

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effectiveness therapeutic reconsolidation process model (TRP) on executive functions, neuroplasticity and schemas associated with major depressive disorder and post-traumatic stress in veterans over 25% of psychiatric nerves

Protocol summary

Study aim

Determining the effectiveness of the Reintegration Process (TRP) treatment model on improving executive functions, increasing neurological flexibility, and modifying schemas associated with major depressive disorder and post-traumatic stress in veterans over 25% of psychiatric nerves.

Design

The present research is an applied quasi-experimental study as a pre-test-post-test with a control and follow-up group of 45 days. Regular or systematic random sampling of 20 people in each experimental and control groups will be selected from a total of 80 people from Sadr and Niayesh hospitals.

Settings and conduct

The experimental groups are trained for 12 sessions (reintegration process therapy model) in a group manner. 90-minute sessions once a week. The control group does not receive treatment protocols. Meetings will be held at Niayesh and Sadr Hospital

Participants/Inclusion and exclusion criteria

Veterans over 25% Have the signs and symptoms of major depressive disorder and PTSD - Agree to participate in the research and sign a written consent. No symptoms and psychotic disorders Lack of criteria for personality disorders No symptoms of substance abuse.

Intervention groups

veterans over 25% of psychiatric nerves.

Main outcome variables

Executive functions, - Neurological flexibility - Plans related to major depressive disorder - Post-traumatic stress - Veterans over 25% of psychiatric nerves

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220112053702N1**

Registration date: **2023-10-05, 1402/07/13**

Registration timing: **retrospective**

Last update: **2023-10-05, 1402/07/13**

Update count: **0**

Registration date

2023-10-05, 1402/07/13

Registrant information

Name

reza salmanipour noglebari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2217 2020

Email address

reza_salmanipoor@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

2022-01-05, 1400/10/15

Actual recruitment end date

2022-05-20, 1401/02/30

Trial completion date

2022-09-21, 1401/06/30

Scientific title

Evaluation of the effectiveness therapeutic reconsolidation process model (TRP) on executive functions, neuroplasticity and schemas associated with major depressive disorder and post-traumatic stress in veterans over 25% of psychiatric nerves

Public title

therapeutic reconsolidation process model (TRP)

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Veterans over 25% Having the signs and symptoms of major depressive disorder and PTSD - In case of drug use, the possibility of keeping constant the type and amount of drug used during the research

Exclusion criteria:

Having psychotic symptoms and disorders at the discretion of a clinical psychologist or psychiatrist. Having criteria for personality disorders at the discretion of a clinical psychologist or psychiatrist Having symptoms of substance abuse

Age

From **45 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

After compiling the list by regular or systematic random sampling method, using the Kerchsey and Morgan table, 20 people in each experimental and control group, a total of 80 people from Sadr and Niayesh hospitals will be selected.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Working Group / Research Ethics Committee of Islamic Azad University - Sanandaj Branch

Street address

7XXQ+33J, Sanandaj, Kurdistan Province

City

Sanandaj

Province

Kurdistan

Postal code

168

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

IR.IAU.SDJ.REC.1400.021

2**Ethics committee****Name of ethics committee**

کمیته اخلاق در پژوهش بنیاد شهید وامور ایثارگران

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No. 17, Farrokh St., Ardabili moghdasSt

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Province

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Postal code

4720899511

Approval date

1962-07-03, 1341/04/12

Ethics committee reference number

IR.ISAAR.REC.1401.003

Health conditions studied**1****Description of health condition studied**

Post-Traumatic Stress Disorder

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Major Depressive Disorder

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The effectiveness of treatment on major depressive disorder

Timepoint

For 12sessions for 3 months

Method of measurement

Beck Depression Inventory, Second Edition: (BDI 2)

2**Description**

The effectiveness of treatment on Post traumatic Stress Disorder

Timepoint

For 12 sessions for 3 months

Method of measurement

(The Post Traumatic Stress Disorder CheckList / PCL

3

Description

Effectiveness of treatment on executive function and flexibility and schemas associated

Timepoint

For 12 sessions for 3months

Method of measurement

WCST /Stroop test/Leahy Emotional Schemas

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Other

2

Description

Control group:

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurological Psychiatric Hospital

Full name of responsible person

DR. Danashmand

Street address

No. 1, Golestan St., No. 1, Niayesh Psychiatric Hospital, Baghestan 1st St., Saadat Abad, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Veterans Engineering and Medical Sciences Research Institute

Full name of responsible person

Dr. Javad Minavi

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No. 17, Farrokh St., Moqaddas Ardabili St., Yemen St., Jamran Highway, Tehran

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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

Veterans Engineering and Medical Sciences Research Institute

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Veterans Engineering and Medical Sciences Research Institute

Full name of responsible person

Reza salmanipoor

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Psychology

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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

Part of the data

When the data will become available and for how long

Six months after printing

To whom data/document is available

For academic researchers

Under which criteria data/document could be used

In PDF format

From where data/document is obtainable

Veterans Engineering and Medical Sciences Research Institute

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

Administrative correspondence after 15 days

Comments