

# 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

Vida Yousefi Asl

##### Name of organization / entity

Zanjan University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3342 4766

##### Email address

vida.yousefi@zums.ac.ir

##### 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

Zanjan

## 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

### Street address

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

#### Street address

Department of clinical psychology, Saadi street, zanjan,Iran

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4513615788

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## Person responsible for scientific inquiries

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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****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*