

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:
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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

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West molavi.,Mohamadih square., Tehran town

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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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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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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