

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The Effect of Traditional Music on Sleep Quality in Elderlies

Protocol summary

Study aim

The Effect of Traditional Music on Sleep Quality in Elderlies

Design

This study is a randomized clinical trial (Randomized Controlled Trial). Sampling was done randomly from among elderly people with sleep disorders in Sirjan city . In this study, 70 people were selected using randomized block sampling (35 in the intervention group and 35 in the control group) from the elderly over 60 years old.

Settings and conduct

This study is a randomized clinical trial (Randomized Controlled Trial). The population is the elderly of Sirjan Hospital Clinic and subsidiary clinics who are referred to the clinic due to sleep disorders. The sampling was easy and available, but the allocation of individuals to intervention and control groups was random.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The Pittsburgh Sleep Quality Index more than 5; Exclusion criteria: mental health problems, alcohol or drug use history, previous use of drugs for sleep disorders, severe physical disease, hearing impairment, night shift workers.

Intervention groups

The study has two groups . music was played for the cases For 45 minutes before bedtime . To ensure proper intervention, all details were communicated to one of the family members. Listen to the music of the selected band every night. Every week, the researcher made phone calls twice to encourage the group to continue the music and also to accurately record the requested information. and the control group were asked to not listen to music at night

Main outcome variables

quality of sleep

General information

Reason for update

Acronym

Pittsburgh Sleep Quality Index; PSQI

IRCT registration information

IRCT registration number: **IRCT20150519022320N10**

Registration date: **2018-03-09, 1396/12/18**

Registration timing: **retrospective**

Last update: **2018-03-09, 1396/12/18**

Update count: **0**

Registration date

2018-03-09, 1396/12/18

Registrant information

Name

Tayebeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 3425 5900

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-02-17, 1395/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Traditional Music on Sleep Quality in Elderlies

Public title

The Effect of Traditional Music on Sleep Quality in Elderlies

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
lack of mental health problems
lack of alcohol or drug history
lack of previous use of drugs for sleep disorders
lack of severe physical disease
lack of hearing impairment
lack of the night shift
Get a score of more than 5 from the Pittsburgh Inventory

Exclusion criteria:

Age
From 60 years old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: 70

Randomization (investigator's opinion)
Randomized

Randomization description
After the initial state of sleep disorder was measured. By knowing the sample size, each numerical code is allocated to each hypothetical person and then randomly, half of these individuals are assigned to the intervention group and the other half to the control group and divided into two groups of intervention and control

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 Rafsanjan University of Medical Sciences

Street address

Emam Ali Bilvar

City

Rafsanjan

Province

Kerman

Postal code

7718174715

Approval date

2015-12-13, 1394/09/22

Ethics committee reference number

IR.RUMS.REC.1394.125

Health conditions studied

1

Description of health condition studied

Sleep quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep Quality

Timepoint

Measurement of sleep quality was performed before and after intervention, 7, 14 and 21 days after the onset of intervention after waking up.

Method of measurement

Pittsburgh Sleep Quality Index; PSQI

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After selecting the music of the participants in group were asked to sleep in a darkened room, quiet and has a ventilation system, appropriate temperature and enough light . The researchers suggest music pieces, music by a group of professionals was assembled from parts Iranian music which instrumental flute and dulcimer instrument was used in this piece and of the same quality and there was no sudden changes in sound and rhythm. For 45 minutes before bedtime music was played for the cases.

Category

Rehabilitation

2

Description

Control group: the control group were asked to not listen to music at night

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized clinic of Gharazi Hospital

Full name of responsible person

Zahra Rahimpour

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Shafa Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Ali Shamce Zadeh

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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

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Tayyebah mirzaei

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

mohadeseh raeesi

Position

Research expert

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Bachelor

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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

Not applicable