

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

AgeFrom **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

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2

Recruitment center

Name of recruitment center

Mahta Substance Abuse Treatment Center

Full name of responsible person

Mojtaba Ebrahim Nejad

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Hamid Molaei

Street address

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr. Alireza Manzari Tavakoli

Position
Associate Professor

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Other areas of specialty/work
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Person responsible for updating data

Contact

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Position
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Other areas of specialty/work
Psychology

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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

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