Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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 Rahimpoor

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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
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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. Tayyebeh mirzaei

Position
Academic staff

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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