

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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

Country

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 intervention 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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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