

# 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**

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**Street address**

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**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

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### 2

**Recruitment center**

**Name of recruitment center**

Jantabad addiction treatment center

**Full name of responsible person**

Hossein Azari

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### 3

#### Recruitment center

**Name of recruitment center**

Better future addiction treatment center

**Full name of responsible person**

Parviz Azarm

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Sepehr Building, Unit 3

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### Sponsors / Funding sources

#### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University, Semnan Branch

**Full name of responsible person**

Bitas Salasi

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**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

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### Person responsible for scientific inquiries

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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**

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.