

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 2026

Comparing the effectiveness of pharmacotherapy and Mindfulness-integrated Cognitive Behavior Therapy (MiCBT) in suicidal adults following hospitalization

Protocol summary

Study aim

To compare the effectiveness of Mindfulness-integrated CBT versus medication in improving symptoms among suicide attempters.

Design

A randomized clinical trial with two parallel groups (intervention and control) was conducted on 30 participants using simple randomization (lottery method), the study was single-blinded, with the clinical evaluator being blinded to group assignments

Settings and conduct

The interventions will be conducted at the psychology clinic of Ghods Hospital in Sanandaj, Iran, and participants will not be required to pay any fees for the treatments received. The groups will be evaluated at three stages. The collected data will be coded and provided to a statistical evaluator who will be blinded to the group assignments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Willingness to participate in the study, 2- At least a basic literacy level (minimum early middle school education), 3- History of suicide attempts. Exclusion criteria: 1- No psychotic symptoms or intellectual/cognitive impairment, 2- No substance or alcohol use disorders, 3- Not currently undergoing any other psychotherapy during this study

Intervention groups

The present study includes two groups. The first group receives 8 sessions MiCBT.

Main outcome variables

Beck Scale for Suicidal Ideation Depression, Anxiety and stress scale Billings-and-Mouse-Coping-Strategies-Questionnaire

General information

Reason for update

Acronym

Mindfulness integrated CBT (MiCBT)

IRCT registration information

IRCT registration number: **IRCT20220113053705N3**

Registration date: **2025-07-09, 1404/04/18**

Registration timing: **prospective**

Last update: **2025-07-09, 1404/04/18**

Update count: **0**

Registration date

2025-07-09, 1404/04/18

Registrant information

Name

Fateh Sohrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3371 8025

Email address

f.sohrabi20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-23, 1404/05/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of pharmacotherapy and Mindfulness-integrated Cognitive Behavior Therapy (MiCBT) in suicidal adults following hospitalization	
Public title	Comparing the effectiveness of pharmacotherapy and Mindfulness-integrated Cognitive Behavior Therapy (MiCBT) on suicide
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Providing consent to participate in the study, Having at least middle school literacy, Having a history of suicide attempts, Absence of psychotic symptoms or intellectual/cognitive impairment, No substance or alcohol dependence or abuse, Not participating in any other psychotherapy simultaneously with the current study Exclusion criteria: Withdrawal from the study, Substance or alcohol dependence or abuse, Diagnosis of psychotic disorders, Intellectual or cognitive impairment before or during the study, Suicide attempts, and the need for hospitalization
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	• Data analyser
Sample size	Target sample size: 30
Randomization (investigator's opinion)	Randomized
Randomization description	After selecting the participants, all of them will be randomly assigned to the control and intervention groups through a simple lottery method. To do this, each participant's code will be written on identical cards, which will then be randomly drawn to allocate them to the two study groups. This way, all participants will have an equal chance of being placed in either group.
Blinding (investigator's opinion)	Single blinded
Blinding description	The statistical evaluator of the results will be blinded to the group assignments and will not know which group is the intervention or control.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees
<u>1</u>
Ethics committee
Name of ethics committee
Research Ethics Committees of Kurdistan University of Medical Sciences
Street address
Kurdistan University of Medical Sciences., Pasdaran Ave.
City
Sanandaj
Province
Kurdistan
Postal code
6617713446
Approval date
2025-06-10, 1404/03/20
Ethics committee reference number
IR.MUK.REC.1404.090
Health conditions studied
<u>1</u>
Description of health condition studied
Suicide
ICD-10 code
T14.91
ICD-10 code description
Suicide attempt
Primary outcomes
<u>1</u>
Description
Suicide
Timepoint
Measurement of suicide before the start of the intervention (Pre-assessment), after the completion of the intervention (Post-assessment), and two months after the last intervention session (Follow-up).
Method of measurement
Beck Scale for Suicidal Ideation
<u>2</u>
Description
Depression, Anxiety and Stress
Timepoint
Measurement of Depression, Anxiety, and Stress before the start of the intervention (Pre-assessment), after the completion of the intervention (Post-assessment), and two months after the last intervention session (Follow-up).
Method of measurement
Depression, Anxiety and Stress scale

3

Description

Coping-Strategies

Timepoint

Measurement of Coping-Strategies before the start of the intervention (Pre-assessment), after the completion of the intervention (Post-assessment), and two months after the last intervention session (Follow-up).

Method of measurement

Billings-and-Mouse-Coping-Strategies-Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive 8 to 10 psychotherapy sessions based on the mindfulness-integrated cognitive-behavioral therapy protocol.

Category

Treatment - Other

2

Description

Control group: The control group will continue only their pre-prescribed medication treatment and will not receive any specific psychotherapy concurrently.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychological Clinic of Ghods Hospital

Full name of responsible person

Dr Fateh Sohrabi

Street address

Ghods Hospital., Pasdaran Ave., Shohadayy Nirooy Entezami Blv.

City

Sanandaj

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6617713141

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+98 87 3366 0025

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F.sohrabi20@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Afshin Maleki

Street address

Kurdistan University of Medical Sciences., Pasdaran Ave.

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Email

Research@muk.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Fateh Sohrabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Clinical Psychology Branch., Faculty of Medicine., Kurdistan University of Medical Sciences., Pasdaran Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Title and more details about the data/document

Data related to the study will be provided in response to
legitimate requests from the relevant organizations.

When the data will become available and for how long

6 month after publication of the related paper

To whom data/document is available

Academic researchers can access the data upon
submitting a formal and justified request.

Under which criteria data/document could be used

The individual must have a verified identity and submit
the request through an official or academic organization.
They must accept responsibility for maintaining
confidentiality and not disclosing the data without
permission, in accordance with ethical principles.

From where data/document is obtainable

They can correspond via the following email to make a
request: F.sohrabi20@gmail.com

What processes are involved for a request to access data/document

After receiving the email and reviewing it through official
channels, the request will be responded to as soon as
possible.

Comments