Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Pilates effect on pregnancy outcomes of pregnant women

Protocol summary

Study aim
Pilates effect on pregnancy outcomes of pregnant women
Design
Pilates exercise was performed from 18 to 30 weeks of gestation and the pregnancy outcomes were compared with the control group.
Settings and conduct
Health centers in Shahrekord Two intervention groups and one control group For the intervention group 1, exercise starts from the 8th week and the intervention group 2 starts the exercise from the 18th week of pregnancy. Individuals of both groups exercise Pilates exercise in an exercise room under the supervision of a trainer during pregnancy 2 sessions per week for 12 weeks and each session for 30 minutes with moderate severity. The control group will receive routine care during pregnancy. A researcher-made questionnaire will be used to measure pregnancy outcomes
Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy pregnant woman, Not taking any medications (such as hormonal medications) during pregnancy, Not having any illness, Absolute and relative ban on exercise during pregnancy, Non-use of antidepressants, Having reading and writing skills. Exclusion criteria: Prohibition of relative or absolute exercise during pregnancy, Not attending Pilates sports exercises for more than one session, Canceling the continuation of the study.
Intervention groups
Two intervention groups (Pilates in pregnancy) and control group
Main outcome variables
Maternal outcomes: Gestational age at the time of delivery, Placental abruption, Coriomaniacitis, Postpartum hemorrhage, Postpartum fever, Gestational diabetes, Preeclampsia, Pregnancy blood pressure, Oligo or Polyhydramnios, Inability to breastfeed after childbirth, And the type of delivery, And low back pain during pregnancy. Neonatal Outcome: Baby weight, Baby's height, Baby head circumference, Apgar one and five minutes after birth, Fetal presentation at birth. The most important outcome is the severity of back pain.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170124032161N2**
Registration date: **2019-05-02, 1398/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-02, 1398/02/12**
Update count: **0**
Registration date
2019-05-02, 1398/02/12

Registrant information
Name
Bahare Motaghi Dastenaei
Name of organization / entity
Shahrekord University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-04-09, 1398/01/20
Expected recruitment end date
2019-12-21, 1398/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Pilates effect on pregnancy outcomes of pregnant women

Public title
Pilates effect on pregnancy outcomes
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy pregnant woman Not taking any medications (such as hormonal medications) during pregnancy Not having any illness Lack of relative and absolute ban on exercise during pregnancy Non-use of antidepressants Having reading and writing skills
Exclusion criteria:
Prohibition of relative or absolute exercise during pregnancy Not attending Pilates sports exercises for more than one session Canceling the continuation of the study
Age
From **16 years** old to **40 years** old
Gender
Female

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment to intervention and control groups Based on random numbers table
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
Shahrekord University of Medical Sciences. Kashani Bld. Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8838136115767
Approval date
2016-11-20, 1395/08/30
Ethics committee reference number
IR.SKUMS.REC.1395.332

Health conditions studied

1

Description of health condition studied
pregnancy
ICD-10 code
O75
ICD-10 code description
Other complications of obstetric surgery and procedures

Primary outcomes

1

Description
outcome maternal
Timepoint
at the beginning of the study, during and one month after intervention
Method of measurement
researchers Made questionnaire,interview, examination

2

Description
outcome neonatal
Timepoint
after intervention
Method of measurement
researchers Made questionnaire, examination

Secondary outcomes

1

Description
general health
Timepoint
at the beginning of the study, after intervention
Method of measurement
general health Questionnaire

2

Description
Postpartum depression Questionnaire
Timepoint
after child birth
Method of measurement
Beck Depression Questionnaire

3

Description
Severity of back pain
Timepoint
at the beginning of the study, after intervention
Method of measurement
Self-report measure

Intervention groups

1

Description
Intervention group 1: Perform Pilates exercises from week 8 of pregnancy twice a week for 30 minutes for 12 weeks
Category
Prevention

2

Description
Intervention group 2: Perform Pilates exercises from week 18 of pregnancy twice a week for 30 minutes for 12 weeks
Category
Prevention

3

Description
Control group: Pregnant women entered the study by doing routine pregnancy care and activities
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
مراکز بهداشتی شهر شهرکرد
Full name of responsible person
بهاره متقی دستنائی
Street address
shahrekord
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
دکتر سید کمال صولتی
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Shahrekord University of Medical Sciences. Kashani Bld. Shahrekord
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Bahare Motaghi Dastenaei
Position
member of faculty Shahrekord University of Medical Sciences
Latest degree
Master
Other areas of specialty/work
Midwifery
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Name of organization / entity

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Full name of responsible person

Dastenaei Motaghi Bahare

Position

Lecturer, faculty member

Latest degree

Master

Other areas of specialty/work

Midwifery

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Staff of Medical Sciences، Kashani street، Shahrekord

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

25/5000 Personalized study data

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available