Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Matenal 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
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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 writting Min score of anxiety;150(wendenberg questionnaire) Min score of stress ;21.8(cohen questionnaire)

Exclusion criteria:

History of cardiac-polmonary desease. Obstetric complicatios:placenta previa,Incompetence cervix Treatened 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

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Province

Khouzestan

Postal code

6135715794

Approval date

2019-08-19, 1398/05/28

Ethics committee reference number

IR.AJUMS.REC.1398.395

2

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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 racord by exprimental group.control group resive 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Afshin zarghi

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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
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

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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 resultes will share after unrecognising of subgets.
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