Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ≤), 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 ≤) 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 boulvar, Ahvaz city, khozestan province

City
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Province
Khouzestan

Postal code
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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 Q̋uestionnaire 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

Respiratory Function Questionnaire

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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Ahvaz Jundishapour University of Medical Science, Golestan, Ahvaz city, khozestan province
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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
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Master
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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