

# 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

**Street address**

No. 17, Farrokh St., Ardabili moghdasSt

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**Province**

Tehran

**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

##### **City**

Tehran

##### **Province**

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##### **Postal code**

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##### **Email**

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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

##### **Street address**

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

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##### **Email**

jminooefar@yahoo.com

#### **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 salmanipour

##### **Position**

Research Expert

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Psychology

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## Person responsible for scientific inquiries

### Contact

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Veterans Engineering and Medical Sciences Research Institute  
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## Person responsible for updating data

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**Full name of responsible person**  
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**Latest degree**  
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REZA\_SALMANIPOOR@YAHOO.COM

## 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