

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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)

##### Phone

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alizades@tbzmed.ac.ir

##### 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, 26-28 & 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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iro@tbzmed.ac.ir  
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<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  
**Position**  
PhD student in Midwifery  
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**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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Sakineh Mohammad-Alizadeh-Charandabi  
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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.veysy@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**