

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the effectiveness of emotion-focused therapy and schema therapy on self-efficacy, impulsivity, shame and self-blame of addicts with Methadone Maintenance Therapy.

Protocol summary

Study aim

Comparing the effectiveness of emotion-oriented treatment and schema therapy on self-efficacy, impulsivity, shame and self-blame of addicts with methadone maintenance treatment.

Design

The addicts of three clinics in Tehran region 5 are the statistical sample of the present study. And sampling will be done by multi-stage cluster random sampling method. In this way, from the list of all addiction treatment clinics in Tehran, which was prepared in cooperation with the Tehran Medical Science Center, 3 clinics will be randomly selected from the addiction treatment clinics in the 5th district of Tehran using a table of random numbers.

Settings and conduct

The location of the study was three clinics located in the 5th district of Tehran and three groups, two of which were intervention and one control, were selected by one-sided blinding method and work therapy was performed in two experimental groups.

Participants/Inclusion and exclusion criteria

Entry criteria: people whose main use of substances: heroin, opium, juice, and crack for 5 to 10 years and their only method of use is smoking will be selected.

Intervention groups

experiment 1: emotion-oriented therapy, experiment 2: schema therapy and a control and follow-up group three months. At the end of the research, the four mentioned questionnaires will be taken as a post-test

Main outcome variables

Self-efficacy, impulsivity, shame and self-blame of addicts are considered the main outcomes of this research because they are the variables that are measured, which is expected in the current research considering the background of the research, the effectiveness of the two treatments schema therapy and emotion-oriented on these four variables. show

significance with the control group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220807055632N1**

Registration date: **2022-10-03, 1401/07/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-03, 1401/07/11**

Update count: **0**

Registration date

2022-10-03, 1401/07/11

Registrant information

Name

Bitas Salasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4411 2064

Email address

bt.salasi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-24, 1401/07/02

Expected recruitment end date

2022-10-24, 1401/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of emotion-focused therapy and schema therapy on self-efficacy, impulsivity, shame and self-blame of addicts with Methadone Maintenance Therapy.

Public title

Comparison of the effectiveness of emotion-focused therapy and schema therapy of addicts with Methadone Maintenance Therapy.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Entry criteria: In the initial screening, only people whose main use of substances: heroin, opium, juice, and crack for 5 to 10 years and their only method of use is smoking will be selected. The participants in the study must have been on maintenance treatment with methadone for one year and must not have used any other substance. Other inclusion criteria include receiving a diagnosis of only using methadone maintenance treatment by the clinic doctor, free willingness to participate in treatment sessions, education level of at least first high school, exclusion criteria: suffering from other disorders (such as schizophrenia, bipolar disorder, obsessive compulsive disorder), alcohol consumption, The use of other drugs, use of antidepressants, refusal to participate in treatment sessions, as well as the medical background of the people participating in the research will be carefully examined in terms of underlying physical diseases and will be examined by the clinic doctor, and diabetic patients, heart patients, cancer patients, and liver patients And patients who are taking drugs that increase the risk of overdose with methadone will be excluded from the study.

Exclusion criteria:**Age**

From **18 years** old to **54 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

The research population is all drug addiction treatment clinics in Tehran, which were selected by multi-stage cluster sampling method, first from the entire list of drug addiction treatment clinics using the table of random numbers in Region 5 of Tehran, and three clinics were randomly selected from the list of all clinics in Region 5. and after matching in terms of age, education, and gender, they will be randomly assigned in three groups:

schema therapy, emotion-oriented therapy, and the control group. The studied sample includes 54 clients (27 women and 27 men) who receive maintenance treatment with methadone and will refer to addiction treatment clinics in 5th district of Tehran between 1401-1402. 18 people for the first test group, 18 people for the second test group and 18 people for the control group will be randomly assigned.

Blinding (investigator's opinion)

Single blinded

Blinding description

After fully explaining the objectives of the study and giving full knowledge of the absence of any risk for the participants and respect for individuals and independence in making decisions and obtaining an informed consent form, in this study, clinical samples were divided into three groups using one-way blinding method.)): that is, the samples were kept unaware of being assigned to the intervention groups 1 and 2 and the control group, that is, the sample did not know whether it was in the schema therapy or emotion-oriented or control group, but the researcher was doing the treatment and evaluation. He was fully aware of the experimental and control conditions in the three groups.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

کمیته اخلاق دانشگاه آزاد اسلامی واحد سمنان

Street address

Tehran - Ferdous Gharb - Northern Bahar St. -
Manochehri Gharbi - Ezzati Alley - Plate 33 - Unit 4

City

semnan

Province

Semnan

Postal code

1484757981

Approval date

2022-09-26, 1401/07/04

Ethics committee reference number

IR.IAU.SEMNAN.REC.1401.036

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

Addicts undergoing maintenance treatment with methadone

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

self-efficacy

Timepoint

6 weeks

Method of measurement

Sharr self-efficacy questionnaire

2

Description

impulsivity

Timepoint

6 weeks

Method of measurement

Barat impulsivity questionnaire

3

Description

shame

Timepoint

6 weeks

Method of measurement

guilt and shame Cohen Questionnaire

4

Description

self blame

Timepoint

6 weeks

Method of measurement

The self-criticism questionnaire of Gilbert et al

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Schema therapy according to the treatment protocol for 12 sessions, twice a week, on addicts with methadone maintenance treatment

Category

Treatment - Other

2

Description

Second Intervention group: Emotion-Focused Therapy according to the treatment protocol for 12 sessions, i.e. twice a week, on addicts with methadone maintenance treatment.

Category

Treatment - Other

3

Description

Control group: In the three selected groups, the first intervention: schema therapy, the second intervention: emotion-oriented therapy without intervention of the control group. The third group is the control group, which did not receive any treatment, and filled the four mentioned questionnaires in the pre-test and post-test without any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Pendar Nu addiction treatment center

Full name of responsible person

Shohreh Shahriyari

Street address

Janat Abad Central St., above Hammet highway,
Touba building, 5th floor, unit 506

City

Tehran

Province

Tehran

Postal code

1475634813

Phone

+98 21 4448 8913

Email

Shohreh.shahri@gmail.com

2

Recruitment center

Name of recruitment center

Jantabad addiction treatment center

Full name of responsible person

Hossein Azari

Street address

Jenatabad Central St., above Hammet highway, Sina
Building, Unit 192

City

Tehran

Province

Tehran

Postal code

1475687611

Phone

+98 21 4444 5666

Email

Azari.H@gmail.com

3

Recruitment center

Name of recruitment center

Better future addiction treatment center

Full name of responsible person

Parviz Azarm

Street address

Simon Bolivar, the beginning of Shahid Fakuri St.,
Sepehr Building, Unit 3

City

Tehran

Province

Tehran

Postal code

1477684955

Phone

+98 21 4482 2420

Email

Dr.Pa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Semnan Branch

Full name of responsible person

Bitas Salasi

Street address

Ferdous Gharb St., Nasser Hejazi St., North Bahar St.,
No. 33, Ezzati Alley

City

Tehran

Province

Tehran

Postal code

1484757981

Phone

+98 21 4411 2064

Email

bt.salasi@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University, Semnan Branch

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Bitas Salasi

Position

phd student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Ferdous Gharb St., Nasser Hijazi St., North Bahar St.,
West Manochehri St., Ezzati Alley, No. 33

City

Tehran

Province

Tehran

Postal code

1484757981

Phone

+98 21 4411 2064

Email

bt.salasi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University, Semnan branch

Full name of responsible person

Bitas Salasi

Position

Phd Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Ferdous Gharb St., Nasser Hijazi St., North Bahar St.,
West Manochehri St., Ezzati Alley, No. 33, Islamic
Azad University, Semnan Branch

City

Tehran

Province

Tehran

Postal code

1484757981

Phone

+98 21 4411 2064

Email

bt.salasi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University, Semnan branch

Full name of responsible person

Bitu Salasi

Position

Phd Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Unit 33, Ferdous Gharb St., Nasser Hejazi St., West Manouchehri St., Ezzati Alley

City

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Province

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Postal code

1484757981

Phone

+98 21 4411 2064

Email

bt.salasi@gmail.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

Undecided - It is not yet known if there will be 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

All the data of this study before and after the presentation of schema therapy and emotion-oriented therapy in the form of a questionnaire in the four variables of self-efficacy, impulsivity, shame and self-blame, and only the demographic information of each clinical sample, which includes age, education and gender, It is given accurately and the name and surname are recorded as a pseudonym. The informed consent form was filled by all people before the implementation of the treatment protocol.

When the data will become available and for how long

This research is my doctoral thesis that will be defended in March 1401 and the articles extracted from this research will probably be published and accessible after about 6 months.

To whom data/document is available

All researchers interested in the field of psychology, especially in the field of addiction, and other interdisciplinary researchers can use these data.

Under which criteria data/document could be used

The Excel file of the raw data collected in the research as well as the descriptive and inferential analysis is available by spss software.

From where data/document is obtainable

All data are available in the researcher's archive.

Researcher's email address: bt.salasi@gmail.com Postal address: Ezzati Alley, Unit 33, Nasser Hijazi St., West Ferdous Gharb St., Manouchehri West, Tehran

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

It is enough for him to send a Gmail and present his goals for having the data in a justified manner, and it will be sent immediately after verification. 33

Comments

This research, with clear and accurate data and documentation, with the aim of finding effective psychological treatments, tries to know more effective solutions to solve the serious pathological problem of addiction.