

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of Buteyko Breathing Retraining on Respiratory Indices, activity and anxiety level, in Patients with Anxiety Disorder - A Randomized controlled Trial

Protocol summary

Study aim

1) Determine the effect of improving the breathing pattern based on the buteyko method on respiratory volume and biochemical indices and respiration rates of patients with anxiety disorder.

Design

samples selected from 23 to 64 of Nijmegen Q, and then will be matched to gender and body mass. Individuals will be matched according to normal BMI ($25 <$), overweight (25 to 29.99) and obese ($30 \leq$), and then the same couples will be randomly divided into two groups of test and control.

Settings and conduct

Skeleton Muscular Research Center, Ahvaz Rehabilitation Faculty, spring and summer 2019

Participants/Inclusion and exclusion criteria

1- Adults of all genders aged 18 to 45 years 2. Not having any illness or musculoskeletal-musculoskeletal system interfering with breathing. 3. Not having addiction to any drugs or cigarettes and alcohol. 4. Having a high level of diploma. 5- Not taking part in physical or sporting activities in a professional manner . 6-They have not performed any breathing exercises, 7. Individuals with hyperventilation respiratory pattern,

Intervention groups

1- Patients with anxiety disorder are drug treatment and routine counseling which is called training of exercises based on biteic breathing techniques and respiratory pattern correction as an intervention group. 2- Patients with anxiety disorder are considered to be drug treatment and routine counseling.

Main outcome variables

Determine drug dependence and other psychiatric interventions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181017041374N1**

Registration date: **2020-01-27, 1398/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-27, 1398/11/07**

Update count: **0**

Registration date

2020-01-27, 1398/11/07

Registrant information

Name

Alireza maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3372 1401

Email address

maleki.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-21, 1398/03/31

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Buteyko Breathing Retraining on Respiratory Indices, activity and anxiety level, in Patients with Anxiety Disorder - A Randomized controlled Trial

Public title

Effect of Buteyko Breathing Retraining on Respiratory Indices, activity and anxiety level, in Patients with Anxiety Disorder - A Randomized controlled Trial

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with anxiety disorder diagnosed by a physician Not having any illness or musculoskeletal-musculoskeletal system interfering with breathing and based on the examination and evaluation that the investigator will examine. Not having addiction to any drugs or cigarettes and alcohol Have a high school diploma degree The company does not have to do any physical or sporting activities professionally and earn points from the Beck Action Level Questionnaire. No breathing exercises have been performed, such as Buteyko exercises or other exercises Individuals with respiratory pattern of hyperventilation, who were evaluated by a semiann questionnaire score 23 to 64 to enter the study.

Exclusion criteria:

In case of unwillingness and tolerance of treatment intervention Pulse of heart over normal range based on age The presence of any problems with the upper airways, including polyps, and the deviation of the nasal blades that lead to breathing through the mouth and preventing breathing. This criterion is made through the rapid and common tests in the auditory services of the ENT and by the research team. Any dizziness and headache or nausea during or after exercise Excessive concern during the implementation of the project in such a way that the process of conducting research is compromised Cardiovascular disease based on self-expression Mentally retarded patients Pregnant

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

First, patients who are referred to the Rehabilitation Clinic will be selected by individuals who have been homogenized in the genus and body mass; individuals are classified according to normal BMI (25), overweight (25 to 29.99), and obese ($30 \leq$) And then the same couples will be split into an accident between the two

groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and researcher in the study will be blind in intervention groups, and the individuals in each treatment group will not be aware of the other group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapour University of Medical science Golestan bouvar, Ahvaz city, khozestan province

City

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Province

Khuzestan

Postal code

0051742675

Approval date

2019-04-09, 1398/01/20

Ethics committee reference number

IR.AJUMS.REC.1398.221

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

Patients with General Anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

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

GAD-7 and Beck Anxiety Qüestionnaire Scores

Timepoint

At the beginning of the intervention, during the study, approximately 4 weeks later, and at the end of the study, 8 weeks later.

Method of measurement

Beck and GAD-7 Anxiety Inventory and Nigmegen

Secondary outcomes

1

Description

Forced Expiratory Volume in First second

Timepoint

Baseline and one month and two months later

Method of measurement

spirometry

2

Description

Forced Vital Capacity

Timepoint

Baseline and one month and two months later

Method of measurement

spirometry

3

Description

Ratio between Forced Expiratory Volume in First second/Forced Vital Capacity

Timepoint

Baseline and one month and two months later

Method of measurement

spirometry

4

Description

End tidal volume Expiratory carbon dioxide pressure

Timepoint

Baseline and one month and two months later

Method of measurement

Capnometry

5

Description

Heart Rate

Timepoint

Baseline and one month and two months later

Method of measurement

Capnometry

6

Description

Respiratory Rate

Timepoint

Baseline and one month and two months later

Method of measurement

Capnometry

7

Description

Respiratory function questionnaire score - Nijmegen

Timepoint

Baseline and one month and two months later

Method of measurement

Nijmegen questionnaire

8

Description

Beck Anxiety Inventory

Timepoint

Baseline and one month and two months later

Method of measurement

Beck Anxiety Inventory

9

Description

General Anxiety Disorder Questionnaire score

Timepoint

Baseline and one month and two months later

Method of measurement

General Anxiety Disorder Questionnaire GAD-7

Intervention groups

1

Description

Intervention group: Individuals with anxiety disorder are treated under the medication and routine counseling, which is referred to as intervention group by training exercises based on biteic breathing techniques and respiratory pattern correction. Medication is prescribed by a physician.

Category

Rehabilitation

2

Description

Control group: Anxious patients are treated under the medication and routine counseling, which are considered as a control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Skeleton Muscular Research Center of Ahvaz
Rehabilitation Faculty

Full name of responsible person

Majid Ravanbakhsh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ms Najarzadeh
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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

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Alireza Maleki
Position
Candidate Phd Physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available