Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The effect of music therapy on anxiety level of patients undergoing LASIK eye surgery before operation

Protocol summary

Summary

In a clinical trial 62 patients that referred to Apadana Hospital and were candidate for LASIK were evaluated. Aim of this study is to determine state and trait anxiety and compare them in intervention and control group. A Spielberg questionnaire for measuring level of anxiety was used and filled out by patients in 2 times. The first time one hour before LASIK operation that represents the basic anxiety and second time after intervention, before LASIK. For intervention group in a separate room,one hour before LASIK music therapy is performed by a psychiatric assistant for 45 minutes. participants should able to communicate, and can speak Farsi and Exclusion criteria like having cognitive problem, and if they had history of major psychological disorder and cognitive problem, they were excluded. music therapy will be used by Instrumental pieces from the sounds of nature like the sound of sea waves and are inspired by the sounds of the forest. State Anxiety is evaluated feeling at this moment and that response time and Trait anxiety is evaluated public sentiment and the usual measures. For control group in a separate room without playing music, are preparing for LASIK. participants should able to communicate, and can speak Farsi and Exclusion criteria like having cognitive problem, and if they had history of major psychological disorder and cognitive problem, they were excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122831626N1**
Registration date: **2017-01-18, 1395/10/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-01-18, 1395/10/29

Registrant information

Name

Hatam Boostani

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3374 3038

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of music therapy on anxiety level of patients undergoing LASIK eye surgery before operation

Public title

The effect of music therapy on anxiety level of patients undergoing LASIK eye surgery before operation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18-40 years؛ the language Farsi؛ the ability to communicate verbally؛ with no history of previous LASIK; a consent to enter the scheme. Exclusion criteria: the risk of dementia؛ mental retardation؛ distinctive physical problems that interfere consultation; history of major psychiatric disorders؛ that the patients is not cooperative.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization was done by random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz

City
Ahvaz

Postal code

Approval date
2016-08-12, 1395/05/22

Ethics committee reference number
IR.AJUMS.REC.1395.326

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F40,F41,F4

ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
State Anxiety

Timepoint
Before intervention- After intervention

Method of measurement
Spielberg questioner

Secondary outcomes

1

Description
Trait Anxiety

Timepoint
Before intervention- After intervention

Method of measurement
Spielberge questioner

Intervention groups

1

Description
Intervention group: A Spielberg questionnaire for measuring level of anxiety was used and filled out by patients in 2 times. The first time one hour before LASIK operation that represents the basic anxiety and second time after intervention, before LASIK. For intervention group in a separate room,one hour before LASIK music therapy is performed by a psychiatric assistant for 45 minutes. music therapy will be used by Instrumental pieces from the sounds of nature like the sound of sea waves and are inspired by the sounds of the forest. State Anxiety is evaluated feeling at this moment and that response time and Trait anxiety is evaluated public sentiment and the usual measures.

Category
Behavior

2

Description
Control group: The control group in a separate room without playing music, are preparing for LASIK.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahvaz Apadana treatment centre

Full name of responsible person
Hatam Boostani
Street address
Ghods highway, South Soroosh St, Kampoloo, Ahvaz
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Hatam Boostani
Street address
Golestan Hospital, Golestan Blvd, Ahvaz
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research Ahvaz Jundishapur 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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Person responsible for updating data

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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