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)
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+98 87 3371 8025
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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

1

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

1

Description of health condition studied

Suicide

ICD-10 code

T14.91

ICD-10 code description

Suicide attempt

Primary outcomes

1

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

2

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.
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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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66177-13141
Phone
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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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F.sohrabi20@gmail.com

Person responsible for scientific 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

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Person responsible for updating data

Contact

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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