Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Iran (Islamic Republic of)

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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 AllameTababaee 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

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Tehran

Province

Tehran

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-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 haspital
Full name of responsible person
Laila Panahi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Allameh Tabatabaei University
Full name of responsible person
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Olympic village boulevard, intersection of Shahid Hemet highway, central campus of Allameh Tabatabai University
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Email
Farideh.Babakhani@atu.ac
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
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

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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
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