Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 hormons 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; chang 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 Univercity 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 questionare

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
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Elham Rezaei
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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