

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of supportive-educational group therapy on the level of self-care in clients under MMT methadone

Protocol summary

Study aim

the determining effect of supportive-educational therapy group on the level of self-care in clients undergoing methadone treatment.

Design

This study is a parallel clinical trial with an experimental and control group.

Settings and conduct

Study Subjects Drug users now receiving methadone in MMT centers. These people will be selected from MMT clinics in Khorram Abad-Lorestan after obtaining informed consent and will be organized into two groups. One group received self-care training and the other group received no training.

Participants/Inclusion and exclusion criteria

Willingness to participate in the study, at least six months of methadone use, age over 18 years and not having a mental illness, and withdrawal criteria for withdrawing from participating in the study, in case of absenteeism for several sessions, were determined.

Intervention groups

Educational-supportive intervention for the intervention group in 8 supportive-educational group therapy sessions of 5.1/5 hours (the topics of the session will be designed based on past studies as well as authentic books. The control group will receive only the usual interventions of drug abuse clinics.

Main outcome variables

self care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221106056412N1**

Registration date: **2023-01-25, 1401/11/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-25, 1401/11/05**

Update count: **0**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name

Amir Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3845 6866

Email address

jalali_amir@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive-educational group therapy on the level of self-care in clients under MMT methadone

Public title

The effect of supportive-educational group therapy on the level of self-care in clients under MMT methadone

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

willingness to participate in the study, At least six months of methadone use Age above 18 years Not having a mental illness

Exclusion criteria:
The only condition for withdrawal from the study was defined as being absent for several sessions.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done using the block method and with blocks of size 4 and 6 by the methodology consultant

Blinding (investigator's opinion)
Single blinded

Blinding description
Unlabeled codes are entered into the data and the data is analyzed blindly.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics in Research of Kermanshah University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Isar Square, Bahnar Blvd, Dolatabad Town

City

kermanshah

Province

Kermanshah

Postal code

6719851351

Approval date

2022-08-23, 1401/06/01

Ethics committee reference number

IR.KUMS.REC.1401.227

Health conditions studied

1

Description of health condition studied

Drug users

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

Primary outcomes

1

Description

Self- care

Timepoint

Self-care measurement will be done at the beginning of the study (before the start of the intervention) and after 8 weeks after the start of the intervention.

Method of measurement

The self-care ability questionnaire is based on Orem's self-care model, which was used for the first time in the research of Moghadamnia et al. (2014), and it is used to measure self-care ability and mental health self-care.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, addiction treatment is conducted in 8 sessions of group therapy with a supportive educational approach for 90 minutes and one session every week for the clients of the intervention group in addition to the usual interventions of the clinics. Group therapy sessions are held in each session with topics such as drug abuse, lifestyle, relapse, treatment and rehabilitation process, and other issues.

Category

Lifestyle

2

Description

Control group: The control group will receive only the usual interventions of addiction treatment clinics.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Taravat Methadone Maintenance Treatment clinic

Full name of responsible person

Amir Jalali

Street address

Taravat MMT Clinic, second floor,Razi St, next to Sina Pharmacy

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Khorramabad

Province

Lorestan

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6816166667

Phone

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Email

jalali_amir@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Cyrus Jalili

Street address

No. 2,Medical Sciences Building,Research and Technology Vice-Chancellor,Beheshti Blvd.

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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

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Amir Jalali

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The report will be provided only in the form of printed articles in scientific journals.

When the data will become available and for how long

The report will be provided only in the form of printed articles in scientific journals.

To whom data/document is available

The report will be provided only in the form of printed articles in scientific journals.

Under which criteria data/document could be used

The report will be provided only in the form of printed articles in scientific journals.

From where data/document is obtainable

The report will be provided only in the form of printed articles in scientific journals.

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

The report will be provided only in the form of printed articles in scientific journals.

Comments

Considering that in the above sections, we have not agreed to share, but in the lower sections, we have been asked to provide explanations, which has caused confusion.