

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison of the effectiveness of interpersonal psychotherapy with cognitive behavioral therapy on alexithymia, emotional regulation and psychological capital of male Substance abuser

#### Protocol summary

##### Study aim

Comparison of the effect of cognitive behavioral therapy with interpersonal psychotherapy on alexithymia, emotional regulation and psychological capital of male substance abusers referred to addiction treatment centers in Kerman.

##### Design

Clinical trial with 2 experimental groups: interpersonal psychotherapy and cognitive behavioral therapy and a control group, Double blind, randomized using random number table and concealment (numbered, sealed and opaque envelopes) And has a volume of 75 people.

##### Settings and conduct

This double-blind clinical trial was performed in the field of substance abuse and in addiction treatment centers in Kerman. At first, a center (Moein center) was randomly selected. Then, 75 participants in this center were randomly selected using a random number table, and randomly and concealed (numbered, sealed and opaque envelopes) using a random number table by an individual Unaware of the objectives of the research, they were assigned into two experimental groups and a control group.

##### Participants/Inclusion and exclusion criteria

Admission Requirements: Being a substance abuser based on Diagnostic and Statistical Criteria for Mental Disorders Version 5, absence of severe mental disorder, having a minimum education of primary school level, and willingness to participate in research. Exclusion criteria: Absence of more than two sessions and unwillingness to continue participating in the research.

##### Intervention groups

Interpersonal psychotherapy training package according to the book "Interpersonal psychotherapy A quick guide for the therapist", Author: Mirna Weiss Man et al., Translator: Mehdi Dadashi et al. (2012) For the experimental group a, "Carl Cognitive Behavior Therapy

Training Package" for Experimental Group b, the control group won't receive any intervention.

##### Main outcome variables

Alexithymia scores; Emotional regulation scores and psychological capital scores.

#### General information

##### Reason for update

##### Acronym

IPT and CBT

##### IRCT registration information

IRCT registration number: **IRCT20211113053052N1**

Registration date: **2021-12-27, 1400/10/06**

Registration timing: **retrospective**

Last update: **2021-12-27, 1400/10/06**

Update count: **0**

##### Registration date

2021-12-27, 1400/10/06

##### Registrant information

##### Name

Ali Saeedi Rashk olya

##### Name of organization / entity

Islamic Azad University, Zarand Branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3212 0723

##### Email address

a.manzari@iauk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

**Expected recruitment end date**

2021-08-06, 1400/05/15

**Actual recruitment start date**

2021-05-22, 1400/03/01

**Actual recruitment end date**

2021-08-16, 1400/05/25

**Trial completion date**

2021-08-16, 1400/05/25

**Scientific title**

Comparison of the effectiveness of interpersonal psychotherapy with cognitive behavioral therapy on alexithymia, emotional regulation and psychological capital of male Substance abuser

**Public title**

Comparison of the effectiveness of interpersonal psychotherapy with cognitive behavioral therapy on alexithymia, emotional regulation and psychological capital of male Substance abuser

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being a substance abuser according to Diagnostic and Statistical Manual of Mental Disorders, 5th Edition criteria  
Absence of severe mental disorders having a minimum education of primary school level  
Willingness to participate in the study  
Age between 15 to 50 years

**Exclusion criteria:**

Absences of more than two sessions unwillingness to continue participating in research

**Age**

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

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **75**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To conduct this research, first a list of addiction treatment centers was prepared. Then, a center was selected for research using a simple random method (lottery) based on the names of the centers, by a person who was not aware of the objectives of the project. this person will randomly select 75 of the center's clients using a random number table. Again in a simple random method, using a random number table and a concealment method (numbered, sealed and opaque envelopes), this person will assign the participants into experimental and control groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants in the experimental group will not aware about the control group. They will also initially be unaware of which group they belong to. Questionnaires will be completed under the supervision of an individual unaware of the objectives of the research. The analyzer is only aware of the hypotheses, and the data will be provided to him with sufficient supervision.

**Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Islamic Azad University, Kerman Branch

**Street address**

Islamic Azad University, Kerman Branch, Valiasr Blvd., Kerman

**City**

kerman

**Province**

Kerman

**Postal code**

۷۶۳۵۱۳۱۱۶۷

**Approval date**

2021-05-12, 1400/02/22

**Ethics committee reference number**

IR.IAU.KERMAN.REC.1400.012

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

substance abusers

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

Alexithymia score in Toronto alexithymia scale

**Timepoint**

Evaluation of alexithymia (before intervention), 42 days after intervention (post-test) .

**Method of measurement**

Toronto Alexithymia scale (TAS-20)

## 2

### **Description**

Emotion regulation score in the cognitive emotional regulation questionnaire

### **Timepoint**

Evaluation of emotional regulation (before intervention), 42 days after intervention (post-test).

### **Method of measurement**

Cognitive emotional regulation questionnaire developed by Garnowski.

## 3

### **Description**

Psychological capital score in the Luthans psychological capital questionnaire

### **Timepoint**

Evaluation of Psychological capital (before intervention), 42 days after intervention (post-test).

### **Method of measurement**

Psychological capital questionnaire 24 developed by Luthans

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The intervention group a: In this study, interpersonal psychotherapy training was taught to participants in twelve sessions per 42 days.

#### **Category**

Treatment - Other

### 2

#### **Description**

The intervention group b: In this study, participants were taught a cognitive behavioral therapy training package in ten sessions per 35 days.

#### **Category**

Treatment - Other

### 3

#### **Description**

The control group: The control group did not receive any intervention.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Moein substance abuse treatment center.

#### **Full name of responsible person**

Dr. Naser Ebrahimpour

#### **Street address**

Moin Addiction Treatment Center, between 24th and 26th Alley, above Dr. Mollai Pharmacy, Shahid Mostafa Khomeini St., Kerman

#### **City**

kerman

#### **Province**

Kermanshah

#### **Postal code**

7617669845

#### **Phone**

+98 34 3323 8533

#### **Fax**

#### **Email**

nasser.ebrahimpour@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

nasser.ebrahimpour@gmail.com

##### **Street address**

Islamic Azad University, Zarand Branch, Sarbagh Road, University Square, Zarand city, Kerman

##### **City**

zarand

##### **Province**

Kerman

##### **Postal code**

7761146595

##### **Phone**

+98 34 2425 0856

##### **Fax**

+98 34 3345 0855

##### **Email**

Hamid.molayi@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Islamic Azad University

#### **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**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ali Saeedi Rashk Olya

**Position**

PhD Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

3rd North dead end, No. 30, Komeil Ave., Jomhuri Blvd.

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**Postal code**

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**Phone**

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**Email**

ali.saeedi1352@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ali Saeedi Rashk olya

**Position**

PhD Candidate

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Islamic Azad University

**Full name of responsible person**

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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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All documents of this study include: information about the main outcomes of the study, statistical analysis map, informed consent form and clinical study report, in a file entitled: "Comparison of the effectiveness of interpersonal psychotherapy with cognitive-behavioral therapy on alexithymia, emotional regulation and psychological capital in substance abusers", can be shared.

**When the data will become available and for how long**

The start of the access period is 6 months after the results are published.

**To whom data/document is available**

Researchers working in academic and scientific institutions as well as officials of addiction treatment centers can apply for the file.

**Under which criteria data/document could be used**

Those who receive this file can use the data and results in addiction treatment centers and conduct research.

**From where data/document is obtainable**

Applicants can send their application to the e-mail address: ali.saeedi1352@yahoo.com to receive the documents.

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

Send your request to receive the research documentation file to the e-mail:

ali.saeedi1352@yahoo.com. after reviewing, the requested documents and data will be sent to your e-mail within 72 hours.

**Comments**