

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effectiveness of combination of pharmacotherapy with metacognitive therapy versus pharmacotherapy in patient with posttraumatic stress disorder

Protocol summary

Summary

The aim of this research is to investigate the effectiveness of combination of pharmacotherapy with metacognitive therapy versus pharmacotherapy in patient with posttraumatic stress disorder. Method: six males selected by convenient sampling and randomly assigned to two treatment groups. The methodology is a multiple-baseline experimental single case study. Subjects complete Clinician-Administered PTSD Scale (CAPS), Beck Depression Inventory (BDI-II), Beck Anxiety Inventory (BAI), Subject Unit of Stress (SUDs), at pre-treatment(baseline), treatment (4 and 8 sessions), post-treatment (twelfth) and at follow-up (two months after treatment). Also subjects will complete, Metacognition questionnaire (MCQ-30), General assessment scale (GAFs), at pre-treatment (baseline) and post-treatment. Key word: metacognitive therapy, posttraumatic stress disorder, pharmacotherapy pharmacotherapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060828504N2**
Registration date: **2017-06-27, 1396/04/06**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-27, 1396/04/06

Registrant information

Name

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Name of organization / entity

Zanjan University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Iran University of medical Sciences

Expected recruitment start date

2009-04-25, 1388/02/05

Expected recruitment end date

2009-11-21, 1388/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of combination of pharmacotherapy with metacognitive therapy versus pharmacotherapy in patient with posttraumatic stress disorder

Public title

Effectiveness of combination of pharmacotherapy with metacognitive therapy versus pharmacotherapy in patient with posttraumatic stress disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having a chronic PTSD based on DSM-4 criterias! Do not receive psychological treatment before the study! In the case of using medicine, the possibility of keeping the type and dose of drugs during the study!

Minimum 18 years and maximum 50 years, with at least third level education: The patient agreed to participate in the study and signed a written consent. Exclusion criteria: having a psychotic disorder and substance use disorder: Having full criteria for personality disorder in Axis II: There are risks for the patient such as having serious thoughts of suicide.

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **6**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Shahid mansouri street, niyayesh street, satarkhan street, Tehran

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

1544700

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

Primary outcomes

1

Description

Subjective unit of distress

Timepoint

Pre test, Post test, Follow up (1month), Follow up (2 month)

Method of measurement

Subjective unit of distress scale

2

Description

Anxiety

Timepoint

Pre test, Post test, Follow up (1 month) , Follow up (2 month)

Method of measurement

Beck anxiety inventory

3

Description

PTSD Signs

Timepoint

Pre test, Post test, Follow up (1 month) , Follow up (2 month)

Method of measurement

PTSD Inventory

4

Description

Depression

Timepoint

Pre test, Post test, Follow up(1 month), Follow up(month)

Method of measurement

Beck depression inventory

5

Description

Metacognition

Timepoint

Pre test, Post test, Follow up(1 month), Follow up(2 month)

Method of measurement

Metacognition Questionnaire-30 (MCQ-30)

6

Description

General functioning

Timepoint

Pre test, Post test, Follow up (1 month), Follow up (2 month)

Method of measurement

General assessment of functioning

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group1: (Drug treatment) Patients receive medication in addition, questionnaires: Clinician-Administered PTSD Scale (CAPS), beck anxiety (BAI), beck depression(BDI-II), Metacognition questionare (MCQ-30), subjective units of discomfort(SUDs), complete and general functioning will be assesed.

Category

Treatment - Drugs

2

Description

Intervention group2: Combination of pharmacotherapy with metacognitive therapy: Subjects complete CAPS, BDI-II, BAI, SUDs, MCQ-30, GAFs at pre test, post test and follow up.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Zanjan

Full name of responsible person

Mohsen Dadashi

Street address

Shahid beheshti Hospital, Sadi street, Zanjan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakuti

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Mansouri Street, Niyayesh Street, Sattra khan Street, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mohsen Dadashi

Position

Assistant professor of Zanjan University of Medical Sciences

Other areas of specialty/work

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Full name of responsible person

Mohsen Dadashi

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Assistant professor of Zanjan University of Medical
Sciences

Other areas of specialty/work**Street address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty