Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Randomized Controlled Trial Comparing the Effectiveness of the Unified Protocol (UP) and Metacognitive Therapy (MCT) on Transdiagnostic Variables in Adults with Posttraumatic Stress Disorder (PTSD).

Protocol summary

Study aim
The aim of this study is to provide empirical evidence for the selection of effective and evidence-based psychological interventions for adults with post-traumatic stress disorder (PTSD), with a focus on key transdiagnostic processes.

Design
A randomized clinical trial involving 62 adults with PTSD, assigned equally to two parallel groups: the Unified Protocol (UP) group and the Metacognitive Therapy (MCT) group.

Settings and conduct
This study is a randomized controlled clinical trial with a pretest–posttest design and a three-month follow-up. A total of 60 adults diagnosed with PTSD will be recruited using convenience sampling and randomly assigned to two treatment groups: the Unified Protocol (UP) and Metacognitive Therapy (MCT).

Participants/Inclusion and exclusion criteria
Inclusion criterion: Diagnosis of PTSD based on the SCID-5-CV in accordance with the DSM-5-TR criteria.
Exclusion criterion: Absence of PTSD

Intervention groups
Unified Protocol (UP): Receiving the transdiagnostic Unified Protocol treatment Metacognitive Therapy (MCT): Receiving metacognitive therapy

Main outcome variables
Symptoms of Post-Traumatic Stress Disorder (PTSD)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260901070856N1**
Registration date: **2026-10-28, 1405/08/06**
Registration timing: **registered_while_recruiting**
Last update: **2026-10-28, 1405/08/06**
Update count: **0**

Registration date
2026-10-28, 1405/08/06

Registrant information

Name
Bahareh Moradhasel

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
2026-09-23, 1405/07/01

Expected recruitment end date
2027-09-23, 1406/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Randomized Controlled Trial Comparing the Effectiveness of the Unified Protocol (UP) and Metacognitive Therapy (MCT) on Transdiagnostic Variables in Adults with Posttraumatic Stress Disorder (PTSD).

Public title
A Randomized Controlled Trial Comparing the

Effectiveness of the Unified Protocol (UP) and Metacognitive Therapy (MCT) on Transdiagnostic Variables in Adults with Posttraumatic Stress Disorder (PTSD).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of PTSD based on the SCID-5-CV, in accordance with the DSM-5-TR criteria A score above 31 on the PCL-5 No current use of psychiatric medication; if the participant is taking psychiatric medication, the type and dosage of the medication(s) must have remained stable for at least 8 weeks prior to the start of the intervention, with no changes in the type or dosage of medication(s) throughout the study period No concurrent receipt of psychotherapy (individual or group) during the study Provision of written informed consent to participate in the study

Exclusion criteria:

Substance and alcohol abuse Presence of a severe psychiatric disorder, such as psychotic disorders or bipolar disorder. The SCID-5-CV will be used to assess psychotic and bipolar disorders. Experiencing suicidal ideation or attempting suicide during treatment Severe cognitive or neurological disorders, such as intellectual disability, dementia, or organic brain disorders, that may interfere with effective participation in the intervention Missing more than two treatment sessions

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

After confirming the eligibility criteria and obtaining written informed consent, eligible participants will be randomly allocated in a 1:1 ratio to either the Unified Protocol (UP) or Metacognitive Therapy (MCT) group. The random allocation sequence will be generated using a computer-based randomization procedure.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blinding will be used in this study. Due to the nature of psychological interventions, blinding of participants and therapists to the treatment condition is not feasible. However, the data analyst will be blinded to the participants' group allocation and the type of intervention received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran

Street address

Velenjak Ave.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2026-08-11, 1405/05/20

Ethics committee reference number

IR.SBMU.MSP.REC.1405.341

Health conditions studied

1

Description of health condition studied

Patients with post-traumatic stress disorder (PTSD)

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description

Symptoms of post-traumatic stress disorder (PTSD)

Timepoint

Pre-test (before the start of the intervention), post-test (after completion of the tenth week of the intervention), follow-up (three months after completion of the intervention)

Method of measurement

The PTSD Checklist for DSM-5 (PCL-5)

2

Description

symptoms of depression

Timepoint

Pre-test (before the start of the intervention), post-test (after completion of the tenth week of the intervention), follow-up (three months after completion of the intervention)

Method of measurement
The Patient Health Questionnaire-9

3

Description
Symptoms of anxiety
Timepoint
Pre-test (before the start of the intervention), post-test (after completion of the tenth week of the intervention), follow-up (three months after completion of the intervention)
Method of measurement
A 7-item anxiety scale (GAD-7)

4

Description
Emotion regulation
Timepoint
Pre-test (before the start of the intervention), post-test (after completion of the tenth week of the intervention), follow-up (three months after completion of the intervention)
Method of measurement
Difficulties in Emotion Regulation Scale(DERS)

5

Description
The intolerance of uncertainty
Timepoint
Pre-test (before the start of the intervention), post-test (after completion of the tenth week of the intervention), follow-up (three months after completion of the intervention)
Method of measurement
Intolerance of Uncertainty Scale-12 (IUS-12)

6

Description
Quality of Life
Timepoint
Pre-test (before the start of the intervention), post-test (after completion of the tenth week of the intervention), follow-up (three months after completion of the intervention)
Method of measurement
Assessment of Quality of Life 8 Dimension

7

Description
Client Satisfaction
Timepoint
Pre-test (before the start of the intervention), post-test (after completion of the tenth week of the intervention), follow-up (three months after completion of the intervention)
Method of measurement
Client Satisfaction Questionnaire (CSQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1:lThe Unified Protocol (UP) is a process-based approach that targets shared emotional processes across different psychological disorders, particularly in the treatment of co-occurring emotional disorders. This treatment consists of 10 weekly sessions, each lasting 60–90 minutes, and focuses on addressing core mechanisms such as emotional avoidance, emotion dysregulation, and cognitive errors.The session content is structured around eight core components, including enhancing motivation, psychoeducation, emotional awareness, cognitive restructuring, interoceptive and situational exposure, and relapse prevention. Using cognitive-behavioral and exposure-based techniques, therapists aim to modify clients' maladaptive coping styles and enhance their emotional resilience.This protocol was developed by Barlow and colleagues, and its efficacy has been well documented in populations with post-traumatic stress disorder (PTSD).
Category
Treatment - Other

2

Description
Intervention Group 2: Metacognitive TherapyMetacognitive Therapy (MCT) is designed based on the metacognitive model of emotional disorders. Rather than focusing on the content of thoughts, it targets cognitive processing styles and higher-order beliefs about thoughts. The treatment is delivered over 10 weekly sessions, each lasting 60–90 minutes, and employs techniques such as detached mindfulness, disengagement from perseverative thinking, and the cessation of threat monitoring.The primary goal of treatment is to reduce maladaptive coping strategies, including rumination, chronic worry, cognitive avoidance, and thought suppression. In MCT, positive and negative metacognitive beliefs about rumination and PTSD symptoms are challenged, and clients are gradually guided toward healthier cognitive processing styles.This approach has shown promise, particularly in populations whose disorders are characterized by cognitive avoidance and persistent cognitive engagement.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان شهید طالقانی تهران

Full name of responsible person
Bahareh Moradhasel
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Bahareh Moradhasel
Position
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

PhD dissertation research proposal entitled “A Randomized Controlled Trial Comparing the Effectiveness of the Unified Protocol (UP) and Metacognitive Therapy (MCT) on Posttraumatic Stress Symptoms and Transdiagnostic Variables in Adults with Posttraumatic Stress Disorder (PTSD).” The document includes the study design, methodology, objectives, hypotheses, study variables, and measurement instruments.

When the data will become available and for how long

From the date of research proposal approval until the end of the study implementation period (12 months).

To whom data/document is available

The researcher (PhD student), the supervisor, the consultant, and authorized members of the research team involved in conducting the study. Access to individual participant data will be limited to the purposes of the study and will be subject to confidentiality requirements

Under which criteria data/document could be used

The research documents and data may be used solely for scientific, research, and educational purposes related to the present study and within the approved research objectives. Data use is subject to maintaining participant confidentiality and privacy. Any use of identifiable data, transfer of data to unauthorized individuals, or use beyond the approved research objectives is not permitted.

From where data/document is obtainable

Requests for access to the research documents or data should be addressed to Bahareh Moradhasel, PhD student in Clinical Psychology and the researcher responsible for the study. Requests will be reviewed and approved by the research supervisor, Dr. Hoda Doos-Alivand, in accordance with confidentiality and research ethics requirements.

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

Requests will be reviewed based on the intended purpose of use, the type of requested data or documents, the applicant’s eligibility, and compliance with ethical and confidentiality requirements. If approved, only the minimum necessary data or documents will be provided, with participants’ identifying information removed or anonymized. Where applicable, access will be subject to confidentiality and restrictions on use beyond the approved purpose.

Comments