Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Efficacy of Mindfulness-Based Interventions on Psychological Distress in Depressed University Students with Suicidal Ideation

Protocol summary

Study aim
the efficacy of mindfulness treatment
Design
This study is a randomized, controlled clinical trial with a parallel-group design. A total of 30 students were assigned to either the intervention or control group using a stratified block randomization method. The randomization process was performed using the RAND function in Excel.
Settings and conduct
Approximately 50 students from Torbat-e Heydarieh University of Medical Sciences will be screened using the BDI and a suicidal ideation scale. The 30 students with the highest scores will be randomly assigned (simple randomization) to either the experimental or control group (
Participants/Inclusion and exclusion criteria
criteria prior to randomization: A score ranging from 1 to 5 on the Beck Suicide ideation Scale (BSS). Willingness to participate in all scheduled intervention sessions. Ability to provide informed consent by signing the consent form. Exclusion Criteria: A history of active suicide attempt within the last 6 months.
Intervention groups
1. Intervention Group: Participants in this group will receive Mindfulness-Based Therapy (MBT) in accordance with the established protocol. 2. Control Group: receiving the same therapeutic protocol during a period following the completion of the primary study phase.
Main outcome variables
Psychological Distress: Measured using the Kessler Psychological Distress Scale (K10) to evaluate changes in overall psychological well-being. Suicidal Ideation: Assessed via the Beck Suicide Ideation Scale (BSS) to monitor changes in suicidal thoughts and intentions.

General information

Reason for update

Acronym
IRCT registration information
IRCT registration number: **IRCT20260727070380N1**
Registration date: **2026-10-13, 1405/07/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-13, 1405/07/21**
Update count: **0**
Registration date
2026-10-13, 1405/07/21

Registrant information
Name
Simaye Mohammadi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-08-23, 1405/06/01
Expected recruitment end date
2026-11-22, 1405/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Efficacy of Mindfulness-Based Interventions on Psychological Distress in Depressed University Students with Suicidal Ideation

Public title
The effectiveness of mindfulness in depressed students.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
A score between 1 and 5 on the Beck Scale for Suicide Ideation (BSS), indicating the presence of suicidal ideation.No use of psychiatric medications within the past three months.No diagnosis of severe mental disorders (e.g., schizophrenia or bipolar disorder) by a psychiatrist.Willingness to attend all intervention sessions.Signing the informed consent form.
Exclusion criteria:
A history of active suicide attempts within the past six months.
Age
From **19 years** old to **27 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
To control for confounding variables (gender and major) and ensure the homogeneity of the intervention and control groups, a ‘stratified randomization’ method will be employed. First, the list of all participants will be organized based on the combination of ‘gender’ (male/female) and ‘field of study’ (Midwifery, Nursing, Emergency Medical Services, Anesthesiology). Based on these combinations, 10 distinct and homogeneous strata will be formed. To generate the allocation sequence within each stratum, Microsoft Excel software will be used. A random number between 0 and 1 will be generated for every participant in each stratum and recorded in the column adjacent to their name. After assigning the random numbers, the list of participants in each stratum will be sorted in ascending order (from smallest to largest) based on the generated values. Subsequently, based on the resulting order, participants will be allocated to the intervention and control groups in a 1:1 ratio. For instance, in a stratum with 12 participants, the first 6 individuals on the sorted list will be assigned to the intervention group, and the remaining 6 to the control group. This process ensures that every participant within each stratum has an equal probability of being assigned to either group, thereby minimizing the impact of confounding variables on the final composition of the groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Torbat Heydariyeh University of Medical Sciences
Street address
Torbat Heydariyeh University of Medical Sciences, Salamat Town, Shahid Borounsi St., Torbat Heydariyeh, Iran
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Approval date
2026-06-21, 1405/03/31
Ethics committee reference number
IR.THUMS.REC.1405.015

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
level of psychological distress
Timepoint
Psychological distress will be measured at baseline, prior to the intervention
Method of measurement
will be measured using the Kessler Psychological Distress Scale (K10)

Secondary outcomes

1

Description
Suicide Ideation
Timepoint
will be measured at baseline, prior to the intervention
Method of measurement
Beck Suicide Ideation Scale (BSS).

Intervention groups

1

Description
Intervention group: Mindfulness-based therapy:
Category
N/A

2

Description
Control group: Non-receipt of mindfulness-based therapy
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Torbat Heydariyeh University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Torbate-Heidaria University of Medical Sciences
Proportion provided by this source
80
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
Torbate-Heidaria University of Medical Sciences
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Position
psycologist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Individual participant data are not disclosed; only the aggregated group-level analysis of the therapeutic outcomes is presented.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
Following the implementation of the treatment protocol, data were analyzed using statistical software and subsequently reported
When the data will become available and for how long
Three months after the publication of the results
To whom data/document is available
Researchers employed at the university
Under which criteria data/document could be used
Access to the data is strictly limited to non-commercial, academic research purposes. Permissible use is confined to statistical analyses; any attempt to re-identify individuals or perform de-anonymization is strictly prohibited. Furthermore, the data may not be utilized in independent publications without explicit prior authorization from the primary investigators
From where data/document is obtainable
mohammadii.som7241@gmail.com
What processes are involved for a request to access data/document
Requests may be submitted via email to the corresponding author
Comments