Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The effect of cognitive-behavioral counseling with/without Neroli essence on sleep quality of pregnant women: a randomised controlled trial

Protocol summary

Study aim
The effect of cognitive-behavioral counseling with/without Neroli essence on sleep quality of pregnant women

Design
Randomized controlled trial with three parallel arms

Settings and conduct
This trial will be performed on 75 pregnant women who referring to health centers of Tabriz. Pregnant women will be assessed according to the eligibility criteria and if they have criteria and willingness to participate in the study, the written informed consent will obtained and primary evaluations will be conducted. Participants will be assigned to the three groups including: Intervention group 1: Recipient of cognitive-behavioral counseling and placebo of Neroli essence, Second intervention group: Recipient of cognitive-behavioral counseling with aromatherapy with Neroli essence and control group by the block randomization method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women with a gestational age of 20 to 24 weeks, Women with poor sleep quality based on the Pittsburgh Sleep Quality Questionnaire (score above 5) Exclusion criteria: Pregnant mothers with mental illnesses and a history of hospitalization in a psychiatric hospital and the use of any psychological medication based on the individual expression, Mothers with drug and smoking addiction according to the individual expression.

Intervention groups
The first intervention group: the recipient of cognitive-behavioral counseling and placebo of Neroli essence; The second intervention group: the recipient of cognitive-behavioral counseling with aromatherapy with Neroli essence and the control group: the recipient of routine care.

Main outcome variables
Sleep quality of pregnant women

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N63**
Registration date: **2021-02-13, 1399/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-13, 1399/11/25**
Update count: **0**

Registration date
2021-02-13, 1399/11/25

Registrant information

Name
Mojgan Mirghafourvand

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-08, 1399/10/19

Expected recruitment end date
2021-05-19, 1400/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of cognitive-behavioral counseling with/without Neroli essence on sleep quality of pregnant women: a randomised controlled trial

Public title
The effect of cognitive-behavioral counseling on sleep quality of pregnant women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women with a gestational age of 20 to 24 weeks Women with poor sleep quality based on the Pittsburgh Sleep Quality Questionnaire (score above 5) Has a minimum secondary education degree Living in Tabriz Pregnant women with a file in the health center (Sib system) No olfactory problems and sensitivity to herbal medicines according to the patient's report Achieving a depression score of 12 or lower based on the Edinburgh Depression Inventory

Exclusion criteria:
Pregnant mothers with mental illnesses and a history of hospitalization in a psychiatric hospital and the use of any psychological medication based on the individual expression Mothers addicted to drugs and cigarettes according to the individual expression Mothers with high-risk pregnancies, including diabetes, high blood pressure, chronic diseases affecting pregnancy, such as cardiovascular, lung and .... Mothers with obstetrics problems including bleeding, history of preterm delivery and ...

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be assigned to the three groups including: Intervention group 1: Recipient of cognitive-behavioral counseling and placebo of Neroli essence, Second intervention group: Recipient of cognitive-behavioral counseling with aromatherapy with Neroli essence and control group by the block randomization method with block sizes of 6 and 9 and with a 1: 1: 1 allocation ratio. In order to hide the allocation (Allocation Concealment), the type of intervention is written on paper and sealed in opaque envelopes. The envelopes will be opened in order of the participants entering the study and the type of group will be determined. Random allocation and preparation of envelopes will be done by a person not involved in sampling and data collection.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
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
Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2020-12-29, 1399/10/09

Ethics committee reference number
IR.TBZMED.REC.1399.905

Health conditions studied

1

Description of health condition studied
Sleep quality

ICD-10 code
G47.9

ICD-10 code description
Sleep disorder, unspecified

Primary outcomes

1

Description
Sleep quality

Timepoint
Immediately and four weeks after the intervention

Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

1

Description
Anxiety

Timepoint
Immediately and four weeks after the intervention
Method of measurement
Pregnancy Anxiety Questionnaire

2

Description
Quality of life
Timepoint
Immediately and four weeks after the intervention
Method of measurement
Quality of Life Questionnaire

Intervention groups

1

Description
The first intervention group will receive cognitive-behavioral counseling and placebo of Neroli essence. Counseling will be provided in 8 group sessions in native language. The average duration of counseling sessions will be 60 to 90 minutes. Also, 2 drops of placebo of Neroli essence will be inhaled by the participants for 15-20 minutes before going to bed. The protocol of cognitive-behavioral counseling approach will be as follows: Session 1: Explaining the goals of training and acquaintance with members, conducting a pre-test, teaching how to monitor the baseline of sleep with a sleep report table, reminding the importance of treatment tasks, a complete assessment of the nature of insomnia; Session 2: Presenting the principles and logic of treatment, teaching the mechanism of sleep and its stages, sleep-wake cycles, predisposing, maintenance and persistence factors of insomnia, relaxation education; Session 3: Reviewing the previous treatment session, assessing the findings of the sleep report form, sleep hygiene training, and reviewing the relaxation and new sleep schedule; Session 4: Restricting sleep, preventing daily naps, evaluating thoughts and teaching how to record thoughts related to insomnia, reviewing and assessing the assignments of previous sessions (sleep report form and homework assignment); Session 5: Summarizing thoughts, problem solving skills, reviewing the sleep report form and homework assignments and troubleshooting; Session 6: Introduce the cycle of thinking, feeling and behavior, reviewing the relaxation and teaching not to try in vain to fall asleep and apply all the instructions of the previous sessions and reviewing the homework of the previous sessions (sleep report form and homework assignments); Session 7: Training the thought blocking, mental imaging, troubleshooting about cognitive-behavioral therapy plan, reviewing the patient's homework; Session 8: Reviewing and troubleshooting the cognitive-behavioral treatment plan, noting the progress of treatment according to the sleep calendar.
Category
Behavior

2

Description
The second ntervention group will receive cognitive-behavioral counseling and Neroli essence. Counseling will be provided in 8 group sessions in native language. The average duration of counseling sessions will be 60 to 90 minutes. Also, 2 drops of Neroli essence will be inhaled by the participants for 15-20 minutes before going to bed. The protocol of cognitive-behavioral counseling approach will be as follows: Session 1: Explaining the goals of training and acquaintance with members, conducting a pre-test, teaching how to monitor the baseline of sleep with a sleep report table, reminding the importance of treatment tasks, a complete assessment of the nature of insomnia; Session 2: Presenting the principles and logic of treatment, teaching the mechanism of sleep and its stages, sleep-wake cycles, predisposing, maintenance and persistence factors of insomnia, relaxation education; Session 3: Reviewing the previous treatment session, assessing the findings of the sleep report form, sleep hygiene training, and reviewing the relaxation and new sleep schedule; Session 4: Restricting sleep, preventing daily naps, evaluating thoughts and teaching how to record thoughts related to insomnia, reviewing and assessing the assignments of previous sessions (sleep report form and homework assignment); Session 5: Summarizing thoughts, problem solving skills, reviewing the sleep report form and homework assignments and troubleshooting; Session 6: Introduce the cycle of thinking, feeling and behavior, reviewing the relaxation and teaching not to try in vain to fall asleep and apply all the instructions of the previous sessions and reviewing the homework of the previous sessions (sleep report form and homework assignments); Session 7: Training the thought blocking, mental imaging, troubleshooting about cognitive-behavioral therapy plan, reviewing the patient's homework; Session 8: Reviewing and troubleshooting the cognitive-behavioral treatment plan, noting the progress of treatment according to the sleep calendar.
Category
Behavior

3

Description
The control group will receive pregnancy routine care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz city health centers
Full name of responsible person
Narges Rahmani
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Faculty of Nursing & Midwifery, South Shariati Street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
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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
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
Narges Rahmani
Position
MSc student of counseling in midwifery
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant data is confidential

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

Undecided - It is not yet known if there will be 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