

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Effect of pilates exercise program on stress and anxiety in primigravida women.

#### Protocol summary

##### Study aim

Determination of affecting of Pilates program exercise on Maternal stress and anxiety in primigravida women.

##### Design

This study is randomiseg clinic trial with designing pre-post test .

##### Settings and conduct

This study carry out in the area Ahvaz west Health center-2 and 3.The sample includ a total of 100 primigravida womem, who through block randomization split into an intervention group and a control group.All the women have voluntery access from the prenatal clinic to participante in the study,and are informed of the procedures,risk and benefits of study.They sign a written consent form at the biginning of the study.

##### Participants/Inclusion and exclusion criteria

primigravida women (18-35 years old )and(BMI;20-30)that no have medical desease and obestetric complications.

##### Intervention groups

pregnant women recive an eight-week programme of physical exercise using the pilates method,with three sessions per week lasting 40-45 minutes.

##### Main outcome variables

Independent Variable:Exercise programme using pilates method. Dependent Variable1:Maternal stress  
Dependent Variable:Maternal anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190822044583N1**

Registration date: **2019-09-23, 1398/07/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-23, 1398/07/01**

Update count: **0**

##### Registration date

2019-09-23, 1398/07/01

##### Registrant information

###### Name

Ebtesam Taherirad

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7722 6280

###### Email address

taherirad.e@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-01-21, 1398/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of pilates exercise program on stress and anxiety in primigravida women.

##### Public title

Effect of pilates exercise program on stress and anxiety in primigravida women

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Iranian nation Gestational age 26-24 week BMI:30-20

kg/m2 primigravida mono fetus pregnancy Able to study and writing Min score of anxiety;150(wendenberg questionnaire) Min score of stress ;21.8(cohen questionnaire)

**Exclusion criteria:**

History of cardiac-polmonary disease. Obstetric complications:placenta previa,Incompetence cervix Treated abortion,bleeding,PROM. History of depression participate other exercise program or physiologic delivery class.

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the block randomization method is used for randomization.In this way, blocks create with pair numbers(4 or 6) and half the people in each block are randomly assigned to one group and half to another.Then, the block is selected to reach the required sample.For example, if we want to put 100 peoples in two groups of A and B,we must first find all four states in which half of the people to group A and other group B, are assigned to specify.Then go to each of these modes, we attribute 1 to 6.Next we have to make 25 four blocks randomly and write its combinations together.To do this, we have to sample this community 25 times up to the required sample size(50 peoples group A , 50 peoples group B).

**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 Ahvaz Jundishapoor University of Medical sciences.

**Street address**

Medical Bolv, Khozestan provice, Ahvaz.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Approval date**

2019-08-19, 1398/05/28

**Ethics committee reference number**

IR.AJUMS.REC.1398.395

**2**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ahvaz Jundishapoor University of Medical sciences.

**Street address**

Medical Bolv, Khozestan provice, Ahvaz.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Approval date**

2019-08-19, 1398/05/28

**Ethics committee reference number**

IR.AJUMS.REC.1398.395

**Health conditions studied**

**1**

**Description of health condition studied**

Maternal stress and anxiety

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Maternal anxiety in primigravida women.

**Timepoint**

0 ,8 week

**Method of measurement**

vandenberg questionnaire

**Secondary outcomes**

**1**

**Description**

Maternal stress in primigravida women.

**Timepoint**

0,8 week

**Method of measurement**

cohen questionnaire

## Intervention groups

1

### Description

Intervention group: Intervention is carried out through an eight-week programme of physical exercise using the pilates method, three time per week lasting 40-45 minutes. This program is supervised by professional in this area and researcher in Health center weekly. The pilates programme sessions are conducted two time per week in home with using habdbook and DVD and record by experimental group. control group receive only routine prenatal care.

### Category

Behavior

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Ahvaz West Health Center

#### Full name of responsible person

mehrdad sharifi

#### Street address

Between 15 and 16 street, Kian Abad Bolv, Ahvaz.

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

6155745477

#### Phone

+98 61 3391 4234

#### Fax

#### Email

info@ajums.ac.ir

#### Web page address

<https://www.hn-wah.ajums.ac.ir>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Ahvaz University of Medical Sciences

#### Full name of responsible person

Afshin zarghi

#### Street address

school of Nursing and Midwifery of Jundishapur  
,golestan Bolv, Ahvaz.

#### City

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#### Province

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#### Postal code

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#### Phone

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#### Fax

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#### Email

fnursing-ahvaz@ajums.ac.ir

#### Web page address

<https://www.ajums.ac.ir>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

#### Full name of responsible person

Parvaneh mousavi

#### Position

Educator

#### Latest degree

Master

#### Other areas of specialty/work

Midwifery

#### Street address

school of Nursing and Midwifery of Jundishapur,  
Golestan Bolv, Ahvaz

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ahvaz University of Medical Sciences

**Full name of responsible person**

Parvaneh

**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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**Web page address**<https://fnursing.ajums.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

parvaneh mousavi

**Position**

Educator

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

School of Nursing and Midwifery of Jundishapur, Golestan Bolv,Ahvaz

**City**

Ahvaz

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Information related to results will share after unrecognising of subjets.

**When the data will become available and for how long**

6 month after publication of results

**To whom data/document is available**

Researchers working in medical Institues.

**Under which criteria data/document could be used**

Only researchers can analyzed the results.

**From where data/document is obtainable**

Email of responsible of study.

**What processes are involved for a request to access data/document**

By requesting of responsible of the research.

**Comments**