

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of short cognitive - behavioral therapy on addicts' mental health in comparison to control group

Protocol summary

Study aim

Effectiveness of short cognitive - behavioral therapy on opium addicts' mental health

Design

Randomized Controlled Trial with parallel groups

Settings and conduct

This study is a randomized clinical trial conducted in Ahvaz drop in center. The study population is addicts referring to this center, which according to previous studies and using Morgan table, sample size of 36 person has been calculated. They will divided into 2 equal groups of 18 person as intervention and control groups using random number table. Both groups will be on Methadone maintenance therapy. GHQ 28 questionnaire will be completed by both groups. The intervention group will receive 4 session of 90 minutes cognitive-behavioral therapy in accordance to the Ministry of Health's Cognitive-Behavioral Therapy Protocol and drop-in centers Action Plan. Finally, using the GHQ 28 questionnaire, mental health status in the areas of depression, anxiety, somatization and social performance will be compared in each group.

Participants/Inclusion and exclusion criteria

Addiction to opium

Intervention groups

This Study consist of 2 groups including intervention and control groups. Both groups are on Methadone maintenance therapy. While the intervention group will receive four 90 minutes cognitive behavioral therapy sessions, but the control group will not.

Main outcome variables

Mental health status; Depression; Anxiety; Somatization; Social performance based on GHQ 28 questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190929044917N1**

Registration date: **2020-01-13, 1398/10/23**

Registration timing: **prospective**

Last update: **2020-01-13, 1398/10/23**

Update count: **0**

Registration date

2020-01-13, 1398/10/23

Registrant information

Name

Seyed Mohammad Amin Alavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3338 9541

Email address

alavi.sma@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of short cognitive - behavioral therapy on addicts' mental health in comparison to control group

Public title

Effectiveness of short cognitive - behavioral therapy on addicts' mental health

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Addiction to opium

Exclusion criteria:

No exclusion criteria

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, individual, using table of random numbers, assign by third party for allocation concealment

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 Golestan Educational, Research and Medical Center

Street address

Research Ethics Committee, Golestan Hospital, Golestan Blvd., Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2019-12-30, 1398/10/09

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1398.025

Health conditions studied

1

Description of health condition studied

Mental health in opioid addiction

ICD-10 code

F11.1

ICD-10 code description

Opioid abuse

Primary outcomes

1

Description

General Health Score

Timepoint

Before intervention and 2 weeks after intervention(after 4 session of cognitive behavioral therapy)

Method of measurement

GHQ-28 Questionnaire

2

Description

Depression Score

Timepoint

Before intervention and 2 weeks after intervention(after 4 session of cognitive behavioral therapy)

Method of measurement

GHQ-28 Questionnaire

3

Description

Anxiety Score

Timepoint

Before intervention and 2 weeks after intervention(after 4 session of cognitive behavioral therapy)

Method of measurement

GHQ-28 Questionnaire

4

Description

Somatization Score

Timepoint

Before intervention and 2 weeks after intervention(after 4 session of cognitive behavioral therapy)

Method of measurement

GHQ-28 Questionnaire

5

Description

Social Performance Score

Timepoint

Before intervention and 2 weeks after intervention(after 4 session of cognitive behavioral therapy)

Method of measurement

GHQ-28 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: short cognitive behavioral therapy accordance to the Ministry of Health's Cognitive-Behavioral Therapy Protocol and drop-in centers Action Plan for 90 minutes in 4 sessions during 2 weeks

Category

Behavior

2

Description

Control group: without any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Drop-in Center

Full name of responsible person

Ashraf Falahi

Street address

No. 96, 7th St. , Asiye Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Ground Floor, Chancellor of Research and Technology Development, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Golestan

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Email

itc@ajums.ac.ir

Web page address

http://vchresearch.ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

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

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Davasaz Irani

Position

Head of Mental health, Social and Addiction Unit

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Sirus Pakseresht

Position
Assistant Professor

Latest degree
Specialist

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Psychiatrics

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Student

Latest degree
Bachelor

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General Practitioner

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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

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

Information about main outcome or similar can be shared.

When the data will become available and for how long

Available access 6 months after the publication of results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Under ethical considerations

From where data/document is obtainable

Seyed Mohammad Amin Alavi

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

Communicate with the responsible person

Comments