Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of music therapy and hand-holding on perceived stress and pain of patients undergoing endoscopy referring to Rafsanjan Gastroenterology Clinic

Protocol summary

Study aim
Comparison of the effect of music therapy with hand holding on stress and pain levels of patients undergoing endoscopy

Design
Clinical trial with parallel groups, single-blind, randomized, on 64 patients. A lottery method was used for randomization.

Settings and conduct
This study will be conducted in the endoscopy department of Ali Ibn Abitaleb Hospital of Rafsanjan in 2022. After providing the necessary explanations and obtaining informed consent, the subjects entered the study and completed the perceived stress questionnaire, the visual pain scale and the study checklist. Then, based on the random allocation table obtained by using random allocation software, they are assigned to one of three groups. The first group will listen to nature music through headphones during the endoscopy. The second group will have their hand in the hand of their companion during the endoscopy process. The third group will not receive any intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: informed consent to participate in the study; age: 15-55 years old; ability to speak and understand Farsi; full alertness; healthy hearing and vision; no history of gastrointestinal endoscopy; no history of high blood pressure under medical treatment. Exclusion criteria: unwillingness to continue cooperation in the study.

Intervention groups
Intervention group 1: This group will undergo music therapy. Intervention group 2: This group will be subjected to hand holding.

Main outcome variables
Change in the amount of stress; pain level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150317021497N8**
Registration date: **2022-10-09, 1401/07/17**
Registration timing: **prospective**

Last update: **2022-10-09, 1401/07/17**
Update count: **0**

Registration date
2022-10-09, 1401/07/17

Registrant information

Name
Mohammadreza Mokhtaree

Name of organization / entity
Rafsanjan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 34260081

Email address
mrmokhtaree@rums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of music therapy and hand-holding on perceived stress and pain of patients undergoing endoscopy referring to Rafsanjan Gastroenterology Clinic

Public title
Comparison of the effectiveness of music therapy and hand-holding on stress and pain of patients undergoing endoscopy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Ability to speak and understand Farsi language Full consciousness Hearing and vision health

Exclusion criteria:
History of gastrointestinal endoscopy History of high blood pressure under medical treatment Unwillingness to continue cooperation in the study

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Using computer software (Random Allocation), patients are placed in three groups of music therapy, hand-holding, or control through four blocks with an allocation ratio of 1:1:1. During the endoscopy procedure, the music therapy group will listen to nature music through headphones. The hand-holding group will have their hand in their companion's hand during the endoscopy process, and the control group will not receive any of these two interventions. The random allocation sequence will be generated by a person not involved in the research. Both groups will receive routine treatments.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Rafsanjan University of Medical Sciences

Street address
University of medical sciences, Imam Ali Blvd., Rafsanjan Town

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2020-12-12, 1399/09/22

Ethics committee reference number
IR.RUMS.REC.1399.212

Health conditions studied

1

Description of health condition studied
Peptic Ulcer

ICD-10 code
K27

ICD-10 code description
Peptic ulcer, site unspecified

2

Description of health condition studied
Dyspepsia

ICD-10 code
K30

ICD-10 code description
Functional dyspepsia

3

Description of health condition studied
Duodenal ulcer

ICD-10 code
K26

ICD-10 code description
Duodenal ulcer

4

Description of health condition studied
Gastrointestinal hemorrhage

ICD-10 code
K92.2

ICD-10 code description
Gastrointestinal hemorrhage, unspecified

Primary outcomes

1

Description

Stress score in perceived stress questionnaire

Timepoint

Stress measurement before the intervention and 2 hours after the completion of the intervention process

Method of measurement

Cohen's Perceived Stress Questionnaire

2

Description

Pain score on visual pain scale

Timepoint

Pain assessment before the intervention and 2 hours after the completion of the intervention process

Method of measurement

Visual pain scale

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: listening to a nature background music through headphones during endoscopy process

Category

Rehabilitation

2

Description

The second intervention group: partner's hand holding during the endoscopy process

Category

Rehabilitation

3

Description

Control group: without any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi-Talib Hospital

Full name of responsible person

Vahid Mirzaee

Street address

Ali Ibn Abi-Talib Hospital, Imam Ali Blvd, Rafsanjan Town

City

Rafsanjan

Province

Kerman

Postal code

7717937555

Phone

+98 34 3428 0000

Email

name@domian.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Reza Vazirinejad

Street address

Building No. 3, Research and Technology chancellor, Rafsanjan University of Medical Science, Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

vcrt@rums.ac.ir

Web page address

https://vcrt.rums.ac.ir/home

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Vahid Mirzaee

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work
Adult gastroenterology and hepatology
Street address
Ali Ibn Abi-talib hospital, Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717937555
Phone
+98 34 3428 0000
Email
vah_mirzaee@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Vahid Mirzaee
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Adult gastroenterology and hepatology
Street address
Ali Ibn Abi-Talib Hospital, Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717937555
Phone
+98 34 3428 0000
Email
vah_mirzaee@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Mohammadreza Mokhtaree
Position
Consultant
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Moradi hospital, Shohada ST
City
Rafsanjan
Province
Kerman
Postal code
7713961151
Phone
+98 34 3426 0080
Fax
Email
mrmokhtaree@rums.ac.ir
Web page address

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
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Commitment to the principle of fiduciary
From where data/document is obtainable
Sending an official letter to the Research Vice-Chancellor of Rafsanjan University of Medical Sciences
What processes are involved for a request to access data/document
After the approval of the research vice-chancellor of Rafsanjan University of Medical Sciences, the data will be provided to the applicant.
Comments