

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effectiveness of Acceptance and Commitment Group Therapy on control of symptoms, quality of life and mood state in Asthma patients in Isfahan

Protocol summary

Study aim

Determination of the effectiveness of acceptance and commitment therapy on the symptom control, quality of life and mood status of asthmatic patients in Isfahan

Design

Two arms parallel-group randomized trial without blinding on 30 patients. The randomization will be done using Random Allocation software

Settings and conduct

The evaluation of acceptance and commitment therapy on the asthma symptoms, quality of life, and mood disorders will be assessed in asthmatic patients referring to Noor Center. The patients will fill the questionnaires at baseline, at the end of the intervention and within three months. Blinding will not be done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Over 18 years old -Documented diagnosis of asthma based on response to bronchodilator -Medical therapy for the least period of three months -Adherence to medical therapy
Unmet criteria: -The diagnosis of psychiatric disorders irrelevant to the underlying asthma -Reluctance to participate in the study

Intervention groups

The intervention group: The asthmatic patients of this group will be trained about the acceptance and commitment therapy for 8 sessions, each endures for 90 minutes and also should administer their asthma-related medical therapies as well. Control group: اهس لقخج خب، حشهدفقس شقت خدمغ فقتشفتی ئیهرشمغ

Main outcome variables

Asthma symptoms Quality of life Mood status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200512047411N1**

Registration date: **2020-06-16, 1399/03/27**

Registration timing: **retrospective**

Last update: **2020-06-16, 1399/03/27**

Update count: **0**

Registration date

2020-06-16, 1399/03/27

Registrant information

Name

Mahin Rabiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3444 7707

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2020-01-10, 1398/10/20

Actual recruitment start date

2019-10-12, 1398/07/20

Actual recruitment end date

2020-01-20, 1398/10/30

Trial completion date

2020-04-05, 1399/01/17

Scientific title

Effectiveness of Acceptance and Commitment Group Therapy on control of symptoms, quality of life and mood state in Asthma patients in Isfahan

Public title

Effectiveness of Acceptance and Commitment Group

Therapy on asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years old Documented diagnosis of asthma based on response to bronchodilator Medical therapy for the least period of three months Adherence to the medical therapy

Exclusion criteria:

The diagnosis of psychiatric disorders irrelevant to the underlying asthma Reluctance to participate in the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization will be performed through convenience sampling. Therefore, each of the patients will be provided with a particular number using random number table. If the number is even, the patient will be allocated to the intervention group and if odd to the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.MUI.MED.REC.1398.356

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Asthma symptoms

Timepoint

At baseline, at the end of the intervention and within three months

Method of measurement

Asthma control questionnaire

2

Description

Quality of life

Timepoint

At baseline, at the end of the intervention and within three months

Method of measurement

Asthma Quality of life questionnaire

3

Description

mood status

Timepoint

At baseline, at the end of the intervention and within three months

Method of measurement

Hospital anxiety and depression scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Asthma medical therapy plus Acceptance and Commitment Therapy in which the patients will be trained Acceptance and Commitment Psychotherapy for eight sessions each consisted of 90 minutes plus asthma medication based on the Global Initiative for Asthma protocol in which the patients will

be treated in 4 categories. The ACT consists of sessions, including 1) Primary introduction and introduction of mental abilities (thoughts, feelings, bodily senses, memories, and impulses); 2) the introduction of the control is the problem and the way of reaction to the problems; 3) teaching the difference between pain and suffering and increasing the psychological acceptance and willingness to thoughts and feelings; 4) Clarification of the values and goals and provision of a table in which the values are categorized; 5) teaching the concept of fusion to the mental products and exercises for defusion of the thoughts; 6) teaching the concept of self-conceptualization and how to face this concept; 7) the introduction of commitment and the values of performing purposeful activities; 8) conclusion of the previous 7 sessions and teaching the concept of psychological flexibility.

Category

Treatment - Other

2**Description**

Control group: Asthma medical therapy will be medically treated based on the Global Initiative for Asthma protocolin which the patients will be treated in 4 categories..

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Mahin Rabiei

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All of the data are accessible if the Professor permits

When the data will become available and for how long

Following the publication of the article

To whom data/document is available

The university students who have proposals related to the published article

Under which criteria data/document could be used

Only for the publication of an article and by the permission of the professor

From where data/document is obtainable

It should be taken through an email from the Professor

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

It should be taken through an email from the Professor

Comments