

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

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5138665793

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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

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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

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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