Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Mindfulness-Integrated Cognitive Behaviour Therapy (MiCBT) and Spiritually based Psychotherapy on Post-Traumatic Stress, Sleep Disturbance, Anxiety, Depression, and Somatic Complaints among Civilian, Following the 40-Day War

Protocol summary

Study aim

To determine the effectiveness of Mindfulness-integrated Cognitive Behavioral Therapy and Spiritually based Psychotherapy on reducing Post-traumatic stress disorder, sleep disturbance, anxiety, depression, and somatic complaints among civilians, following the 40-day War

Design

A randomized controlled trial with two intervention groups and one control group, parallel groups, unblinded, with 105 participants. Randomization was performed using STATA software.

Settings and conduct

Civilian residents of Shiraz who resided in the city during the 40-day war will be included in the study if eligible and will be randomly assigned to three intervention and control groups. Screening, clinical interviews, interventions, and assessments will be conducted online. This study will be unblinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Residence in Shiraz; age 18 years and older; scoring above the clinical cut-off on pre-test screening and confirmation in clinical interview; informed consent; no concurrent receipt of other psychological interventions; no use of medications affecting consciousness; internet access; no active psychotic disorder. Exclusion criteria: Presence of comorbid disorders (psychosis, substance use)

Intervention groups

Group 1: Eight weekly 90-minute online sessions of group Mindfulness-integrated Cognitive Behavioral Therapy. Group 2: Eight weekly 90-minute online sessions of spiritually based psychotherapy. Control group: Receives no intervention. After the study, one of the effective interventions will be offered based on participant choice.

Main outcome variables

Post-Traumatic Stress Disorder; Sleep Disturbance; Depression, Anxiety and Stress Disorders; Somatic Complaints

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220903055860N3**
Registration date: **2026-08-13, 1405/05/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-13, 1405/05/22**
Update count: **0**

Registration date

2026-08-13, 1405/05/22

Registrant information

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Mohsen Arefian
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The University of Isfahan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-01, 1405/05/10

Expected recruitment end date
2026-08-21, 1405/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Mindfulness-Integrated Cognitive Behaviour Therapy (MiCBT) and Spiritually based Psychotherapy on Post-Traumatic Stress, Sleep Disturbance, Anxiety, Depression, and Somatic Complaints among Civilian, Following the 40-Day War

Public title
Comparing the Effectiveness of Two Psychotherapy Approaches (Mindfulness-Integrated and Spiritually-Based) on War-Related Psychological Symptoms in Citizens
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Residence in Shiraz during the 40day war period full fluency in Persian Age 18 years and older Scoring above 14 for depressive symptoms on the Depression, Anxiety, and Stress Scale (DASS-21) at the screening stage. Scoring above 10 for anxiety symptoms on the DASS-21 at the screening stage. Scoring above 18 for stress symptoms on the DASS-21 at the screening stage. Scoring above 33 on the Post-Traumatic Stress Disorder Checklist at the screening stage. Symptom severity confirmed during the initial clinical interview. Informed consent and voluntary willingness to participate in all study phases No concurrent receipt of other structured psychological interventions for trauma-related symptoms during the intervention period Access to internet, computer, or suitable smartphone for participating in online sessions No acute suicide risk requiring immediate intervention
Exclusion criteria:
Presence of an active psychotic disorder Presence of a severe substance use disorder Use of medications affecting consciousness level without a stable dose for at least four weeks
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is block randomization with variable block sizes (3 and 6) and a 1:1:1 allocation ratio. The unit of randomization is the individual, and no stratified randomization is used. The random sequence will be generated using STATA software version 17, employing the random number generation function with a system-time-based seed. The randomization process and sequence generation will be performed by an independent statistician who has no role in intervention delivery or data analysis. For allocation concealment, the generated sequence will be kept in coded, opaque, sealed envelopes held by a third party and will not be disclosed to the interventionists or the principal investigator until after final eligibility confirmation and completion of baseline assessments. Following final confirmation, the third party will assign each participant sequentially to one of the three groups (MiCBT, Spiritually Integrated Psychotherapy, or Control) based on the predetermined sequence.
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 Islamic Azad University, Marvdasht Branch
Street address
Islamic Azad University of Marvdasht, Three kilometers of Persepolis Boulevard, Marvdasht, Fars, Iran
City
Marvdasht
Province
Fars
Postal code
73711-13119
Approval date
2026-07-15, 1405/04/24
Ethics committee reference number
IR.IAU.M.REC.1405.284

Health conditions studied

1

Description of health condition studied
Post Traumatic Stress Disorder
ICD-10 code
F43.1
ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
Post Traumatic Stress Disorder
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Total score on the Persian version of the Post Traumatic Stress Disorder Checklist for DSM5, with scores ranging from 0 to 80; higher scores indicate greater symptom severity.

2

Description
Sleep Disturbance (Insomnia)
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Total score on the Persian version of the Insomnia Severity Index, with scores ranging from 0 to 28; higher scores indicate greater insomnia severity.

Secondary outcomes

1

Description
Depression
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Score on the Depression subscale of the Persian version of the 21-item Depression, Anxiety, and Stress Scale, with scores ranging from 0 to 21; higher scores indicate greater Depression.

2

Description
Somatic Complaints
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Total score on the Persian version of the Somatic Symptom Scale8 (SSS8), with scores ranging from 0 to 32; higher scores indicate greater somatic symptom burden.

3

Description
Anxiety
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Score on the anxiety subscale of the Persian version of the 21-item Depression, Anxiety, and Stress Scale, with scores ranging from 0 to 21; higher scores indicate greater anxiety.

4

Description
Stress
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Score on the Stress subscale of the Persian version of the 21-item Depression, Anxiety, and Stress Scale, with scores ranging from 0 to 21; higher scores indicate greater Stress.

Intervention groups

1

Description
Intervention group 1: Receives 8 sessions of 120 minutes each of group Mindfulness-Integrated Cognitive Behaviour Therapy (MiCBT) delivered online (weekly). This intervention is based on Cayoun's co-emergence model of reinforcement. Session content includes: session 1, introduction to the group and treatment rationale; session 2, progressive muscle relaxation; session 3, breathing meditation; session 4, body scanning (somatic awareness); session 5, Mindfulness-Integrated Exposure Therapy (MIET); session 6, deepening of exposure techniques; session 7, equanimity-based interpersonal skills; and session 8, empathic skills, consolidation, and relapse prevention. Each session is delivered via video conferencing.
Category
Behavior

2

Description
Intervention group 2: Receives 8 sessions of 120 minutes each of group spiritually integrated psychotherapy delivered online (weekly). This intervention is designed based on Pargament's (2007) spiritually integrated psychotherapy framework and Rajaei's (2010) Religious Cognitive-Emotional Therapy model, adapted to the dominant religious beliefs in Iranian-Islamic society. Session content includes: session 1, introduction, treatment rationale, and group rules; session 2, positive thinking about God and meaning-making after trauma; session 3, attention to the presence of a higher power; session 4, trust in God (part 1); session 5, trust in God (part 2); session 6, God's caregiving (part 1); session 7, God's caregiving (part 2): gratitude and forgiveness; and session 8, consolidation, relapse prevention, and closure. Participation in religious content is voluntary and

implemented with sensitivity to participants' diverse beliefs. Each session is delivered via video conferencing.

Category

Behavior

3

Description

Control group: No active intervention (waitlist control). Participants in this group receive no therapy sessions and only complete pretest, posttest, and followup assessments. During the waiting period, this group is under passive monitoring for acute crises. For ethical reasons, after the data collection is completed, one of the two interventions (based on participant's preference) will be offered to them free of charge.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Center for Behavioral and Cognitive Sciences, Jahrom University

Full name of responsible person

Mohsen Arefian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Jahrom

Full name of responsible person

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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

The University of Jahrom

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

The University of Jahrom

Full name of responsible person

Mohsen Arefian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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 from this study include scores for all outcome variables (PTSD, sleep disturbance, anxiety, depression, and somatic complaints) at three assessment time points (preintervention, postintervention, and 2month followup). These data will be shared with other researchers after complete anonymization (removal of all identifying information). No data that could lead to participant identification will be shared.
When the data will become available and for how long
Access to the anonymized data from this study will begin 6 months after the end of the study.
To whom data/document is available
All researchers working in academic, scientific, or research institutions (both public and private) may request access to the anonymized data from this study. Researchers working in the nonacademic sector may also request access if they have valid scientific aims.
Under which criteria data/document could be used
Additional conditions for using the anonymized data from this study are as follows: 1. Requesters must submit a research proposal clearly stating their scientific aims. 2. The request must include ethics approval from the requester's institution. 3. Data will only be used for the approved purposes. 4. Any publication resulting from these data must cite the original study. 5. Any attempt to reidentify participants is prohibited. 6. Sharing the received data with third parties without permission of the original study team is not allowed.
From where data/document is obtainable
Applicants requesting anonymized data from this study should send a written request, including a research proposal and ethics approval, to the email address of the responsible author, Dr. Mohsen Arefian, at arefian@jahromu.ac.ir. The research team will respond to requests within a maximum of 4 weeks.
What processes are involved for a request to access data/document
The applicant must first send a written request including a research proposal and ethics approval to the responsible author's email address. The research team reviews the request. If approved, a data sharing agreement will be sent to the applicant. After signing the agreement, anonymized data will be provided within a maximum of 4 weeks from the date of final approval. The entire process from request submission to data receipt takes 6 to 8 weeks.
Comments