

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of music therapy counseling on sleep quality among primigravida women

Protocol summary

Summary

Objective: This study is to determine the effect of music therapy counselling on sleep quality among primigravida women. This study is a semi experimental with two groups (experimental and control) with pre-test and post-test. This study comprised pregnant women attending to health care centers in Hamadan. Simple randomization will be done. The sample size is 44 women in the intervention group and 44 women in control group. Inclusion criteria: First pregnancy; single fetus and gestational age 30-34 weeks; having sleep disturbance(Pittsburgh scale 5 or more) Exclusion criteria: Any problems in pregnancy during the study period. In the intervention group music therapy counseling will be trained by the researcher in two sessions. The intervention group will listen to relaxing music CD for 4 weeks, once daily each night for 45 minutes before sleep. In this study primary outcome measure is sleep quality and secondary outcome measure is music therapy counseling.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506216888N9**

Registration date: **2015-09-09, 1394/06/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-09, 1394/06/18

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research Technology, Hamedan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of music therapy counseling on sleep quality among primigravida women

Public title

The effect of music therapy counseling on sleep quality among primigravida women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The age range 18-35 years; first pregnancy and wanted pregnancy; single fetus and gestational age 30-34week; not being addicted; Not taking drugs affecting sleep quality; not having difficulty of hearing; Not taking antidepressants; ability to access to a music player at home; having sleep disturbance(Pittsburgh scale 5 or more); not having

physical and mental disorders, according to the pregnancy records exclusion criteria: Any problems in pregnancy during the study period (abruption, fetal abnormal situation, cord prolapse, bleeding, diabetes, hypertension, preterm labor and ...); major mental and emotional changes (such as death or serious disputes)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 88

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The participants will be divided into two groups by using simple randomization by using a table of random numbers.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Postal code

65178

Approval date

2015-06-29, 1394/04/08

Ethics committee reference number

IR.UMSHA.REC.1394.189

Health conditions studied**1****Description of health condition studied**

sleep

ICD-10 code

F51

ICD-10 code description

In many cases, a disturbance of sleep is one of the symptoms of another disorder, either mental or physical. Whether a sleep disorder in a given patient is an independent condition or simply one of the features of another disorder classified elsewhere, ei

Primary outcomes**1****Description**

Sleep quality

Timepoint

weeks 30-34 and 34-38 of gestational age

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes**1****Description**

music therapy

Timepoint

week 34-38 of gestational age

Method of measurement

Checklist

Intervention groups**1****Description**

listening to relaxing music at home from 30-34 weeks for 4 weeks, each night for 45 minutes each time

Category

Other

2**Description**

The control group will receive regular prenatal care

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Healthcare center Samii 9

Full name of responsible person

Susan Khaledi

Street address

Madani settlements

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Research Technology, Hamadan
University of Medical Sciences

Full name of responsible person

Dr. Bashirian Saeed

Street address

Fahmideh Street, Hamadan University of Medical
Sciences, Department of Research and Technology

City

Hamadan

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor of Research Technology, Hamadan
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**

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Full name of responsible person

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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