Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of metacognitive detached mindfulness intervention and mentalization based-therapy on intolerance of uncertainty, cognitive avoidance, emotion regulation, and attention of the conscious mind in children of veterans with generalized anxiety disorder

Protocol summary

Study aim
Investigating the effectiveness of metacognitive therapy based on dissociative mindfulness and mentalization-based therapy on intolerance of uncertainty, cognitive avoidance, emotion regulation, and mindful attention in patients with generalized anxiety disorder.

Design
A quasi-experimental study with a pre-test-post-test design and a 3-month follow-up period. The sample was selected in the first stage purposefully based on inclusion and exclusion criteria, and in the second stage, it was randomly assigned to two separate intervention groups and a control group on 45 subjects through a simple lottery method.

Settings and conduct
After announcing the call for research through the official information channel of the Shahed and Isagar Counseling Center, eligible applicants were screened for generalized anxiety disorder based on a clinical and diagnostic interview. Blinding was not performed in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children of veterans, generalized anxiety disorder, age range 20 to 35 years, no psychotic disorders

Intervention groups
The study includes two intervention groups and a control group. The first intervention group will receive an 8-session protocol of mindfulness-based metacognitive therapy, and the second intervention group will receive a 12-session protocol of mentalization-based therapy. In this study, no intervention will be provided to the control group.

Main outcome variables
Intolerance of uncertainty, Cognitive avoidance, Emotion regulation, Mindful attention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240930063208N2**
Registration date: **2025-01-18, 1403/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-18, 1403/10/29**
Update count: **0**

Registration date
2025-01-18, 1403/10/29

Registrant information

Name
Hamid Nejat

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3847 3761

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-30, 1403/10/10

Expected recruitment end date
2025-01-29, 1403/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of metacognitive detached mindfulness intervention and mentalization based-therapy on intolerance of uncertainty, cognitive avoidance, emotion regulation, and attention of the conscious mind in children of veterans with generalized anxiety disorder

Public title
Investigating the effectiveness of metacognitive intervention based on mindfulness and mentalizing intervention on generalized anxiety disorder

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
People with generalized anxiety disorder Having at least a diploma Child of a mentally ill veteran

Exclusion criteria:
Comorbidity with psychotic disorders Drug and medication abuse Receiving psychological intervention within the past 6 months

Age
From **20 years** old to **35 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
First, 45 people from the target population will be selected purposefully according to the inclusion and exclusion criteria, and then each subject will be assigned to the first intervention group, the second intervention group, and the control group through simple randomization through drawing lots.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Faculty of Medicine, Islamic Azad University, Mashhad Medical Sciences Branc

Street address
Islamic Azad University of Medical Sciences, Mashhad, Chamran 15

City
Mashhad

Province
Razavi Khorasan

Postal code
9133736351

Approval date
2024-08-07, 1403/05/17

Ethics committee reference number
IR.IAU.MSHD.REC.1403.077

Health conditions studied

1

Description of health condition studied
Intolerance of uncertainty

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Cognitive avoidance

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Emotion regulation

ICD-10 code

ICD-10 code description

4

Description of health condition studied
Attention of the conscious mind

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intolerance of Uncertainty Score on the Freestone Questionnaire

Timepoint
Before and after the intervention, and three months after the intervention ended

Method of measurement
Freestone Intolerance of Uncertainty Questionnaire

2

Description
Cognitive avoidance score in the Dagas questionnaire

Timepoint
Before and after the intervention, and three months after the intervention ended
Method of measurement
Dugas and Sexton Cognitive Avoidance Questionnaire

3

Description
Emotional dysregulation score on the Gratz questionnaire
Timepoint
Before and after the intervention, and three months after the intervention ended
Method of measurement
Gratz and Romer's Difficulty in Emotion Regulation Questionnaire

4

Description
Mindful attention score in the Brown Questionnaire
Timepoint
Before and after the intervention, and three months after the intervention ended
Method of measurement
Brown and Ryan Mindful Attention Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first intervention group includes subjects who will undergo metacognitive therapy based on dissociative mindfulness. This treatment includes an 8-session educational-therapeutic protocol that is implemented one day per week and each session lasts 60 minutes. In order to examine the effectiveness of the intervention, a research study will be conducted in the form of a pre-test, post-test, and a three-month follow-up period.
Category
Treatment - Other

2

Description
Intervention group:The second intervention group includes subjects who will undergo mentalization-based therapy. This treatment includes a 12-session educational-therapeutic protocol that is implemented one day per week and each session lasts 60 minutes. In order to examine the effectiveness of the intervention, a research study will be implemented in the form of a pre-test, post-test, and a three-month follow-up period.
Category
Treatment - Other

3

Description
Control group: The control group will consist of 15 subjects, for whom no intervention will be provided.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Witness and Sacrifice Counseling Center
Full name of responsible person
Sina erfanian majdi
Street address
No 8 , Shahid Islami 2 Ave., Kouhsangi Blvd
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Mashhad
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Razavi Khorasan
Postal code
9185379379
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+98 51 3840 2554
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Sina.erfani888@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Jamshid Yousefi
Street address
Islamic Azad University of Medical Sciences, Mashhad, Chamran 15
City
Mashhad
Province
Razavi Khorasan
Postal code
9133736351
Phone
+98 51 3853 5381
Email
info@iaumshms.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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

Sina erfanian majdi

Position

Teaching assistant

Latest degree

Master

Other areas of specialty/work

Psychology

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Full name of responsible person

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Position

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Latest degree

Master

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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no need to disclose the personal information of participants in this study.

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

No - There is not 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

Not applicable

Title and more details about the data/document

The data obtained is based on changes that are based on questionnaires and statistical analysis that show how effective each of the treatments was, so no individual information is published, the criterion is individual changes.

When the data will become available and for how long

3 months after completion of the intervention

To whom data/document is available

All researchers working in scientific and academic centers

Under which criteria data/document could be used

If a new analysis needs to be performed, while maintaining confidentiality

From where data/document is obtainable

If a new analysis needs to be performed, while maintaining confidentiality

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

Requests submitted via email, stating the details and purpose of the request, will be responded to within 7 business days after review.

Comments