Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

Summary

The aim of this research is to investigate the effectiveness of combination of pharmachothrapy with metacognitive therapy versus pharmachotherapy 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 completeی Clincian-Adminestered 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 questonare (MCQ-30), General assessment scale (GAFs), at pre-treatment (baseline) and post-treatment. Key word: metacognitive therapy, posttraumatic stress disorder, pharmachotherapy pharmachotherapy.

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

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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 pharmachothrapy with metacognitive therapy versus pharmachotherapy in patient with posttraumatic stress disorder

Public title

Effectiveness of combination of pharmachothrapy with metacognitive therapy versus pharmachotherapy 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: Clincian-Adminestered PTSD Scale (CAPS), beck anxiety (BAI), beck depression(BDI-II), Metacognition questonare (MCQ-30), subjective units of discomfort(SUDs), complete and general functioning will be assesed.
Category
Treatment - Drugs

2

Description
Intervention group2: Combination of pharmachothrapy 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
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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