

# 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*

