

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of exercise on postnatal depression and fatigue in clients of health centers: A randomized controlled clinical trial

Protocol summary

Summary

The purpose of this randomized controlled clinical trial is to determine the effect of exercise on the postpartum depression and postpartum fatigue. 126 pregnant clients with an alive fetus and gestational age of 26-32 weeks will be chosen in selected health centers. The women should have the Edinburgh score less than 15 and have no contraindications for performing exercise. Women will randomly be allocated in one of three groups. A (control): in this group women will get prenatal and postpartum ordinary educations in 3 sessions (each session takes 15-20 minutes). B (prenatal exercise): in this group women after getting one session of theoretical and practical education about prenatal exercise (30-40 min) will exercise 3 times a week according to the CD (the materials of this CD was approved by ministry of health and medical education). C (prenatal and postpartum exercise): women in this group in addition to getting education and doing prenatal exercise will do postpartum exercise in 4 first weeks if they can and then 3 times a week according to the postpartum exercise CD. We will phone B and C group women monthly for follow up. The self-administered questionnaires (Edinburgh and fatigue identification form) will be filled by the women before intervention, then 4 and 8 weeks after birth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008193706N5**

Registration date: **2010-11-20, 1389/08/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-11-20, 1389/08/29

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2011-04-19, 1390/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of exercise on postnatal depression and fatigue in clients of health centers: A randomized controlled clinical trial

Public title

Effect of exercise on postpartum depression and postpartum fatigue

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with 26-32 weeks of gestational age and with an alive fetus; 6 years or over education; not currently suffering from disease that would limit exercise (cardiopulmonary,

musculoskeletal,...); not currently taking medication that interferes with heart rate response to exercise - no history of threaded to abortion in present pregnancy - no signs of preterm labor in present pregnancy; not having the placenta previa in present pregnancy; nonexistence of fetal malformations; score of less than 15 on the Edinburgh scale; no history of medication and hospitalization for a psychiatric disorder in the past 6 months; not currently participating in regular high intensity exercise (60 min or more in a week); having the CD-player set or computer and knowing how to use it. Exclusion criteria: obstetric or concomitant disease which would have preclude participation in an exercise program; any condition that would make exercise unsafe or unwise (vaginal bleeding, rupture of membrane, palpitation, dyspnea,...); occurring the fetal or infant death during the study; confirmed fetal malformations.

Age

From **15 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Research deputy, Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code**Approval date**

2010-10-14, 1389/07/22

Ethics committee reference number

8934

Health conditions studied**1****Description of health condition studied**

postpartum depression

ICD-10 code

F32

ICD-10 code description

depressive episode

Primary outcomes**1****Description**

postpartum depression

Timepoint

1) befor intervention, 2) 4 and 8 weeks after birth

Method of measurement

Edinburgh scale

Secondary outcomes**1****Description**

potpartum fatigue

Timepoint

1)before intervention, 2) 4 and 8 weeks after birth

Method of measurement

fatigue identification form

Intervention groups**1****Description**

C (prenatal and postpartum exercise): women in this group in addition to getting education and doing prenatal exercise will do postpartum exercise in 4 first weeks if they can and then 3 times a week according to the postpartum exercise CD.

Category

Other

2**Description**

B (prenatal exercise): in this group women after getting one session of theoretical and practical education about prenatal exercise (30-40 min) will exercise 3 times a week according to the CD (the materials of this CD was approved by ministry of health and medical education).

Category

Other

3**Description**

A (control): in this group women will get prenatal and postpartum ordinary educations in 3 sessions (each

session takes 15-20 minutes).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Health Post

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

2

Recruitment center

Name of recruitment center

Shahidan Ebrahimi Health Center

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

3

Recruitment center

Name of recruitment center

Emamieh Health Center

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

4

Recruitment center

Name of recruitment center

Seyyed Bavafa Health Center

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

5

Recruitment center

Name of recruitment center

Gomtapeh Health Center

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

Tabriz

City

east Azarbijan

6

Recruitment center

Name of recruitment center

Azadi Health Center

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

7

Recruitment center

Name of recruitment center

Mojahedin Health Center

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

8

Recruitment center

Name of recruitment center

Aboutaleb Health Post

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

9

Recruitment center

Name of recruitment center

Sayyad Shirazi Health Center

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

10

Recruitment center

Name of recruitment center

Montazeri Health Post

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

11

Recruitment center

Name of recruitment center

Molla Hassan Health Center

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address

City

Tabriz

12

Recruitment center

Name of recruitment center

Gorbani Health Post

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address**City**

Tabriz

13

Recruitment center

Name of recruitment center

Ashrafi Laleh Health center

Full name of responsible person

Mohammadi-Fatemeh - master student of midwifery

Street address**City**

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz university of medical sciences

Full name of responsible person

Dr. Mohammad-Reza Rashidi

Street address

Golgasht st.

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research deputy of Tabriz university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Mohammadi Fatemeh

Position

MSc student in midwifery

Other areas of specialty/work**Street address**

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Fax

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Email

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh Charandabi

Position

Assistant professor, PhD in Reproductive Health

Other areas of specialty/work**Street address**

Faculty of Nursing and Midwifery, South Shariati

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Tabriz

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alizades@tbzmed.ac.ir smolch@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Mohammadi Fatemeh

Position

MSc student in midwifery

Other areas of specialty/work**Street address**

Golgasht St.

City

Tabriz

Postal code**Phone**

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Fax

+98 41 1479 6969

Email

f.mohammadi87@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty