Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the impact of health behavior education on the quality of sleep in the pregnant women

Protocol summary

Summary

This research is a quazi-exprimental study, research community will be visiting pregnant women a two chosen health care center of mako township in dependent on Euromie University of Medical Science, method of sampling will be continuum, score of sleep assesses with the Pittsburgh Sleep Quality Index in the seven “component” scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of scores for these seven components yields one global score. The pregnant women with sleep score over 5 will participant this study,one center rest control group and the other center experience group. experience group will include on four group with 6-9person and health behavior education will educate on one hour duration in four meeting, start 22week , end25week and different content in each meeting.Control group will receive routin prenatal care without intervention . post test will assess to complete Pittsburgh Sleep Quality Index questionnaire via two groups in 29,33and37 weeks then result analysis with Spss 16.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904162248N6**
Registration date: **2012-03-03, 1390/12/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-03, 1390/12/13

Registrant information

Name
Fereshteh Jahdi
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
00982188773073,00982182471404
Email address
f.jahdi@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran Medical University

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-05-22, 1391/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the impact of health behavior education on the quality of sleep in the pregnant women

Public title

The impact of health behavior education on the quality of sleep in the pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian- pregnant women; Women with gestational age 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: **84**

Randomization (investigator's opinion)
Not 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 sience

Street address
Near Ghods Street on keshavarz Boulevard

City
Tehran

Postal code

Approval date
2011-12-24, 1390/10/03

Ethics committee reference number
15211

Health conditions studied

1

Description of health condition studied
The impact of health behavior education on the quality of sleep in the pregnant women.

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

Secondary outcomes

1

Description
Habitual sleep efficiency

Timepoint
29, 33 and 39 weeks of pregnancy

Method of measurement
مدت زمان خواب

2

Description
Sleep disturbances

Timepoint
29, 33 and 39 weeks of pregnancy

Method of measurement
Pittsburgh Sleep Quality Index

3

Description
Use of sleeping medication

Timepoint
29, 33 and 39 weeks of pregnancy

Method of measurement
Pittsburgh Sleep Quality Index

4

Description
Daytime dystunction

Timepoint
29, 33 and 39 weeks of pregnancy

Method of measurement
Pittsburgh Sleep Quality Index

5

Description
Subjective sleep quality

Timepoint
29, 33 and 39 weeks of pregnancy

Method of measurement
Pittsburgh Sleep Quality Index

6

Description
Sleep latency
Timepoint
29, 33 and 39 weeks of pregnancy
Method of measurement
Pittsburgh Sleep Quality Index

7

Description
Sleep duration
Timepoint
29, 33 and 39 weeks of pregnancy
Method of measurement
Pittsburgh Sleep Quality Index

Intervention groups

1

Description
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
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
maku township in dependent on Euromiea University of Medical Science
Full name of responsible person
Elham Rezai
Street address
City
Maku

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
Street address
Maku township,Euromiea
City
Maku
Postal code
Phone
+98 914 463 3116
Fax
Email
rezai520@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran university of medicaal sciences
Full name of responsible person
Fereshte Jahdi
Position
master of science
Other areas of specialty/work
Street address
Tohid squar, school of midwifery and nursing
City
Tehran
Postal code
Phone
+98 912 188 9125

Fax
Email
jahdi_fr@yahoo.com
Web page address

Person responsible for updating data

Contact

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