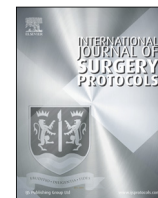


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International Journal of Surgery Protocols

journal homepage: www.elsevier.com/locate/isjpp

Protocols

Designing an intervention program over the effects of Pilates on pregnancy outcomes among the pregnant women: A protocol study

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ARTICLE INFO

Article history:

Received 28 October 2020

Accepted 31 October 2020

Available online 5 November 2020

Keywords:

Pilates exercise

Pregnancy

Protocol

ABSTRACT

Background: Pregnancy is a pleasure for most women, it is often considered as a stressful period with physiological, anatomical, biochemical, and psychological changes. Pilates exercise improved quality of life in women. Therefore, the present study targeted at designing an intervention program over the effects of Pilates on pregnancy outcomes among the pregnant women.

Methods: In this protocol, a clinical intervention will be designed in three phases. In the first phase of the study, a researcher-made checklist will be used to evaluate the pregnancy and neonatal outcomes based on the literature review. In the second phase, an intervention program of Pilates exercise will be conducted according to different studies and viewpoints of a panel of reproductive health and physical activity specialists. The exercises will include two sessions of 30 minutes per week for 12 weeks conducted under the supervision of a qualified trainer. The third phase of the intervention will include the pre-test and post-test using a standard questionnaire and a researcher-made checklist for the two intervention groups and one control group.

Discussions: The present study provides useful data regarding the design of a Pilates exercise intervention program for pregnant women with the aim of influencing pregnancy and neonatal outcomes, reducing depression, low back pain and improving maternal mental health. It can also reduce their medical and treatment costs. The strategies of this program could be important and cost effective, and therefore we hope that the success of such a program is a step forward in improving reproductive health status.

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1. Plain English summary

Recent studies found positive effects of Pilates on improved pelvic muscle function, decreased back pain, reduced postmenopausal osteoporosis, decreased body mass index, reduced subcutaneous fat, developed sleep quality after the delivery, and improved quality of life in women. In this protocol, a clinical intervention will be designed in three phases to investigate the effect of Pilates on the pregnancy outcomes among the pregnant women. In the first phase of the study, a researcher-made checklist will be used to evaluate the pregnancy and neonatal outcomes based on the literature review. The reliability and validity of this checklist will also be confirmed in this phase. In the second phase, an

intervention program of Pilates exercise will be conducted according to different studies and viewpoints of a panel of reproductive health and physical activity specialists. The exercises will include two sessions of 30 minutes per week for 12 weeks conducted under the supervision of a qualified trainer. The research team will finalize the investigation process based on the priorities. The checklist will be completed by the trainer and phone calls will be made by the researchers to follow up the participants. The third phase of the intervention will include the pre-test and post-test using a standard questionnaire and a researcher-made checklist for the two intervention groups (starting Pilates exercises from the 8th and 18th week of pregnancy) and one control group.

2. Background

Pregnancy is known as a unique physiological window through which the maternal and fetal adaptation can have major implications for the long-term health of the mother and the fetus [1].

Abbreviations: GHQ, General Health Questionnaire; EPDS, Edinburgh Postnatal Depression Scale; BMI, Body Mass Index.

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<https://doi.org/10.1016/j.isjpp.2020.10.004>

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Although this period is a pleasure for most women, it is often considered as a stressful period with physiological, anatomical, biochemical, and psychological changes [2,3]. In addition, a series of discomforts and problems are common in pregnancy, such as fatigue, pain (back, leg, groin, etc.), cramp especially in the lower limb, edema, heartburn, headache, as well as worries about mother and fetal weight gain during pregnancy [2–4]. Even in a natural pregnancy, these changes can have a significant effect on the life of a pregnant woman and her ability to perform the routine roles. In other words, it affects the quality of life in this period [2,4].

Common problems during pregnancy can be treated in various ways. One of the safest, most appropriate, and least costly methods for eliminating the pregnancy complications and improving the health and quality of life in pregnant women is regular exercises [5,6]. The American College of Obstetric and Gynecology (ACOG) recommends 150 minutes of moderate-intensity aerobic exercises for all pregnant women [7]. According to ACOG, exercising during pregnancy reduces the back pain, severity of constipation, risk of gestational diabetes, preeclampsia, and delivery with cesarean section. Exercises also improve appropriate weight gain during pregnancy, develop the overall adaptability of the body with pregnancy, strengthen the blood vessels and heart, and accelerate the process of weight loss after the delivery [7]. Pilates exercise is recommended by ACOG during pregnancy [7].

Recent studies found positive effects of Pilates on improved pelvic muscle function, decreased back pain, reduced postmenopausal osteoporosis, decreased body mass index, reduced subcutaneous fat, developed sleep quality after the delivery, and improved quality of life in women [8–10]. Since a systematic review represented no strong evidence over the effects of Pilates on women's health during pregnancy, further studies are needed to clarify the issue [10]. Despite the reported benefits of Pilates and the ACOG's recommendations in this regard, the advantages of Pilates are still under discussion and appropriate interventions are rare in this regard. Therefore, the present study targeted at designing an intervention program over the effects of Pilates on pregnancy outcomes among the pregnant women.

3. Methods/design

In this protocol, a clinical intervention will be designed in three phases to investigate the effect of Pilates on the pregnancy outcomes among the pregnant women. In the first phase of the study, a researcher-made checklist will be used to evaluate the pregnancy and neonatal outcomes based on the literature review. The reliability and validity of this checklist will also be confirmed in this phase. In the second phase, an intervention program of Pilates exercise will be conducted according to different studies and viewpoints of a panel of reproductive health and physical activity specialists. The exercises will include two sessions of 30 minutes per week for 12 weeks conducted under the supervision of a qualified trainer. The research team will finalize the investigation process based on the priorities. The checklist will be completed by the trainer and phone calls will be made by the researchers to follow up the participants. The third phase of the intervention will include the pre-test and post-test using a standard questionnaire and a researcher-made checklist for the two intervention groups (starting Pilates exercises from the 8th and 18th week of pregnancy) and one control group.

4. Aim

The aim of this study is to design and implement a Pilates exercise program to improve the pregnancy outcomes among the pregnant women in order to promote the neonatal and pregnancy outcomes.

5. Research hypotheses

According to the main purpose of the study, some hypotheses will be considered according to the viewpoints of reproductive health professionals. The hypotheses will include: The pregnancy and neonatal outcomes as well as the maternal mental health will be better in the intervention than the control group. The intensity of back pain and postpartum depression will be lower in the intervention compared to the control group. Different outcomes will be observed between the first (starting Pilates exercise from the 8th week of pregnancy) and the second (starting Pilates exercises from the 18th week of pregnancy) intervention groups.

5.1. The first phase: designing and assessing the validity and reliability of the researcher-made checklist for evaluating the pregnancy and neonatal outcomes

At this stage, the literature will be reviewed and an appropriate model will be selected. An expert panel of reproductive health and research specialties will be interviewed and the related studies will be investigated. The items of the researcher-made checklist will be designed in two sections of the pregnancy outcomes and neonatal outcomes.

The pregnancy outcomes' checklist will include items dealing with the gestational age (in weeks) at the time of delivery, postpartum fever, gestational diabetes mellitus, preeclampsia, gestational hypertension, Oligohydramnios or Polyhydramnios, inability to breastfeed after delivery, type of delivery, and low back pain during pregnancy.

The neonatal outcomes' checklist will contain evaluation of the neonatal outcomes such as birth weight, height, and head circumference of the baby, 1- and 5-minute Apgar scores, and fetal presentation at birth.

To assess the validity of the questionnaire, the viewpoints of 10 experts from the panel of reproductive health professionals will be used. In this regard, CVR and CVI will also be obtained to confirm the constructs. To verify the reliability of the questionnaire, an internal consistency measurement will be conducted using Cronbach alpha. Finally, this checklist will be completed by the researcher after the delivery.

5.2. The second phase: designing the Pilates exercise intervention program

At this stage, the intervention will be designed and the target audience will be recognized based on a review of the literature, review of similar studies, and information collected from questionnaires. The Pilates exercise program will be performed under the supervision of a qualified instructor.

The two intervention groups will perform the Pilates exercises under the supervision of an instructor with Pilates coaching qualification and on the basis of safe Pilates exercises during pregnancy [9]. The exercises will be conducted two sessions per week for 12 weeks and each session will last 30 minutes with a moderate intensity (8 to 10 strength exercises per session) [11].

The trainer will be asked to complete, date, and sign the checklists for each participant, so that the researchers can ensure about implementation of the intervention.

At the beginning of the exercises, the participants will be explained about the start time, place, and time of the intervention. Furthermore, they will be provided with the researcher's phone number to contact her in case of any problem during the intervention. Furthermore, the researcher will follow up the participants' participation in the training sessions by making phone calls and by checking the sports schedule checklist weekly.

5.2.1. Experts' team

The content and visual validity of the check list and Pilates exercise program will be measured, and the comments received from the panel of experts. The panel of experts will be included ten professionals from the reproductive health and two experts from the field of physical activity.

5.3. The third phase: implementation educational intervention

In this step a randomized controlled clinical trial will design to assess the efficacy of prepared protocol. Participants randomly (random numbers) will allocate into three groups. In two experimental groups we will implement our designed protocol, and control group will not receive any intervention, but they follow as same as experimental group [Table 1](#).

5.3.1. Study environment and population

The health centers affiliated to Shahrekord University of Medical Sciences and sports halls will be considered for the intervention.

5.3.2. Sample size calculation

The target participants in this study are the pregnant women who referred to health centers in Shahrekord to receive prenatal care. According to the statistical indices $d = 0.5$, $z(1-\alpha/2) = 1.96$, $z(1-\beta) = 0.84$, the sample size ($N = 25$) will be estimated. Including 20% fall, 30 people in each group will be considered.

5.3.3. Sampling method

Random sampling's method will apply to select the participants. Participants will be divided into two intervention groups and one control group. For the first and second intervention groups, exercises will start from the 8th and the 18th week of pregnancy, respectively.

5.3.4. Inclusion criteria

The inclusion criteria will be: 1- Healthy pregnant woman 2- Lack of consuming medications (such as hormonal drugs, etc.) during pregnancy 3. Lack of having underlying diseases and absolute or relative prohibition of exercises during pregnancy, including severe hemodynamic heart disease, congenital lung disease, cervical dysfunction or cervical cervix, multiple pregnancy associated with preterm labor risk, persistent hemorrhage in the second or third trimester, postpartum placement after the 26th week of gestation, preterm labor in the current pregnancy, rupture of the curves and preeclampsia or pregnancy-induced hypertension, severe anemia, unexplored cardiac arrhythmia in the mother, chronic bronchitis, inappropriately controlled type 1 diabetes mellitus, severe obesity, very low weight of the mother (BMI less than 12), history of completely sedentary life history, embryonic growth limitation in the present pregnancy, musculoskeletal constraints, uncontrolled seizure disorder, inappropriately controlled hyperthyroidism and severe smoking, 4. Not being a professional athlete,

Table 1
Pilates sports intervention program and its follow ups.

Program	Type of intervention
Pilates sports intervention	-Safe Pilates exercises during pregnancy under the supervision of the instructor. -Duration and intensity: Two sessions of 30 minutes per week for 12 weeks with moderate intensity (8–10 strength exercises per session).
Participants' follow up	-The attendance checklist: It will be completed by the trainer and reviewed by the researcher. Phone calls: The researcher will call participants to ensure about their participation.

5- Having willing to participate in the research, 6. Lack of having depression or anxiety problems (lack of consuming anti-depressant or anxiolytic medications), and 6. Having the minimum reading and writing literacy.

5.3.5. Exclusion criteria

The exclusion criteria will include the occurrence of relative or absolute prohibition cases during pregnancy after initiation of the study, not participating in Pilates exercises more than one session, and withdrawal from the study.

5.3.6. Data collection method

1. The instrument for collecting data is the researcher-made check list. This check list has subscales including pregnancy and neonatal outcome.
2. The General Health Questionnaire (GHQ) will be used to measure the mothers' mental health during pregnancy. This questionnaire contains 12 items on a 4-point Likert scale scored from zero to 3. The validity and reliability of this questionnaire were confirmed in previous research [29].
3. The Standard questionnaire of Edinburgh Postnatal Depression Scale (EPDS) will be used to assess the mothers' postpartum depression. The questionnaire contains 10 questions with a 4-point Likert scale while the scores range from 1 (always) to 3 (never); scores higher than 13 indicate maternal affliction to postpartum depression. The accuracy of this tool for measuring postpartum depression was confirmed among the Iranian women [28,30].
4. The visual analogue scale (VAS) will be used to measure the intensity of back pain before and after the intervention; the scores range from zero to 10. This tool is a self-monitoring criterion in which zero means no pain and 10 means unbearable pain.

5.3.7. Data analysis

We will apply X2 and independent T test to analysis our data by using SPSS version 21.

5.3.8. Outcome measures

1. The maternal outcomes, which will be investigated by the checklist of postpartum pregnancy outcomes after the delivery, include gestational age at birth, placental abruption, Chorioamnionitis, postpartum hemorrhage, postpartum fever, gestational diabetes, preeclampsia, gestational hypertension, Oligo or polydramnios, inability to breastfeed the child after delivery, and the type of delivery.
2. Neonatal outcomes, which will be investigated by a checklist after the delivery, include birth weight, height, head circumference, 1- and 5-minute Apgar scores, and fetal presentation at birth.
3. Maternal mental health during pregnancy will be measured by GHQ at the beginning of the study (pre-test) and between the gestational weeks 28 and 34 (post-test).
4. The participants' postpartum depression will be assessed one month after delivery using the EPDS standard questionnaire.
5. The intensity of back pain will be measured in the beginning of the study (pre-test) and between the gestational weeks 28 and 34 (post-test) using the VAS from zero to 10.

6. Discussion

The related literature reported different weeks of pregnancy for the onset of exercises [3]. In the present study, the two intervention groups started the Pilates exercises in the 8th and 18th weeks

of pregnancy. A systematic review of the clinical trials by Mazzarino et al. showed little evidences over the positive effects of Pilates exercises on the health status of pregnant women or conditions such as breast cancer, obesity, or back pain. Therefore, they concluded that clinical trials were required to determine the effectiveness of Pilates in order to improve the health outcomes of women [10]. Culligan et al. carried out a clinical trial and compared the outcomes of pelvic floor exercises and Pilates exercises with regard to improving the pelvic floor muscle strengths. They emphasized that future studies were required to show the effect of Pilates exercises on improving the pelvic floor muscle disorders [12]. Segal et al. studied the effect of Pilates exercises on the body flexibility and composition. They found that Pilates exercises led to more body flexibility. However, the related evidences on the effect of Pilates on the mental and physical health status of women are limited [13].

The effect of Pilates exercises on the physical and psychological health of women was determined in some studies [14,15]. The present research will provide useful data on designing a Pilates intervention program among the pregnant women to improve the pregnancy and neonatal outcomes, reduce depression, decrease back pain, and enhance the maternal mental health.

It can also reduce their medical and treatment costs. We suppose this program has capacity to integrate into the professionally health care guidelines, so that it can help medical and health care providers pay attention to the important role of the women health, especially during gestational age. The strategies of this program could be important and cost effective, and therefore we hope that the success of such a program is a step forward in improving reproductive health status.

Ethics approval and consent to participate

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). Written informed consent was obtained from all participants. Registration of this randomized control trial has been completed with the **Iranian Registry of Clinical Trials**.

Trial registration

IRCT20170124032161N2. Registered 2 May 2019, <http://en.irct.ir/trial/37938>.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable. We confirm that stage our study is currently at collecting data.

Funding

This research protocol was funded by the Shahrekord University of Medical Sciences, Shahrekord, Iran. This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Authors contributions

All authors were involved in study conception, design, drafting of the manuscript, BM, ZK, FS and F.A were involved in write and revise the manuscript. All authors have read and approved the final version of the manuscript.

Declaration of Competing Interest

The authors declare that they have no competing interests. Ethical and funding approval in Shahrekord university of medical sciences, Shahrekord, Iran. The research plan for this protocol was approved by the Shahrekord University of Medical Sciences in Iran and received funding from the same organization and the Ethics Approval Code.

Acknowledgements

This paper was extracted from a research project. The authors would like to thank Shahrekord University of Medical Sciences for supporting this research. We also appreciate Shahrekord Branch Islamic Azad University.

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