

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effectiveness of cognitive behavioral therapy on Cognitive flexibility, rumination and mindfulness in people with depression

Protocol summary

Study aim

Determining the effectiveness of cognitive behavioral therapy on cognitive flexibility, rumination and mindfulness in people with depression

Design

The clinical trial has a control group, community-based and practice-oriented, with parallel groups.

Settings and conduct

A clinical trial has been conducted in the field of depression. The statistical population will include all depressed people who refer to Shana and Aram counseling centers in Karaj, and the statistical sample will be selected using available sampling method, from which 30 people will be randomly replaced in each group of 15 people for testing and control. First, the relevant questionnaires will be completed by all participants, and then the intervention group will receive 13 sessions of cognitive-behavioral therapy, and finally, after training, both groups will complete the relevant questionnaires again, and their scores will be The test is recorded.

Participants/Inclusion and exclusion criteria

The conditions for entering the study are depressed people who are between the ages of 20 and 50, and the conditions for not entering are those who are old and do not have the ability to provide appropriate information.

Intervention groups

In addition to the usual interventions in the treatment center, the experimental group is subjected to cognitive-behavioral therapy intervention. The control group receives only the usual interventions in the treatment center.

Main outcome variables

Cognitive flexibility, rumination, mindfulness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230708058718N1**

Registration date: **2023-07-16, 1402/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-16, 1402/04/25**

Update count: **0**

Registration date

2023-07-16, 1402/04/25

Registrant information

Name

Masoumeh Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7704 0640

Email address

sadeghi2002@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-13, 1402/04/22

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive behavioral therapy on Cognitive flexibility, rumination and mindfulness in people with depression

Public title

The effect of cognitive behavioral therapy on cognitive flexibility, rumination and mindfulness in depressed people

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All depressed people who are between 20 and 50 years old

Exclusion criteria:

People whose age is high and it is difficult to get information from them

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

2

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University, Semnan branch

Street address

Semnan, university campus, Islamic Azad University, Semnan branch

City

Semnan

Province

Semnan

Postal code

3513137111

Approval date

2023-07-04, 1402/04/13

Ethics committee reference number

IR.IAU.SEMNAN.REC.1402.012

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cognitive flexibility

Timepoint

Before starting the therapeutic intervention on the first day - after completing the therapeutic intervention on the 40th day

Method of measurement

Dennis and Vanderwaal's Cognitive Flexibility Questionnaire (2010)

2

Description

Rumination

Timepoint

Before starting the therapeutic intervention on the first day - after

Method of measurement

Nolen Hoeksma and Maro rumination questionnaire (1991)

3

Description

Mindfulness

Timepoint

Before starting the therapeutic intervention on the first day - after

Method of measurement

Bauer et al.'s five-factor mindfulness questionnaire (2006)

Secondary outcomes

empty

Intervention groups

Description

Intervention group: The experimental group is subjected to cognitive-behavioral therapy intervention in the treatment center. The treatment is done in 13 sessions. The contents of the treatment sessions in brief are: introducing cognitive behavioral therapy for the participants, assigning tasks according to the training and intervention carried out in each session, reviewing and checking the tasks of the previous sessions at the beginning of each session, teaching the connection between spontaneous thoughts and the feelings of the patient and the group. classifying distorted spontaneous thoughts into them, presenting a cognitive-behavioral model for cognitive distortion and rumination, challenging negative spontaneous thoughts and identifying assumptions and challenging them and applying cognitive techniques to challenge negative spontaneous thoughts, identifying Dysfunctional schemas, examining the origin of schemas and how it affects important life events, mindfulness skill training and mindfulness barriers and mindfulness program solutions for it, defining cognitive flexibility for participants and discussing the individual's ability to adapt and changing demands and responding appropriately to new experiences, helping the patient to review past episodes of depression, and providing strategies to prevent future depression. The duration of each session is 45 minutes and the duration of the course is 40 days.

Category

Treatment - Other

2

Description

Control group: The control group does not receive any intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Meaning and Aram Counseling Center in Karaj

Full name of responsible person

Masoumeh Sadeghi

Street address

No. 50, Unit 17Tehranpars, between 3rd and 4th floors, East 220 St., between Khairi and Mozafari

City

Tehran

Province

Tehran

Postal code

1655767799

Phone

+98 21 7704 0640

Email**Sponsors / Funding sources**

1

Sponsor**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Masoumeh Sadeghi

Street address

No. 50, Unit 17Tehranpars, between 3rd and 4th floors, East 220 St., between Khairi and Mozafari St

City

Tehran

Province

Tehran

Postal code

1655767799

Phone

+98 21 7704 0640

Email

sadeghi2002@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Masoumeh Sadeghi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

No. 50, Unit 2Tehranpars, Between Third and Fourth, 220 East Street, between Khairi and Mozaffari Street

City

Tehran

Province

Tehran
Postal code
1655767799
Phone
+98 21 7704 0640
Email
sadeghi2002@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Masoumeh Sadeghi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 50, Unit 2Tehranpars, Between Third and Fourth,
220 East Street, between Khairi and Mozaffari Street
City
Tehran
Province
Tehran
Postal code
1655767799
Phone
+98 21 7704 0640
Email
sadeghi2002@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Masoumeh Sadeghi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 50, Unit 17Tehranpars, between 3rd and 4th
floors, East 220 St., between Khairi and Mozafari St
City
Tehran
Province
Tehran
Postal code
1655767799
Phone
+98 21 7704 0640
Email
sadeghi2002@yahoo.com

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