

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effects of massage and guided imagery during pregnancy on anxiety among nulliparous women

Protocol summary

Summary

Objective: the aim of this study is comparing the effect of massage and guided imagery on anxiety of nulliparous women during pregnancy referred to health centers in Zahedan city in 1395. This study is a randomized clinical trial with pretest and posttest control group. The studied population is nulliparous pregnant women with 75 sample size. Samples put in three groups of massage, guided imagery and control accidentally and then it continues until reaching the sample size. Inclusion criteria: singleton pregnancy; being in the second trimester; having literacy; lack of stressful life event during six months; disuse of any anti-anxiety medication; lack of physical illness that has health risks for her and her fetus by massage such as spinal cord injury or surgery; no history of recurrent pregnancy loss; lack of obstetric complications such as cervical cerclage. Exclusion criteria: the occurrence of stressful events or the creation of any obstetrical complication in the long run; childbirth during the study. Before intervention, revised questionnaire about pregnancy related to anxiety is completed. Exercises will be done once a week during six weeks (from 22 to 28 weeks of pregnancy). In addition, it will be asked the guided imagery group of participants to practice every day at home and record it in the form. Questionnaire is completed six weeks after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070428794N1**
Registration date: **2016-07-30, 1395/05/09**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-30, 1395/05/09

Registrant information

Name

farnoosh khojasteh

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 33442481

Email address

khojasteh@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of massage and guided imagery during pregnancy on anxiety among nulliparous women

Public title

Comparing the effects of massage and guided imagery during pregnancy on anxiety among nulliparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 and 35 years;

singleton pregnancy; being in the second trimester (22 to 28 weeks of pregnancy); Iranian race; having literacy; lack of stressful life event during six months; disuse of any anti-anxiety medication; do not use massage therapy and similar methods during pregnancy; lack of physical illness that has health risks for her and her fetus by massage such as spinal cord injury or surgery; the ability of the regular participation in meetings; no history of recurrent pregnancy loss; lack of drug addiction; lack of physical and mental illness; lack of obstetric complications such as cervical cerclage, placenta previa, high fever, premature rupture of membranes, polyhydramnios. Exclusion criteria: the occurrence of stressful events or the creation of any obstetrical complication in the long run which has risk for the health of the mother or her baby such as high-blood pressure during pregnancy; A skin lesion at the site of massage that creates during massage; childbirth during the study; not desire to continue study; no intervention (listen to CDs less than three days a week).

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: **75**

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**

zahedan university of Medical Sciences

Street address

field doctor hesabi - College of Medical Sciences

City

zahedan

Postal code**Approval date**

2015-12-27, 1394/10/06

Ethics committee reference number

IR.ZAUMS.REC.1394.343

Health conditions studied**1****Description of health condition studied**

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

anxiety

Timepoint

pre- intervention and 6 weeks after intervention

Method of measurement

Pregnancy related anxiety questionnaire - revised

Secondary outcomes

empty

Intervention groups**1****Description**

In massage group, participants after pre-test have the head and neck, back, arms and legs massage for 20 minutes, once a week during six weeks (from 22 to 28 weeks gestation) in training classes for mothers in health centers equipped with facilities such as appropriate mats. First session will take about half an hour and other sessions take 20 minutes. In the first session, it will be explained about the causes of anxiety and ways to control it and the purpose of the intervention. To maintain patient privacy, the room where massage will be done is equipped with thick curtains and paravan. To maintain more privacy for patients during the massage, the room doors will be locked to prevent possible entry and exit.

Category

Behavior

2**Description**

In the guided imagery group, intervention after pre-test will be done when participants receive the guided imagery techniques for 20 minutes, once a week during for six weeks (from 22 to 28 weeks gestation) in the training classes of health center. In addition, the registration daily workouts form will be given to the mothers. They have to listen to the CD in a quiet environment for 20 minutes every day, and insert it in the form. We called the mother twice a week while remind them of importance of exercise. Forms will be collected by a researcher at the next meeting.

Category
Behavior

3

Description

The control group will receive the routine and common care during pregnancy. At the end of the sixth week, we will call and invite them to participate in the post-test.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Jawad Health Center
Full name of responsible person
Parisa Zargari
Street address
City
Zahedan

2

Recruitment center

Name of recruitment center
Imam Hadi Health Center
Full name of responsible person
Cimin Lyaghat
Street address
City
Zahedan

3

Recruitment center

Name of recruitment center
Nastaran Health centers
Full name of responsible person
Zahra Dehbashi
Street address
City
Zahedan

4

Recruitment center

Name of recruitment center
Moaallem Health Center
Full name of responsible person
Batool Kaikavooci
Street address
City
Zahedan

5

Recruitment center

Name of recruitment center
Moses Ibn Jafar Health Center

Full name of responsible person
Zahra Meir
Street address
City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Hoshang Rafighdost
Street address
University of Medical Sciences, Field docter Hesabi,
Zahedan
City
Zahedan

Grant name

Grant code / Reference number

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

Title of funding source

Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Esmat sahlabadi
Position
Masters student in the field Consultation of midwifery
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Square Of Mashahir,
Zahedan
City
Zahedan
Postal code
Phone
+98 54 3344 2482
Fax
Email
Essahlabadi84@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Farnoosh khojasteh

Position

Master science

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

School of Nursing and Midwifery, Square Of Mashahir,
Zahedan

City

Zahedan

Postal code**Phone**

+98 54 3344 2482

Fax**Email**

khojastehfarnoosh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Esmat sahlabadi

Position

Masters student in the field consultationof midwifery

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

School of Nursing and Midwifery, Square Of Mashahir,
Zahedan

City

Zahedan

Postal code**Phone**

00

Fax**Email**

Essahlabadi84@gmail.com

Web page address

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