

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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 Robot

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 0755

Email address

afsaneh_alaei@yahoo.com

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, NO.11 Resalat alley
,Daroopaksh 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 Robot

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2**Recruitment center****Name of recruitment center**

Shahid Mohammadi Hospital

Full name of responsible person

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Shahid Mohammadi Hospital, Jomhori Eslami Blvd,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

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No. 6 , Banafshe Ave., Islamic Republic Blvd., Bandar
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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 Robot

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Ph.D.

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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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 Robot

What processes are involved for a request to access data/document

A valid written request from the college

Comments