

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effects of physical exercise on positive emotion and vitality of primigravid women

Protocol summary

Summary

This study has been designed to evaluate the effect of childbirth preparation classes emphasizing on physical exercise on the positive emotion and vitality of nulliparous pregnant women in 2015. Sampling is done by random sampling method. The study population consists of all nulliparous pregnant women attending prenatal clinics of Health Network at Famenin city. Inclusion criteria: 20-28 weeks gestational age; absence of anxiety and depression; avoiding the use of psychotropic drugs before pregnancy and during the current pregnancy, according to patient records in Health Center and the doctor's visits; normal and planned pregnancy without obstetric and medical complications. Exclusion criterion: twice or more absences in classes; the incidence of horrible life events, such as death of a spouse, divorce, etc.; medical and obstetric problems during the study; diagnosis of fetal malformation or death during the study. A sample of 50 women in the test group and 50 women in the control group are determined. In the test group, 50 people are selected by draw method and using the numbers of their records. Then among nulliparous pregnant women eligible for inclusion in the study who wish to attend classes in preparation for childbirth, 50 women selected by the same method and placed in the control group. In the test group, antenatal educations are done with special emphasis on physical exercises and relaxation, and the control group members receive usual clinic cares. The main variable in this project is the positive emotion and vitality.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081623640N1**

Registration date: **2015-11-10, 1394/08/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-10, 1394/08/19

Registrant information

Name

Farzaneh Soltani

Name of organization / entity

Hamedan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research Technolog, Hamedan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of physical exercise on positive emotion and vitality of primigravid women

Public title

The effect of exercise on the vitality and positive emotion primigravid

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria to study:" gestational age of 20 weeks or more";" lack of anxiety and depression and lack of psychoactive medications before pregnancy and during pregnancy, according to doctor's comments and patient records in health center";" normal pregnancy without midwifery and medical side effects" Exclusion criterion:" more than two times of absence in classes";" the incidence of unpleasant life events";" such as death of a spouse, divorce";" medical and midwifery problems during the study ";" detection of abnormalities or fetal death during the study.

Age
 No age limit

Gender
 Female

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: 50

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 the University of Medical Sciences

Street address

Vice Chancellor of Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Avenue, Hamadan

City

hamadan

Postal code

6516645977

Approval date

2015-08-15, 1394/05/24

Ethics committee reference number

IR.UMSHA.REC.1394.256

Health conditions studied

1

Description of health condition studied

The effects of physical exercise on positive emotion and vitality of primigravid women

ICD-10 code

O94-O99

ICD-10 code description

Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description

Positive emotion

Timepoint

4 month

Method of measurement

Positive and Negative Affect Scale Panas

2

Description

vitality

Timepoint

4month

Method of measurement

Deci and Ryan vitality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The classes will be held every two weeks for an hour and a half, for 8 times, with a maximum of 10 pregnant women, and includes 5 minutes of greetings, 30 minutes of training, 10 minutes for questions and answers, 30 minutes of physical exercise, and 10-15 minutes of relaxation, and the last 10-15 minutes is dedicated to video playback and questions and answers. Mothers wear comfortable clothes at the time of exercises and do their workouts with the trainer for 30 minutes at a suitable place. Mothers are recommended to do exercises and relaxation at home every day, and every two days, mother will receive a phone call, and they will be encouraged to exercise at home. After 36 weeks of the end of the classes, the questionnaires will be completed again by test group. Then the data analysis will be conducted and the results of the impacts of training and exercise classes on positive affection and vitality before and after the intervention

Category

Lifestyle

2

Description

The control group: receives the routine cares of prenatal clinic. and In order to regard the ethical principles in the control group, after the completion of training, they will be given educational pamphlet After 36 weeks of the end of the classes, the questionnaires will be completed again by control group. Then the data analysis will be conducted and the results of the impacts of training and exercise classes on positive affection and vitality before and after the intervention

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Network famenin

Full name of responsible person

Samereh Ghelichkhani- Student Of Master of Midwifery Counseling

Street address

City famenin

City

famenin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research Technolog, Hamedan University of Medical Sciences

Full name of responsible person

Doctor Bashirian Saeed

Street address

Hvice Chancellor of Research Technology, Hamedan University of Medical Sciences, Shahid Fahmideh Avenue, Hamedan

City

hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research Technolog, Hamedan 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

Hamedan University of Medical Science

Full name of responsible person

dr farzaneh soltani

Position

PhD in Reproductive Health

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

PhD in Reproductive Health

Other areas of specialty/work

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Counseling

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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