add = 0.338, P-no = 0.301, P-reduce = 0.537, P-overall = 0.145) and I^2 tests-value (I^2-add = 12.1%, I^2-no = 17.4%, I^2-reduce = 0.00%, I^2-overall = 26.0%), we chose fixed-effect model to analyze the POP-Q stages improvement. The pooled results showed that add one or more POP-Q stage from baseline to follow-up had no significant difference (OR: 0.98, 95% CI: 0.74-1.29, **Figure 2**) after PFMT intervention, as compared with the control group. The no change of POP-Q stage also had no difference (OR: 0.97, 95% CI: 0.77-1.23, **Figure 2**) between the two groups after treatment. The PFMT could significant decrease the POP-Q stage (OR: 1.76, 95% CI: 1.24-2.48, **Figure 2**), as compared with the control group. The overall analysis revealed no significant difference (OR: 1.11, 95% CI: 0.95-1.30, **Figure 2**) of POP-Q stages change between the two groups.

Four studies with 845 patients (PFMT group = 426, control group = 419) reported the PFDI-20 after the PFMT intervention. Based on the Chi-squared test *P*-value of = 0.012 < 0.05 and I^2 tests-value = 72.5% > 50%, we chose random-effect model to analyze the PFDI-20. The pooled results revealed no significant difference of the value change of PFDI-20 (SMD: 0.13, 95% CI: -0.14-0.40, **Figure 3**) after PFMT intervention, as compared with the control group.

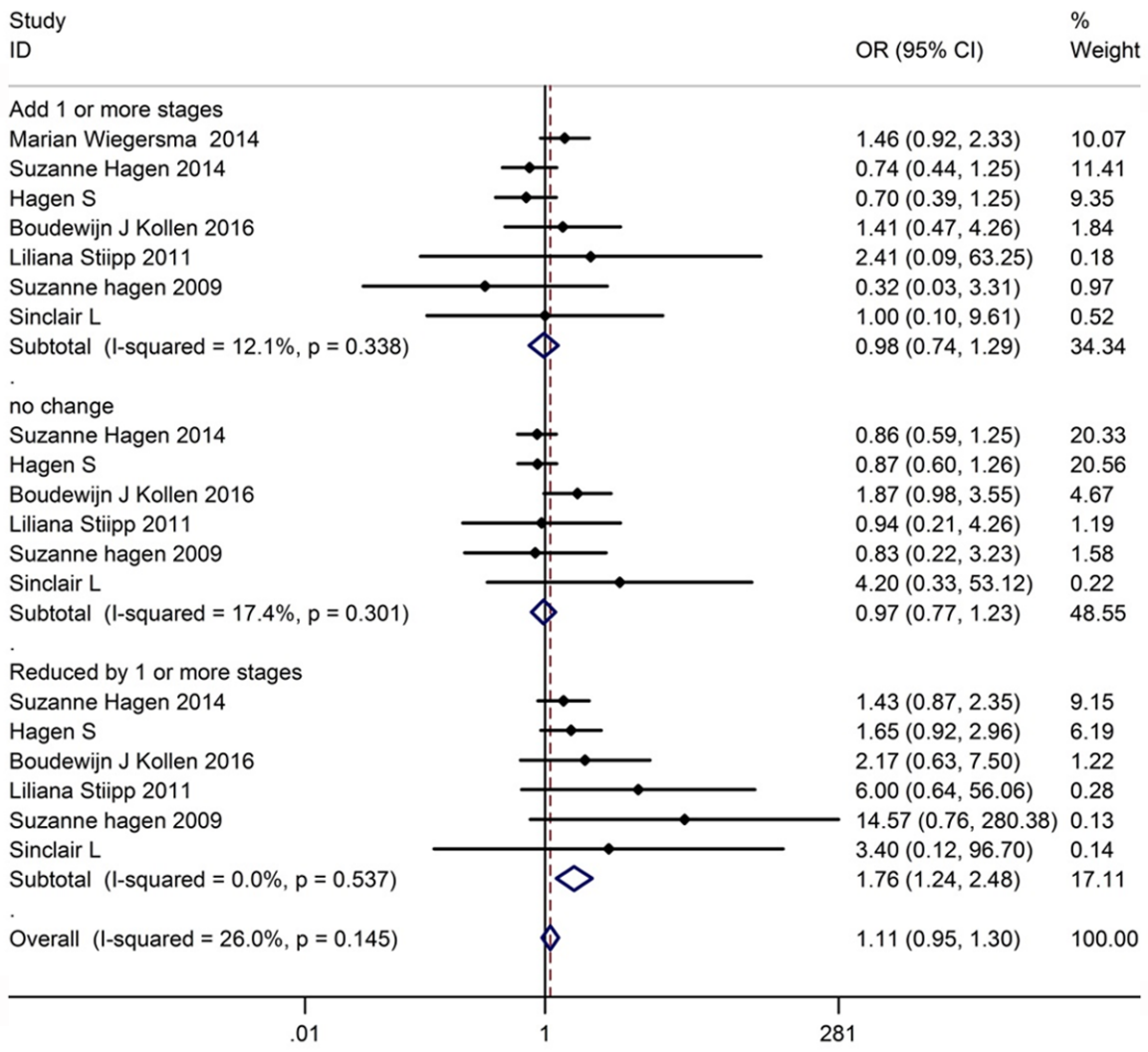

Figure 2. Forest plot showing the effect of PFMT on POP-Q stages change.

Four studies with 845 patients (PFMT group = 426, control group = 419) reported the POPDI-6 after the PFMT intervention. Based on the Chi-squared test *P*-value of = 0.005 < 0.05 and I^2 tests-value = 76.9% > 50%, we chose random-effect model to analyze the POPDI-6. The pooled results showed there was no significant difference of the value change of POPDI-6 (SMD: 0.14, 95% CI: -0.15-0.43, **Figure 4**) after PFMT intervention, as compared with the control group.

Four studies with 845 patients (PFMT group = 426, control group = 419) reported the CRADI-8 after the PFMT intervention. Based on the Chi-squared test *P*-value of = 0.171 > 0.05 and I^2 tests-value = 40.2% < 50%, we chose fixed-effect model to analyze the CRADI-8. The pooled results showed no significant difference of the value change of CRADI-8 (SMD: 0.03, 95% CI: -0.11-0.16, **Figure 5**) after PFMT intervention, as compared with the control group.

Four studies with 845 patients (PFMT group = 426, control group = 419) reported the UDI-6 after the PFMT intervention. Based on the Chi-squared test *P*-value of = 0.013 < 0.05 and I^2 tests-value = 72.2% > 50%, we chose random-effect model to analyze the UDI-6. There was no significant difference of the value change of UDI-6 (SMD: 0.17, 95% CI: -0.10-0.43, **Figure 6**) after PFMT intervention, as compared with the control group.

Four studies with 845 patients (PFMT group = 426, control group = 419) reported the PFIQ-7

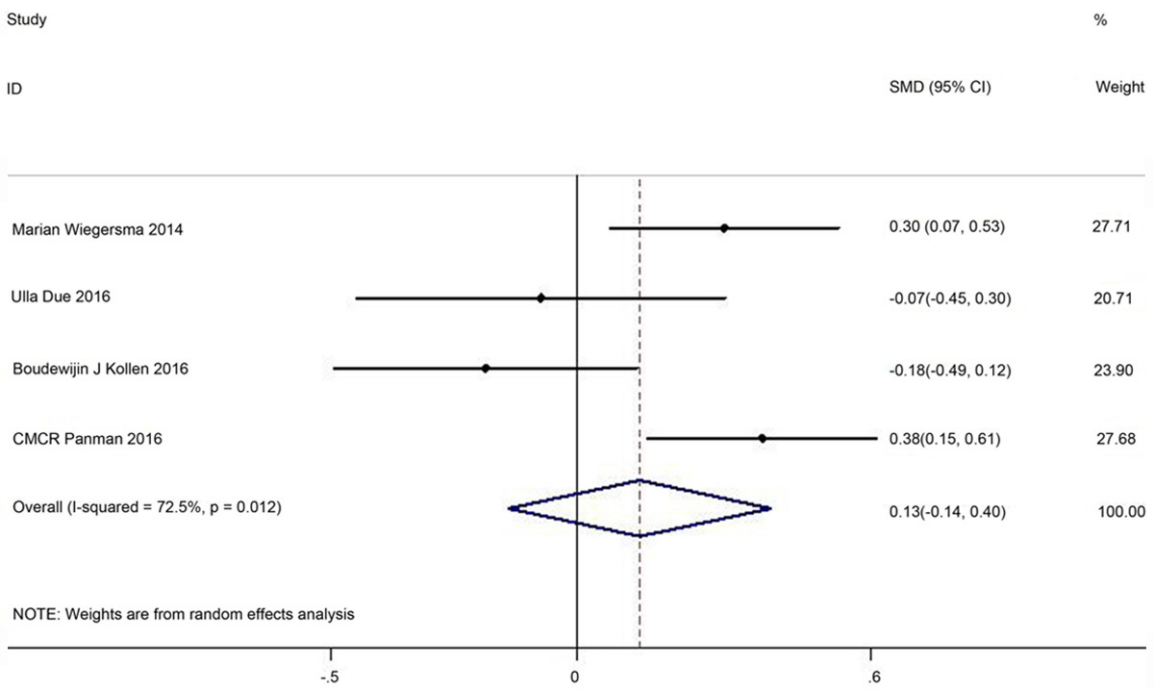

Figure 3. Forest plot showing the effect of PFMT on PFDI-20.

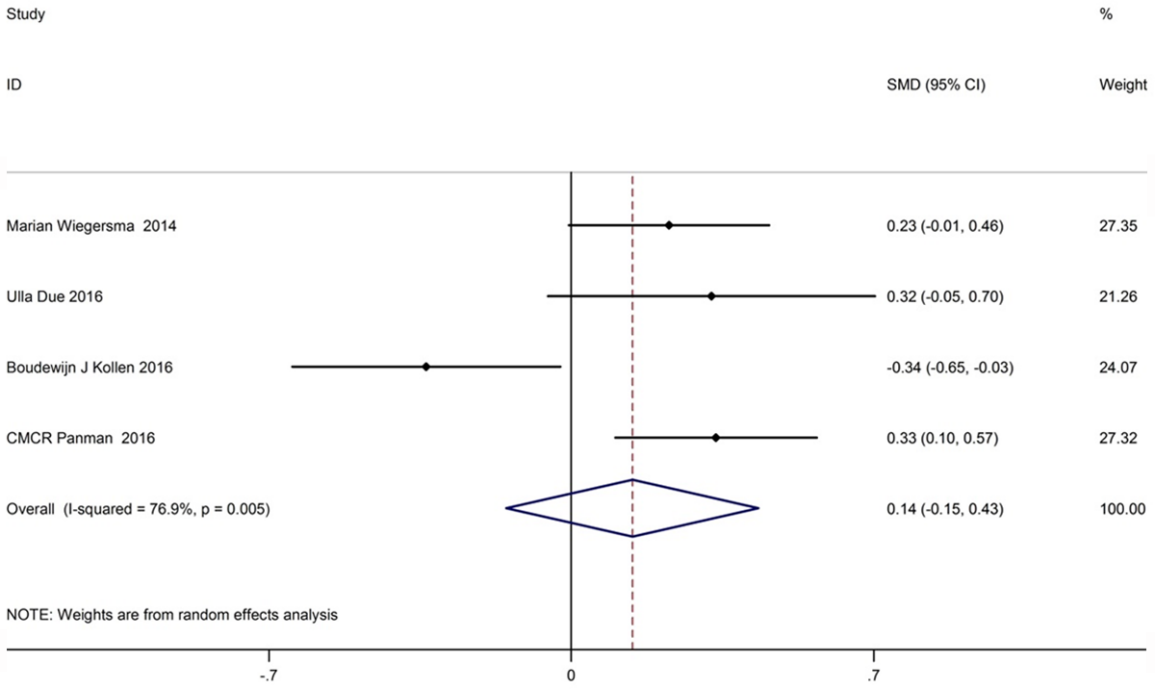

Figure 4. Forest plot showing the effect of PFMT on POPDI-6.

after the PFMT intervention. Based on the Chi-squared test *P*-value of = 0.162 > 0.05 and I^2 tests-value = 41.6% < 50%, we chose fixed-effect model to analyze the PFIQ-7. There was no significant difference of the value change of PFIQ-7 (SMD: 0.05, 95% CI: -0.09-0.18, **Figure 7**) after PFMT intervention, as compared with the control group.

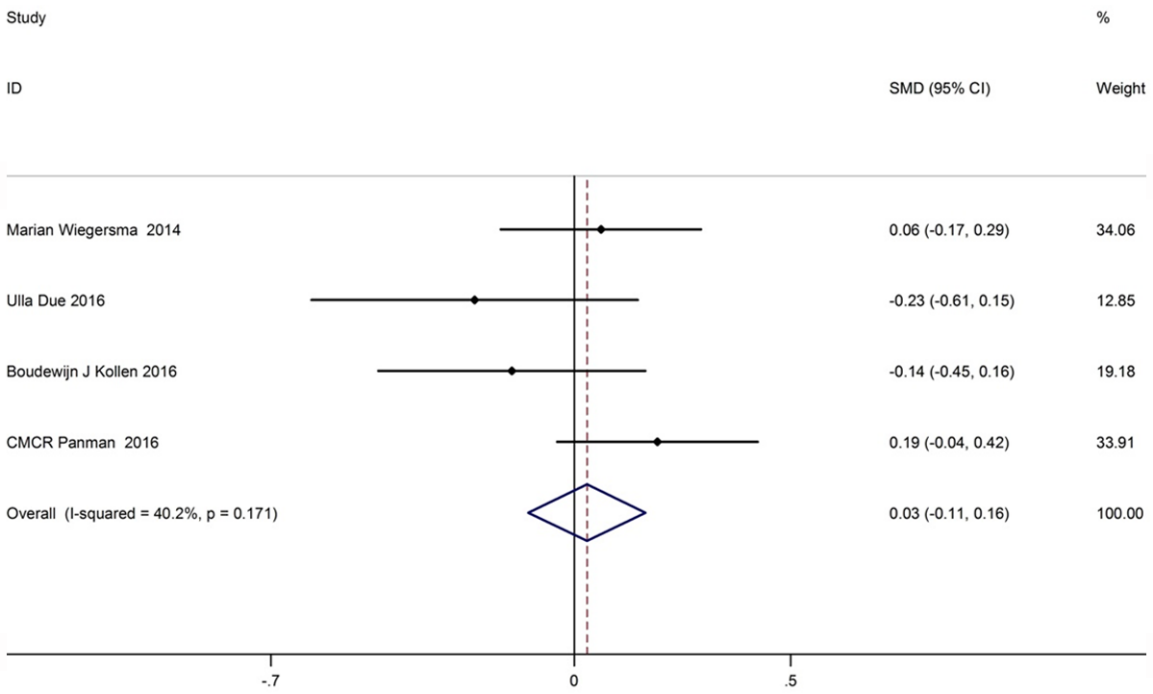

Figure 5. Forest plot showing the effect of PFMT on CRADI-8.

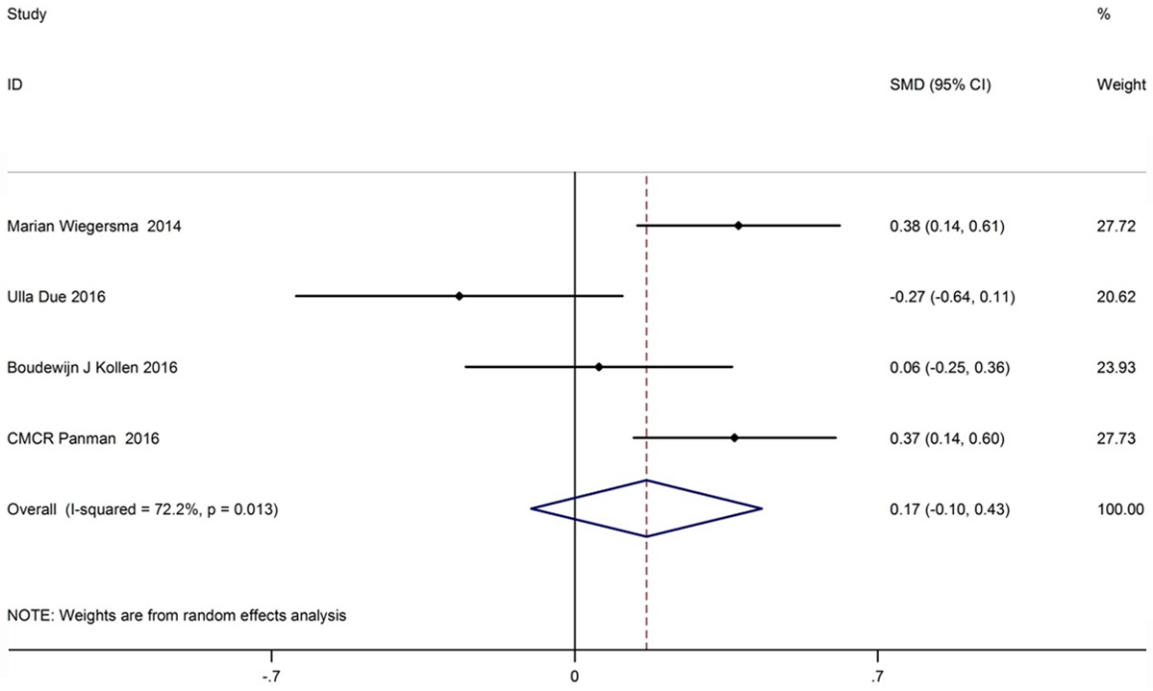

Figure 6. Forest plot showing the effect of PFMT on UDI-6.

Publication bias

We did not assess publication bias because of the low power associated with the low number of the included studies. The potential publication bias of primary outcomes was presented with funnel plot in **Figure 8**. The funnel plot of the effect of PFMT on POP-Q stages change is

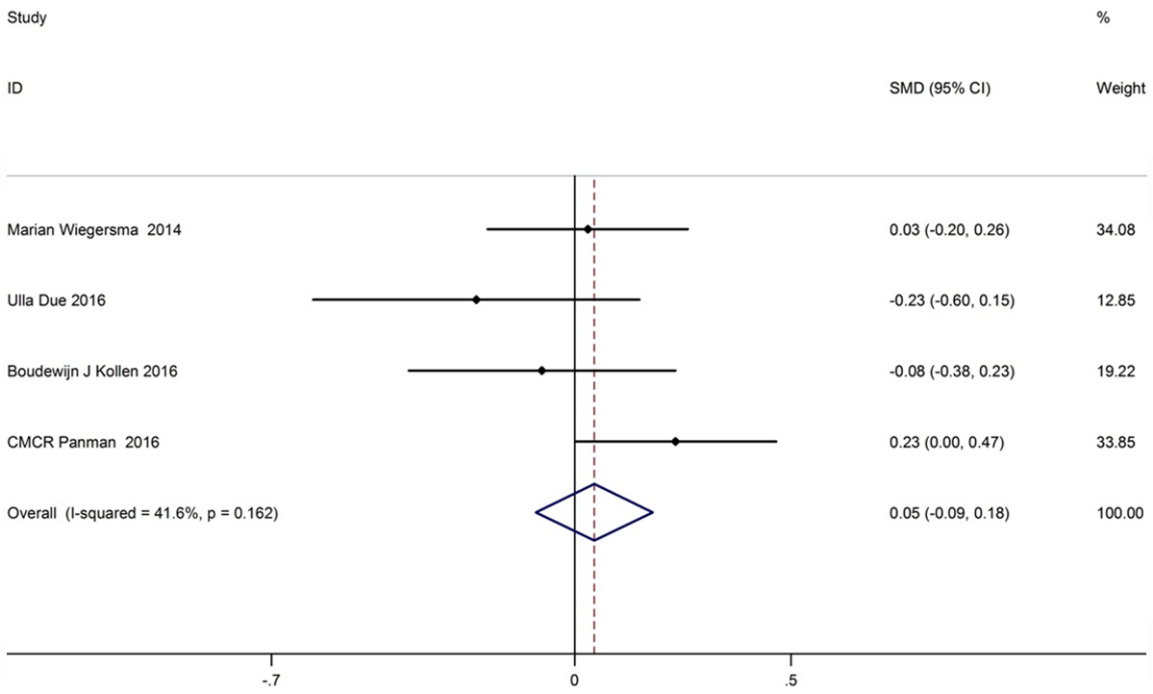

Figure 7. Forest plot showing the effect of PFMT on PFIQ-7.

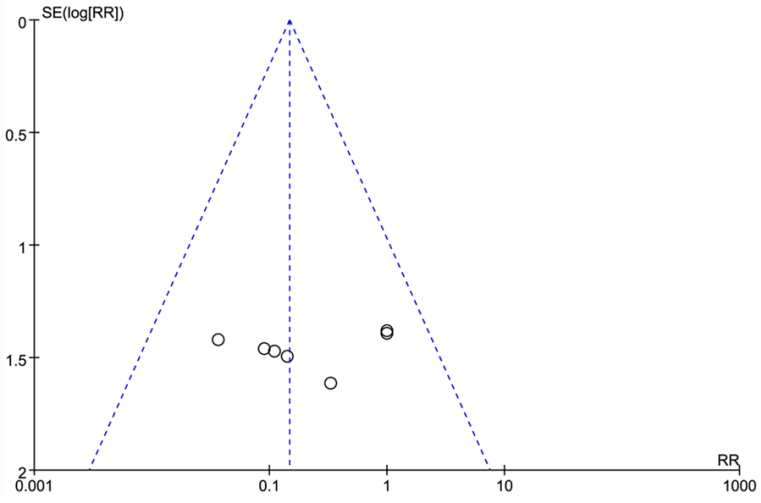

Figure 8. Funnel plot of the effect of PFMT on POP-Q stages change.

basically symmetric. Therefore, we believe that the risk of publication bias is low in this meta-analysis.

Discussion

In previous similar study, Li *et al.* [15] found that based on 13 studies, women receiving PFMT would significant improve the prolapse symptom score and POP stages than the control group. The number of women who said their prolapse was getting better and other discomfort syndromes such as vaginal, bladder, and rectum, were lower in the PFMT groups. Meanwhile, women after PFMT had greater improvement in muscle strength and endurance, but did not show a significant difference. In addition, the results evaluating PFMT as an adjunct to prolapse surgery were inconclusive because of the variability in methods of measuring outcome. Some latest evidences [16-18] indicated that PFMT is beneficial to women with symptomatic mild prolapse or urinary incontinence. Studies [19, 20] indicated PFMT could effectively support the pelvic organ in the normal anatomic position by contracting pelvic floor muscles before and during any increase in abdominal pressure. According to a Cochrane Review [21], PFMT should be recommended as the first-line conservative management for stress urinary incontinence. Hagen *et al.* [16] reported that six studies had been published, in which two studies showed a positive effect of PFMT as an adjunct for women undergoing cor-

rective surgery and four trials demonstrated that PFMT, as a treatment for women with POP, resulted in a significant improvement of prolapse symptoms and severity of POP as compared with the control group.

Our pooled results indicated that females receiving PFMT could decrease the POP-Q stage compared with the control group, and this was consistent with the previous studies. There was no statistical difference in adding one or more POP-Q stage, no change of POP-Q stage, the overall POP-Q stage change, PFDI-20, POPDI-6, CRADI-8, UDI-6, PFIQ-7 after PMFT treatment as compared with the control group.

However, the results described in the present study do have limitations. The limitations are as follows: (1) only randomized controlled trials (RCTs) were included; (2) differences in the inclusion criteria and exclusion criteria for patients; (3) different patients with previous disease and treatments were unavailable; (4) most trials with low quality and low Jadad score were included in our study; (5) different treatment times of PFMT; (6) pooled data were used for analysis, and individual patient's data were unavailable, so it limited us to make more comprehensive analysis.

Based on the available evidences, our meta-analysis demonstrated that the applied PFMT program could be an effective way to improve POP stage as compared with the control group. PFMT intervention also significantly decreased PFDI-20, POPDI-6, CRADI-8, UDI-6 and PFIQ-7, but had no significant difference. For PFMT as an adjunct to prolapse surgery, the results from the included trials were inconclusive because of the variability in methods of measuring outcomes. Thus, further pragmatic trials are warranted based on the same protocol, and longer follow-up studies are need to confirm or refute the results presented in our meta-analysis.

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Disclosure of conflict of interest

None.

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