Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Controlled trial of effectiveness of Acceptance and Commitment Therapy on depression, anxiety, risky decision making, craving and cessation in male smokers.

Protocol summary

Summary

(1) Objectives: This study aims at investigating the effectiveness of acceptance and commitment therapy on smoker's depression, anxiety, risky decision making, craving and cessation at Kashan. (2) Design: This is a pretest-posttest experimental study. The intervention also includes a six-weeks follow-up course.(3) Methods: A sample of 70 eligible male smokers will be recruited. That will be randomly allocated to either the experimental or the control groups. smokers in the experimental group will receive acceptance and commitment therapy while the smokers in the control group will receive Treatment As Usual(TAU) in smoking cessation clinics. Study instruments include the Beck Depression inventory, the Beck Anxiety Inventory, and Iowa gambling test, fagestrom and exhaled CO2 detector. These instruments will be completed before, immediately after, and one month after the intervention. (4) Inclusion Criterias: 1. Having an age of 18–40 years, 2.Having a degree in secondary education or higher, 3.nicotine dependence based on DSM 5 diagnostic criterias. (5)exclusion criterias:1.Having a known-cause depression or anxiety following problems such as loss, marital conflicts and divorce, 2.Having a history of psychotic disorders, 3.Receiving psychotherapy or drug therapy during past six months, 4.Unwillingness to continue participating in the study , 5.Failing to participate in more than two sessions of the study intervention 6.Having a history of substance abuse disorders; (6)Intervention: The intervention of this study is acceptance and commitment therapy which includes eight 90-minute sessions. (7) Primary outcomes: The primary outcomes are depression, anxiety, risky decision making, craving and cessation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011932057N1**
Registration date: **2017-06-19, 1396/03/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-19, 1396/03/29

Registrant information

Name

Mohamad Reza Davoudi

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 31 5554 2999

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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

2017-02-03, 1395/11/15

Expected recruitment end date

2017-02-08, 1395/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Controlled trial of effectiveness of Acceptance and Commitment Therapy on depression, anxiety, risky decision making, craving and cessation in male smokers.

Public title

Effectiveness Of Acceptance and Commitment Therapy on male smokers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1.Having an age of 18–40 years, 2.Having a degree in secondary education or higher, 3.nicotine dependence based on DSM 5 diagnostic criteria exclusion criteria:1.Having a known-cause depression or anxiety following problems such as loss, marital conflicts and divorce, 2.Having a history of psychotic disorders, 3.Receiving psychotherapy or drug therapy during past six months, 4.Unwillingness to continue participating in the study , 5.Failing to participate in more than two sessions of the study intervention 6.Had a history of substance abuse disorders;

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The population consisted of all male smokers admitted to center treatment of drug abuse and smoking in Kargrnzhad psychiatric hospital. from all participation's that meets inclusion criteria,35 participants for each group selected by Random assignment will be done,that by the use of computer-generated random numbers. intervention duration is six weeks. one week after intervention, post-test data is collecting. six weeks later follow-up data was measured.pre-test data is done by the investigator prior to the intervention.intervention duration is six weeks. one week after intervention, post-test data is collecting. six weeks later follow-up data was measured.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kashan University of Medical Sciences

Street address

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

City

kashan

Postal code

8715988141

Approval date

2016-12-08, 1395/09/18

Ethics committee reference number

ir.kaums.rec.1395.103

Health conditions studied

1

Description of health condition studied

nicotine dependence

ICD-10 code

F17

ICD-10 code description

Mental and behavioural disorders due to use of tobacco

2

Description of health condition studied

depression

ICD-10 code

F32.0

ICD-10 code description

Two or three of the above symptoms are usually present. The patient is usually distressed by these but will probably be able to continue with most activities.

3

Description of health condition studied

anxiety

ICD-10 code

F49.1

ICD-10 code description

Anxiety NOS

Primary outcomes

1

Description

depression

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Beck depression inventory

2

Description

anxiety

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Beck Anxiety Inventory

3

Description

craving(nicotine dependence)

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

fagestrom Craving scale

4

Description

Risky decision making

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Iowa gambling test

5

Description

smoking cessation

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Expiratory CO2 concentration

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This study is conducted to determine the effectiveness of Acceptance and Commitment Therapy (ACT) on depression, anxiety, risky decision making, craving and cessation in male smokers . The aim of this approach is invites people to open up to unpleasant feelings, and learn not to overreact to 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 experienced flexible life. this treatment is during the eight 90-minute sessions for two months.

Category

Behavior

2

Description

Control Group: This group will receive behavioral interventions for smoking cessation that approved by the Ministry of Health of Iran that is used for the smoking cessation centers and based on the psych-education and motivational interview.this protocol like intervention group during the eight 90-minute sessions for two months.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kargarnejad Psychiatric Hospital

Full name of responsible person

MD.Fateme Sadat Ghoreyshi

Street address

Kargarnejad psychiatric Hospital, Pezeshk Blvd, 5th of Qotbe 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 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

Mohammadreza Davoudi

Position

M.Sc candidate in clinical psychology

Other areas of specialty/work

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Person responsible for scientific inquiries

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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