

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of exercise training mode on maternal blood pressure and maternal and fetal heart rate variability

#### Protocol summary

##### Study aim

The effect of aerobic ,resistant ,and combined training on maternal blood pressure and fetal and maternal heart rate variability is studied.

##### Design

4 arm parallel group randomized trial with blinded outcome assessment and 10 person in each group is done.

##### Settings and conduct

The research is done in Shahid Akbarabadi hospital in Tehran.Low risk pregnant women are assessed with wellbeing checklist ,physical activity, and nutrition questionnaires. Also their anthropometric criteria are assessed .All assessments are done at 8-12 AM. Electrocardiogram and NST are done for all subjects at gestational age of 24-26 and after 8 week training as well.

##### Participants/Inclusion and exclusion criteria

Pregnant women at age of 20-35 years with no pregnancy complications and no history of programmed exercise participate in this study

##### Intervention groups

Intervention groups are : aerobic, resistant, combined, and control group . All groups primarily do warm up. Then they do special training.At the last stage cool down is done. The aerobic group do light dance. The resistant group use theraband . The combined group do light dance and resistant activities by theraband. The control group do no programmed exercise.

##### Main outcome variables

Maternal blood pressure : Maternal and Fetal Heart rate : and Maternal and Fetal Heart rate variability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190227042856N1**

Registration date: **2019-06-01, 1398/03/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-01, 1398/03/11**

Update count: **0**

##### Registration date

2019-06-01, 1398/03/11

##### Registrant information

###### Name

khadijeh ahrari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2275 4109

###### Email address

kh.ahrari@srbiau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-11, 1397/12/20

##### Expected recruitment end date

2019-07-11, 1398/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of exercise training mode on maternal blood pressure and maternal and fetal heart rate variability

##### Public title

The effect of exercise training mode on maternal blood pressure and maternal and fetal heart rate variability

## Purpose

Basic science

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women at 20-35 years Women with no pregnancy complications women with no history of programmed exercise.

### Exclusion criteria:

multiple pregnancy vaginal bleeding uterine contractions , history of premature delivery dyspnea chest pain smoking, alcohol consumption , and drug abused sleep disorder participation in another programmed exercise Hypothyroidism and Hyperthyroidism Diabetes cervical incompetency hypertension History of infertility BMI more than 25 and less than 18.5 Anemia

## Age

From **20 years** old to **35 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple random sampling is used. Randomization is done individually with Random number table. Pregnant women file numbers with inclusion criteria are used. Number of pregnant women is divided on 40 . Considering the obtained number and random number table, subjects are chosen. After that they allocate to control and intervention groups.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

During the post-intervention measurements, neither the participants nor the assessor was blinded for group assignment. The data analyzer blinded to the participants' allocation throughout the entire project.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University Science and Research Branch

## Street address

Islamic Azad University Science and Research Branch  
Simon Bulivar Blvd, Tehran Post Office Box:  
14515/775

## City

Tehran

## Province

Tehran

## Postal code

1477893855

## Approval date

2019-01-22, 1397/11/02

## Ethics committee reference number

IR.IAU.SRB.REC.1397.101

## Health conditions studied

### 1

#### Description of health condition studied

Blood pressure and Heart rate variability

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Maternal blood pressure that is measured by digital sphygmomanometer device

#### Timepoint

The 26th and 34th week of pregnancy

#### Method of measurement

Blood pressure is measured with digital sphygmomanometer made in Switzerland sensitivity 3 mmhg

### 2

#### Description

Maternal heart rate variability that is assessed with electrocardiogram machine.

#### Timepoint

The 26th and 34th week of pregnancy

#### Method of measurement

Maternal heart rate variability is assessed with electrocardiogram machine Kenzecg 1210 model made in Japan

### 3

#### Description

Fetal heart rate variability Is assessed with fetal heart rate monitoring machine .

#### Timepoint

The 26th and 34th week of pregnancy

#### Method of measurement

Fetal heart rate variability Is assessed with Bionet fetal heart rate monitoring machine made in south korea FC1900 model with sensitivity of 5% is assessed.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first Intervention group: This group do aerobic exercise 3 times per week ,each session 50 minutes for 8 weeks.

#### Category

Lifestyle

### 2

#### Description

Second Intervention group: This group do resistance exercise 3 times per week ,each session 50 minutes for 8 weeks.

#### Category

Lifestyle

### 3

#### Description

Third Intervention group: This group do aerobic and resistance exercise 3 times per week ,each session 50 minutes for 8 weeks.

#### Category

Lifestyle

### 4

#### Description

Control group: This group do no special exercise.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Akbar abadi Hospital of Tehran

##### Full name of responsible person

khadijeh ahrati

##### Street address

West molavi.,Mohamadih square., Tehran town

##### City

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##### Phone

+98 21 5560 6034

##### Email

akbarabadihosp@yahoo.com

##### Web page address

<http://crta.iums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

khadijeh ahrari

##### Street address

Science and Research Branch, Daneshgah Blvd,  
Simon Bulivar Blvd, Tehran

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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

Islamic Azad University

#### Proportion provided by this source

100

#### Public or private sector

Private

#### 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

Islamic Azad University

##### Full name of responsible person

khadijeh ahrari

##### Position

student

##### Latest degree

Master

##### Other areas of specialty/work

Physiology

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no 4,saeedi ave.,fereshteh street.,parkway

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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

there is no more information.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable