

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 referred 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 Bvklit 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 occurred 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 bklt 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 bklt 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

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Ebne-sina street, Doktora cross.

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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

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Other areas of specialty/work

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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

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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