

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

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zarand

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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

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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

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