

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The effectiveness of posture reform self-care education on physical and mental health of pregnant women

Protocol summary

Summary

This study aims to investigate the effectiveness of posture reform self-care education on physical and mental health of pregnant women. Design: A randomized multicenter non-blinded controlled trial. Setting and conduct: The overall aim and setting of the study are explained for eligible people. Samples will be allocated to intervention and control groups through block randomization with block size of 4 and informed consents are completed. The control group will receive routine care. The intervention group will participate in training sessions (3 sessions) as well as receiving routine care. Sessions are held weekly. Training by multimedia such PowerPoint, role playing, group discussions, pamphlets and educational CDs will be performed. Content includes: anatomic and physiologic changes during pregnancy, the most common pregnancy complaints and posture reform in pregnancy. Then they are followed by phone until the end of the pregnancy. Inclusion criteria: gestational age between 20 and 24 weeks; low back pain; chest pain and lumbar pain, non-pathological; maximum number of pregnancy is 2; maternal age between 18 and 35 years; singleton pregnancy; healthy and normal fetus; negative history of disease; no history of uterine bleeding; no history of orthopedic disease and low back pain; pathological chest pain and lumbar pain before and during pregnancy; no history of accidents that have been caused musculoskeletal problems; no history of congenital musculoskeletal problems; having at least primary education. Exclusion criteria: refuse the training program; development of the disease (hypertension, diabetes, etc.) and complications of pregnancy (oligo/polyhydramnios, fetal abnormalities, intrauterine fetal death, etc.); abnormal bleeding such as placenta previa,; losing their own or husband's jobs during pregnancy; relatives' death

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070425480N2**

Registration date: **2016-08-03, 1395/05/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-03, 1395/05/13

Registrant information

Name

Masoumeh Sharifzadeh

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4466 6828

Email address

sharifzade@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research; Shahroud University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of posture reform self-care education on physical and mental health of pregnant women

Public title

The effectiveness of posture reform self-care education on physical and mental health of pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age between 20 and 24 weeks; low back pain; chest pain and lumbar pain, non-pathological; maximum number of pregnancy is 2; maternal age between 18 and 35 years; singleton pregnancy; healthy and normal fetus; negative history of disease; no history of uterine bleeding; no history of orthopedic disease and low back pain; pathological chest pain and lumbar pain before and during pregnancy; no history of accidents that have been caused musculoskeletal problems; no history of congenital musculoskeletal problems; having at least primary education. Exclusion criteria: refuse the training program; development of the disease (hypertension, diabetes, etc.) and complications of pregnancy (oligo/polyhydramnios, fetal abnormalities, intrauterine fetal death, etc.); abnormal bleeding such as placenta previa,; losing their own or husband's jobs during pregnancy; relatives' death

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: **116**

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 Shahroud University of Medical Sciences

Street address

Central building of Shahroud University of Medical Sciences, Tir Square, Shahroud

City

Shahroud

Postal code

3614773955

Approval date

2016-06-25, 1395/04/05

Ethics committee reference number

IR. SHMU.REC.1395.30

Health conditions studied

1

Description of health condition studied

Mental health of pregnant

ICD-10 code

O99

ICD-10 code description

Other mental disorders complicating the puerperium

2

Description of health condition studied

Physical health of pregnant

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

physical health

Timepoint

Gestational age between 20 and 24 weeks and then 36 weeks

Method of measurement

Roland-Morris Disability Questionnaire- Iranian Version, Body Map, Ware and Sherbourne -MOS 36-Item Short-Form Health Survey (SF-36)

2

Description

mental health

Timepoint

Gestational age between 20 and 24 weeks and then 36 weeks

Method of measurement

well being, Ware and Sherbourne -MOS 36-Item Short-Form Health Survey (SF-36)questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

The control group will receive routine care.

Category

Lifestyle

2

Description

The intervention group will participate in training sessions (3sessions) as well as receiving routine care. Sessions are held weekly. training by multimedia such PowerPoint, role playing, group discussions, pamphlets and educational CDs is perform. Content includes: anatomic and physiologic changes during pregnancy, the most common pregnancy complaints and reform posture in pregnancy. Then they are followed by phone call.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Urban Health Center of Sabzevar University of Medical Sciences

Full name of responsible person

Masoumeh Sharifzadeh

Street address

Central building of Shahroud University of Medical Sciences, Tir Square,Shahroud. Semnan Iran, Islamic Republic Of

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahroud University of Medical Sciences

Full name of responsible person

Dr Mohammadhasan Emamian

Street address

Central building of Shahroud University of Medical Sciences, Tir Square,Shahroud. Semnan Iran, Islamic Republic Of

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Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Masoumeh Sharifzadeh

Position

Master science of student counseling midwiferys

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Nahid bolbol haghghi

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Faculty member

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work**Street address**

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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