

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The impact of behavioral health sleep education on the quality of life in the pregnant women with sleep disorder

Protocol summary

Summary

It is a Randomized Controlled Trial study. Research population will be 100 pregnant women 20-40 years old with the pregnancy age of 16-20 weeks that visit a two chosen health care center of Mako Township from Euromie University of Medical Science and have inclusion criteria. We will use convenience sampling to recruit people to the study. After completing the informed consent form the demographic questionnaire and Pittsburg sleep quality index will be completed by the participants. The pregnant women with sleep score over five will complete Quality of life questionnaire (WHOQOL: BREF) after that they will randomly divide into case and control groups. Cases will divide into five groups based on the gestational age. They will receive Health behavior education in four one- hour meeting from the 22th to 25th week of pregnancy. Control group will receive routine prenatal care. Follow-ups will assess by completing Quality of life questionnaire (WHOQOL: BREF) in both groups in 29, 33 and 37 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204149463N1**

Registration date: **2012-06-15, 1391/03/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-15, 1391/03/26

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

behboodi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science, vice chancellor for research(primary sponsor)

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-07-19, 1391/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of behavioral health sleep education on the quality of life in the pregnant women with sleep disorder

Public title

The impact of behavioral health sleep education on the quality of life in the pregnant women with sleep disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian- pregnant women; Women with gestational age 16-20 weeks; Without known physical , mental and psychological illnesses; Ages 20 to 40 years; Able for reading and writing; Dont use of smoking, drugs, drinking, sleep and hormones drugs; Don't exist abortion in previous pregnancy. Exclusion criteria: During the study, mothers who are involved in adverse events such

as death of loved ones; Mothers who don't desire to continue; Appearance of psychological and physical illness during study; Change of sleep condition with trip; change of diet and habitat; use of drugs in during study.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery, Tehran University of Medical Science

Street address

Near Ghods Street on keshavarz Boulevard

City

Tehran

Postal code

Approval date

2012-05-19, 1391/02/30

Ethics committee reference number

54839

Health conditions studied

1

Description of health condition studied

Quality of life

ICD-10 code

z34.8

ICD-10 code description

Supervision of other normal pregnancy

Primary outcomes

1

Description

sleep quality

Timepoint

16-20 weeks of pregnancy

Method of measurement

Pittsburgh Sleep Quality Index questionnaire

2

Description

Quality of life

Timepoint

16-20 weeks of pregnancy

Method of measurement

Quality of life questionnaire of WHO(WHOQOL: BREF)

Secondary outcomes

1

Description

Physical health OF Quality of life

Timepoint

29, 33 and 39 weeks of pregnancy

Method of measurement

Quality of life questionnaire OF WHO(WHOQOL: BREF)

2

Description

Psychological Health OF Quality of life

Timepoint

29, 33 and 39 weeks of pregnancy

Method of measurement

Quality of life questionnaire of WHO(WHOQOL: BREF)

3

Description

Social Relationships OF Quality of life

Timepoint

29, 33 and 39 weeks of pregnancy

Method of measurement

Quality of life questionnaire of WHO (WHOQOL: BREF)

4

Description

Environmental Quality of life

Timepoint

29, 33 and 39 weeks of pregnancy

Method of measurement

Quality of life questionnaire OF WHO(WHOQOL: BREF)

Intervention groups

1

Description

Intervention group: health behavior education will educate on one hour duration in four meeting, start 22week , end25week and different content in each meeting

Category

Other

2

Description

Control group: Routine normal care on prenatal care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Maku Township, Euromiea University of Medical Science

Full name of responsible person

Elham Rezai

Street address

Maku

City

Euromiea

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science, vice chancellor for research(primary sponsor

Full name of responsible person

Dr. Akbar Fotuhi

Street address

khods street, keshavarz boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Science, vice chancellor for research(primary sponsor

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Elham Rezaei

Position

master of science student of midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Person responsible for updating data

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty