

The Effect of Pilates Exercise on Maternal and Neonatal Outcomes in Pregnancy

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ABSTRACT

Background & aim: Some pregnant women experience pregnancy complications that can lead to maternal and fetal mortality and morbidity. The aim of this study was to evaluate the effect of Pilates Exercise on maternal and newborn outcomes.

Methods: In the present double-blind randomized clinical trial, participants and outcome assessors were blinded to group assignment. Participants included 60 pregnant women who were at 20 weeks of gestation referred to the health care centers in Shahrekord, Iran. They were initially entered the study by a stratified random sampling method and then randomly divided into intervention and control groups. The intervention group were required to attend two moderate-intensity Pilates exercise sessions per week for 12 weeks. Each session lasted 30 minutes. Maternal outcomes were assessed using a self-report checklist combined with medical record review. Neonatal outcomes (including jaundice, transient tachypnea, stillbirth, and birth weight) were obtained exclusively from medical records. Data were analyzed with SPSS software version 23 using independent t-test, Chi square and ANOVA.

Results: After the intervention, maternal outcomes including low back pain ($P=0.001$), pelvic pain ($P<0.001$), gestational diabetes ($P<0.001$), transient hypertension of pregnancy ($P=0.002$) and urinary incontinence ($P=0.013$) were significantly lower in the intervention than the control group. However, no statistically significant differences were observed between the groups for any neonatal outcomes including jaundice, transient tachypnea of the newborn, stillbirth, and birth weight.

Conclusion: Pilates exercise significantly improved maternal outcomes without affecting neonatal health, supporting its inclusion in prenatal education programs.

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Introduction

As one of the most significant periods in a woman's life, pregnancy is recognized as a special physiological window through which a fetus and mother's long-term health may be significantly affected (2). Despite the fact that most women enjoy being pregnant, mothers may experience stress due to the physiological,

anatomical, and biochemical changes (3-4). Pregnancy is often accompanied by typical discomforts such as physical aches, exhaustion, headaches, heartburn, and edema (1, 3-4). In addition to the mentioned complications, about 15% of pregnant women experience pregnancy complications that can lead to maternal and fetal

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mortality and morbidity (5). In response to the limitations of existing treatments for pregnancy-related disorders, leading health authorities such as the American College of Obstetricians and Gynecologists (ACOG) and the World Health Organization (WHO) now emphasize the role of physical activity (3, 5).

Given the necessity of physical activity in women with uncomplicated pregnancy, the American College of Obstetricians and Gynecologists (ACOG) recommended exercise at an average intensity for 20 to 30 minutes a day in most or all days of the week during pregnancy (6). According to the WHO recommendations and literature, exercising during pregnancy reduces the risk of preeclampsia, cesarean delivery, gestational diabetes, blood pressure disorders (30%), and accelerates recovery from prenatal and postpartum depression, and has no negative effect on birth weight. The protective effect of exercise on cardiovascular problems was also confirmed throughout life (7-9).

The modified Pilates as one of exercise activities was recommended by ACOG during pregnancy (10). Pilates improves body strength, stability, and flexibility by saving and increasing energy levels, reduces stress and fatigue, musculoskeletal pain, creates relaxation, improves sleep quality, and quality of life (9-13). Unlike general exercise, Pilates focuses on strengthening the deep core and pelvic floor muscles, improving postural alignment, and emphasizing controlled breathing and precise movement. This specific focus makes it particularly effective in managing common pregnancy-related issues, such as lumbopelvic pain and urinary incontinence, by providing better musculoskeletal support and stability, while the direct effects on neonatal outcomes are less clear and may be influenced by improved maternal homeostasis, the primary benefits for maternal well-being are substantial (9-13). In the second and third trimesters of pregnancy, light strength exercises like Pilates can be done once or twice a week, with eight to ten muscle strength exercises per session, according to a systematic review of physical activities during pregnancy. But there has been limited research on the effects of these exercises (14). According to another systematic review, investigating the effect of Pilates on women's health showed that

no strong evidence are available over the impact of Pilates during pregnancy and so such studies are needed (13). Despite the numerous benefits of Pilates and the ACOG's recommendation to perform this exercise during pregnancy, its benefits on pregnancy are still debated and further related investigations are required (15). So this study performed to examine the effect of Pilates exercise on maternal and neonatal outcomes.

Materials and Methods

The present double-blind randomized clinical trial was carried out among pregnant women who referred to the health care centers of Shahrekord, Iran from June 2019 to March 2020. Registration of this randomized control trial has been completed with the Iranian Registry of Clinical Trials (IRCT), under code ocIRCT20170124032161N2.

According to similar study (6), considering the significance level ($\alpha=0.05$) and test power ($\beta=80\%$) and the standard deviation of the pregnancy outcome score (mean /SD pain score) ($S=5.5$), and in order to achieve a significant difference (at least 2 points) in the average score in the intervention and control groups, the sample size was calculated 30 participants in each group.

This study was a double-blind trial. The participants were blinded to their group assignment; they were informed that they were participating in a study comparing two different types of prenatal wellness programs to minimize bias in their self-reported outcomes (such as pain levels). The midwives and obstetricians responsible for assessing the maternal and neonatal outcomes after delivery, as well as the data analyst, were also blinded to the group allocation (intervention or control). This ensured that the collection and interpretation of outcome data were not influenced by knowledge of which group each participant belonged to. The Pilates instructor, however, could not be blinded due to the nature of the intervention.

To recruit samples, a cluster randomized controlled trial design was employed. First, six health centers were randomly selected from strata of high ($n=2$), medium ($n=2$), and low ($n=2$) socioeconomic areas in Shahrekord to ensure representativeness. The unit of randomization was the health center (the

cluster), not the individual participant. This method was chosen to minimize the risk of contamination between the intervention and control groups, as the geographical distance between centers prevented contact among participants.

The allocation of these clusters to the study groups was performed using a stratified, computer-generated randomization sequence to maintain balance across socioeconomic strata. This process was overseen by an independent statistician who was not involved in participant recruitment or data collection. Specifically, within each socioeconomic stratum (high, medium, low), one health center was randomly assigned to the Pilates intervention group and the other to the routine care control group. This approach ensured that each study group contained an equal number of centers from each socioeconomic level, thereby controlling for potential confounding related to socioeconomic status.

Following the cluster allocation, eligible pregnant women were recruited from within these pre-assigned health centers.

The participants were chosen based on the following inclusion criteria: healthy pregnant women with no underlying medical conditions; no absolute or relative prohibition of exercise during pregnancy (e.g., vaginal bleeding, preterm labor, twin pregnancies, $BMI < 18.5$, etc) (3), abstinence from medication, consent to take part in the study, and instruction in literacy. The exclusion criteria included not being able to continue with the study, not being able to complete the questionnaire, not receiving Pilates instruction for more than one session, and having an absolute or partial exercise contraindication during the study.

The sampling process started by studying the files of pregnant women in the selected health centers, followed by calling to mothers who had the inclusion criteria, and then explaining the research purpose and procedure to them. Of 135 women who met the inclusion criteria, 75 individuals refused the study because of worry about the safety issues. After providing their written consent, mothers who consented to take part in the study filled out the Exercise checklist and the demographic questionnaire.

Participants also had access to the researcher's cell phone number, which they could use to get in touch with her if they had any problems with the exercises.

The intervention group began Pilates exercises at week 20 of pregnancy. Exercises based on safe Pilates exercises during pregnancy protocol were done in the gym under the supervision of a teacher who holds a certificate in Pilates exercise coaching. For 12 weeks, the intervention was carried out twice a week for 30 minutes at a moderate intensity. Eight to ten strength exercises were done during each session (6, 12,14). The Pilates intervention consisted of mat exercises that were specifically modified for pregnancy. These exercises focused on strengthening the deep core and pelvic floor muscles, improving postural alignment, and practicing controlled breathing. Key modifications were implemented in accordance with standard guidelines for prenatal exercise, including the avoidance of supine (on-the-back) positions after the first trimester and the exclusion of exercises that involved excessive stretching or flexion of the abdominal muscles. The program was designed to be safe and targeted the musculoskeletal changes specific to pregnancy.

Ultrasound was used to determine gestational age at the beginning of the study. In order to verify that the participants consistently completed the exercises, the trainer was requested to date and sign an attendance list at the end of each session. The participants in the intervention group received weekly reviews of the exercise checklist and phone follow-ups from the researcher. During their pregnancy, the control group received standard medical care. In the event that control group participants engaged in Pilates exercises while expecting, they were substituted and removed from the study. Data on low back and pelvic pain were collected using self-report checklists administered during the participants' most recent prenatal visit at the health centers. The researcher collected these completed forms to assess pain levels until delivery.

Low back and pelvic pain during pregnancy were assessed once, after the completion of the 12-week exercise intervention and before

delivery, using a self-reported Visual Analog Scale (VAS). A brief interview guide equipped

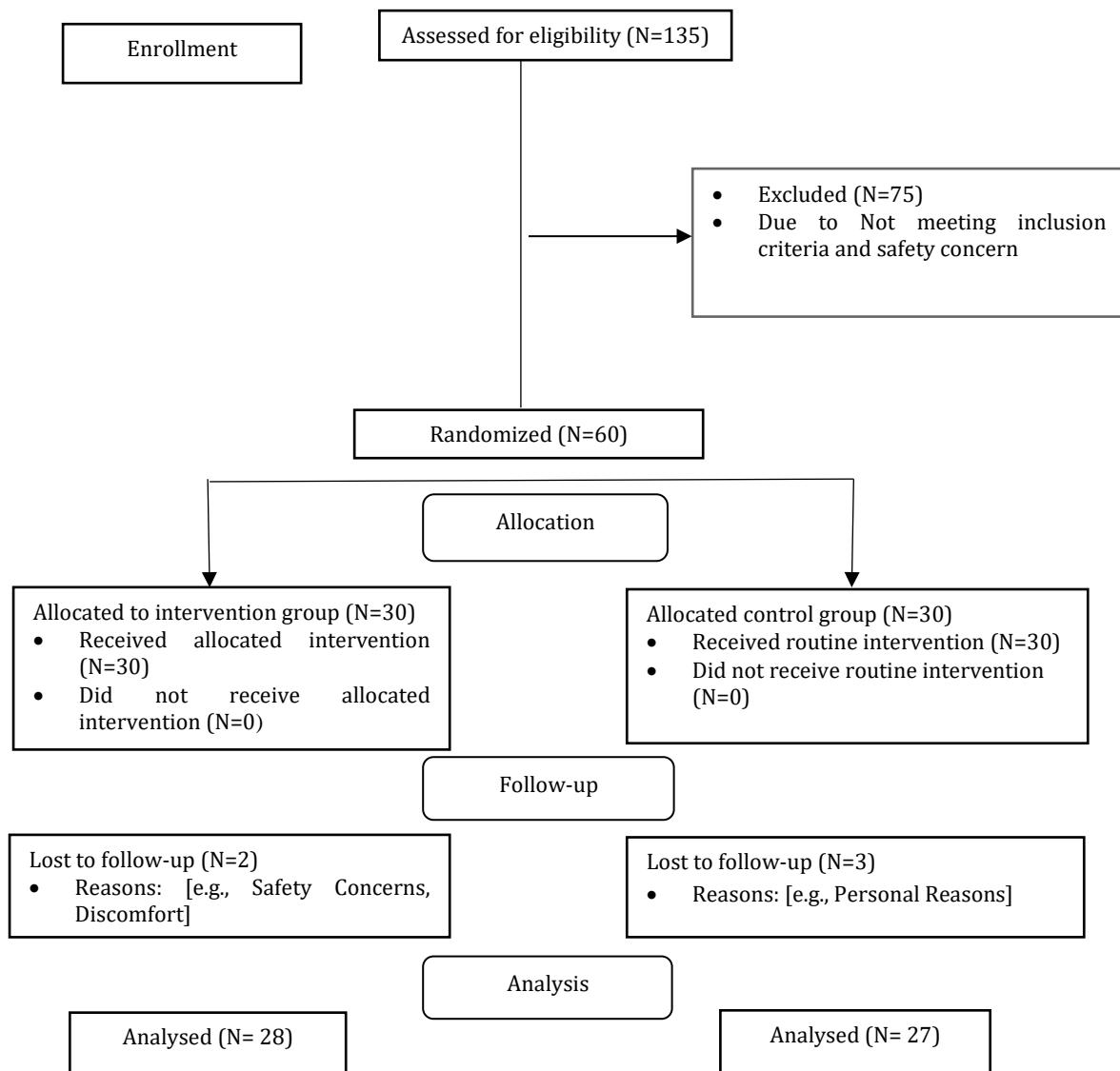


Figure 1. CONSORT Flowchart of the participants' selection

with images corresponding to specific pain scale ratings was used to facilitate accurate self-reporting. We also included a brief interview guide equipped with images corresponding to specific pain scale ratings. Pain assessment was performed after completion of the entire period of exercise (15). To meet the participants after their delivery, researcher assistant attended the health centers, where sampling was performed

near the probable dates of delivery of the intervention and control groups. As a result, the mothers who returned to the health centers to receive postnatal special care (3 to 5 day after delivery) were interviewed and their hospital records were studied. In this study, outcomes were categorized as primary maternal, secondary maternal, and neonatal. The primary maternal outcomes—specifically low back pain

and pelvic pain—were assessed using self-report methods, including a Visual Analog Scale (VAS) and a checklist, administered after the 12-week intervention. Secondary maternal outcomes were collected via a mixed-methods approach: subjective experiences such as urinary incontinence, constipation, and heartburn were obtained through self-report interviews, while objective diagnoses including gestational diabetes, transient hypertension, delivery mode (e.g., cesarean section, instrumental), hemorrhoids, and postpartum hemorrhage were extracted from medical record reviews. Finally, all neonatal outcomes—such as jaundice, transient tachypnea of the newborn, stillbirth, and birth weight—were ascertained exclusively through medical record review.

The data collection tool was a maternal and newborn outcome assessment checklist with 12 maternal and 4 neonatal items, based on a literature review. Data were primarily extracted from patient records, and interviews with doctors were conducted to clarify any ambiguous information in the records for items such as (gestational diabetes, transient hypertension, type of delivery, instrumental delivery, postpartum hemorrhage, and neonatal conditions like jaundice and transient tachypnea). The checklist used yes/no questions, and its validity and reliability (Cronbach's alpha >0.8) were confirmed by a panel of experts and a pilot study. A midwife collected all data 3-5 days after delivery.

Regarding all the above-mentioned factors, the participants were asked to report their experience using 'yes' and 'no' options. In the case of ambiguity in explanations of the mother, the researcher referred to the hospital where the mother gave birth to her child and obtained the required information by talking with the doctor in charge of the delivery and studying the hospital profile.

Finally, data were analyzed using SPSS software version 23 and descriptive and analytical statistics. Independent t-test was used to compare basic quantitative variables between two groups and ANOVA test for categorical variables with more than two levels (e.g., nutritional status, income level). Chi-square test was used to compare qualitative variables

between different groups. The level of significance in all tests was considered at 0.05.

The two groups were almost comparable regarding baseline characteristics, except for the women's occupations (Table 1). All participants delivered via vaginal birth.

Results

The demographic data of the participants in the two study groups was homogenous with respect to factors like age, number of pregnancies, length of time since the last pregnancy (month), use of supplement during pregnancy, weight before intervention, exercise prior to pregnancy, nutritional status during pregnancy, husband behavior, smoking prior to pregnancy, employment, income, and education.

Of the 60 women who fulfilled the requirements for participation in the study, five were not allowed to proceed because they were unwilling, worried about safety, or were not confident in the effectiveness of the research. Thus, in the intervention ($n = 28$) and control ($n = 27$) groups, 55 women finished the study. A flow diagram of participant progress through the phases of the trial (enrollment, allocation, follow-up, and analysis) is provided in Figure 1, in accordance with CONSORT guidelines.

With a mean age of 24 ± 5.64 years, the participants' ages ranged from 18 to 36 years old. There was an average of 31 ± 12 months from the participants' previous pregnancy, ranging from 18 to 45 months. Table 1 indicates that there was no statistically significant distinction found between the demographic data of the intervention and control groups. Participant demographics for the intervention and control groups are shown in Table 1.

Table 2 provides a comparison between the study groups in terms of their maternal pregnancy outcomes after the intervention. Based on the findings, no significant difference was found between the intervention and control groups in terms of their constipation, heartburn, cesarean section, hemorrhoids, postpartum hemorrhage, instrumental delivery, maternal gestational age at delivery after the intervention. However, low back pain (0.001), pelvic pain ($p < 0.001$), urinary incontinence (0.013), gestational diabetes ($p < 0.001$) and transient hypertension of pregnancy ($P = 0.002$) were

significantly lower in the intervention group in comparison with the control group after the intervention.

Table 1. Baseline demographic and clinical characteristics of the participants in the two groups

| Characteristic | Control | Intervention | P-Value |
|--|-------------|--------------|---------|
| | Mean±SD | Mean±SD | |
| Age | 24.36±5.5 | 24.82±5.85 | 0.28* |
| Mean time after the last pregnancy(month) | 33.25±14.06 | 30.87±13.85 | 0.47* |
| Characteristic | N(%) | N(%) | P-Value |
| Having a previous pregnancy | | | |
| Yes | 13(48.1) | 12(42.9) | |
| No | 14(51.9) | 16(51) | 0.69 |
| Use of supplements during pregnancy | | | |
| Yes | 17(63) | 14(50) | |
| No | 10(37) | 14(50) | 0.33 |
| Maternal BMI before intervention | | | |
| BMI<18.5 | 4(14.8) | 5(17.9) | |
| 18.5<BMI<24.9 | 5(18.5) | 6(21.7) | |
| 25<BMI<29.9 | 6(22.2) | 5(17.9) | 0.99 |
| 30<BMI<34.9 | 6(22.2) | 6(21.4) | |
| BMI>35 | 6(22.2) | 6(21.4) | |
| Doing exercise before pregnancy | | | |
| Yes | 13(48.1) | 13(46.4) | |
| No | 14(51.9) | 15(53.6) | 0.9 |
| Nutritional status in pregnancy | | | |
| Poor | 6(22.2) | 8(28.6) | |
| Medium | 7(25.9) | 7(25) | |
| Good | 7(25.9) | 7(25) | |
| Excellent | 7(25.9) | 6(21.4) | 0.95 |
| Job | | | |
| unemployment | 4(14.8) | 5(17.9) | |
| Employment | 6(22.2) | 5(17.9) | |
| Housewife | 8(29.6) | 9(32.1) | |
| Student | 9(33.3) | 9(32.1) | 0.97 |
| Income | | | |
| Insufficient | 6(22.2) | 10(35.7) | |
| Sufficient | 12(44.4) | 10(35.7) | |
| Relatively sufficient | 9(33.3) | 8(28.6) | 0.59' |

*t-test/ Chi-square test

The remarkably large reduction in gestational diabetes and pregnancy-induced hypertension observed in the intervention group warrants caution in interpretation. The small sample size may have led to a chance imbalance in underlying risk factors between the groups despite randomization. These findings should be confirmed in larger studies.

Table 3 provides a comparison between the study groups in terms of their neonatal pregnancy outcome after the intervention. Based on the findings, no significant difference was found between the intervention and control groups in terms of their Jaundice, Neonatal, Transient Tachypnea of the Newborn, Stillbirth and Birth weight after the intervention.

Table 2. Comparison of maternal pregnancy outcomes between the intervention and control group after the intervention

| Characteristic | Control | Intervention | P-Value |
|--------------------------------------|-----------|--------------|----------|
| | Mean±SD | Mean±SD | |
| Constipation | 5.41±2.91 | 4.5±3 | 0.26* |
| Heartburn | 5.59±2.95 | 5.96±3.02 | 0.65* |
| Low back pain | 5.7±2.98 | 3.25±2.04 | 0.001* |
| Pelvic pain | 5.51±2.78 | 2.82±1.78 | P<0.001* |
| Urinary incontinence | 5.52±3.04 | 3.38±2.25 | 0.013* |
| Characteristic | N(%) | N(%) | P-Value |
| Gestational diabetes | | | |
| Yes | 20(74.1) | 6(21.4) | |
| No | 7(25.9) | 22(78.6) | P<0.001' |
| Transient hypertension of pregnancy | | | |
| Yes | 19(70.4) | 8(28.6) | |
| No | 8(29.6) | 20(71.4) | 0.002' |
| Cesarean Section | | | |
| Yes | 9(33.3) | 9(32.1) | |
| No | 18(66.7) | 19(67.9) | 0.93' |
| Hemorrhoids | | | |
| Yes | 1(0.03) | 0(0) | |
| No | 26(97) | 28(100) | 0.78' |
| Postpartum hemorrhage | | | |
| Yes | 2(0.07) | 2(0.07) | |
| No | 25(93) | 26(93) | 0.87' |
| Instrumental delivery | | | |
| Yes | 2(0.07) | 2(7) | |
| No | 25(93) | 26(93) | 0.87' |
| Maternal gestational age at delivery | | | |
| <37 | 5(18.5) | 6(21.4) | |
| 37 ¹ <GA<38 ⁶ | 5(18.5) | 7(25) | |
| 39 ¹ <GA<41 ⁶ | 8(29.6) | 6(21.4) | 0.88' |
| ≥42 | 9(33.3) | 9(32.1) | |

*t-test/ Chi-square test

Table 3. Comparison of neonatal outcomes between the intervention and control groups after the intervention

| Complication | Control N (%) | Intervention N (%) | P-Value |
|---|------------------|-----------------------|---------|
| Neonatal Jaundice | | | |
| Yes | 13(48) | 12(44.4) | |
| No | 14(52) | 15(55.6) | 0.68' |
| Transient Tachypnea of the Newborn | | | |
| Yes | 2(0.7) | 3(10) | |
| No | 25(93) | 25(90) | 0.7' |
| Stillbirth | | | |
| Yes | 0(0) | 0(0) | |
| No | 27(100) | 28(100) | 0.78' |
| Birth weight | | | |
| <2500 | 6(4.21) | 7(9.27) | |
| 2500<GW<3500 | 6(4.21) | 6(2.22) | |
| 3500<GW<4500 | 7(25) | 5(5.18) | 0.94" |
| ≥4500 | 9(1.31) | 9(3.33) | |

'Chi-square test/ "one way anova

Discussion

This research aimed to examine the effect of Pilates exercise on maternal and newborn outcomes during pregnancy. Based on the results, there was a substantial decrease in occurrences of lower back pain, pelvic pain, urinary incontinence, gestational diabetes, and temporary high blood pressure in pregnancy (preeclampsia) in the intervention group compared to the control group. While numerous studies have investigated the impact of exercise on pregnancy, few reports exist on the impact of Pilates. The study found that Pilates exercise did not increase the risk of preterm birth, supporting its safety for use during pregnancy. In a related study, Kassia conducted a comprehensive review and analysis of the effects of continuing high-intensity workouts up until the third trimester of pregnancy. They concluded that such exercises are generally safe for most healthy pregnancies. Although we found no impact on delivery time, Beetham reported a reduced risk of preterm delivery in women who exercised during pregnancy (8).

According to Sheperd's research, a diet and exercise regimen can effectively lower gestational diabetes, but it has no beneficial effects on blood pressure, gestational complications, or perinatal mortality. Da Silva also demonstrated that exercise had no effect on preterm delivery or preeclampsia, and Sheperd's findings regarding diabetes and stillbirth were consistent with our study (16). Exercise has no effect on gestational diabetes, according to Da Silva (6), in contrast to the Pilates intervention's beneficial effect on the condition in the current study. Considering how Pilates affects other populations, Chen observed that it helps diabetic patients' blood sugar levels (5) and Rocha J demonstrated that it helps patients with hypertension (17).

A few mechanisms exist to explain why hypertensive disorders occur. A compelling theory is that vasoconstriction and reduced oxidative activity cause hypertension and are caused by activation of the endothelium system. An alternative theory posits that cytokines, including interleukins and tumor

necrosis factor alpha, play a role in oxidative stress and subsequent preeclampsia. Preeclamptic pregnant women have higher levels of endothelins, another powerful vasoconstrictors, than non-eclamptic pregnant women (18). Through the following pathways, cardiovascular health is enhanced and hypertension prevention is improved by exercises that have a direct impact on artery walls and an indirect effect on the release of anti-inflammatory mediators. The first mechanism that has been proposed states that increased tension stress during exercise causes the release of Enos and a decrease in NAD (P) H, both of which reduce the number of inflammatory responses that follow (16, 19). According to the second mechanism, pro-inflammatory cytokines (IL18,8.1-b) are decreased by endurance exercises like Pilates, but anti-inflammatory cytokines are increased. Furthermore, reductions in body fat improve adaptation and induce systemic changes in innate immunity through the release of anabolic and anti-inflammatory mediators from active skeletal muscles. According to the third theory, exercise creates a balance between vasoconstricting and vasodilating factors by raising the vasoconstrictor thromboxane and lowering endothelin-1 and noradrenaline (19). Larger sample sizes for interventions are advised in order to bolster Pilates's contribution to fewer pregnancy complications.

Moderate-intensity exercise can alleviate lumbopelvic pain during pregnancy, according to Peng's investigation into various exercise intensities for this purpose (20). According to Andersen's study, exercise may have a preventive effect on pelvic girdle pain during pregnancy (21). These investigations' findings concurred with the current investigation. Interventions for treating and preventing pelvic and low back pain during pregnancy were studied by Liddle SD (Review). This meta-analysis's findings showed that while exercise has no discernible impact on pelvic pain during pregnancy, it does significantly lessen low back pain (22). Similar to the current study, this one also found a reduction in low back pain; however, unlike our study, exercise had no impact on pelvic pain. Naturally,

rather than focusing on Pilates, all of the aforementioned studies examined the impact of exercise on pregnancy pain. Ika Oktaviani's study's findings demonstrated that Pilates is a useful technique for easing pregnancy discomfort (23). This study's findings were consistent with the current investigation.

According to the results, taking part in pilates exercises reduced the intervention group's low back and pelvic pain. Back in antiquity, there were theories regarding pain. While psychological and emotional factors have been more prominent in recent studies, those theories still explain pain as a brain-related phenomenon (24-25). The increase in the mother's serum levels of relaxin, progesterone, or estradiol was previously thought to be the cause of back and pelvic pain in pregnancy. This is because elevated hormones cause ligaments to loosen, causing pain in the back and pelvis area of pregnant women (3, 23). Nonetheless, research has demonstrated that the majority of the relaxation happens in the first half of pregnancy, and that elevated joint relaxation and associated discomfort during pregnancy are not correlated with elevated thyroid function. The mother's posture may alter as a result of this loosening, which could eventually result in back pain (3). Pilates' powerful style can be used to reduce lower back and pelvic pain during pregnancy by strengthening the muscles in these areas and enhancing their internal strength (22).

One of the study's strengths is the Pilates intervention method, which can be used as a protocol for sport intervention with expectant mothers. It involves multiple sessions. Another strong point of the study is its attention to maternal and newborn outcomes and their evaluation. It is recommended that future studies examine these limitations in addition to the checklist with objective indicators in order to evaluate maternal and newborn outcomes.

This study has several limitations that should be considered when interpreting the results. First, the remarkably large effect sizes observed for gestational diabetes and transient hypertension, while statistically significant, must be interpreted with extreme caution. The small

sample size increases the susceptibility to chance imbalance in unmeasured or residual confounders (e.g., genetic predisposition, detailed dietary habits), and these findings should be viewed as hypothesis-generating rather than definitive evidence of efficacy. Second, the sample size also limited the statistical power to detect significant differences in less common outcomes, such as cesarean delivery or preeclampsia. Third, the reliance on self-reported data for several maternal outcomes introduces the potential for recall or reporting bias. Fourth, the cluster randomized design, while minimizing contamination, may affect the generalizability of the findings to individual patients in different care settings. Finally, the high initial refusal rate, largely due to safety concerns, may limit the applicability of our results to a more motivated and exercise-receptive population. Despite these limitations, the findings provide valuable preliminary evidence supporting the integration of Pilates into prenatal care.

Conclusion

The results of this study showed that Pilates exercise had a beneficial impact on a number of unfavorable pregnancy outcomes including low back pain, pelvic pain, gestational diabetes, transient hypertension of pregnancy and urinary incontinence. Additionally, during the intervention period, no particular complications were noted, supporting Pilates' safety during pregnancy. To support the findings, though, more interventions with larger sample sizes are required.

Declarations

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Conflicts of interest

The authors declared no conflicts of interest.

Ethical approval

Written informed consent was obtained from all participants prior to their enrollment in the study. The principles of confidentiality and the

right to withdraw from the study at any time without penalty were strictly maintained throughout the research process.

Code of Ethics

Ethical approval for this study has been obtained by the ethics committee affiliated with Shahrekord University of Medical Sciences, Shahrekord, Iran (IR.SKUMS.REC.1395.332).

Use of Artificial Intelligence (AI)

Not applicable.

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Authors' contribution

The authors' contributions were as follows: BMD and FA conceived and designed the study. ZK and BMD were responsible for data collection. MN and FA contributed to the collection of clinical data. ZK and MN performed the statistical analysis. All authors reviewed and approved the final manuscript.

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