

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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 MRI

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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ghodratita171@yahoo.com

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		Ethics committee reference number IR.THUMS.REC.1402.002	
Public title	The effectiveness of music therapy on perceived anxiety and stress during MRI	Health conditions studied	
Purpose	Prevention	<u>1</u>	
Inclusion/Exclusion criteria		Description of health condition studied Anxiety	
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,...)	ICD-10 code	F41.0
Exclusion criteria:	Unwillingness to participate in research	ICD-10 code description	Panic disorder [episodic paroxysmal anxiety] without agoraphobia
Age	No age limit	<u>2</u>	
Gender	Both	Description of health condition studied Stress	
Phase	N/A	ICD-10 code	F43.0
Groups that have been masked	No information	ICD-10 code description	Acute stress reaction
Sample size	Target sample size: 50	Primary outcomes	
Randomization (investigator's opinion)	Randomized	<u>1</u>	
Randomization description	Samples will be randomly assigned to two groups and random allocation will be done by random permutation block method.	Description	Anxiety
Blinding (investigator's opinion)	Not blinded	Timepoint	Before and immediately after the intervention (MRI)
Blinding description		Method of measurement	Self-Rating Anxiety Scale
Placebo	Not used	<u>2</u>	
Assignment	Other	Description	Stress
Other design features		Timepoint	Before and immediately after the intervention (MRI)
Secondary Ids	empty	Method of measurement	Cohen's Perceived Stress Questionnaire
Ethics committees		Secondary outcomes empty	
<u>1</u>		Intervention groups	
Ethics committee		<u>1</u>	
Name of ethics committee	Torbat Heydariyeh University of Medical Sciences	Description	Intervention group: Relaxation and wordless music by Arnd Stein
Street address	Razi Street Torbat Heydariyeh	Category	Behavior
City	Torbat Heydariyeh	Recruitment centers	
Province	Razavi Khorasan		
Postal code	9515953196		
Approval date	2023-04-25, 1402/02/05		

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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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