

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparative survey of progressive muscle relaxation and physical exercise on general health of pregnant women

Protocol summary

Summary

Objectives: Compare of effects of progressive muscle relaxation and physical exercise on general health of pregnant women. Design: This survey is experimental study and clinical trial. Samples of survey are selected by purposive based method and then randomly are divided to experimental and control Groups. The final volume in each group is 30 people. Setting and conduct: experimental groups are performing training for 8 weeks and the results are recording in the daily report sheet. General health of the three groups is being measured before and after 8 weeks by the General Health Questionnaire (GHQ-28). Participants including major eligibility criteria: age between 18-35 years old; single pregnancy; a wanted pregnancy first pregnant; have a maximum 12 week of gestation Exclusion criterion: lack of regular and active participation in the intervention of relaxation or physical exercise. Intervention: After teaching of progressive muscle relaxation and exercise groups, training were being performed for 8 weeks in home. In relaxation method that included gradual contraction and release fourteen groups of muscles, CD for training is available for participants to do at home. In exercise group intensity of training in walking is maintained in range of 50-65 percent of maximum heart rate, and is performed from 15 minute in first week to 30 minute in eighth week. The control group does not receive any intervention. The main outcome: Scores of general health in experimental and control groups in four dimensions of general health

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205159764N1**

Registration date: **2013-08-26, 1392/06/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-26, 1392/06/04

Registrant information

Name

Zahra Hajiamini

Name of organization / entity

Nursing Department, Baqiatallah University of Medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Baghiatollah University of Medical Science

Expected recruitment start date

2008-02-29, 1386/12/10

Expected recruitment end date

2008-05-09, 1387/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative survey of progressive muscle relaxation and physical exercise on general health of pregnant women

Public title

Comparative survey of progressive muscle relaxation

and physical exercise on general health

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Between 18-35 years old; Have a minimum education necessary to read and understand the training provided; Single pregnancy; Prime pregnant with wanted pregnancy; Have a maximum of 12 weeks of gestation (first trimester); Low-risk pregnancies and no history of disease; Lack of specific drug; No smoking; drugs and alcohol; The absence of a history of recurrent miscarriage and not using fertility treatments Exclusion criteria: Having any kind of illness or hospitalization during the intervention; Lack of regular and active participation in the intervention, relaxation training or physical exercise

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Ethics Committee of Baghiatollah University of
Medical Science

Street address

Baghiatollah University of Medical Science, Molasadra
Street, Vanak Square, Tehran

City

Tehran

Postal code

Approval date

2008-03-10, 1386/12/20

Ethics committee reference number

326

Health conditions studied

1

Description of health condition studied

General Health of pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

General Health of Pregnant Women

Timepoint

8 weeks after the intervention

Method of measurement

General Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Practical and theoretical training of progressive muscle relaxation group is performed for 3 sessions, 1.5-2 hours in a week. Training are being performed at home for 8 weeks and twice a day and the results are being recorded in the daily report sheet

Category

Other

2

Description

Experimental groups are performing training for 8 weeks at least twice a day in home and recording the results in the daily report sheet. Training of exercise group is performed by researcher in lecture or questions and answers for 1.5-2 hours. Intensity of training is maintained in range of 50-65 percent of maximum heart rate. Walking for 8 weeks, 3 sessions in week and every session based on the training protocol from 15 minutes in first week to 30 minutes in eighth week is performed and the results are recorded in the daily report sheet.

Category

Other

3

Description

The control group does not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Women Clinic, Baghiatollah Hospital

Full name of responsible person

Zahra Bahrami

Street address

Women Clinic, Baghiatollah Hospital, Mollasadra Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for reseaech Baghiatollah University of Medical Science

Full name of responsible person

Dr. Morteza Izadi

Street address

Baghiatollah University of Medical Science, Mollasadra Ave.

City

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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

Vice chancellor for reseaech Baghiatollah University of Medical Science

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

Akhtar Hospital, Shahid Beheshti Univercity of Medical Science

Full name of responsible person

Azam Sadeghi

Position

MS in Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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MS of Midwifery

Other areas of specialty/work

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Person responsible for updating data

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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