Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Nov 2026

Investigating the role of acceptance and commitment therapy on reducing internalized stigma in patients with substance use disorder

Protocol summary

Study aim
Determining the role of acceptance and commitment therapy on reducing internal stigma in drug users

Design
Double-blind non randomized clinical trial with parallel group is performed on 80 patients.Computer software is used for randomization

Settings and conduct
The sample consists of all people who refer to Ostad Moharrari Hospital of Shiraz during two months to quit addiction.First, demographic conditions and perceived stigma are measured, then the volunteers are assigned to two groups that are matched in terms of demographic conditions and perceived stigma.The therapist and the patient are blind to what group they are in and the division is done by the secretary of the department.For one group, ACT treatment is performed by a psychologist and placebo group therapy is performed for the other group.The subjects receive a total of 12 hours of treatment for three weeks.Then the questionnaires will be completed again and the results will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria:-Age 18-50year-Diagnosis of substance use disorder-informed consent Exclusion criteria:-medical disease-cognitive problems-psychiatric disorders

Intervention groups
In the intervention group, there are four subgroups of 10 persons who receive admission and commitment therapy for three weeks including 12 hours in total.The sessions are based on 5 issues including willingness and values and committed action and efficiency of transfer and two non-specific objectives including stigma and shame. In the control group, placebo group therapy is performed with the same duration.

Main outcome variables
The effect of acceptance and commitment therapy on internalized stigma in drug users The effect of acceptance and commitment therapy on quality of life in drug users

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211118053093N1**
Registration date: **2021-12-04, 1400/09/13**
Registration timing: **prospective**

Last update: **2021-12-04, 1400/09/13**
Update count: **0**

Registration date
2021-12-04, 1400/09/13

Registrant information

Name
Kimia Sahraian

Name of organization / entity
Eghlid Higher Education Center

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-15, 1400/09/24

Expected recruitment end date
2022-03-15, 1400/12/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the role of acceptance and commitment therapy on reducing internalized stigma in patients with substance use disorder

Public title
Investigating the role of acceptance and commitment therapy in patients with substance use disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-50 year Diagnosis of substance use disorder Informed consent

Exclusion criteria:
Medical disease Cognitive problems Psychiatric disorders

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants do not know which group they are in. The data analyser does not know which group it is analysing. The number of people in the intervention and treatment groups is the same (we have 10 patients in each group for the treatment group). The duration for both intervention and control groups is 12 hours for three weeks.The number of sessions is equal, so the patient is blind to the type of treatment.Data analysis is given only data and does not know what treatment was done for either group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
13 km shiraz-isfahan highway, Ostad Mehrari Hospital

City
Shiraz

Province
Fars

Postal code
71441-13331

Approval date
2021-11-09, 1400/08/18

Ethics committee reference number
IR.SUMS.MED.REC.1400.432

Health conditions studied

1

Description of health condition studied
Substance use disorder

ICD-10 code
F19.1

ICD-10 code description
Other psychoactive substance abuse

Primary outcomes

1

Description
Internalized stigma score

Timepoint
Before the study and one week after the intervention

Method of measurement
Internalized Stigma Questionnaire that includes 28 Likert questions

Secondary outcomes

1

Description
Quality of life score.

Timepoint
Before the intervention and one week after the intervention

Method of measurement
World Health Organization Quality of Life Questionnaire

Intervention groups

1

Description
Intervention group: It consists of four groups of ten. Subjects receive their treatment in groups for three weeks including 12 hours in total (two two-hour sessions a week) and after one week after the end of the treatment, they will be asked again. ACT sessions consist of 5 cases including willingness and values and committed action and efficiency and two non-specific objectives including stigma and shame.How to run

meetings is as follows:Session 1 achieves the basic goals of the patient and familiarizes himself with his past efforts to accomplish the goal. Session 2: Logic training of behavioral activation and initial regulation of functional behavioral goal. Session 3 Continue extracting the patient's experience to strengthen the cognition of "controlling a problem" and introducing desire as an alternative and introducing the concept of depressive thoughts.Session 4 The 4th session is to know your mind is not your friend and identifying the simple behavioral goal.Session 5 assesses the patient's ability to pass on depressing thoughts and feelings.Session 6 introduces self-conceptualized distinction against the observer himself.Session 7 showing the importance of values and understanding the references and continuing the practice of mindfulness.Session 8 is a help for the patient who continuously recognizes the areas of life that do not conform to one's values.Session 9The finding the relationship between goals, activities.Session 10 Continues to emphasize the components that are related to the clients' issues.Session 11 Training to the patient to be a therapist himself.Session 12show the progress achieved and the continuous goals of the patient.

Category

Treatment - Other

2

Description

Control group: The subjects receive their treatment in groups for three weeks including 12 hours in total (two two-hour sessions a week) and after one week after the end of the treatment, they are asked again to complete the internalized stigma questionnaire and quality of life questionnaire.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ostad Mohrari Hospital

Full name of responsible person

Leila Razeghian Jahromi

Street address

13 km Shiraz-Isfahan, Ostad Mehrari Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz 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?

No

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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