

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 2026

### Investigating the effect of sleep hygiene methods on improving sleep quality in pregnant women with insomnia in the first trimester: a Randomized Clinical Trial

#### Protocol summary

##### Study aim

Investigating the effect of sleep hygiene methods on improving sleep quality in pregnant women with insomnia in the first trimester

##### Design

Clinical trial with intervention and control groups, with parallel groups, single blind, randomized using Randomiser software, on 108 patients.

##### Settings and conduct

Study place: The clinic of AlZahra Hospital will be in Tabriz; Study population: 108 pregnant women in the first trimester of pregnancy who scored 5 and higher in the Pittsburgh Sleep Quality Questionnaire; Type of blinding: one-way blind; How to blind: After completing the questionnaires, they will be provided to the analyzer in sealed envelopes, labeled Group A and Group B. In this way, the analyzer will be blinded in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 40 years; Pregnant women in the first trimester of pregnancy; Getting more than 5 Point Based On The Pittsburgh Sleep Quality Index. Non inclusion criteria: Having chronic medical diseases; Smoking and alcohol consumption; Occurrence of severe stressors

##### Intervention groups

Intervention group: The group receiving sleep hygiene training, which is a 60-minute session Control group: A group that will not receive any training.

##### Main outcome variables

Sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190304042912N3**

Registration date: **2022-04-11, 1401/01/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-11, 1401/01/22**

Update count: **0**

##### Registration date

2022-04-11, 1401/01/22

##### Registrant information

###### Name

sanaz moosavi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3553 9161

###### Email address

musevis@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-09, 1401/01/20

##### Expected recruitment end date

2023-04-09, 1402/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of sleep hygiene methods on improving sleep quality in pregnant women with insomnia in the first trimester: a Randomized Clinical Trial

**Public title**

The effect of sleep hygiene methods on improving sleep quality in pregnant women with insomnia

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 18 and 40 years Pregnant women in the first trimester of pregnancy Getting more than 5 Point Based On The Pittsburgh Sleep Quality Index Literacy to complete questionnaires Willingness to participate in the study

**Exclusion criteria:**

Having chronic medical diseases Smoking and alcohol consumption Occurrence of severe stressors such as death of first-degree relatives during the last month before the study

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **108**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will be divided into two groups of intervention and control, using random blocking method with the blocks of size of four and six with 1: 1 allocation sequence. The allocation sequence will be determined by the researcher in the study using Randomiser software.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

After completing the questionnaires, they will be provided to the analyzer in sealed envelopes, labeled Group A and Group B. In this way, the analyzer will be blinded in this study.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee Of Tabriz University Of Medical Sciences

**Street address**

Third Floor, Number 2 Central Building, Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166616471

**Approval date**

2022-03-09, 1400/12/18

**Ethics committee reference number**

IR.TBZMED.REC.1401.004

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

Insomnia

**ICD-10 code**

G47.0

**ICD-10 code description**

Insomnia

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

Sleep Quality

**Timepoint**

Before the intervention, every week after the intervention for three weeks

**Method of measurement**

Pittsburgh Sleep Quality Index

**Secondary outcomes**

empty

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

Intervention group: After coordination with the participants, sleep hygiene training will be held in the form of a 60-minute face-to-face session, in which sleep hygiene items will be fully taught and also provided to individuals in printed form.

**Category**

Rehabilitation

**2****Description**

Control group: The control group will not receive any training.

**Category**

Rehabilitation

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Sanaz Moosavi

**Street address**

Alzahra Hospital, South Artesh St.,Tabriz, iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138665793

**Phone**

+98 41 3553 9161

**Email**

moosavisanz@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for Research,Tabriz University Of Medical Sciences

**Full name of responsible person**

Dr Parviz Shahabi

**Street address**

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138665793

**Phone**

+98 41 3335 7310

**Email**

research-vice@tbzmed.ac.ir

**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,Tabriz University Of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

## Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sanaz Moosavi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

moosavisanz@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sanaz Moosavi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available