Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of exercise on fatigue during pregnancy: A randomized controlled trial

Protocol summary

Study aim
Determining the effect of exercise training on fatigue during pregnancy: a randomized controlled trial

Design
Clinical trial with a control group, with parallel groups, single blind, randomized, on 68 pregnant mothers. A table of random numbers is used for randomization.

Settings and conduct
The samples of this study will be randomly divided into two groups after selection. In the intervention group, in addition to exercising in class, they exercise at home at least four times a week, for 45 minutes each time. The training protocol includes warming up for 15 minutes, stretching exercises for 15 minutes and flexibility exercises for 15 minutes.The entire intervention period for each mother lasts eight weeks. Group B samples only do sports exercises in class and do not repeat sports at home.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women with a gestational age of 20 to 30 weeks; Having a live and healthy fetus; Having a singleton pregnancy; The tendency of the research units. Exclusion criteria: Absence of more than two sessions in childbirth preparation classes; Prohibition of exercise during pregnancy according to consultation with obstetrician and gynecologist.

Intervention groups
In addition to participating in eight childbirth preparation class sessions and doing pregnancy exercises in the last half hour of the class, the intervention group does exercises at home at least four times a week for 45 minutes each time. The control group samples only In class, they do sports exercises and do not repeat sports at home.

Main outcome variables
Fatigue during pregnancy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180218038783N9**
Registration date: **2024-04-19, 1403/01/31**
Registration timing: **prospective**

Last update: **2024-04-19, 1403/01/31**
Update count: **0**

Registration date
2024-04-19, 1403/01/31

Registrant information
Name
Fereshteh Behmanesh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-05-03, 1403/02/14
Expected recruitment end date
2026-06-20, 1405/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigating the effect of exercise on fatigue during pregnancy: A randomized controlled trial

Public title
The effect of exercise on fatigue during pregnancy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women with a gestational age of 20 to 30 weeks Having a live and healthy fetus Having a singleton pregnancy The willingness of the research units
Exclusion criteria:
Absence of more than two sessions in childbirth preparation classes Prohibition of exercise during pregnancy according to consultation with obstetrician and gynecologist
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
After selection, the samples are randomly divided into two groups using a table of random numbers.The block randomization method with 12 blocks will be utilized. Participants will be allocated to one of two groups in a 1:1 ratio following the block randomization protocol (generated by Random Allocation Software).
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
Health Research Institute- Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Keshavarz Street
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2024-02-18, 1402/11/29
Ethics committee reference number
IR.MUBABOL.HRI.REC.1402.174

Health conditions studied

1

Description of health condition studied
Normal pregnancy
ICD-10 code
Z34
ICD-10 code description
Encounter for supervision of normal pregnancy

Primary outcomes

1

Description
Fatigue during pregnancy
Timepoint
Before the start of the study and after 8 weeks from the start of the study
Method of measurement
Smets Multidimensional Fatigue Measurement Inventory

Secondary outcomes

1

Description
Pregnancy outcomes (type of delivery, preterm delivery, gestational hypertension, gestational diabetes)
Timepoint
Postpartum
Method of measurement
Check list

Intervention groups

1

Description
Intervention group: They will have eight weeks of exercise training in the preparation class for childbirth and at home (once in the class and at least four times at home for 45 minutes).
Category
Lifestyle

2

Description
Control group: The control group samples only In class, they do sports exercises and do not repeat sports at

home.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Yahya Nejad Hospital

Full name of responsible person
Fereshteh Behmanesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
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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
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Fereshteh Behmanesh

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Email

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