

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2244 9062

###### Email address

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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**

Tehran

**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

**Name of organization / entity**

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**Full name of responsible person**

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MS of Midwifery

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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*