Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect Of Midwifery Counseling With spiritual approach In Improving The Sleep Quality Of Pregnant Women

Protocol summary

Study aim
To Determine The Effect Of Midwifery Counseling With Spiritual Approach In Improving Sleep Quality Among Pregnant Women

Design
The Present Study Is Phase 3 Of A Randomized Clinical Trial, Has A Control Group With Parallel Groups. That Will Be Performed On 40 Patients (20 Interventions And 20 Control Interventions). We Do Not Have Blinding. Eligible Women Will Be Selected By Convenience Sampling Method And Will Be Assigned To Two Intervention And Control Groups Using 4 Random Blocks.

Settings and conduct
The Research Setting Includes Health Centers Of Abhar City. For The Intervention Group, 8 Sessions Counseling With Spiritual Approach Will Be Held. The Control Group Will Be Received Routine Prenatal Care.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Gestational Age 16-20 weeks; Getting More Than 5 Point Based On The Pittsburgh Sleep Quality Index; Getting Score Less Than 22 Based On The 28-Items General Health Questionnaire Exclusion Criteria: Having A Medical And Obstetric Complication; Taking Sleeping Pills; Having A Known Mental Disease

Intervention groups
The Intervention Group Will Be Received Counseling With Spiritual Approach At 20 Week Of Gestation. Spiritual Group Counseling Will Be Held In 8 Sessions, Twice Per A Week, Each Session For 45 To 60 Minutes.To Compile The Content Of The Sessions Bualehri's Book Has Been Used, which includes: Talking About The Concept Of Sleep, Sleep Quality, Changes In Sleep Patterns During Pregnancy.The Causes And Problems Of Insomnia. One's Attitude Towards Spiritual Issues, The Role Of God And Religion In Her Life. Sleep Health Education. Relaxation, Breathing Exercises With Focusing On Mentioning Allah and repeating it 10 to 15 times In a day.To Emphasis on Faith In God, Trust, Forgiveness, And Repentance In Relaxation And Controlling Of Insomnia Stimuli.

Main outcome variables
Sleep Quality

General information

Reason for update
The sampling date is before the confirmation date

Acronym

IRCT registration information
IRCT registration number: **IRCT20150731023423N15**
Registration date: **2020-06-24, 1399/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-03, 1399/05/13**
Update count: **1**

Registration date
2020-06-24, 1399/04/04

Registrant information

Name
Azam Maleki

Name of organization / entity
Zanjan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 24 3345 4264

Email address
malekia@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-24, 1399/04/04

Expected recruitment end date
2020-09-29, 1399/07/08

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect Of Midwifery Counseling With spiritual approach In Improving The Sleep Quality Of Pregnant Women

Public title
The Effect Of Midwifery Counseling With Spiritual Approach In Improving The Sleep Quality Of Pregnant Women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational Age 20-16 weeks The Desire To Participate In The Study Getting More Than 5 Point Based On The Pittsburgh Sleep Quality Index Getting Score Less Than 22 Based On The 28-Item General Health Questionnaire Normal Pregnancy Wanted Pregnancy
Exclusion criteria:
Having A Medical And Obstetric Complication Taking Sleeping Pills Having A Known Mental Disease Participate In A Spiritual-Oriented Training Program
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Convenience Sampling Method will Be Employed to Select The Eligible Mothers.They Will Be Allocated Into The Two Groups (Intervention and Control) Based On The Four Block Design. In This Way, Six Possible Blocks Will Be Assigned To Group A (Intervention) And Group B (Control). Then, The Number Of Blocks Will Be Selected From The Random Number Table Until The Study Sample Size Will Be Reached. To Ensure The Concealment of The Sequence of Enrollment, We Will Be Used The Sequentially Numbered, Opaque Sealed Envelopes.
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
Ethics Committee Of Zanjan University of Medical Sciences
Street address
Zanjan, Azadi Blvd., Zanjan University of Medical Sciences
City
Zanjan
Province
Zanjan
Postal code
4515613191
Approval date
2019-06-25, 1398/04/04
Ethics committee reference number
IR.ZUMS.REC.1398.153

Health conditions studied

1

Description of health condition studied
Sleep Quality
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Severity Of Insomnia
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Spiritual Sxperience
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep Quality
Timepoint
Before The Intervention, 28 And 36 Weeks Of Gestation
Method of measurement
Pittsburgh Sleep Quality questionnaire

2

Description
The Severity Of Insomnia
Timepoint
Before The Intervention, 28 And 36 Weeks Of Gestation

Method of measurement
Insomnia Severity Questionnaire

3

Description
Spiritual Experience
Timepoint
Before The Intervention, 28 And 36 Weeks Of Gestation
Method of measurement
The Daily Spiritual Experience Scale

Secondary outcomes

1

Description
The severity of insomnia
Timepoint
Before the intervention, week 28 and week 36 of pregnancy
Method of measurement
ISI Sleep Disorders Index Questionnaire

2

Description
Daily spiritual experiences
Timepoint
Before the intervention, week 28 and week 36 of pregnancy
Method of measurement
The scale of daily spiritual experiences (DSES)

Intervention groups

1

Description
Intervention group:The Intervention Group Will Be Received Counseling With Spiritual Approach At 20 Week Of Gestation. Spiritual Group Counseling Will Be Held In 8 Sessions, Twice Per A Week, Each Session For 45 To 60 Minutes.To Compile The Content Of The Sessions Bouleri's Book Has Been Used, Which Includes: Talking About The Concept Of Sleep, Sleep Quality, Changes In Sleep Patterns During Pregnancy.The Causes And Problems Of Insomnia. One's Attitude Towards Spiritual Issues, The Role Of God And Religion In Her Life. Sleep Health Education. Relaxation, Breathing Exercises With Focusing On Mentioning Allah And Repeating It 10 To 15 Times In A Day.To Emphasis On Faith In God, Trust, Forgiveness, And Repentance In Relaxation And Controlling Of Insomnia Stimuli.
Category
Prevention

2

Description
Control group: They Will Receive Routine Prenatal care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Centers Of Abhar City,Zanjan, Iran
Full name of responsible person
Nahid Moradi
Street address
Zanjan - Abhar Qaleh Tappeh Abhar Health Center
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4515613191
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midwifmoradi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Alireza Shoghli
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4515613191
Phone
+98 24 3534 2075
Email
midwifmoradi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Nahid Moradi
Position
Msc Student in Midwifery Counseling
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Maleki Azam
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PhD in Maternal & Child Health
Latest degree
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Person responsible for updating data

Contact

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Zanjan University of Medical Sciences
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Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Gavazang Road, Zanjan University Of Medical Sciences, Zanjan
City
Zanjan
Province
Zanjan
Postal code
4515613191
Phone
+98 24334206519
Email
Malekia@zums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Dissatisfaction participants
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available