Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Cognitive Processing Therapy in Post-Traumatic Stress Disorder and Investigating the Mechanism of Symptom Change During Treatment Using Idiographic Network Analysis: A Clinical Trial

Protocol summary

Study aim

To determine the efficacy of cognitive processing therapy in post-traumatic stress disorder (PTSD). To identify the mechanisms of symptom change during treatment using idiographic dynamic network analysis.

Design

The clinical trial has a control group, with parallel groups, single-blinded and randomized on 45 patients. For randomization, the random block method will be used by selecting the sequence of each block using R or Excel software.

Settings and conduct

The location will be in the university clinic. First, a pre-test and then an individual network analysis will be conducted. The intervention will be for the experimental group and continued evaluation, and finally a post-test will be taken and analyzed. Blinding will be for the analysts and the statistical analysis section.

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study included: 1. Diagnosis of post-traumatic stress disorder 2. No history of participating in cognitive processing therapy 3. No substance use disorder 4. Minimum age 18 years 5. Minimum literacy 6. No chronic psychiatric disorders such as bipolar disorder, psychosis spectrum disorders, and serious suicidal thoughts Exclusion criteria included: 1. Failure to participate in more than 3 therapy sessions 2. Newly started psychotherapy or during treatment 3. Failure to complete more than 50% of the questions in the individualized network analysis section

Intervention groups

Intervention group received cognitive processing therapy Usual control group received treatment at the end of the study

Main outcome variables

The outcome of the study is to examine the network of individual symptoms and the effectiveness of cognitive processing therapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251009067560N1**
Registration date: **2025-11-23, 1404/09/02**
Registration timing: **prospective**

Last update: **2025-11-23, 1404/09/02**
Update count: **0**

Registration date

2025-11-23, 1404/09/02

Registrant information

Name

Kamyar Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 0000 0000

Email address

kamyar.mansouri2018@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of Cognitive Processing Therapy in Post-Traumatic Stress Disorder and Investigating the Mechanism of Symptom Change During Treatment Using Idiographic Network Analysis: A Clinical Trial

Public title
Effectiveness of Cognitive Processing Therapy in Post-Traumatic Stress Disorder and Investigating the Mechanism of Symptom Change During Treatment Using Idiographic Network Analysis: A Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1. Diagnosis of post-traumatic stress disorder2. No history of participating in cognitive processing therapy3. No substance use disorder4. Minimum age 18 years5. Minimum literacy6. No chronic psychiatric disorders such as bipolar disorder, psychosis spectrum disorders, and serious suicidal ideation

Exclusion criteria:
1. Failure to attend more than 3 therapy sessions2. Newly started psychotherapy or during treatment3. Failure to complete more than 50% of the questions in the Individualized Network Analysis section

Age
From **18 years** old

Gender
Both

Phase
1

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Method For participant allocation to study groups, block randomization will be used to maintain balance in the number of individuals between experimental and control groups throughout the sampling process. Block randomization is particularly important in studies with relatively small sample sizes, such as the present study, to prevent the accumulation of participants in one group and to ensure that baseline characteristics of participants remain balanced across groups. Method Details Block Size: Given the allocation ratio of 2:1 (experimental group: 30 participants, control group: 15 participants), blocks will consist of three participants, such that in each block, two participants will be assigned to the experimental group and one to the control group. Generation of Random Sequence: For each block, the order of participant allocation will be determined randomly. For example, in a three-participant block, possible sequences could be: Experimental–Control–Experimental Control–Experimental–Experimental Experimental–Experimental–Control The selection of each block's sequence will be performed using software such as R or Excel. Implementation of Randomization: After generating the block sequences, each participant will be assigned to a group according to the order of entry into the study and the predetermined random sequence. This ensures that the number of participants in each group always remains consistent with the specified ratio and that baseline characteristics are balanced. Blinding and Coding: To maintain study impartiality, the randomization sequence will be prepared by an independent researcher, and group codes will be sealed in opaque envelopes or stored in an encrypted electronic system. This ensures that team members administering the intervention remain unaware of group assignments. Advantage of This Method: Block randomization ensures that throughout the study, groups are nearly equal in size and in important baseline variables, thereby reducing error due to unbalanced allocation.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the intervention, complete blinding of participants and intervention providers is not feasible. However, to reduce bias, full blinding of the outcome assessor and the statistical analyst will be implemented. Specifically: The researcher responsible for recruiting participants will become aware of group allocation only after confirming each participant's eligibility, using a sealed envelope or centralized electronic system. Other research team members will not have access to the allocation sequence. The assessor of primary and secondary outcomes (the individual conducting measurements and data collection) will be blinded to participant groupings and will work exclusively using anonymous codes (ID) at all stages. The statistical analyst will receive the dataset only after coding. The analyst will remain blinded to group allocation until the completion of the final analysis. In case of any adverse event or clinical necessity, unblinding will only be permitted with committee approval and proper documentation of the reason. To ensure the integrity of this process, at the end of the study the outcome assessor and the analyst will be asked the standard "guess the group" question to evaluate the success of the blinding.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم توانبخشی و سلامت اجتماعی
Street address
kodakyar Ave, daneshjo Blvd,Evin, Tehran, Iran
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Postal code
1985713871
Approval date
2025-09-02, 1404/06/11
Ethics committee reference number
IR.USWR.REC.1404.120

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 symptoms, anxiety symptoms, depression symptoms, emotion regulation
Timepoint
First, pre-test, daily assessment 4 times a day only for symptoms of post-traumatic stress disorder, post-test, final intervention rejection
Method of measurement
Pre-test and post-test with questionnaire, daily assessment of post-traumatic stress disorder symptoms with ecological momentary assessment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receive 12 sessions of cognitive processing therapy
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
شهر تهران
Full name of responsible person
kamyar mansori
Street address
Koodakyar End, Shahid Shahriari Square, Close
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
kamyar mansouri
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
University of Social Welfare and Rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
kamyar mansouri
Position
P.HD student
Latest degree
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Person responsible for updating data

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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
No further information available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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