

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effect of eight weeks councarent training on pain intensity and functional disability and quality of life in pregnant women with pregnancy low back pain

Protocol summary

Study aim

Comparison of the effect of 8 weeks of aerobic and resistance exercises on pain intensity, functional disability and quality of life in pregnant women.

Design

The study includes 40 convenient samples who are randomly divided into two experimental and control groups of 20 people. The experimental group performs exercises for 8 weeks and the control group does not participate in any physical exercises.

Settings and conduct

The samples are randomly selected from among pregnant women with back pain referring to Nikan hospital in Tehran for pregnancy exercise. Pregnant women with back pain, with the doctor's confirmation that they have the necessary conditions to perform exercises under the supervision of a pregnancy trainer, perform exercises privately and online for a period of 8 weeks and 3 sessions per week. Each exercise session is 45 to 60 minutes long.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Between 16th and 36th weeks of pregnancy. First and singleton pregnancy& without history of abortion. with mechanical & non-specific back pain. Not participating in any specific treatment in last 3 months. Signing informed consent. ability to perform practical activities. Non-entry criteria: without Doctor's approval to perform pregnancy exercises. below 20 years & above 35 years. with any disease related or not related to pregnancy such as diabetes, high blood pressure, etc.

Intervention groups

The experimental group performs 8 weeks of combined exercises under the supervision of a pregnancy trainer. The control group does not participate in any specific physical exercises or treatment.

Main outcome variables

Back pain during pregnancy, quality of life, disability

caused by pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230620058543N1**

Registration date: **2023-08-09, 1402/05/18**

Registration timing: **prospective**

Last update: **2023-08-09, 1402/05/18**

Update count: **0**

Registration date

2023-08-09, 1402/05/18

Registrant information

Name

Hengame Rostamy

Name of organization / entity

The Allame Tabatabaee university

Country

Iran (Islamic Republic of)

Phone

+98 21 3316 3929

Email address

hengame.rostami@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of eight weeks councarent training on pain intensity and functional disability and quality of life in pregnant women with pregnancy low back pain

Public title
The effect of pregnancy exercises on pain intensity, functional disability and quality of life in pregnancy back pain

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Between 16 and 38 weeks of pregnancy Doctor approved for pregnancy exercise Having mechanical and non-specific back pain Having no history of back pain before pregnancy It is the person's first pregnancy and no history of abortion Not participating in any specific treatment for back pain in the last three months No restrictions in connection with recognition and attention Sign informed consent to participate in the study
Exclusion criteria:
History of miscarriage and multiple pregnancy History of having any specific or non-specific treatment for back pain Lack of doctor's confirmation that you do not have the necessary conditions for pregnancy exercise Having any disease related or not related to pregnancy such as diabetes, high blood pressure, etc

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of AllameTababae University

Street address

Quds settlement (West), between South Flamak and Zarafshan, Simai Iran street, Ministry of Health and Medical Education headquarters, block A, 13th floor

City

Tehran

Province

Tehran

Postal code

-814555618

Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

IR.ATU.REC.1402.031

Health conditions studied

1

Description of health condition studied

Pragnancy low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Low back pain in pragnancy Quality of life Functional disability

Timepoint

Before doing eight weeks of training and after doing the training protocol

Method of measurement

McGill pain intensity questionnaire, sf36 questionnaire, osseous questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group (intervention): pregnant women with back pain during pregnancy referring to Nikan Hospital with the doctor's approval do 8 weeks of combined exercises (aerobic and strength) under the supervision of a pregnancy trainer 3 sessions a week and each session lasts 45-60 minutes. And before Performing the protocol and completing the relevant questionnaires after 8 weeks of practice.

Category

Other

2

Description

The control group : pregnant women with back pain who do not participate in any physical exercise.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikan hospital

Full name of responsible person

Laila Panahi

Street address

Plaque 23, corner of Kocheh 20, North Rabzeh St., Zamzam St., Fourth Bridge, Abu Dhar Blvd, pirozi st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Allameh Tabatabaei University^u

Full name of responsible person

Farideh Babakhani

Street address

Olympic village boulevard, intersection of Shahid Hemet highway, central campus of Allameh Tabatabaei University

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Allameh Tabatabaei University^u

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

The Allame Tabatabae University

Full name of responsible person

Hengame Rostami

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Sports science

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Phone**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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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