Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Neuman's Systems Model on sleep quality and anxiety in nulliparous pregnant women attending comprehensive health service centers in Khoy County: A randomized clinical trial

Protocol summary

Study aim

Determining the impact of Neuman's Systems Model on sleep quality and anxiety in nulliparous mothers attending comprehensive health service centers in Khoy County in 2025.

Design

Clinical trial with a control group, parallel groups, simple randomization, Phase 0 on 80 patients.

Settings and conduct

The sampling method in this study is multi-stage. In the first stage, the city of Khoy is divided into two separate regions based on the municipal classification. Then, from among the health centers in each region, 4 centers will be randomly selected and randomly assigned to intervention (2 sites) and control (2 sites) groups; thus, the study will be conducted at 8 sites (4 intervention and 4 control). Finally, at each base, 20 women are selected at random from the list of eligible pregnant women's names.

Participants/Inclusion and exclusion criteria

Entry Requirements: First-time mothers with a gestational age between 28 and 40 weeks Obtaining informed consent from spouses and first-time mothers themselves. Mothers visiting health centers Not taking psychiatric or sleeping medications in the past month and individuals undergoing specific treatments. Conditions for Non-Entry: Withdrawal from continued participation during the study Occurrence of acute obstetric complications (such as severe preeclampsia, severe bleeding) Delivery before the intervention is completed. Lack of cooperation in completing tools or intervention sessions

Intervention groups

The educational-care intervention program in this study is developed and implemented based on Newman's systems model, consisting of four sessions with specific objectives, content, and scheduling. If necessary, mothers requiring more specialized services will be referred.

Main outcome variables

Sleep Quality; Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250723066609N4**
Registration date: **2026-02-16, 1404/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-16, 1404/11/27**
Update count: **0**

Registration date

2026-02-16, 1404/11/27

Registrant information

Name

Mir Amir Hossein Seyednazari

Name of organization / entity

Khoy Faculty of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-28, 1404/11/08

Expected recruitment end date

2026-04-20, 1405/01/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Neuman's Systems Model on sleep quality and anxiety in nulliparous pregnant women attending comprehensive health service centers in Khoy County: A randomized clinical trial

Public title
Neuman's Systems Model on sleep quality and anxiety in nulliparous pregnant women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Nulliparous mothers with gestational ages between 28 and 40 weeks Obtaining informed consent from spouses and the Nulliparous mothers. Mothers visiting health centers Not taking psychiatric or sleeping medications in the past month and individuals undergoing specific treatments.
Exclusion criteria:
Withdrawal from continued participation during the study Occurrence of acute obstetric complications (such as severe preeclampsia, severe bleeding) Delivery before the intervention is completed. Lack of cooperation in completing tools or intervention sessions
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to intervention and control groups using block randomization with the individual as the unit of randomization. A statistical software (or valid random number generator) will be used to generate the random sequence and block sizes (e.g., blocks of 4). To ensure allocation concealment and prevent selection bias, the assignment sequence will be placed in sealed, opaque, and sequentially numbered envelopes. After initial assessment and obtaining informed consent from eligible mothers at the health centers, the corresponding envelope will be opened by an independent individual to reveal the group assignment.
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 Khoy University of Medical Sciences
Street address
Valiasr Blv
City
Khoy
Province
West Azarbaijan
Postal code
5819637599
Approval date
2025-12-23, 1404/10/02
Ethics committee reference number
IR.KHOY.REC.1404.057

Health conditions studied

1

Description of health condition studied
nulliparous pregnant women
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep Quality, anxiety
Timepoint
Before and After intervention
Method of measurement
Pittsburgh Questionarie, Speilberger Questionarie

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The educational-care intervention program in this study is developed and implemented based on Newman's systems model, consisting of four sessions with specific objectives, content, and

scheduling. The first session (30 to 45 minutes), aimed at diagnosis and evaluation, focuses on identifying actual and potential stressors (such as fear of childbirth, concerns about motherhood, and environmental problems). The mother's state of balance is determined by an initial assessment of anxiety levels and sleep quality. The second session (45 to 60 minutes) includes primary prevention interventions and aims to strengthen the mother's resilient and typical defense lines, providing content such as stress coping skills training, comprehensive sleep hygiene education, time and energy management, and the importance of social support. The third session (45 to 60 minutes) is dedicated to secondary prevention interventions, aiming to address existing stressors and strengthen lines of resistance thru targeted intervention. This will include teaching specific relaxation techniques (such as deep breathing and visualization), counselling focused on the mother's main concerns about pregnancy and childbirth, and modifying harmful behaviors. Finally, the fourth session (30-45 minutes), aimed at evaluation and reconstruction (tertiary prevention) to support a return to balance, includes reassessment of anxiety and sleep quality scores, review and consolidation of learned material, and planning for the sustainability of positive changes. If necessary, mothers requiring more specialized services are referred.

Category

Behavior

2

Description

Control group: The control group will only receive routine and standard healthcare at the health center during this period.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Deputy Health Minister

Full name of responsible person

Dr. Bayram Hashemzadeh

Street address

میدان شهید فهمیده

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoy University of Medical Sciences

Full name of responsible person

Dr. Amin Soheili

Street address

Khoy - Basij Square - Shahid Montazeri Street - Khoy Medical Sciences Central Headquarters

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sci@khoyums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoy 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

Khoy University of Medical Sciences

Full name of responsible person

Mir Amirhossein Seyednazari

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available