

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of pregnancy period sport exercises on the Prevention of Fatigue and Depression in Mothers

Protocol summary

Study aim

The Effect of pregnancy period sport exercises on the Prevention of Fatigue and Depression in Mothers

Design

The clinical trial has a community-based, practice-oriented control group, with parallel groups, randomized

Settings and conduct

Health Centers of Imam Jafar Sadegh and Abuzar Ghaffari Zahedan City. Parallel, Randomized

Participants/Inclusion and exclusion criteria

entry conditions: pregnant women had no complaint of depression and fatigue before the study. gestational age of 16 to 20 weeks, having alive and healthy infant, singleton pregnancy, adequate education to read and write. non entry conditions: cardiovascular diseases, health conditions in pregnancy that are prohibited from exercise_ as major anemia, diabetes, airway inflammation, being severely underweight or overweight, hypertension and hyperthyroidism.

Intervention groups

the intervention group was under the prenatal exercise program according to the instructions of clapp et al. The exercise protocol, was adjusted and performed for at least 30 to 45 minutes, 3 days a week for 8 weeks. Unlike the test group, for the control group did not recommend a specific training program.

Main outcome variables

The state of fatigue and depression of pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180425039418N1**

Registration date: **2018-10-28, 1397/08/06**

Registration timing: **retrospective**

Last update: **2018-10-28, 1397/08/06**

Update count: **0**

Registration date

2018-10-28, 1397/08/06

Registrant information

Name

mohammad Ghena'at Pisheh Sanani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3343 1227

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-12-20, 1394/09/29

Actual recruitment start date

2015-09-23, 1394/07/01

Actual recruitment end date

2015-12-20, 1394/09/29

Trial completion date

2015-12-20, 1394/09/29

Scientific title

The Effect of pregnancy period sport exercises on the Prevention of Fatigue and Depression in Mothers

Public title

The Effect of pregnancy period sport exercises on the Prevention of Fatigue and Depression in Mothers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women with a gestational age of 16 to 20 weeks (in consultation with a gynecologist) having a live and healthy embryo having singleton pregnancy having a reading and writing education

Exclusion criteria:

cardiovascular disease musculoskeletal disorders
Diseases that prohibited exercise in pregnancy such as severe anemia, diabetes, respiratory infections, obesity or severe weight loss, hypertension and hyperthyroidism history of abortion signs of preterm labor Having placenta previa or vaginal bleeding or any symptoms of abortion high risk pregnancy

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Actual sample size reached: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, individual, packed envelope (by selecting the envelope containing No. 1 patient in the intervention group and by selecting the envelope containing the number 2 patient in the control group)

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

Kerman University of Medical Sciences

Street address

Campus of Kerman University of Medical Sciences,
Beginning of the Axis of Alavi Gardens, Kerman, Iran

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2015-08-17, 1394/05/26

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Exercise during pregnancy, fatigue, depression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression of Pregnant Mothers

Timepoint

Before intervention and immediately after intervention

Method of measurement

Beck2 Depression Inventory

2

Description

Fatigue of pregnant mothers

Timepoint

Before intervention and immediately after intervention

Method of measurement

A multidimensional log of fatigue-short form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention group was under the prenatal exercise program according to the instructions of clapp et al. The exercise protocol, including warm up, tensile training, flexibility, followed by continuous aerobic walking, all of which focused on the training of pregnant women, was adjusted and performed for at least 30 to 45 minutes, 3 days a week for 8 weeks. The upper and lower parts of the body were exercised for 15 minutes followed by aerobic exercises, including continuous walking, which included 5 minutes of gentle walking in the first session and then increasing one minute to the training time in each session until reaching 15 minutes, from then until the end of the 24 sessions of practice, the activity time was kept constant and in order to go back to the initial state and cool the body from tensile stretches in sitting position for 10 to 15 minutes until the heart rate of the subjects reaches to less than 100 beats per minute. In order to prevent any potential physical problems, the intensity of exercise was 60% of the maximum heart rate per person and heart rate counting 3 times by carotid pulse controlled by the investigator (1). Aerobic exercises were conducted under the

supervision of an expert in physical education, midwifery expert and researcher. During the exercises and back to the initial state, with the aim of not feeling tired and optimizing the training environment, soft music was used and after exercise in each session, all subjects used liquids such as water or juice.

Category

Rehabilitation

2**Description**

Control group: Unlike the test group, all of whom participated in the exercise according to the program, the control group did not recommend a specific training program and emphasized that they should report if they do regular exercises during the study.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Jafar Sadegh Center of Zahedan

Full name of responsible person

Shokoufeh Mogharabi Ostad Kalayeh

Street address

Zibashahr, Nasr Street 13, Velayat 1 Alley

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9817978761

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Samari

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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

Kerman 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**

Islamic Azad University

Full name of responsible person

Shokoufeh Mogharabi Ostad Kalayeh

Position

science Committee, Director of Nursing Department

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Velayat 1 Alley, Nasr Street 13, Zibashahr

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Person responsible for updating data

Contact

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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

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

No - There is not a plan to make this available