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

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Name of organization / entity

Kashan University of Medical Sciences and Health Services

Country

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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 sympoms
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

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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