Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 existance 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 awake 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 sciencel 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

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

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Other areas of specialty/work
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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