Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The randomised clinical trial of determination the effect of educational intervention on sleep quality of pregnant women

Protocol summary

Summary

The aim of this research is to determine the effect of educational intervention on sleep quality of pregnant women referring to health centers of Meshginshahr. This study is a randomized clinical trial. The research population are pregnant women referring to health centers of Meshginshahr and meet inclusion criteria. The main inclusion criterion is to have a low – risk pregnancy and the pregnancy age between 26-32 weeks. The main exclusion criterion is the appearance of pregnancy complications during the study. Sample size is 150 persons. After receiving a written letter of satisfaction from samples, first the questionnaire of demographic characteristics and Pittsburg sleep quality questionnaire will be completed by research samples. Then, they will be randomly included in two groups of intervention and control. Randomization is done with Randlist software. Control group will receive only routine prenatal care, and intervention group will also receive the package of sleep health education in addition to this care, and the researcher will teach them the content of educational package that consists of general and specific points of sleep health during pregnancy within two 2- hours' sessions with one week interval. The researcher will give her phone number to intervention group for calling her in the cases of presence of problem about educational package. After one month, Pittsburg sleep questionnaire will be completed by both groups again, and pre – intervention and post – intervention sleep quality will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201148459N3**
Registration date: **2013-01-26, 1391/11/07**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-01-26, 1391/11/07

Registrant information

Name
Shirin Hasanpoor
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1479 6770
Email address
hasanpoorsh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-05-23, 1392/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The randomised clinical trial of determination the effect of educational intervention on sleep quality of pregnant women

Public title

The effect of education on sleep quality of pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- The age between 18-35 years. 2- Gestational age between 26-32 weeks. 3- Singleton pregnancy 4- Not having night shift. 5- Having at least guidance education. 6- Not having children under two years old Exclusion criteria: 1-Fetal death 2- Preterm labor

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Samples of research will be allocated in two groups by Randlist software and with blocks of size 4 and 6. To hide the allocation, mothers will be given a number based on their presence priority at hospital. Then by using A and B codes that will be placed in sealed envelopes with sequence numbers, the type of interventions will be determined. So mothers will be placed in one of the two groups randomly.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Central Organization of Tabriz University Of Medical Sciences, Golgasht street,Tabriz

City

Tabriz

Postal code

Approval date

2012-12-03, 1391/09/13

Ethics committee reference number

91152

Health conditions studied

1

Description of health condition studied

Quality of sleep

ICD-10 code

026.9

ICD-10 code description

Pregnancy- related condition, unspecified

Primary outcomes

1

Description

Sleep quality

Timepoint

Before education and one month after education

Method of measurement

Pittsburgh sleep quality questionnaire

Secondary outcomes

1

Description

Pregnancy outcome

Timepoint

After delivery

Method of measurement

Based on medical records

Intervention groups

1

Description

Intervention group: Intervention group will receive the package of sleep health education in addition to routine prenatal care, and the researcher will teach them the content of educational package that consists of general and specific points of sleep health during pregnancy within two 2- hours' sessions with the interval of one week. After one month, sleep quality will be measured by Pittsburg sleep questionnaire.

Category

Treatment - Other

2

Description

Control group: The control group will receive routine prenatal care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Meshginshahr Health Center

Full name of responsible person
Mansoureh Eshgi

Street address
22 Bahman Street, Imam Square, Meshginshahr City

City
Meshginshahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences, Vice chancellor for research

Full name of responsible person
Dr Sakineh Mohamad Alizadeh

Street address
Faculty of Nursing and Midwifery, South Shariati Street

City
Tabriz

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, Vice chancellor for research

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
Tabriz University of Medical Sciences, School of Nursing and Midwifery, Tabriz

Full name of responsible person
Mansoureh Eshgi

Position
Master of sciences student in midwifery

Other areas of specialty/work

Street address
School of Nursing and Midwifery, South Shariati Street

City
Tabriz

Postal code
51745347

Phone
+98 41 1479 6770

Fax

Email
shirinhasanpoor@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences, School of Nursing and Midwifery, Tabriz

Full name of responsible person
Shirin Hasanpoor

Position
Master of sciences in midwifery

Other areas of specialty/work

Street address
School of Nursing and Midwifery, South Shariati Street

City
Tabriz

Postal code

Phone
+98 41 1479 6969

Fax

Email
shirinhasanpoor@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences, School of Nursing and Midwifery, Tabriz

Full name of responsible person
Mansoureh Eshgi

Position
Master of sciences student in midwifery

Other areas of specialty/work

Street address
School of Nursing and Midwifery, South Shariati Street

City
Tabriz

Postal code

Phone
+98 41 1479 6969

Fax

Email
shirinhasanpoor@yahoo.com

Web page address

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