Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Compliance of supervised and home-based exercises during pregnancy and effects of the exercises on some maternal, fetal and neonatal outcomes

Protocol summary

Study aim

To determine compliance rate of supervised and home-based exercises during pregnancy and effects of the exercises on some maternal, fetal and neonatal outcomes

Design

In this controlled trial, 150 women will be equally allocated into three parallel groups (supervised, home-based or no intervention groups) using a stratified block randomization with block sizes of 6 and 9. The sequence will be generated using the randomizer program. Consecutively numbered opaque sealed envelopes will be used for the allocation concealment.

Settings and conduct

Eligible pregnant women at gestational age of 12-18 weeks enrolled from the public health centers of Mahabad (Iran) will be randomized into one of the three study groups, after receiving written informed consent and will be followed up until 6 months after delivery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18-40 years, First to third pregnancy with a single healthy fetus at gestational age of 12-18 weeks, No history of cesarean section or preterm delivery, being literate, Iranian nationality of wife and husband Exclusion criteria: Having abnormal uterus, incompetent cervix, or any chronic diseases; Performing regular aerobic exercise; BMI > 35; having suicidal thoughts; unwillingness or inability to attend exercise sessions regularly.

Intervention groups

The first intervention group: supervised exercise The second intervention group: home-based exercise The control group: no intervention

Main outcome variables

Compliance rate of the two exercise programs (supervised and home-based) during pregnancy Depression score, positive and negative affect score, birth weight

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100414003706N37**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-07, 1399/06/17**
Update count: **0**

Registration date

2020-09-07, 1399/06/17

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2021-05-05, 1400/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Compliance of supervised and home-based exercises during pregnancy and effects of the exercises on some maternal, fetal and neonatal outcomes

Public title
Effect of exercise on pregnancy outcomes

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women in the 12th-18th weeks of pregnancy 1st to 3rd pregnancy Aged 18-40 years Having a singleton fetus with no known malformation No previous history of cesarean section No previous history of premature labour Be literate Iranian nationality of wife and husband

Exclusion criteria:
Abnormal (unicorn / septum) uterus Incompetent cervix Cardiovascular or respiratory diseases Uncontrolled type I diabetes Chronic hypertension Symptomatic anemia Uncontrolled thyroid disease Shortness of breath before exercise and chest pain Orthopedic limitations Regular aerobic exercise longer than 30 minutes twice a week or more, during current pregnancy BMI > 35 Having suicidal thoughts Unwillingness or inability to attend exercise sessions regularly Severe back pain

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be allocated into three study groups (supervised or home-based exercise, control with no intervention). Allocation sequence will be generated by a person, not involved in the recruitment and data collection, through individual stratified (based on 1st or 2nd-3rd pregnancy) block randomization with random block sizes of six and nine, and allocation ratio of 1:1:1 using a computer program. The sequence will be concealed using sequentially numbered opaque sealed envelopes.

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 Tabriz University of Medical Sciences

Street address
Third floor, Second centralbuilding, Golgasht street

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2020-08-01, 1399/05/11

Ethics committee reference number
IR.TBZMED.REC.1399.481

Health conditions studied

1

Description of health condition studied
Exercise during pregnancy

ICD-10 code
Y93.A3

ICD-10 code description
Activity, aerobic and step exercise

Primary outcomes

1

Description
Compliance rate of the aerobic exercises during pregnancy (average number and duration of exercise in a week)

Timepoint
Two times (1- during 12-18 to 26-28, 2- during 26-28 to 36-38 weeks of pregnancy)

Method of measurement
a diary form

2

Description
Depression Score

Timepoint
At baseline, 26-28 weeks of pregnancy, and 6-8 weeks after delivery

Method of measurement
Edinburgh Depression questionnaire

3

Description
Positive and negative affect Score
Timepoint
At baseline, 26-28 ،36-38 weeks of pregnancy, and 6-8 weeks after delivery
Method of measurement
Positive and Negative Affect Scale (PANAS)

4

Description
Birth weight
Timepoint
After delivery
Method of measurement
Hospital record

Secondary outcomes

1

Description
Anxiety score
Timepoint
At baseline, 26-28 weeks of pregnancy and 6 months after delivery
Method of measurement
Anxiety section of the Depression, Anxiety and Stress Scale (DASS-21)

2

Description
Well-Being Score
Timepoint
At baseline, 26-28 & 36-38 weeks of pregnancy and 6-8 weeks after delivery
Method of measurement
World Health Organization-Five Well-being Index

3

Description
Fatigue score
Timepoint
At baseline, 26-28 weeks of pregnancy, 6-8 weeks and 6 months after delivery
Method of measurement
Multidimensional Assessment of Fatigue scale

4

Description
Sexual function Score
Timepoint
At baseline, 26-28 weeks of pregnancy and 6 months after delivery
Method of measurement
Female sexual function questionnaire (FSFI)

5

Description
Low back pain score
Timepoint
At baseline, 26-38 & 36-38 weeks of pregnancy and 6-8 weeks and 6 months after delivery
Method of measurement
Visual analogue scale (VAS)

6

Description
Urgent and stress urinary incontinence Score
Timepoint
At baseline, 26-28 & 36-38 weeks of pregnancy and 6-8 weeks & 6 months after delivery
Method of measurement
Urinary Incontinence Diagnosis Questionnaire

7

Description
Pregnancy weight gain
Timepoint
During pregnancy
Method of measurement
Using Prenatal record

8

Description
Gestational age
Timepoint
At Birth
Method of measurement
Using date of last menstrual period or ultrasound report and birth date

9

Description
Fear of childbirth
Timepoint
36-38 weeks of pregnancy
Method of measurement
Wijma Delivery Expectancy (W-DEQ)

10

Description
Score of birth satisfaction
Timepoint
6-8 weeks after delivery
Method of measurement
Iranian version of birth satisfaction scale-revised

11

Description
Occurrence of Pregnancy complications (gestational hypertension or pre-eclampsia, gestational diabetes)
Timepoint
26-28 weeks and 36-38 weeks of pregnancy

Method of measurement
Prenatal record

12

Description
Premature or preterm delivery
Timepoint
After delivery
Method of measurement
Using date of last menstrual period or ultrasound report and birth date

13

Description
Cesarean section
Timepoint
After delivery
Method of measurement
Medical record

14

Description
Childbirth trauma
Timepoint
After delivery
Method of measurement
Medical record

15

Description
Postpartum weight loss
Timepoint
6-8 weeks and 6 months after delivery
Method of measurement
Weight scale

16

Description
Apgar score of the first and fifth minutes
Timepoint
First and Fifth minutes after birth
Method of measurement
Hospital record

17

Description
Height and head circumference of infant
Timepoint
After birth
Method of measurement
Hospital record

18

Description
Stress score
Timepoint
At baseline, 26-28 weeks of pregnancy and 6 months after delivery
Method of measurement
Stress section of the Depression, Anxiety, and Stress Scale (DASS-21)

Intervention groups

1

Description
Intervention group1 (supervised exercise): the women will exercise three 30-60 min sessions per week from 12-18th to 38th week of gestational age, adapted to the pregnancy trimesters. One to two of the sessions each week will be under direct guidance of a trained person (in person or in groups of 1-4 persons) while looking at a video tap, and the other one to two sessions will be under indirect supervision (through phone call at the start of each session and 1-2 calls during or end of the sessions).
Category
Lifestyle

2

Description
Intervention group 2 (home-based exercise): following 1-2 educational sessions of the exercises at two time-points (12-18 and 26-28 weeks of gestational age), the video exercise tap will be given to the participants and they will be instructed to adhere to the prescribed aerobic exercise program and have regular exercise (at least three times a week, 30-60 min/session) at home, they will be reminded by sending a short message at the start of each session) and their performance will be monitored via phone calls once a week. All necessary instructions and precautions will be provided to the intervention groups both verbally and in written.
Category
Lifestyle

3

Description
Control group: no intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahabad Public Health Centers
Full name of responsible person
Dr Engineer Qasem Amini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Research department, Third floor, Central Building number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
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Web page address
http://researchvice.tbzmed.ac.ir
Grant name
Special Grant for 20% active researchers in the University
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Afsaneh veisy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All deidentified IPD can be shared
When the data will become available and for how long
Starting soon after publication of the study results for ten years.
To whom data/document is available
Data will be available for researchers working in academic institutions, as well as to chief editor and reviewers of the submitted manuscript.
Under which criteria data/document could be used
The data will be available to researchers upon request and submission of the proposal to perform meta-analysis using IPD. Also, in exceptional cases, data will be made available to chief-editor of the journals for checking.
From where data/document is obtainable
Refer to the email addresses (alizades@tbzmed.ac.ir, a.veisy@yahoo.com)
What processes are involved for a request to access data/document
The requests should be sent by email and data will be available within two week.
Comments