

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of aerobic exercise on neonatal health indicators of nulliparous pregnant women with poor sleep quality

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of aerobic exercise on neonatal health indicators of nulliparous pregnant women with poor sleep quality

Design

Clinical trials with control group, with parallel groups, Randomized, single center trial. Sample size (2 groups of 30 control and intervention).

Settings and conduct

Damghan Health Center Questionnaire, Apgar score at birth, height and head are measured by tape measure, weight by scales at birth

Participants/Inclusion and exclusion criteria

Pregnant women 18 to 35 years old, 24 to 40 weeks pregnant, normal bmi, singleton, healthy water bag, nulliparous, moderate socioeconomic status, Iranian citizenship, willing to cooperate in the project, no medical prohibition to do medical and sports activities, Dissatisfaction with research, non-consumption of alcohol, tobacco and drugs, lack of kidney, lung, cardiovascular, hepatitis, frequency and dietary diversity

Intervention groups

Intervention group: In this group, according to the protocol, aerobic exercises include warming up, followed by step aerobic exercise for 30 to 45 minutes (three days a week) and each time for 10 weeks. Control group: Only for comparison with intervention group, no treatment is performed.

Main outcome variables

Neonatal health indices of transcripts, including Apgar score, head circumference, height, weight

Last update: **2021-05-31, 1400/03/10**

Update count: **0**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

ali niknaiea

Name of organization / entity

Semnan University

Country

Iran (Islamic Republic of)

Phone

+98 23 3522 4553

Email address

aliniknaiea@semnan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-10, 1400/02/20

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aerobic exercise on neonatal health indicators of nulliparous pregnant women with poor sleep quality

Public title

The effect of aerobic exercise on newborn children health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210319050744N1**

Registration date: **2021-05-31, 1400/03/10**

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women 18 to 35 years old They are 24 to 40 weeks pregnant They have a normal body mass index (BMI) They have Iranian citizenship They have almost the same frequency and variety of food They have an average social and economic status Pregnant women are primiparous Have the amount of daily physical activity (light activity)

Exclusion criteria:

Pregnant women who have a medical ban on physical activity They are not satisfied to participate in the research They have kidney, heart, vascular and hepatitis diseases They consume alcohol, tobacco and drugs

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated randomly with simple sequential allocation in one of the two study groups by help of sealed envelope and receive the intervention of the same group. The unit of randomization is patient. Sealed envelopes are delivered to expert. With each patient's visit, one of the envelopes is randomly selected by the patients and determines the study group. The stratification approach is not used.

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**

Semnan University of Medical Sciences

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Semnan University of Medical Sciences, Basij Blvd,
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City

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Postal code

3514799442

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.SEMUMS.REC.1399.341

Health conditions studied**1****Description of health condition studied**

The effect of aerobic exercise on newborn children health indicators with nulliparous pregnant mothers with poor sleep quality.

ICD-10 code

F51.12

ICD-10 code description

Insufficient sleep syndrome

Primary outcomes**1****Description**

The effect of aerobic exercise on neonatal health indices of nulliparous pregnant women

Timepoint

3 days a week for 30 to 45 minutes for 10 weeks

Method of measurement

Exercise Protocol (Pedometer) by Pregnancy Physical Activity Assessment Questionnaire

2**Description**

Petersburg Sleep Quality Questionnaire

Timepoint

It is measured at least twice and three times if possible

Method of measurement

Petersburg Sleep Questionnaire

Secondary outcomes**1****Description**

Remember the 24-hour feed of the pregnant mother

Timepoint

Daily

Method of measurement

24-hour food recall (to control nutrition, frequency and dietary diversity)

Intervention groups**1****Description**

Intervention group: In this group, according to the protocol, aerobic exercises include warming up, followed by step aerobic exercise for 30 to 45 minutes (three days a week) and each time for 10 weeks.

Category

Prevention

2

Description

Control group: Only for comparison with intervention group, no treatment is performed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Damghan Health Center

Full name of responsible person

Dr.Behrad Pourmohammadi

Street address

Shahid Fallahi Street, next to the Civil Registry Office

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Personal

Full name of responsible person

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Grant name

None

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

none

Proportion provided by this source

1

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Education

Full name of responsible person

Ali Niknaei

Position

Secretary of Physical Education

Latest degree

Bachelor

Other areas of specialty/work

Physical Education and Sports Science

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University

Full name of responsible person

Fatemeh Rezaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

PhD in Motor Behavior

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Person responsible for updating data

Contact

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

No - There is not 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