

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of counseling on relaxation on Sleep disturbances on third trimester of pregnancy in primigravida women attendant to health centers in Hamadan , 2015

Protocol summary

Summary

Objective: This study is to determine the effect of counselling on relaxation on sleep disturbances on third trimester of pregnancy in primigravida women. This study is a semi experimental with two groups (experimental and control) with pre-test and post-test. This study comprised pregnant women attending to health care centers in Hamadan. Simple Random permutation block will be done. The sample size is 50 women in the intervention group and 50 women in control group. Inclusion criteria: First pregnancy; single fetus and gestational age 28-32 weeks; having sleep disturbance(Pittsburgh scale 5 or more) Exclusion criteria: Any problems in pregnancy during the study period. In the intervention group relaxation counseling will be trained by the researcher in two sessions. The intervention group each time, twice a day for 4 weeks for 20 minutes of relaxation will do. In this study primary outcome measure is sleep disturbances and secondary outcome measure is relaxation counseling.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509226888N12**

Registration date: **2015-10-02, 1394/07/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-02, 1394/07/10

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 6051

Email address

shobeiri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of Research Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling on relaxation on Sleep disturbances on third trimester of pregnancy in primigravida women attendant to health centers in Hamadan , 2015

Public title

The effect of counseling on relaxation on Sleep disturbances on third trimester of pregnancy in primigravida women attendant to health centers in Hamadan , 2015

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of sleep disturbances; first pregnancy and wanted pregnancy; single fetus and gestational age 28-32 weeks; not having mental disorders, according to a psychiatrist; not having gestational diabetes, preeclampsia, bleeding, premature rupture of membrane...; having sleep disturbance (Pittsburgh scale 5 or more) exclusion criteria: Any problems in pregnancy during the study period (abruption, fetal abnormal situation, cord prolapse, bleeding, diabetes, hypertension, preterm labor and ...); Change Location; Failure to attend training classes

Age

No age limit

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**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 Hamadan University of Medical Sciences

Street address

Fahmih Street, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Postal code

65178

Approval date

2015-07-25, 1394/05/03

Ethics committee reference number

IR.UMSHA.REC.1394.208

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

sleep

ICD-10 code

F51

ICD-10 code description

Nonorganic sleep disorders

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

Sleep disturbance

Timepoint

weeks 28-32 and 32-36 of gestational age

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes**1****Description**

relaxation

Timepoint

week 32-36 of gestational age

Method of measurement

Checklist

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

Relaxation training for 4 weeks twice a day for 20 minutes each time by the intervention group

Category

Other

2**Description**

The control group will receive regular prenatal care

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Healthcare center Samii 2

Full name of responsible person

Reyhaneh Ebrahimi

Street address

Taleghani street

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Research Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr. Bashirian Saeed

Street address

Fahmih Street, Hamadan University of Medical Sciences, Department of Research and Technology

City

Hamadan

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 Technology, Hamadan 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**

Hamadan University of Medical sciences

Full name of responsible person

Fatemeh Shobeiri

Position

Ph.D. in Maternal and Child Health

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

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave, Hamadan

City

Hamadan

Postal code

6516845977

Phone

+98 81 3827 6051

Fax**Email**

shobeiri@umsha.ac.ir

Web page address

Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Hamadan University of Medical sciences

Full name of responsible person

Fatemeh Shobeiri

Position

Ph.D. in Maternal and Child Health

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

Hamadan University of Medical sciences, School of Nursing and Midwifery, Fahmideh Ave, Hamadan

City

Hamadan

Postal code

6516645977

Phone

+98 81 3827 6051

Fax**Email**

shobeiri@umsha.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Fatemeh Shobeiri

Position

Ph.D. in Maternal and Child Health

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

Fahmideh Street, Hamadan University of Medical Sciences

City

Hamedan

Postal code

6516645977

Phone

+98 81 3827 6051

Fax**Email**

shobeiri@umsha.ac.ir

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

