

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Euomie 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 6-9 person and health behavior education will educate on one hour duration in four meeting, start 22 week , end 25 week 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 29,33 and 37 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 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: **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 university of medical science

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 questionnaire

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 dysfunction

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

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Maku township, Euromiea

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Maku

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+98 914 463 3116

Fax

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rezai520@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran university of medical 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

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Tehran

Postal code

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+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