

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparing the effect of training, based on continuous care model and a telehealth on pregnant women sleeping quality

Protocol summary

Study aim

To compare the effect of education on continuous care model and tele-care (telehealth) model on the quality of sleep in pregnant women

Design

Three groups of clinical trials with a control group, community based and pragmatic, parallel groups, no blind, randomized.

Settings and conduct

This randomized, three-group study was performed in Mashhad's health centers. After confirmation of the research by the Ethics Committee of Mashhad University of Medical Sciences and expressing the goals of studying and satisfying the pregnant women and obtaining written consent from them, and taking into account ethical codes, the sample was selected and carried out.

Participants/Inclusion and exclusion criteria

Women aged 35-18; Pregnancy with one fetus with gestational age of 16 to 20 weeks and 5 scores or more in the Pittsburgh Sleep Quality Questionnaire (PSQI).

Intervention groups

For the follow-up care group, first an introductory meeting (familiarization) will be held, then 4 sessions will be held in 4 weeks, and communication with his family will be established by telephone and booklet (sensitization). Then, within three weeks, a 10-minute phone call will be established (control) and, finally, the quality of sleep will be reviewed immediately and 4 weeks later (a total of 12 weeks). In the telehealth group, an awareness session is initiated first, then 4 encoded CDs are provided to mothers and it is recommended that you watch a CD every week, during these 4 weeks and 4 weeks after that (8 weeks), Telephone counseling is done for 10-15 minutes (once a week) and the quality of sleep will be assessed immediately and 4 weeks after the intervention (a total of 12 weeks). For the control group, the usual care was taken by the health centers.

Main outcome variables

Sleep quality in pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060734378N1**

Registration date: **2017-07-15, 1396/04/24**

Registration timing: **prospective**

Last update: **2018-05-12, 1397/02/22**

Update count: **1**

Registration date

2017-07-15, 1396/04/24

Registrant information

Name

Fatemeh Jalalmarvi

Name of organization / entity

Islamic Azad University of Mashhad

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Contact Number 38411538-051; Deputy of Research & Technology University; Mashhad University of Medical Sciences; next to Hoveizeh Cinema; University of Mashhad.

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

2017-07-23, 1396/05/01

Actual recruitment end date

2018-02-19, 1396/11/30

Trial completion date
empty

Scientific title
Comparing the effect of training, based on continuous care model and a telehealth on pregnant women sleeping quality

Public title
Comparing the effect of training, based on continuous care model and a telehealth on sleeping quality

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
have Spontaneous written consent Being Iranian and resident of Mashhad The gestational age is between 16 and 20 weeks Pregnancies with one fetus Mother`s age between 18 to 35 The least literacy of mother and her husband be about fifth grade elementary school In response to the Pittsburgh Sleep Quality Questionnaire, she earns 5 scores and more In response to the restless leg assessment Questionnaire, she earns 3-0 scores In response to STOP Questionnaire , she earns 2-0 scores In response to question 1, the intensity of ISI Questionnaire , she earns 0-5 scores In response to stress , anxiety and depression Questionnaire less than 10, 14, and 17 scores were obtained from depression, anxiety and stress levels; Having fixed or mobile phone numbers
Exclusion criteria:
linguistic, audio or dialectal problems Having sleep disorders history before pregnancy A bad important event has been occurred from three months before the commencement of the study Having medical disease Having mental illness Having midwifery problems Having history of infertility and the current pregnancy does be a result of infertility treatment Pre-pregnancy BMI does be equal to or greater than 30 Having addiction to tobacco (hookah, cigarettes, cheeks, drugs) or alcohol and psychosocial drugs, research unit or his husband During the research she does have night shift work

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **90**
Actual sample size reached: **91**

Randomization (investigator's opinion)
Randomized

Randomization description
The name of the center has been used to randomize the lottery method. Lottery in the name of health centers has been done to locate each group in each health facility.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Contact Number 38411538-051; Fax Number 38430249-051; Deputy of Research & Technology University; Mashhad University of Medical Sciences; next to Hoveizeh Cinema; University of Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2017-06-03, 1396/03/13

Ethics committee reference number

IR.MUMS.REC.1396.68

Health conditions studied

1

Description of health condition studied

Sleep

ICD-10 code

G47.0

ICD-10 code description

Disorders of initiating and maintaining sleep [insomnia]

Primary outcomes

1

Description

Sleep quality

Timepoint

Before the intervention, immediately after intervention and 4 weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description

Severe insomnia

Timepoint

Before, immediately after and 4 weeks after intervention

Method of measurement

Insomnia Severity Index

Intervention groups

1

Description

Control group: usual care health center receives over 8 weeks

Category

N/A

2

Description

Intervention 2: In the Telehealth group, first they become familiar with the stages of the research between the 16th to 20th weeks of pregnancy (30-45 minutes), then 4 coded CDs (60-65 minutes) with the contents of the health and healthy behaviors during sleep is given to moms and they will be advised to watch a CD every week, during these 4 weeks and 4 weeks after that (8 weeks), telephone counseling is provided for 10-15 minutes based on the need of the patient (once a week), Each telephone consultation includes 2 sections, the first part of the consultation is based on the content of the weekly CD, and the second part will be dedicated to the specific needs of each client and the presentation of proposed solutions. Then, the quality of sleep will be evaluated immediately and 4 weeks after the intervention (totally 12 weeks).

Category

N/A

3

Description

Intervention 1: In the group which its education is based on continuous care model, in first meeting (45-30 minutes) pregnant women in 16 to 20 weeks of pregnancy with a family member, after completing the survey device, become familiar with the research steps (orientation) then four 90-60 minutes sessions with consultation, discussion and Q & A, with the contents of the health and healthy behaviors during sleep are held in 4 weeks and communication with his family is established by phone and booklet(sensitization). If, it is needed, to study new problems, maintaining connection with mother, answer to her questions and review the lists some meetings with phone calls (10 minutes) will be held (control) and in the evaluation phase, sleep quality will be discussed immediately and 4 weeks later (totally 12 weeks)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iesargaran health center

Full name of responsible person

Dr. Tabibzadeh

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Recruitment center

Name of recruitment center

Mousavi Ghochani health centers

Full name of responsible person

Dr. Mohammad Javad Jamal khoo

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3

Recruitment center

Name of recruitment center

Motahhari health center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology,
Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Technology, Mashhad
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Jalalmarvi

Position

Counseling in Midwifery student

Latest degree

Master

Other areas of specialty/work

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available