Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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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3319118651
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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 updating data

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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