Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of relaxation and wordless music by Arnd Stein on anxiety and perceived stress during MRI

Protocol summary

Study aim
Determining the Effectiveness of Arandstein's Calming and Instrumental Music on Perceived Stress and Anxiety during MRIv

Design
Clinical trial with control group, parallel group, randomized, phase 2 on 50 patients. For randomization, the rand function of Excel software was used

Settings and conduct
This research is a quasi-experimental study with experimental and control groups and the statistical population includes all patients referred to the imaging department of Torbat Heydariyeh Hospital for MRI examination. Using statistical formula, 50 people will be divided into two groups (25 in experimental group and 25 in control group) (20). First, patients who referred to MRI from different areas of the body that meet the inclusion criteria will be included in the study. Sampling method of this design will be easy or available. After collecting the samples, the samples will be randomly assigned to two groups. Prior to MRI, Zhang Anxiety Scale (SAS) and Perceived Stress Scale (PSS) will be completed by both groups. If a person scores high on these two tests, they will be selected as a sample.

Participants/Inclusion and exclusion criteria
Inclusion criteria are: high perceived anxiety and stress score, lack of mental disability, complete consciousness of the patient and lack of consciousness disorder (Alzheimer's, dementia, etc.). Output criteria include reluctance to participate in research

Intervention groups
1- Experimental group: Playing calming and speechless music of Arndstein during MRI 2- Control Group: No Intervention

Main outcome variables
Arendstein's music, anxiety, perceived stress, MRI

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181022041421N3**
Registration date: **2023-05-08, 1402/02/18**
Registration timing: **prospective**

Last update: **2023-05-08, 1402/02/18**
Update count: **0**

Registration date
2023-05-08, 1402/02/18

Registrant information

Name
Abbas Ghodrati

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of relaxation and wordless music by Arnd Stein on anxiety and perceived stress during MRI

Public title
The effectiveness of music therapy on perceived anxiety and stress during MRI
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
High score of perceived anxiety and stress Lack of mental disability Complete consciousness of the patient and lack of consciousness disorder (Alzheimer, dementia,...)
Exclusion criteria:
Unwillingness to participate in research
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be randomly assigned to two groups and random allocation will be done by random permutation block method.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Torbat Heydariyeh University of Medical Sciences
Street address
Razi Street Torbat Heydariyeh
City
Torbat Heydariyeh
Province
Razavi Khorasan
Postal code
9515953196
Approval date
2023-04-25, 1402/02/05
Ethics committee reference number
IR.THUMS.REC.1402.002

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.0
ICD-10 code description
Panic disorder [episodic paroxysmal anxiety] without agoraphobia

2

Description of health condition studied
Stress
ICD-10 code
F43.0
ICD-10 code description
Acute stress reaction

Primary outcomes

1

Description
Anxiety
Timepoint
Before and immediately after the intervention (MRI)
Method of measurement
Self-Rating Anxiety Scale

2

Description
Stress
Timepoint
Before and immediately after the intervention (MRI)
Method of measurement
Cohen's Perceived Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Relaxation and wordless music by Arnd Stein
Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Nohomdey Day Hospital

Full name of responsible person
DinpanahHossein

Street address
1st Gharni Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Torbate-Heidaria University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Rezaie Manesh

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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
Torbate-Heidaria 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
Torbate-Heidaria University of Medical Sciences

Full name of responsible person
Abbas Ghodrati

Position
Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Publication of research paper
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