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Effect of Pelvic Floor Muscle Training on Female Sexual Function During Pregnancy and Postpartum: A Randomized Controlled Trial

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Abstract

Background: Current evidence on the effect of pelvic floor muscle (PFM) training for promoting sexual function is limited. Recent reviews indicate need for high quality trials in this area.
Objectives: To examine the effect of PFM training on sexual function (primary outcome), sexual quality of life, and PFM strength (secondary outcomes) in pregnant and postpartum women.
Methods: This was an assessor-blind two parallel arm superiority trial. A total of 84 nulliparous women with a singleton pregnancy at 17 - 20 weeks, aged 18 - 35 years, were recruited using purposive sampling among clients of five public health centers or two governmental maternity clinics in Sari-Iran. The recruitment was done from May to November 2014 and follow up ended on July 2015. Participants were equally allocated into either PFM training or routine care groups using block randomization. Women allocated to the PFM group received 4 sessions of supervised training, with practical, oral, and written instructions on how to continue performing regular PFM exercises at home. Female sexual function index, sexual quality of life questionnaire-female, and Oxford scoring were used to assess the outcomes at 28 - 30 weeks gestation and 80 - 90 days following birth.
Results: There was one loss to follow-up from each group. A total of 6 women had not exercised regularly. Compared with the control group, the mean total sexual function score was significantly greater in the PFM training group during both pregnancy (29.3 vs 21.1; adjusted difference 9.4, 95%CI 7.7 to 11.0, $P < 0.001$) and postpartum (28.7 vs 16.0; adjusted difference 13.0, 95%CI 12.1 to 13.9, $P < 0.001$). Also, almost all domains of sexual function, sexual quality of life, and PFM strength during both periods improved significantly in women who received the PFM training compared with the controls.
Conclusions: Based on the results, PFM training during pregnancy and postpartum could improve sexual function in nulliparous women. Therefore, it should be recommended to all of the women.

Keywords: Pelvic Floor, Quality of life, Exercise, Sexual function, Pregnancy, Postpartum

1. Background

Sexual function is an important part of human life (1), with an undeniable effect on the quality of life of the individuals and their partners. Diminished sexual activity or relationship may adversely affect individual health and self-esteem, as well as interpersonal relationships (2), resulting in the loss of an emotional connection and mental tension between partners (3). Such a problem during pregnancy, when couples need greater intimacy, can make the already highly tense period of pregnancy even harder (3).

Sexual dysfunction is a common problem among pregnant and postpartum women. Studies have reported that the prevalence of sexual dysfunction is between 23% and 47% in the 2nd trimester, between 46% and 73% in the 3rd trimester of pregnancy (4, 5), and between 43% and 83% after childbirth (6, 7).

Physical including vascular, neurological, and muscular changes are considered among the reasons for the higher sexual disorders during pregnancy and postpartum (8, 9). Hormonal changes during pregnancy, including an increase in relaxing and progesterone, can lead to hypotonicity of the pelvic floor structures and increased pelvic vascularity (10). Moreover, childbirth injuries and trauma, including pudendal nerve damage, poor healing of perineal muscles, vaginal laxity, and reduced activity of the levator ani muscle, are among physiological factors influencing reduced sexual activities in these periods (11).

Some studies show a positive association between

strength of pelvic floor muscle (PFM) and sexual function (12, 13). It is believed that the pelvic floor muscles have an important role in creating involuntary contractions in women during intercourse by strengthening vaginal lining, increasing blood flow to the genitalia, as well as being responsible for the sensitivity felt by couples during sexual activity (14-16).

Pelvic floor exercises, i.e. repeatedly contracting and relaxing of specific pelvic muscles, are among strategies proposed for strengthening pelvic floor muscles (17). Using these contractions also probably helps increase blood flow to pelvic muscles (18).

Studies regarding effect of PFM on sexual function are limited. Bo et al. (19) reviewed 3 studies published between 2001 and 2011 and concluded that a few trials with supervised PFM training show some promising results on sexual function. Another recent review (20) of 8 trials published between 1997 and 2014 also indicated some positive effects of the PFM training on sexual function in women with pelvic floor dysfunction. This review found no studies done on pregnant women and only 1 study on postpartum women. None of the participants had been selected without regard to their continence status or pelvic floor dysfunction in any of the studies. They reported that the methodological score of the trials was moderate, and sexual function was the primary outcome in only 1 trial (21) with high risk of bias due to high attrition (35%). Both reviews suggested further high quality trials in this area due to the small number of studies with contradictory results and high risk of bias.

Therefore, the present study was conducted to examine the effects of PFM training on sexual function, sexual quality of life, and PFM strength of women during pregnancy and post-partum.

2. Methods

2.1. Study Design and Participants

This randomized controlled trial (RCT) with an assessor-blind 2 parallel arms was conducted in Sari, the provincial capital of Mazandaran with a population of about 300000, located in the north of Iran. The study protocol was approved scientifically by the research committee and ethically by the ethics committee (code: 92203, 2014 - 02 - 19) of Tabriz University of Medical Sciences and registered at the Iranian registry of clinical trials (IRCT201403013706N22) before starting participant recruitment. Written informed consent was obtained from each participant.

A total of 84 nulliparous singleton pregnant women at 17 - 20 weeks gestation, aged 18 - 35 years, were recruited from 5 out of 12 public health centers (those with a large number of pregnant clients selected from different geographical areas with various levels of socio-economic status), and from the only clinic affiliated to the social security insurance, as well as from the clinic of the only public maternity hospital of the city. Public health centers and the clinics cover about 70% of pregnant women in the city.

The exclusion criteria included: 1, having less than 6 years of education; 2, no permanent marriage or not living with husband; 3, prior history of 2 or more abortions; 4, any pregnancy-related complications limiting sexual function (e.g., placenta previa, cervical cerclage); 5, addiction to drugs or alcohol; 6, experience of severe emotional stress within the past 3 months; 7, medical conditions associated with sexual dysfunction (e.g. cardiovascular or respiratory diseases, epilepsy, depression, mania, limb amputation or paralysis, vaginusmus); 8, taking medications likely to influence sexual function (including blood pressure drugs, thiazide diuretics, anti-depressants, anti-histamines, barbiturates, narcotics, diazepines, and amphetamines, cocaine); 9, hereditary diseases affecting connective tissue (such as Marfan syndrome, muscular dystrophy) or known abnormalities in reproductive system; 10, having 12 or more urinary incontinence episodes per day; 11, addiction, or mental or physical problems, of the husband having an effect on a couple's sexual function.

2.2. Sample Size

Considering the mean score of female sexual function index (FSFI) of 24.5 (SD 5.0) extracted from the results of a study on Iranian pregnant women (22), with a significance level of 0.05, power of 0.90, and at least a 15% increase in the mean score by the intervention. The estimated sample size was 38 per group. Considering 10% possible loss to follow-up, we decided to recruit 42 women for each group.

2.3. Randomization and Blinding

The participants were randomized into PFM training and control groups using block randomization, with block sizes of 4 and 6, and equal allocation ratios. A person not involved in the recruitment and data collection determined the allocation sequence using computer-generated random numbers and put group identification papers into sequentially numbered sealed opaque envelops to conceal the allocation sequence. The envelopes were opened sequentially after getting written informed consent, collecting baseline data, and writing participant names on the envelopes.

The person educating the exercises as well as the participants could not be blinded; however, the individual who examined the participants and collected data were blinded to the treatment.

2.4. Interventions

The PFM training group was instructed to perform PFM exercises at least twice a day, at any time and any position based on individual comfort. The exercises include 8 - 12 sets of contractions at each time and each contraction set comprised 1 strong contraction with a maximum possible power holding for 6 - 8 seconds followed by 3 or 4 contractions in a shorter period, with a 10-second complete relaxation after each contraction. They were instructed to perform the exercises from the recruitment day until 36 - 37 weeks gestation and to resume the exercises after giving birth as soon as one can.

At the recruitment day, a midwife with special training on the pelvic exercises (the MSc student, first author) gave theoretical and practical individual education, as well as a pamphlet explaining the exercises to each participant. The session took 20 - 30 minutes and included a brief explanation of the anatomy of pelvic floor muscles and how to do the exercises at different positions, also examining pelvic floor muscle contractions by hand during exercise to ensure accuracy of the exercises. Accuracy of the exercises was also checked at different positions at 3 follow-up group meetings held at 22 - 24, 28 - 30, and 34 - 36 weeks gestation, each meeting lasting about 30-minutes. In addition, telephone follow-ups were done weekly in the first month and every other week afterwards to emphasize the exercises. The women were instructed to record the exercise performance in a diary.

The control group got the routine care, including health education related to any stage of pregnancy by their own healthcare provider. They were also given additional instruction at 28 - 30 weeks gestation by the researcher, explaining individual hygiene and neonatal care.

2.5. Outcomes

The primary outcome was sexual function and the secondary outcomes were sexual quality of life and PFM strength at pregnancy and post-partum. They were assessed at baseline, the 28th - 30th weeks' gestation, and also at the 3rd month (80 - 90 days) following birth by someone not aware of the participant allocation group.

The female sexual function index (FSFI) was used to assess the sexual function. The FSFI is a validated and reliable questionnaire for evaluating sexual function of women during the past 4 weeks. It consists of 19 questions covering the 6 domains of sexual function; desire, arousal, lubrication, orgasm, satisfaction, and pain. Its score ranges 2 to 36 (18). The validity of its Persian version has been confirmed in a study in Tehran, Iran (23). In our study, Cronbach's alpha reliability coefficient was 0.91 for the whole scale and 0.84 to 0.91 for its domains.

Sexual quality of life-female (SQOL-F) was used to assess the sexual quality of life. It contains 18 Likert-type items with 6 options from completely agree to completely disagree (scoring 0 - 5 for each item and 0 - 90 for the total). The validity of its Persian version has been confirmed in Iran (24). In our study, the Cronbach's alpha reliability coefficient was 0.89 for the whole scale.

The Oxford grading system, an accepted international method, was used to determine the strength of the pelvic floor muscles. It involves a digital examination by an examiner and giving score according to strength of the muscles. This is a 6-point scale described as: 0 = no contraction, 1 = flicker, 2 = weak, 3 = moderate (with lift), 4 = good (with lift), and 5 = strong (with lift). The exams were done by a midwife trained by an expert in physiotherapy. The reliability of the exams was determined by examining 10 women, by both the midwife and the expert, and calculating the intraclass correlation coefficient, which was 0.85.

2.6. Data Analysis

The data were analyzed using SPSS-ver.16. Normal distribution of the quantitative data was confirmed using Kolmogorov Smirnov. Normality of quantitative variables by the groups was confirmed using Kolmogrov-Smirnov test. Sphericity was tested with Mauchly's test. Comparison of the groups were conducted in terms of FSFI and SQOL-F scores using repeated measures ANOVA, as well as ANCOVA at each follow-up time point (because of significant interaction effect of time and time*group) adjusted for baseline values and multiple comparisons (with Sidak), also in terms of strength of pelvic floor muscles using the Mann-Whitney U test. $P < 0.05$ was considered as significant.

3. Results

The trial enrollment period was from May to November 2014 and follow up ended on July 2015. A total of 33 out of 117 eligible women declined to participate. Out of 84 women, 42 women were randomly assigned to each group. One from the PFM training group (because of the death of a first degree relative) and 1 from the control group (refused to continue because of personal reasons) were lost to follow-up (Figure 1). A total of 6 women did not exercise regularly. Others performed at least 70% of the exercises. There were 1 - 3 missing values in the FSFI items in 4 cases of the PFM training and 10 cases of the control group, which were imputed with the mean score of other items in that domain.

The 2 groups were comparable in terms of baseline values. Their mean age was 25.6 (SD 4.3) years. One third of the women and their husbands had a university education.

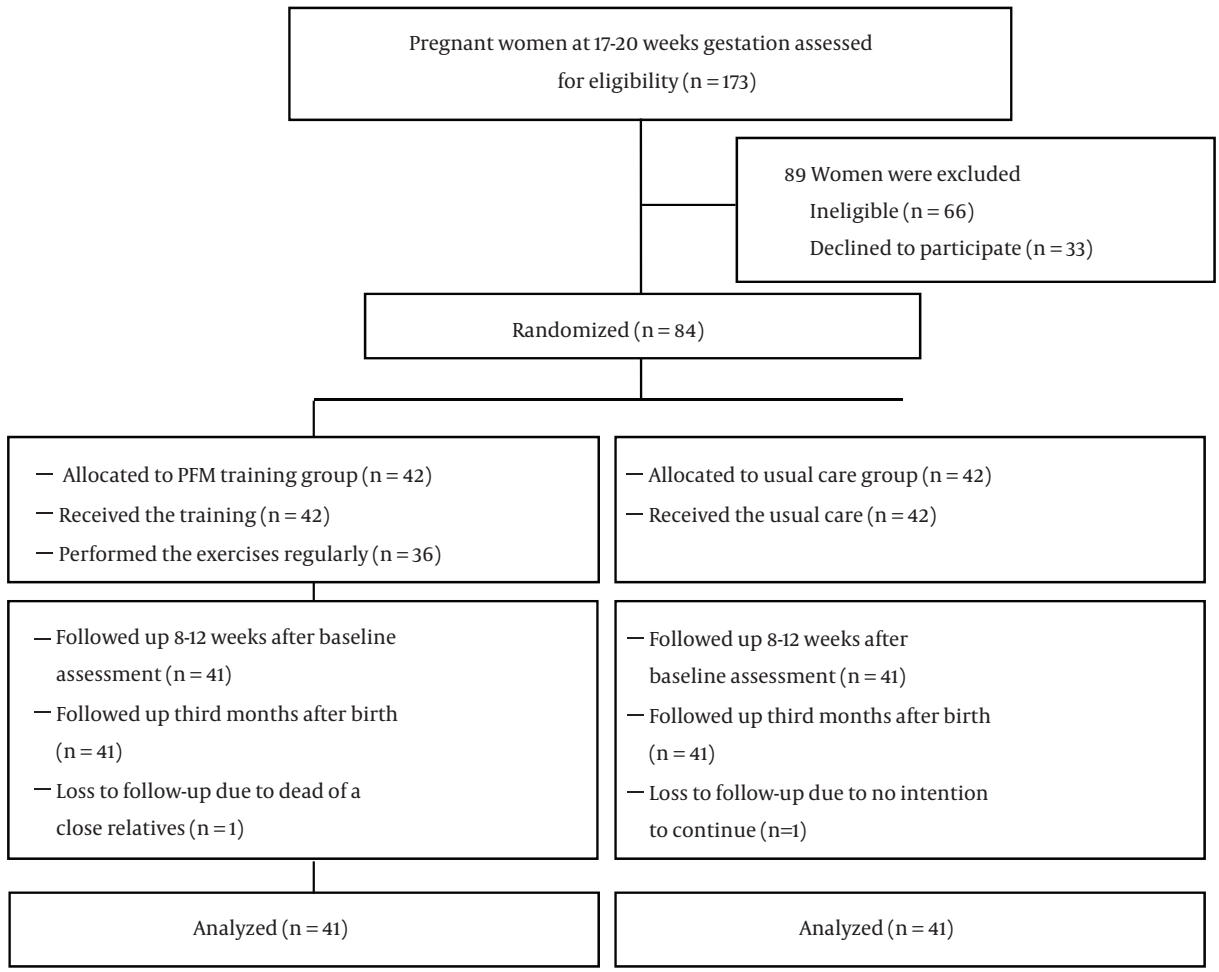


Figure 1. Flow Diagram

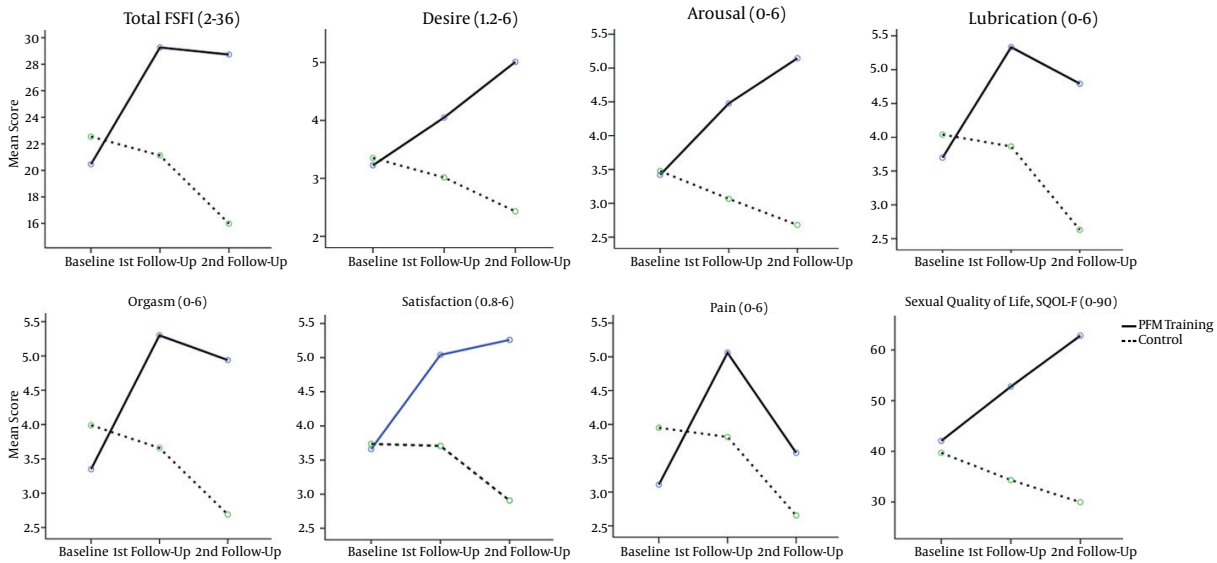
About two thirds were unemployed. About one third mentioned that their family income is insufficient for their expenses (Table 1).

The mean baseline FSFI total score was 20.6 (SD 3.2) with no significant difference between the groups. Wilks' Lambda, in repeated measures ANOVA, showed a significant interaction effect of time (P = 0.001) and time*group (P < 0.001) on the total score. Compared with the control group, mean total FSFI was significantly greater in the PFM training group during both pregnancy (29.3 vs 21.1; adjusted difference (MD) 9.4, 95% CI 7.7 to 11.0, P < 0.001; partial Ea2 0.623) and postpartum (28.7 vs 16.0; MD 13.0, 95% CI 12.1 to 13.9, P < 0.001; partial Ea2 0.881). Such differences were also observed in all domains of sexual performance (arousal, desire, orgasm, satisfaction, pain, lubrication; P < 0.001) (Table 2).

The mean baseline SQOL-F score was 41.0 (SD 9.8) with no significant difference between the groups. Wilks' Lambda, in repeated measures ANOVA, showed a significant interaction effect of time (P < 0.001) and time*group (P < 0.001) on the score. The mean scores were significantly higher in the PFM exercise group than in the control group at both follow-ups, pregnancy (52.8 vs 34.3; MD 16.6, 95% CI 12.7 to 20.5, P < 0.001; partial Ea2 0.481) and postpartum (62.3 vs. 30.5, MD 31.7, 95% CI 28.2 to 35.1, P < 0.001; partial Ea2 0.808) (Table 2).

At the baseline, half of the participants had flicker (4%) or weak (45%) pelvic muscle strength. The proportion was reduced significantly in the intervention group to 10% at 28–30 weeks of gestation and to 7% at 3 months following birth. In the control group, there was no change at pregnancy and a slight reduction (reduced to 36%) at postpartum. The differences between the groups were significant at the both follow-up time points (P < 0.001) (Table 3).

Figure 2. Sexual Function and Sexual Quality of Life Score in Different Time-Points by Study Groups



FSFI: female sexual function index, SQOL-F: sexual quality of life-female; in all outcomes, higher score indicate better function/quality; within the individual domains of sexual function, a domain score of zero indicates that no sexual activity was reported during the past month; baseline assessment was done at 17 - 20 weeks gestation and follow-up assessments were done at 28 - 30 weeks gestation (8 - 12 weeks after the baseline) and 80 - 90 days following birth.

4. Discussion

To the best of our knowledge, this is the first trial examining the effects of PFM training from mid-pregnancy to 3 months postpartum on female sexual function as the primary outcome. The results indicate considerable improvement of the primary outcome (total sexual function) and the secondary outcomes (all domains of sexual function, sexual quality of life and strength of pelvic floor muscle) during both pregnancy and postpartum periods.

Such an effect may have occurred due to the strengthening of the muscles attached to the cavernous body of the clitoris, which could lead to a better involuntary contraction of pelvic floor muscles during orgasm by improving pelvic blood flow, pelvic mobility, and clitoral sensitivity (25). Furthermore, a strengthened levator ani muscle could lead to uterine elevation and to elongation as well as narrowing of the vagina, resulting in an enhanced sexual response (26). Increased blood flow to the pelvis and enhanced clitoral sensitivity may contribute to improvement in arousal, lubrication, and orgasm (27).

The results of this study are consistent with the results of the recent review (20), which reported that 5 out of 8 individual RCTs indicated the positive effect of PFM training on at least 1 domain of sexual function. However, sexual function was the primary outcome measure in only 1 study done by Citak et al. (21), which showed a significant improvement in total FSFI and orgasm domain scores at 7 months postpartum after receiving 3 months of PFM training. In the Citak study, scores of arousal, lubrication, and pain domains were higher in the intervention group than in the control group, however, the differences were not statistically significant. In addition, there are studies showing the positive effects of pelvic floor exercises after delivery on sexual satisfaction (28) and sexual efficacy (29) in primiparous women. Furthermore, a recent trial in Turkey indicated the positive effect of PMF training with home biofeedback therapy on the improvement of all domains of sexual function in patients with sexual dysfunction (30).

The results of this study regarding the positive effect of pelvic floor muscle exercises on the pelvic floor muscle strength are consistent with the results of some other studies conducted on women during pregnancy (31, 32), postpartum (29, 31, 33), and in patients with sexual dysfunction (30).

Since increased laxity of the pelvic floor fascia and ligaments is initiated by hormonal changes during pregnancy, starting exercise during pregnancy may have a preventive effect on the laxity (34). Therefore, the greater effect size shown in our study compared to most other studies could be related to the earlier starting of exercises during pregnancy, and/or the longer period exercises. Also, eligibility criteria of the participants, such as nulliparity, may have influenced the results.

Low attrition in this study (only one from each group),

Table 1. Baseline Characteristics of Participants by the Study Groups[a]

Variable	PFM Training (n = 42)	Usual Care (n = 42)	P
Age (years)	26.0 (4.1)	25.3 (4.7)	0.093[b]
Education (years)			0.128[c]
Guidance (6 - 8)	2 (5%)	7 (17%)	
High school (9 - 12)	23 (55%)	21 (50%)	
University (13+)	17 (40%)	14 (33%)	
Employment			0.857[d]
Housewife	25 (59%)	26 (62%)	
Employed at home	7 (17%)	8 (19%)	
Employed outdoors	10 (24%)	8 (19%)	
Husband education (years)			0.108[c]
Primary (1 - 5)	2 (5%)	4 (9%)	
Guidance (6 - 8)	4 (9.5%)	8 (19%)	
High school (9 - 12)	19 (45%)	18 (43%)	
University (13+)	17 (40.5%)	12 (29%)	
Income adequacy			0.153[c]
Yes	20 (48%)	14 (33%)	
To some extent	8 (19%)	17 (41%)	
No	14 (33%)	11 (26%)	
History of abortion (yes)	5 (12%)	3 (7%)	0.713[e]
Body mass index (kg/m^2)	25.0 (3.3)	24.1 (4.5)	0.136[b]
Weight (kg)	70.4 (11.4)	68.5 (9.4)	0.412[b]
Gestational age (weeks)	19.1 (0.9)	19.0 (1.0)	0.642[b]

Abbreviation: PFM, Pelvic floor muscle.
[a]Data represent mean (standard deviation) or number (percent).
[b]Independent t-test.
[c]Chi-squared for trend.
[d]Chi-square.
[e]Fisher exact test.

resulting in a low risk of attrition bias, can be considered its strength. It may be related to the more frequent reminders and follow-ups about performing the exercises, which is done by the study team. In most of the previous studies, like the only study (21) which sexual function was its primary outcome, attrition was high.

In this study, the assessor was blinded to the participant group allocation. However, as most outcomes assessed (except strength of pelvic floor muscles) were self-reported, there is a possibility of response bias due to no blinding of participants.

This study included nulliparous women with no attention paid to the status of their prior sexual function. Examining the effect of the PFM exercises on multiparous women and considering prior sexual function in future studies is recommended. A longer follow-up is also recommended.

Based on the study results, it seems that PFM training starting from 17 - 20 weeks gestation could improve the sexual function of nulliparous women during pregnancy and postpartum. Therefore, it should be recommended to all women.

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Footnote

Conflict of Interest: The authors declare no conflict of interest in this study.

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Table 2. Outcomes (Sexual Function and Sexual Quality of Life Score) at Different Time-Points by Study Groups[a]

Outcomes	PFM Training (n = 41)			Control (n = 41)			Adj. Difference[b] (95% CI)	
	Baseline	1st Follow-Up	2nd Follow-Up	Baseline	1st Follow-Up	2st Follow-Up	1st Follow-Up	2st Follow-Up
Overall sexual function using FSFI (primary outcome)								
Total (2 - 36)	20.4 (3.8)	29.3 (4.2)	28.7 (1.8)	22.5 (3.5)	21. 1 (4.2)	16.0 (2.1)	9.4 (7.7 to 11.0)	13.0 (12.1 to 13.9)
Domains of sexual function (secondary outcomes)								
Desire (1.2 - 6)	3.1 (1.1)	4.0 (1.0)	5.0 (0.7)	3.3 (0.9)	3.0 (1.1)	2.4 (0.7)	1.1 (0.7 to 1.5)	2.6 (2.3 to 2.9)
Arousal (0 - 6)	3.4 (0.9)	4.5 (1.1)	5.1 (0.6)	3.1 (0.8)	3.1 (0.8)	2.7 (0.6)	1.4 (1.0 to 1.8)	2.5 (2.2 to 2.7)
Lubrication (0 - 6)	3.6 (1.0)	5.3 (0.7)	4.8 (0.7)	4.0 (0.9)	3.9 (0.9)	2.6 (0.6)	1.6 (1.2 to 1.9)	2.1 (1.9 to 2.4)
Orgasm (0 - 6)	3.3 (0.7)	5.3 (0.8)	4.9 (0.6)	3.9 (0.8)	3.6 (0.9)	2.7 (0.5)	2.0 (1.6 to 2.4)	2.2 (2.0 to 2.5)
Satisfaction (0.8 - 6)	3.7 (0.5)	5.0 (0.7)	5.3 (0.5)	3.7 (0.6)	3.7 (0.9)	2.9 (0.8)	1.4 (1.0 to 1.7)	2.4 (2.1 to 2.6)
Pain (0 - 6)	3.1 (1.1)	5.1 (0.8)	3.6 (0.6)	3.9 (1.0)	3.8 (1.1)	2.6 (0.8)	1.7 (1.4 to 2.1)	0. 7 (0.4 to 1.0)
Sexual quality of life (secondary outcome)								
SQOL-F (0 - 90)	42.1 (10.2)	52.8 (13.6)	62.3 (11.4)	40.0 (9.4)	34.3 (9.0)	30.5 (6.1)	16.6 (12.7 to 20.5)	31.7 (28.2 to 35.2)

Abbreviations: FSFI, female sexual function index; SQOL-F, sexual quality of life-female.
[a] In all outcomes, higher scores indicate the better function/quality; within the individual domains of sexual function, a domain score of zero indicates that no sexual activity was reported during the past month; data are means (SD) except otherwise indicated; baseline assessment was done at 17 - 20 weeks gestation and follow-up assessments were done at 28 - 30 weeks gestation (8 - 12 weeks after the baseline) and 80 - 90 days following birth; $P < 0.001$ in all comparisons at the both follow-ups.
[b] Difference between the two groups using ANCOVA adjusted for baseline values; repeated measures ANOVA (adjusted for multiple comparison using Sidak) was used for comparison of the groups adjusted for baseline value, Wilks' Lambda showed significant effect of time ($P = 0.001$ for FSFI, $P < 0.001$ for SQOL-F) and time * Group ($P < 0.001$ for the both outcomes)

Table 3. Pelvic Floor Muscle (PFM) Strength (Secondary Outcome) by Study Groups[a]

Oxford Score	PFM Training (n = 41)			Usual Care (n = 41)		
	Baseline	1st Follow-Up	2nd Follow-Up	Baseline	1st Follow-Up	2nd Follow-Up
1 (flicker)	2 (5%)	0	0	2 (5%)	1 (3%)	1 (2.4%)
2 (weak)	20 (48%)	4 (10%)	3 (7%)	18 (42%)	18 (44%)	15 (36%)
3 (moderate)	16 (38%)	14 (34%)	7 (17%)	19 (45%)	17 (41%)	24 (57%)
4 (good)	4 (9%)	18 (44%)	24 (57%)	2 (5%)	5 (12%)	1 (2%)
5 (strong)	0	5 (12%)	7 (17%)	1 (3%)	0	0

[a] Baseline assessment was done at 17 - 20 weeks gestation and follow-up assessments were done at 28 - 30 weeks gestation and 80 - 90 days following birth; Data represent number (percent); Using Mann-Whitney U test, PFM strength at the baseline was similar in the groups ($P = 0.78$), but at the both post-intervention assessments it was significantly stronger in the PFM training group ($P < 0.001$).

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