Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The comparison of the effectiveness of unified transdiagnostic treatment and mindfulness based cognitive therapy (MBCT) in cognitive avoidance ,emotional regulation and rumination in depression disorder: a double-blind randomized clinical trial

Protocol summary

Study aim
Comparing the effectiveness of integrated transdiagnostic therapy and mindfulness therapy on cognitive avoidance, emotion regulation and rumination in depressive disorder

Design
A clinical trial with a control group with two parallel treatment groups on 45 patients

Settings and conduct
Background: depression disorder, location: Jahad Counseling Center, Mashhad University. Clinical interviews and depression questionnaires were taken from people who referred to the center with depression complaints, and then, if they were eligible, they were randomly divided into three groups of 15 The subjects were divided into (metadiagnostic therapy group, mindfulness therapy group and control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of depressive disorder in structured clinical interview based on SCID-5 Beck depression questionnaire Exclusion criteria: Existence of psychiatric disorders (schizophrenic spectrum disorders and other psychotic disorders and bipolar disorder) Receiving other psychological treatments at the same time

Intervention groups
The first experimental group with integrated metadiagnostic therapeutic intervention, the second experimental group with cognitive therapy intervention based on mindfulness and the control group.

Main outcome variables
Rumination Cognitive avoidance Emotion Regulation

General information

Reason for update

Acronym
UM

IRCT registration information
IRCT registration number: **IRCT20231107059985N1**
Registration date: **2023-11-14, 1402/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-14, 1402/08/23**
Update count: **0**

Registration date
2023-11-14, 1402/08/23

Registrant information

Name
Somayeh Afshar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-09, 1402/08/18

Expected recruitment end date
2024-03-10, 1402/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of the effectiveness of unified transdiagnostic treatment and mindfulness based cognitive therapy (MBCT) in cognitive avoidance ,emotional regulation and rumination in depression disorder: a double-blind randomized clinical trial

Public title
Investigating the effect of integrated transdiagnostic therapy and cognitive therapy based on mindfulness in depression

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosing depression disorder in a structured clinical interview based on SCID-5 Beck Depression Questionnaire not receiving drug treatment (physical and psychological medication) receiving other psychological treatments not having severe psychiatric disorders absence of addiction

Exclusion criteria:
Being less than 18 years old and more than 50 years old having absence of more than 3 sessions having an addiction having a psychiatric disorder receiving drug treatment (physical and psychological medication) receiving Other psychological treatments

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: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method Randomization unit: individual Randomization tool: sealed envelope Explanation about concealment: In order to prevent selection distortion, a number of envelopes are prepared with aluminum foil (in order to make the contents of the envelopes unclear), and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order.In order to preserve the random sequence, the outer surface of the envelope is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order. At the time of the registration of the participants, according to the order of entry of the eligible participants into the study, one of the letter envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
After selecting the sample, none of the people in the sample will know about randomization and the process of allocation to groups. The data analyst will be chosen outside the study and all the data will be provided to him in a coded form.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Faculty of Medicine, Islamic Azad University, Mashhad Medical Sciences Unit

Street address
Mashhad ,Faramarz abbasi Blv,faramarz 15 Avenue, resalat 29,45 No

City
Mashhad

Province
Razavi Khorasan

Postal code
9197964916

Approval date
2023-11-07, 1402/08/16

Ethics committee reference number
IR.IAU.MSHD.REC.1402.128

Health conditions studied

1

Description of health condition studied
Major depressive disorder

ICD-10 code
F33.0

ICD-10 code description
Major depressive disorder, recurrent, mild

Primary outcomes

1

Description
depression

Timepoint
A pre-test، post-test and then follow-up after 3 months.

Method of measurement
Clinical interview(SCID-5), Beck Depression Questionnaire (2nd edition)

Secondary outcomes

1

Description
rumination
Timepoint
pre-test, post-test and follow-up (two months after the post-test)
Method of measurement
Rumination response style scale

2

Description
Cognitive avoidance
Timepoint
pre-test, post-test and follow-up (two months after the post-test)
Method of measurement
Cognitive avoidance questionnaire(CAQ)

3

Description
Emotion Regulation
Timepoint
pre-test, post-test and follow-up (two months after the post-test)
Method of measurement
emotion regulation questionnaire (ERQ)

Intervention groups

1

Description
The first intervention group: integrated metadiagnostic treatment based on the treatment protocol of David Barlow et al. (2009)
Category
Behavior

2

Description
Intervention group 2: cognitive therapy based on mindfulness based on the therapeutic protocol of Segal et al. (2002)
Category
Behavior

3

Description
Control group: no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Academic Jahad Counseling Center
Full name of responsible person
Dr.moghadaszadeh
Street address
serah adabiat Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Fax
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Email
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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
Islamic Azad University Of Bojnourd
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

Islamic Azad University

Full name of responsible person
Negar Asgharipour zahmati

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All information related to the main outcome or similar will be published.

When the data will become available and for how long
Since 1403

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
It is possible to access the documents for the information of other researchers.

From where data/document is obtainable
Mashhad Academic Jihad Counseling Center, Samia Afshar 09151070883

What processes are involved for a request to access data/document
Only by stating the reason for the request via email or phone, the required documents will be shared.

Comments