

# 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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210319050744N1**

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

##### 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

**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

**Street address**

Semnan University of Medical Sciences, Basij Blvd,  
Semnan

**City**

Semnan

**Province**

Semnan

**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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president-office@semums.ac.ir

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Personal

**Full name of responsible person**

Ali Niknaei

**Street address**

Yas 29, North Gol Yas St, Golestan Town

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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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North of Yas 49, Gol Yas street, Golestan town

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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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Opposite Sokan Park, Campus No. 1, Semnan University Central Organization

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## Person responsible for updating data

### 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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## 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