

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Effect of Music and White Noise on the quality of sleep, pain and anxiety of the elderly after surgery

Protocol summary

Study aim

The aim of this study was to determine the effect of silent music and white noise on the quality of sleep, pain and anxiety of the elderly after general surgery in order to minimize the use of palliative medicine in this age group.

Design

The clinical trial has a control group, with a parallel group, the samples are in the form of a random block of 6 without permutation in a ratio of 1 to 1 into three groups: white noise, music without words, and control.

Settings and conduct

This clinical trial is randomized and intervention is performed on three groups (wordless music 33 people, white music 33 people, and control 33 people) in Ayatollah Rouhani Hospital, Babol, on elderly people undergoing general surgery.

Participants/Inclusion and exclusion criteria

Entry criteria include age over 60 years, not having dementia, good sleep quality with an overall score of less than 5 by the Pittsburgh Sleep Quality Scale. Exclusion criteria include age under 60 years, having dementia, poor sleep quality with an overall score of more than 5 by Pittsburgh Sleep Quality Scale.

Intervention groups

Elderly male and female patients who are hospitalized and undergoing general surgery are performed in three groups: white music, silent music and intervention control group.

Main outcome variables

"Sleep quality", "Anxiety", "Pain"

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230607058413N1**

Registration date: **2023-07-20, 1402/04/29**

Registration timing: **prospective**

Last update: **2023-07-20, 1402/04/29**

Update count: **0**

Registration date

2023-07-20, 1402/04/29

Registrant information

Name

seyed mostafa beikaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3533 0187

Email address

mostafa.beikaie@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-05, 1402/05/14

Expected recruitment end date

2024-03-14, 1402/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Music and White Noise on the quality of sleep, pain and anxiety of the elderly after surgery

Public title

The effect of music and white noise on sleep quality, pain and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years Ability to complete the questionnaire
Not having dementia with a score of more than 7 from the Abbreviated Mental Test Score (AMTS). Good sleep quality with an overall score of less than 5 by the Pittsburgh Sleep Quality Scale The surgery is not an emergency Perform the operation under general anesthesia No drug addiction Not having hearing problems and exclusion criteria including hemodynamic instability, loss of consciousness and need for mechanical ventilation

Exclusion criteria:

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is done after the visit of the patients by the surgeon, according to the available method, and the samples are allocated in the form of a random block of 6 without replacement in a ratio of 1:1 to three groups: white noise, music without words, 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
Bioethics Committee of Shahed University

Street address
The north side of Aftab city fair, next to the Persian Gulf highway

City
tehran

Province
Tehran

Postal code
3319118651

Approval date

2023-06-19, 1402/03/29

Ethics committee reference number
IR.SHAHED.REC.1402.023

Health conditions studied

1

Description of health condition studied
"Sleep quality", "Anxiety", "Pain"

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
"Sleep quality based on Richard Campbell's sleep quality questionnaire"

Timepoint
"Night before surgery", "Morning before surgery", "First night after surgery", "Morning after surgery"

Method of measurement
"Richard Campbell Sleep Quality Questionnaire"

2

Description
"Anxiety level based on the anxiety measurement questionnaire"

Timepoint
"The night before surgery"

Method of measurement
"Spielberger Questionnaire"

3

Description
"Pain level based on visual pain scale"

Timepoint
"One hour after surgery"

Method of measurement
"Visual Pain Scale"

Secondary outcomes

1

Description
"Blood pressure"

Timepoint
The night before surgery, one hour after surgery

Method of measurement
"Blood pressure device"

2

Description
"Blood oxygen saturation level"

Timepoint
One hour after surgery

Method of measurement

"Pulse oximetry"

Intervention groups

1

Description

Intervention group: 1- white music 2- silent music

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Babol Ayatollah Rouhani Hospital

Full name of responsible person

Seyyed Mustafa Bikaei

Street address

No. 3, 2 Yusuftabar Alley, 24 Imam Khomeini St

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Babolsar

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4741138589

Phone

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Email

mostafa.beikaie@shahed.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahed University

Full name of responsible person

Seyyed Mustafa Bikaei

Street address

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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

Shahed University

Proportion provided by this source

80

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**

Shahed University

Full name of responsible person

Seyyed Mostafa Bikaei

Position

Master's student in geriatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahed University

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only data can be published

When the data will become available and for how long

2024

To whom data/document is available

General

Under which criteria data/document could be used

If needed by people

From where data/document is obtainable

Send a letter to the researcher's email

What processes are involved for a request to access data/document

After the applicant sends an email to the researcher, the requested file of this research will be sent within a maximum period of two weeks.

Comments