

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of sleep hygiene education on the insomnia severity and sleep quality of pregnant women

Protocol summary

Study aim

Determining the effect of sleep hygiene education on the severity of insomnia and sleep quality of pregnant women referring to comprehensive health centers in Nahavand city in 2023

Design

Phase II clinical trial with control group and 1:1 ratio and with parallel groups will be conducted on 70 pregnant women with SHI score ≥ 16 . Blocked random assignment will be done using web software (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) and with blocks of 4 and 6. Due to the nature of the study, blinding is not possible.

Settings and conduct

Pregnant women are placed in the intervention or control group based on the predetermined allocation sequence if they meet the study entry criteria. Sleep hygiene education sessions are held at Hamedan comprehensive health centers at intervals of one week. The duration of the sessions will be 45-60 minutes. Mothers in the control group received only routine care. To comply with ethical considerations, after the end of the study, a group meeting will be held for the mothers of the control group. In the 36th week of pregnancy, the mothers of both groups are invited to complete the questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women 18-35 years old, singleton pregnancy, gestational age 24-28 weeks at the time of entering the study, having literacy and SHI score ≥ 16 and ability to speak Persian. Exclusion criteria: Sleep disorder before pregnancy, chronic medical problems, pregnancy complications, psychiatric disorders, night shift and cognitive problems

Intervention groups

In addition to routine care, people in the intervention group will participate in 4 sleep hygiene training sessions in groups of 5 people. Control group: routine care

Main outcome variables

Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201102049233N3**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Farideh Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sleep hygiene education on the insomnia severity and sleep quality of pregnant women		Ethics committees	
Public title Sleep hygiene education and the insomnia severity and sleep quality of pregnant women Purpose Education/Guidance Inclusion/Exclusion criteria Inclusion criteria: Be 18-35 years old. The pregnancy is a singleton. The gestational age at the time of entering the study should be 24-28 weeks. Be literate in reading and writing. Have obtained SHI (Sleep Hygiene Index) score ≥ 16 . Have the ability to speak Persian. Exclusion criteria: According to the person's own statements, have a sleep disorder before pregnancy have chronic medical problems (such as diabetes, blood pressure, heart, kidney problems, etc.). Have pregnancy complications (gestational diabetes, pregnancy blood pressure, bleeding, placental abruption, and placenta previa). have psychiatric disorders according to the file in the SIB system Have a night shift Have cognitive problems Age From 18 years old to 35 years old Gender Female Phase N/A Groups that have been masked <i>No information</i> Sample size Target sample size: 70 Randomization (investigator's opinion) Randomized Randomization description In order to assign mothers to the intervention and control groups, a 4 and 6 random blocking method is used. To do this, the allocation sequence is first determined using AABB blocks before the start of the study. Then, the type of intervention is written in opaque closed envelopes based on the specified sequence and is numbered in sequence. Participants will complete a demographic and midwifery information questionnaire and receive an envelope before entering the study. People are then placed in one of the control or intervention groups based on the contents of the envelope. Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features Secondary Ids empty		1 Ethics committee Name of ethics committee Ethics committee of Hamadan University of Medical Sciences Street address In front of Mardom's Park, Research Square City Hamedan Province Hamadan Postal code 6517838687 Approval date 2023-08-26, 1402/06/04 Ethics committee reference number IR.UMSHA.REC.1402.422	
		Health conditions studied	
		1 Description of health condition studied Pregnancy ICD-10 code O99.3 ICD-10 code description Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium	
		Primary outcomes	
		1 Description Sleep quality scores Timepoint Before the intervention and 4 weeks after the end of the educational sessions Method of measurement Pittsburgh Sleep Quality Index (PSQI)	
		Secondary outcomes	
		1 Description Sleep hygiene and insomnia severity Timepoint Before the intervention and 4 weeks after the end of the educational sessions Method of measurement Sleep Hygiene Index (SHI) and Insomnia Severity Index (ISI)	
		Intervention groups	

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Description

Intervention group: Pregnant women in the intervention group, in addition to routine care, will participate in 4 sessions of sleep hygiene education in groups of 5 people. The sessions are weekly and start from the gestational age of 24-28 weeks, and the meeting place will be held in comprehensive health centers of Nahavand city. The time of attendance is determined by prior coordination of pregnant women and by phone. The duration of the sessions will be 45-60 minutes. After the sessions, the training package is given to the participants to carry out the taught principles until the end of the pregnancy.

Category

Lifestyle

2

Description

Control group: Routine prenatal care

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers of Nahavand city

Full name of responsible person

Farideh Kazemi

Street address

Hamedan University of Medical Sciences (UMSHA),
Pazhouhesh Crossroad., Hamadan, Iran.

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hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi, Deputy of research and
technology of Hamadan University of Medical
Sciences

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Farideh Kazemi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be accessible if necessary

When the data will become available and for how long

After the results are published

To whom data/document is available

The data will be provided to academic and scientific institutions if necessary

Under which criteria data/document could be used

If a meta-analysis is required, the data will be made available to the corresponding author

From where data/document is obtainable

Correspondence with the responsible person by email

What processes are involved for a request to access data/document

If you agree to the request, the data will be emailed.

Comments