

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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- positined 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 are 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

newarg

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

City

Bam

Province

Kerman

Postal code

7665981242

Phone

+98 34 4431 9402

Email

A.radfar@mubam.ac.ir

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

Other areas of specialty/work

Infectious diseases

Street address

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

City

Bam

Province

Kerman

Postal code

7665984512

Phone

+98 34 4431 9402

Email

A.radfar@mubam.ac.ir

Person responsible for updating data

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

City

Bam

Province

Kerman

Postal code

7698451265

Phone

+98 34 4431 9402

Email

A.radfar@mubam.ac.ir

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