

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of effectiveness of cognitive-behavioral therapy and therapy based on commitment and acceptance on coping strategies with stress, feeling of psychological cohesion and intimacy of couples in opioid addicts under methadone maintenance treatment

#### Protocol summary

##### Study aim

Comparison of the effectiveness of cognitive-behavioral therapy with commitment-based therapy and acceptance on coping strategies with stress, psychological cohesion and intimacy of couples in opioid addicts under methadone maintenance treatment.

##### Design

The clinical trial will be conducted with two intervention groups and one control group, with 20 people in each group, with random grouping.

##### Settings and conduct

As stated, this study will be conducted in three groups of 20 people (two intervention groups and one control group) from among addicted couples undergoing treatment in addiction treatment centers in Kerman city, which were randomly selected as available samples. Lotteries are placed in test groups. Then, in 12 intervention sessions, two groups are taught the principles and techniques of cognitive behavioral therapy and commitment-based therapy. The third group enters the post-test stage without the slightest intervention along with the two intervention groups.

##### Participants/Inclusion and exclusion criteria

Low score in the problem-oriented coping strategies questionnaire; Low score on the couple intimacy questionnaire; Low score on the Mental Cohesion Questionnaire; Absence of psychotic and paranoid disorders in subjects; Receive voluntary and informed consent; At least a year has passed since their addiction; People addicted to methadone maintenance treatment; Have at least a diploma

##### Intervention groups

First intervention group: cognitive behavioral therapy; The second intervention group: treatment based on commitment and acceptance; Control group: no training to subjects

##### Main outcome variables

strategies to deal with stress; psychological coherence; Intimacy of couples

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220520054933N1**

Registration date: **2022-08-19, 1401/05/28**

Registration timing: **retrospective**

Last update: **2022-08-19, 1401/05/28**

Update count: **0**

##### Registration date

2022-08-19, 1401/05/28

##### Registrant information

##### Name

saleh ghiasi nejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3251 4448

##### Email address

saleh.g1992@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-27, 1401/05/05

##### Expected recruitment end date

2022-08-11, 1401/05/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of effectiveness of cognitive-behavioral therapy and therapy based on commitment and acceptance on coping strategies with stress, feeling of psychological cohesion and intimacy of couples in opioid addicts under methadone maintenance treatment

**Public title**

Comparison of effectiveness of cognitive-behavioral therapy and therapy based on commitment and acceptance on coping strategies with stress, feeling of psychological cohesion and intimacy of couples in opioid addicts under methadone maintenance treatment

**Purpose**

Education/Guidance

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

Low score in the problem-oriented coping strategies questionnaire  
 Low score on the couple intimacy questionnaire  
 Low score on the Mental Cohesion Questionnaire  
 Absence of psychotic and paranoid disorders in subjects  
 Receive voluntary and informed consent  
 At least a year has passed since their addiction  
 People addicted to methadone maintenance treatment  
 Have at least a diploma  
 Married

**Exclusion criteria:**

Single illiterate  
 Substance dependent individuals treated with other treatments than methadone  
 People with psychotic and paranoid disorders  
 High score in psychological coherence questionnaire  
 High score in couple intimacy questionnaire  
 A high score in the problem-oriented stress coping strategies questionnaire

**Age**From **18 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sample consisted of 60 opiate addicts treated with methadone in 3 months of summer 1401 with inclusion criteria and available sampling of 60 people and in the form of simple random allocation so that the samples are numbered and entered in Excel software from 1 to 60, respectively. And then with the data analysis plugin sampling tools the numbers are accidentally messed up and From row 1 to 20, an intervention group from row 21 to 40 will be placed in an intervention group and from row 41 to 60 of the control group.

**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**

Research ethics committee of Islamic Azad University, Kerman branch

**Street address**

No. 37, Alley 45, North Obzar Street

**City**

Kerman

**Province**

Kerman

**Postal code**

7617773793

**Approval date**

2022-02-20, 1400/12/01

**Ethics committee reference number**

IR.IAU.KERMAN.REC.1400.030

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

opioid addicts under methadone maintenance treatment

**ICD-10 code**

F11

**ICD-10 code description**

Opioid related disorders

**Primary outcomes****1****Description**

People's scores in Endler's stress coping strategies questionnaire

**Timepoint**

Measuring stress coping strategies at the beginning of the study and after 12 weeks at the end of the intervention

**Method of measurement**

Endler's stress coping strategies questionnaire

**2****Description**

People's scores in the Flensburg Coherence Questionnaire

### **Timepoint**

Measuring the sense of psychological coherence at the beginning of the study and after 12 weeks at the end of the intervention

### **Method of measurement**

Flensburg sense of coherence questionnaire

## **3**

### **Description**

People's scores in the Walker and Thomson Marital Intimacy Questionnaire

### **Timepoint**

Measuring the feeling of marital intimacy at the beginning of the study and after 12 weeks at the end of the intervention

### **Method of measurement**

Walker and Thomson Marital Intimacy Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

The first intervention group: cognitive behavioral therapy, by teaching the techniques and principles of this therapy in 12 sessions, we help patients to understand the thoughts and feelings that affect their behavior.

#### **Category**

Treatment - Other

### **2**

#### **Description**

The second intervention group: therapy based on commitment and acceptance, which consists of 4 approaches: awareness, acceptance, commitment, and behavior change, and in 12 sessions, by teaching related principles and techniques, we try to create people's psychological flexibility in such a way that they need it is not to remove or eliminate the bad feeling, but despite the existence of this feeling, the person should move towards value-based behavior

#### **Category**

Treatment - Other

### **3**

#### **Description**

Control group: no training to the subjects, who during these 12 sessions that are taught to the two intervention groups, this group does not receive any training.

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Pars Drug Abuse Treatment Center

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

Mojtaba Ebrahim Nejad

##### **Street address**

Firuzeh Crossroads

##### **City**

Kerman

##### **Province**

Kerman

##### **Postal code**

7617783494

##### **Phone**

+98 913 987 1955

##### **Email**

ap.sbuk@gmail.com

### **2**

#### **Recruitment center**

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

Mahta Substance Abuse Treatment Center

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

Mojtaba Ebrahim Nejad

##### **Street address**

Mofateh St. has not reached the Daneshjo Intersection

##### **City**

Kerman

##### **Province**

Kerman

##### **Postal code**

7617783494

##### **Phone**

+98 913 987 1955

##### **Email**

ap.sbuk@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Islamic Azad University

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

Dr. Hamid Molaei

##### **Street address**

Kerman Branch, Islamic Azad University, Waliasr Blvd.

##### **City**

Kerman

##### **Province**

Kerman

##### **Postal code**

7635168111

##### **Phone**

+98 34 3321 0043

**Email**  
Saleh.g1992@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**  
Saleh Ghiasi Nejad

**Position**  
PhD student in psychology

**Latest degree**  
Master

**Other areas of specialty/work**  
Psychology

**Street address**  
No. 37, Alley 45, North Obzar Street

**City**  
Kerman

**Province**  
Kerman

**Postal code**  
7617773793

**Phone**  
+98 34 3251 4448

**Email**  
Saleh.g1992@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Dr. Alireza Manzari Tavakoli

**Position**  
Associate Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Psychology

**Street address**

Kerman Branch, Islamic Azad University, Waliasr Blvd.

**City**  
Kerman

**Province**  
Kerman

**Postal code**  
7635168111

**Phone**  
+98 34 3321 0043

**Email**  
a.manzari@iauk.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Saleh Ghiasi Nejad

**Position**  
PhD student in psychology

**Latest degree**  
Master

**Other areas of specialty/work**  
Psychology

**Street address**  
No. 37, Alley 45, North Obzar Street

**City**  
Kerman

**Province**  
Kerman

**Postal code**  
7617773793

**Phone**  
+98 34 3251 4448

**Email**  
Saleh.g1992@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

No - There is not 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

The raw data file extracted from the questionnaires  
Statistical data analysis file

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

The access period starts 8 months after the results are published

### To whom data/document is available

Only for researchers and employees in academic institutions

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

In order to use these data during communication, necessary arrangements are made regarding the permitted analysis. They can only be used for academic research

**From where data/document is obtainable**

They can make necessary arrangements to receive data

by sending emails and communicating.

Saleh.g1992@gmail.com 09132479877

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

After the request is made by the applicant and confirmation is received from the supervisor, the data file is sent via email

**Comments**