Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
City
Khorramabad
Province
Lorestan
Postal code
6816166667
Phone
+98 66 3342 5534
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.
City
Kermanshah
Province
Kermanshah
Postal code
6714673159
Phone
+98 83 3839 3154
Fax
+98 83 3838 6835
Email
jalali_amir@yahoo.com
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
Street address
Faculty of Nursing and Midwifery, Isar Square, Bahnar Blvd, Dolatabad Town
City
Kermanshah
Province
Kermanshah
Postal code
6714673159
Phone
+98 83 3839 3154
Email
Jalali_amir@yahoo.com

Person responsible for scientific 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
Street address
Faculty of Nursing and Midwifery, Isar Square, Bahnar Blvd, Dolatabad Town
City
Kermanshah
Province
Kermanshah
Postal code
6714673159
Phone
009838393154
Email
jalali_amir@yahoo.com

Person responsible for updating data

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

Street address

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

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Phone

+98 83 3839 3154

Email

jalali_amir@yahoo.com

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.