

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

A Randomized clinical trial to evaluate the effectiveness of Acceptance and Commitment Therapy on Body image, Body Awareness, mindfulness, psychiatric symptoms and psychosomatic symptoms among patients suffering from Psychosomatic disorders

Protocol summary

Summary

1) Objectives: This study aims to investigate the effectiveness of acceptance and commitment therapy on Body image, Body Awareness, mindfulness, psychiatric and psychosomatic symptoms of Kashan Psychosomatic patients. (2) Design: This is a pretest-posttest experimental study. The intervention also includes an eight-week follow-up course. (3) Methods: A sample of eligible male smokers will be recruited. They will be randomly allocated to either the experimental or the control groups (75 patients in each group). Patients in the experimental group will receive acceptance and commitment therapy while the first control group will receive medical Treatment As Usual (TAU) in clinics and other control group receives psycho-education. Study instruments include Brief Symptom Inventory (BSI) in psychiatric outpatients, Body Image - Acceptance & Action Questionnaire (BI-AAQ), body awareness questionnaire shields, Freiburg mindfulness scale and Diagnostic Criteria for Psychosomatic Research (DCPR). These instruments will be completed before, one week after and eight weeks after the intervention. (4) Inclusion criteria: being at the age of 18-50 years; Having high school certificate (Diploma) or higher education degree; Having one of the psychosomatic Disorders based on DSM 5 diagnostic criteria; not having a history of psychotic disorders; not having history of psychotherapy during past six months; not having a history of substance abuse disorders. (5) Exclusion criteria: Unwillingness to continue participating in the study; Failing to participate in more than two sessions of the study intervention. (6) Intervention: The intervention in this study is acceptance and commitment therapy which includes eight 90-minute sessions. (7) Primary outcomes: are Body image, Body Awareness, mindfulness, psychiatric and psychosomatic symptoms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092532057N2**

Registration date: **2017-10-31, 1396/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-31, 1396/08/09

Registrant information

Name

Mohamad Reza Davoudi

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 2999

Email address

davoudi-mr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Kashan University of Medical Sciences and Health Services

Expected recruitment start date

2017-09-01, 1396/06/10

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized clinical trial to evaluate the effectiveness of Acceptance and Commitment Therapy on Body image, Body Awareness, mindfulness, psychiatric symptoms and psychosomatic symptoms among patients suffering from Psychosomatic disorders

Public title

Effectiveness Of Acceptance and Commitment Therapy on psychosomatic disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being at the age of 18-50 years; Having high school certificate (Diploma) or higher education degree; Having one of the psychosomatic Disorders based on DSM 5 diagnostic criteria; not having a history of psychotic disorders; not having history of psychotherapy during past six months; not having a history of substance abuse disorders. Exclusion criteria: Unwillingness to continue participating in the study; Failing to participate in more than two sessions of the study intervention.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The study population include all somatic patients admitted to Shahid Beheshti Hospital. Of all participants who meet inclusion criteria, 25 participants in each group will be selected by Random allocation using random computer-generated numbers. Pre-test will be done by the person responsible for study. Intervention duration is ten weeks. Post-test data will be collected one week after intervention and eight weeks later through follow-up.

Secondary Ids

empty

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

Ethics committee of kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th kilometer of Qotbe Ravandi Blvd

City

Kashan

Postal code**Approval date**

2017-08-23, 1396/06/01

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.6

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

Psychosomatic disorders

ICD-10 code

F45

ICD-10 code description

Somatoform disorders

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

Body image

Timepoint

Before intervention, One week after intervention, eight weeks after intervention

Method of measurement

Body Image - Acceptance & Action Questionnaire

2**Description**

Body Awareness

Timepoint

Before intervention, One week after intervention, eight weeks after intervention

Method of measurement

body awareness questionnaire shields

3**Description**

Mindfulness

Timepoint

Before intervention, One week after intervention, eight weeks after intervention

Method of measurement

freiburg mindfulness scale

4

Description

Psychosomatic symptoms

Timepoint

Before intervention, One week after intervention, eight weeks after intervention

Method of measurement

Diagnostic Criteria for Psychosomatic Research

5

Description

Psychiatric symptoms

Timepoint

Before intervention, One week after intervention, eight weeks after intervention

Method of measurement

include Brief Symptom Inventory (BSI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This study is conducted to determine the effectiveness of Acceptance and Commitment Therapy (ACT) on Body image, Body Awareness, mindfulness, psychiatric and psychosomatic symptoms of Kashan Psychosomatic patients. The aim of this approach is inviting people to open up unpleasant feelings and learn not to overreact them, and not avoiding situations where they are invoked. Its therapeutic effect is a positive spiral where feeling better leads to a better understanding of the truth and also experiencing flexible life. This treatment will be delivered through ten 90-minute sessions for ten weeks

Category

Behavior

2

Description

Control Group: Based on physician prescription this group will receive usual medical treatment.

Category

Treatment - Drugs

3

Description

Control Group: This group will receive behavioral interventions based on the psychoeducation during ten 90-minute per sessions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Complex Of Shahid Beheshti Hospitals

Full name of responsible person

MD.Fateme Sadat Ghoreyshi

Street address

Complex Of Shahid Beheshti Hospitals; Pezeshk Blvd; 5th kilometer of Qotb -e Ravandi Blvd

City

kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Full name of responsible person

Dr Qolam Ali Hamidi

Street address

Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th kilometer of Qotbe Ravandi Blvd

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Abdollah Omidi

Position

Assistant professor of clinical psychology

Other areas of specialty/work

Street address

Department of Clinical Psychology, School of
Medicine, Kashan University of Medical Sciences and
Health Services, Pezeshk Blvd, 5th kilometer of Qotbe
Ravandi Blvd

City

Kashan

Postal code**Phone**

+98 31 5554 9111

Fax**Email**

abomidi20@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences and Health
Services

Full name of responsible person

Abdollah Omid

Position

Assistant professor of clinical psychology

Other areas of specialty/work**Street address**

Department of Clinical Psychology, School of
Medicine, Kashan University of Medical Sciences and
Health Services, Pezeshk Blvd, 5th kilometer of Qotbe
Ravandi Blvd

City

Kashan

Postal code**Phone**

+98 31 5554 9111

Fax**Email**

abomidi20@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences and Health
Services

Full name of responsible person

Mohammadreza Davoudi

Position

M.Sc candidate in clinical psychology

Other areas of specialty/work**Street address**

Department of Clinical Psychology, School of
Medicine, Kashan University of Medical Sciences and
Health Services, Pezeshk Blvd, 5th kilometer of Qotbe
Ravandi Blvd

City

Kashan

Postal code**Phone**

00

Fax**Email**

davoudi-mr@kaums.ac.ir

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty