Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of stress management training on sleep quality and perceived stress in pregnant women at risk of preterm labor

Protocol summary

Study aim

Determining the effect of stress management training on sleep quality and perceived stress in pregnant women at risk of preterm labor referred to Fatemiyeh Hospital in Hamadan.

Design

A semi-experimental study without a control group, using a pre-test – post-test design, will be conducted on 48 pregnant women.

Settings and conduct

After obtaining permission from the Hamadan University of Medical Sciences, we will refer to the prenatal ward of Fatemieh Hospital and prepare a list of pregnant women with preterm labor. They will be invited to participate in the research project if they are willing and meet the inclusion criteria. First, the Perceived Stress Scale will be completed by all potential research subjects. Those who score above 21.8 will enter the study. Subsequently, the demographic information form, the Perceived Stress Questionnaire, and the sleep quality questionnaire will be completed by the research subjects before the intervention begins (pre-test design). One month after the completion of the training sessions, the stress and sleep quality questionnaires will be completed again by the participants (post-test design).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-45 years, gestational age 28-30 weeks, symptomatic preterm labor, singleton pregnancy. Exclusion criteria: Unwillingness to participate in the study, despite initial consent.

Intervention groups

The intervention consists of stress management training. The training sessions include six 45-60 minute sessions will be held over a period of 3 weeks, twice a week in the prenatal ward.

Main outcome variables

Perceived stress, Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250622066217N2**
Registration date: **2025-09-27, 1404/07/05**
Registration timing: **prospective**

Last update: **2025-09-27, 1404/07/05**
Update count: **0**

Registration date

2025-09-27, 1404/07/05

Registrant information

Name

sara abdoli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-21, 1404/09/30

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of stress management training on sleep quality and perceived stress in pregnant women at risk of preterm labor

Public title
The effect of stress management training on sleep quality and perceived stress
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 18-45 years Gestational age of 28-30 weeks A score of 21.8 or higher on the Cohen scale (a cut-off point of 21.8 or higher indicates high perceived stress) Symptomatic preterm labor as confirmed by a physician and medical documentation Singleton pregnancy
Exclusion criteria:
Unwillingness to continue participation in the study, despite initial consent Termination of pregnancy
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
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
Hamadan University of Medical Sciences Headquarters, Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
6517838678
Approval date
2025-08-30, 1404/06/08
Ethics committee reference number
IR.UMSHA.REC.1404.412

Health conditions studied

1

Description of health condition studied
Perceived stress
ICD-10 code
Z73.3
ICD-10 code description
Stress, not elsewhere classified.

2

Description of health condition studied
Sleep quality
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep Quality: Sleep quality has seven components: subjective quality, sleep latency (time taken to fall asleep), sleep duration, sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction.
Timepoint
Before the intervention and one month after the completion of the intervention.
Method of measurement
Pittsburgh Sleep Quality Index (PSQI) Questionnaire

Secondary outcomes

1

Description
Perceived stress: can be defined as a state in which there is an imbalance between the perception of situational demands and the perception of one's ability to cope.
Timepoint
Before the intervention and one month after the completion of the intervention
Method of measurement
Cohen's Perceived Stress Scale

Intervention groups

1

Description
Intervention group: The training sessions consist of six

45-60 minute sessions held over a period of 3 weeks, taking place twice a week in the prenatal ward of Fatemieh Hospital in Hamadan. At the end of each session, the researcher will assign tasks related to the topics covered in that session. The research participants are required to complete these tasks between sessions and provide a report on their progress during each subsequent session. At the beginning of every training session, participants will be asked to recap the content of the previous session to clarify any potential ambiguities. This approach will promote repetition, practice, and reinforce mental recall of the discussed topics.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Hospital, Hamadan City
Full name of responsible person
Seyedeh Zahra Masoumi Ghazinoori Tabatabaei
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Hamadan University of Medical Sciences
Full name of responsible person
Seyedeh Zahra Masoumi Ghazinoori Tabatabaei
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Some data, such as information related to the main outcome or the like, can be shared.
When the data will become available and for how long
6 months after results are published
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Analysis on the data is permitted with the author's permission.
From where data/document is obtainable
It is accessible through the following email address. zahramid2001@yahoo.com
What processes are involved for a request to access data/document
The file will be available within one week after email is sent.
Comments