# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the effect of thought distraction by music therapy and the presence of patient accompaniment on anxiety level of patients undergoing endoscopy

## Protocol summary

**Study aim**
Music Therapy and the presence of patient accompaniment on level of anxiety

**Design**
A double-blind clinical trial consist of 105 samples with the range of age 15 to 55 years old, including control group and two groups, random allocation.

**Settings and conduct**
The endoscopy study site is Shahid Mohammadi and Khalige Fars hospitals in Bandar Abbas. The patients will be randomly assigned according to the random number table to three group. Each patient will receive one special code, so the patients will be blinded for the intervention they will receive. On the other hand the statistical specialist who will analyze the data, won't be aware about patients allocation and intervention (double blind).

**Participants/Inclusion and exclusion criteria**
inclusion criteria:Age of 55-15 years; Ability to understand Persian language;consciousness;Hearing Health;No history of endoscopy Non-inclusion criteria: Recognized and treated psychological problems; Pre-endoscopic drug use; Pre-endoscopic sedative and anxiolytic drugs; Emergency endoscopy

**Intervention groups**
intervention group 1 (music therapy): these patients will receive the nature sound, through a headphone during endoscopy intervention group 2 (Endoscopy with accompanying presence): escort the patient during the endoscopy Control group: these patients only receive the routine care for the operation

**Main outcome variables**
anxiety ;music therapy;presence of patient accompaniment

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190715044215N1**
Registration date: **2020-01-06, 1398/10/16**
Registration timing: **retrospective**

Last update: **2020-01-06, 1398/10/16**
Update count: **0**

**Registration date**
2020-01-06, 1398/10/16

**Registrant information**

**Name**
Afsaneh Alaei Sheikh Robat

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 76 3333 0755

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-07-16, 1398/04/25

**Expected recruitment end date**
2019-08-16, 1398/05/25

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of the effect of thought distraction by music therapy and the presence of patient accompaniment on anxiety level of patients undergoing endoscopy

**Public title**
Effect of music therapy and the presence of patient accompaniment on anxiety level during endoscopy

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
15-55 years of age Ability to speak and understand Persian language Full conscious and healthy hearing and visual ability No history of gastrointestinal endoscopy

**Exclusion criteria:**
History of known and under treatment psychological problems taking drug before endoscopy Taking sedation and anxiolytics drugs before endoscopy Emergency endoscopy

**Age**
From **15 years** old to **55 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**
Target sample size: **105**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
We randomly chose participants using random numbers table through random allocation software

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Individuals according to the table will be included in the study and each group and members of each group will be assigned a specific code and assigned according to the table into three groups, because this is done so that we can blind patients and patients from The type of interventions is not known to other patients (a single blind), and the other is a statistician blind who will analyze the data without knowing the groups studied (the other side blindness).

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Hormozgan University of Medical Sciences

**Street address**
No 2, Sarmad Building, N0.11 Resalat alley ,Daroopakhsh street

**City**
Bandar Abbas

**Province**
Hormozgan

**Postal code**
7915866764

**Approval date**
2019-03-09, 1397/12/18

**Ethics committee reference number**
IR.HUMS.REC.1397.322

## Health conditions studied

**1**

**Description of health condition studied**
Anxiety

**ICD-10 code**
F06.4

**ICD-10 code description**
Anxiety disorder due to known physiological condition

## Primary outcomes

**1**

**Description**
anxiety

**Timepoint**
Before and after intervention

**Method of measurement**
Spill Burger Questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1 (Music therapy group) ; these patients receive natural sounds (river, rain, tree leaves, birds) through a headphone during the endoscopy

**Category**
Prevention

**2**

**Description**
Intervention group 2: (Accompanying group); accompanying the patient (a relative or friend) or any

patient who wishes to accompany the patient during the endoscopic procedure.

**Category**

Prevention

**3**

**Description**

Control group: (No intervention); these patients receive only routine care before endoscopy.

**Category**

Diagnosis

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Khalij Fars hospital

**Full name of responsible person**

Afsaneh Alaei Sheikh Robat

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**2**

**Recruitment center**

**Name of recruitment center**

Shahid Mohammadi Hospital

**Full name of responsible person**

Afsane Alaei Sheikh Robat

**Street address**

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Teimoor Agha Molaei

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**Web page 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**

Bandare-abbas 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**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Afsaneh Alaei Sheikh Robat

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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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**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
The main outcome
**When the data will become available and for how long**
10 months after publishing the article.
**To whom data/document is available**
Academic Institutions
**Under which criteria data/document could be used**
By mentioning the source and for doing research
**From where data/document is obtainable**
Afsaneh Alaei Shiekh Robat
**What processes are involved for a request to access data/document**
A valid written request from the college
**Comments**