

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of effect of music on dyspnea, anxiety and depression during exercise in individuals with chronic obstructive pulmonary disease

#### Protocol summary

##### Study aim

Investigate the effect of music on dyspnea, anxiety and depression in patients with chronic obstructive pulmonary disease

##### Design

The clinical trial has a one-way blinded and control group

##### Settings and conduct

Music will be played for Intervention group during exercise test in Pasteur Hospital. Researchers and outcome assessors are unaware of intervention and control group.

##### Participants/Inclusion and exclusion criteria

1. Confirmation of diagnosis of moderate to severe COPD by a pulmonary specialist according to criteria Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria. 2 -70-45 years -3 BMI less than 30; 4-non existence of Nervous System Diseases, Cancer and Myocardial Infarction; No Psychiatric Disorder; 5- Having literacy in reading and writing, 6- Having a fixed medication regimen (Salmeterol spray 2 puffs every 12 hours, Atrovent spray 2 puffs every 6 hours. Exclusion criteria 1- non-cooperative Patient 2- positioned in Acute phase of disease

##### Intervention groups

Intervention and control groups should walk for 6 minutes which is followed by pre-test and then each group walk for 10 minutes and no music will be played in the control group. The post-test questionnaires are filled. Music is played for the intervention group plays music and the stage after the test is completed by filling out the questionnaires.

##### Main outcome variables

Music Effectiveness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111019007844N14**

Registration date: **2020-04-06, 1399/01/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

##### Registration date

2020-04-06, 1399/01/18

##### Registrant information

###### Name

Mansour Arab

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 1320 5179

###### Email address

marab@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-19, 1398/11/30

##### Expected recruitment end date

2021-02-18, 1399/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of effect of music on dyspnea, anxiety and depression during exercise in individuals with chronic obstructive pulmonary disease

**Public title**

The effect of music on dyspnea, anxiety and depression

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

Chronic obstructive pulmonary disease of moderate to severe

**Exclusion criteria:**

Patient not positioned in a specified age range

**Age**

From **45 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Outcome assessor

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This study is a randomized controlled clinical trial. The samples are selected using available sampling method and according to entry conditions. They are assigned to two groups of music and control using random allocation method.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The researcher and outcome assessors are kept blind in this study and Patients are aware that they being studied due to ethical issues

**Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Bam University of Medical sciences

**Street address**

newarge

**City**

Bam

**Province**

Kerman

**Postal code**

7618147867

**Approval date**

2019-03-16, 1397/12/25

**Ethics committee reference number**

IR.MUBAM.REC.1398.066

**Health conditions studied****1****Description of health condition studied**

Dyspnea

**ICD-10 code**

R06.0

**ICD-10 code description**

Dyspnea

**2****Description of health condition studied**

Anxiety

**ICD-10 code**

F06.4

**ICD-10 code description**

Anxiety disorder due to known physiological condition

**3****Description of health condition studied**

Depression

**ICD-10 code**

F06.31

**ICD-10 code description**

Mood disorder due to known physiological condition with depressive features

**Primary outcomes****1****Description**

Depression score based on questionnaire PHQ8

**Timepoint**

Before of the intervention and after of the intervention

**Method of measurement**

PHQ8 questionnaire

**2****Description**

Anxiety score based on Spielberger anxiety questionnaire

**Timepoint**

Before of the intervention and after of the intervention

**Method of measurement**

Spielberger anxiety questionnaire

**3****Description**

Borg's dyspnea scale

**Timepoint**

Before of the intervention and after of the intervention  
**Method of measurement**  
Borg's dyspnea scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group should walk for 6 minutes which is followed by pre-test and walk for 10 minutes . music played for the intervention during exercise and the stage after the test is completed by filling out the questionnaires

#### Category

Rehabilitation

### 2

#### Description

Control group:control groupshould walk for 6 minutes and then followed by pre-test and then walk for 10 minutes and no music will be played in the control group. The post-test questionnaires are filled.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bam Pastour Hospital

##### Full name of responsible person

Dr. Ali Radfer

##### Street address

Pastor Hospital., Persian Gulf Blvd., Bam-Baravtat Road., Bam

##### City

Bam

##### Province

Kerman

##### Postal code

76197745

##### Phone

+98 34 4431 9403

##### Fax

+98 34 4431 9403

##### Email

A.radfar@mubam.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Bam University of Medical Sciences  
**Full name of responsible person**  
Dr Fariba Borhani  
**Street address**  
Bam University of Medical Science., Shahid Rajaiee Blvd., Sardaran Shahid Square., Bam City  
**City**  
Bam  
**Province**  
Kerman  
**Postal code**  
7667548912  
**Phone**  
+98 34 4431 9403  
**Email**  
A.radfar@mubam.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Bam 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

Bam University of Medical Sciences

##### Full name of responsible person

Ali Radfar

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Infectious diseases

##### Street address

Pastor Hospital., Persian Gulf Blvd., Bam-Baravat Road., Bam

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7665981242

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bam University of Medical Sciences

**Full name of responsible person**

Dr Ali Radfar

**Position**

Associate professor

**Latest degree**

Specialist

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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**

publishing article

**When the data will become available and for how long**

The year 1400

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Contact to the researcher

**From where data/document is obtainable**

E-mail to Dr. Ali Radfar@gmail.com

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

We will respond by e-mail one week after the request

**Comments**