Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Compare the effect of two educational program of progressive muscle relaxation and guided imagery on sleep quality of primigravide women referred to health centers of Mashhad.

Protocol summary

Summary

This study will be done with aim of comparing the effects of Progressive Muscle Relaxation and Guided Imagery on sleep quality of pregnant women. Methods : This study will be clinical trial. Inclusion criteria included 18-35 years old primigravida women, singleton pregnancy with gestational age of 29-32 weeks and earn a score of 5 or higher in Pittsburgh Sleep Quality index (PSQI).100 of pregnant women reffered to health centers of Mashhad Randomly will be allocated to three groups of Progressive Muscle Relaxation and Guided Imagery and control. Then, every 10 days will be allocated to one of three groups mentioned. For two groups of intervention , relaxation training sessions will be held in 45-60 minutes . At the end of the session, a Bvklt about sleep hygiene, relaxation CD and daily record sheet will be gave to research units. Pregnant women will done the exercises twice a day for 4 weeks using a relaxation CD at home and after each time, the data will be recorded in the daily record sheet. at the end of each week, researcher will discuss with phone calls about the research units relaxation exercises and problems. 4 weeks After intervention, Pittsburgh Sleep Quality Index (PSQI) will be completed again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042917488N1**
Registration date: **2014-06-07, 1393/03/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-07, 1393/03/17

Registrant information

Name
Farnaz sadat Seyed ahmadi nejad
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1859 1511
Email address
seyedaf911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-08-21, 1393/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of two educational program of progressive muscle relaxation and guided imagery on sleep quality of primigravide women referred to health centers of Mashhad.

Public title

Compare the effect of two educational program of progressive muscle relaxation and guided imagery on sleep quality

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria:(Iranian and resident of Mashhad ؛has the phone number to call35-18 ؛ years old primi gravida women؛ Singleton pregnancy with gestational age of 32-29 weeks؛ sub diploma minimum education؛ did not occurred Stressful life events in the past six months؛ did not suffer from physical and mental illness؛has not obstetric problems؛ during pre-pregnancy, did not treat for sleep disorder؛ before pregnancy BMI did not equal to or greater than 29 ؛ not addict to drugs, alcohol, cigarettes or hookah؛ do not use Relaxation techniques during pregnancy؛ During the study, has not night shifts؛ In Pittsburgh Sleep Quality Index (PSQI) earn score of 5 or higher). Exclusion criteria during study: (obstetric complications occurred ؛ stressful events occurred؛ delivery occured during the study).

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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Mashhad University of Medical Sciences

Street address
central building of Mashhad University of Medical Sciences, Daneshgah Avenue

City
Mashhad

Postal code

Approval date
2014-04-26, 1393/02/06

Ethics committee reference number
research/922247/1/824

Health conditions studied

1

Description of health condition studied
sleep disorder

ICD-10 code
G47.0

ICD-10 code description
Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description
sleep quality

Timepoint
pre- intervention and 4 weeks after intervention

Method of measurement
pitsborg sleep quality index

Secondary outcomes

empty

Intervention groups

1

Description
In the progressive muscle relaxation group, two sessions of relaxation training will hold during 45-60 minutes. Finally, an educational bvklt about sleep hygiene and CD of progressive muscle relaxation will give to the subjects and they will be ask to do relaxation practices twice a day (morning and half an hour before bed at night) for 4 weeks. At the end of each week, researcher will call and speak about the practice and the their potential problems. 4 weeks after the start of study the Pittsburgh Sleep Quality Index will be completed again.

Category
Behavior

2

Description
In the guided imagery relaxation group, two sessions of relaxation training will hold during 45-60 minutes. Finally, an educational bvklt about sleep hygiene and CD of guided imagery relaxation will give to the subjects and they will be ask to do relaxation practices twice a day (morning and half an hour before bed at night) for 4 weeks. At the end of each week, researcher will call and speak about the practice and the their potential problems. 4 weeks after the start of study the Pittsburgh Sleep Quality Index will be completed again.

Category
Behavior

3

Description
In the control group, at the end of each week telephone contact is established in order to maintain contact. After 4 weeks, the Pittsburgh Sleep Quality Index will be completed again.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ab-o-bargh ,Lashgar Health centers and Omolbanin hospital
Full name of responsible person
Street address
City
mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Central building of Mashhad University of Medical Sciences, Daneshgah avenue
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences
Full name of responsible person
Farnaz sadat Seyed ahmadi nejad
Position
Master science student of Midwifery
Other areas of specialty/work
Street address
Ebne-sina street, Doktora cross.
City
Mashhad
Postal code
Phone
+98 51 1859 1511
Fax
Email
seyedaf911@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Nahid Golmakani
Position
Master science of Midwifery
Other areas of specialty/work
Street address
Ebne-sina street, Doktora cross.
City
Mashhad
Postal code
Phone
+98 51 1859 1511
Fax
Email
golmakanin@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farnaz sadat Seyed ahmadi nejad
Position
Master science student of Midwifery
Other areas of specialty/work
Street address
Ebne-sina street, Doktora cross
City
Mashhad
Postal code
Phone
+98 51 1859 1511
Fax
Email
seyedaf911@mums.ac.irf_seyedahmadi@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