Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of family counseling on the family support and acceptance among methadone maintenance treatment client referred to addiction management center

Protocol summary

Summary

The present study is a Randomized Clinical Trial (RCT). Convenience sampling conducts among clients who refer to public and private clinics of addiction treatment in Kermanshah city. After random selection, samples will be divided into two groups including case (intervention) group and control group and these groups will adjusted based on the demographic variables. Then, in case group, beside routine interventions that conduct in clinics, two family members of each client (father, mother, spouse, brother or children) will be chosen along with receiving consent form; and these two members will attend the cognitive group consulting sessions according to the with Michael Frey approach. Moreover, routine interventions of clinic will be done in control group. Family group counseling will be hold by attending maximum number of 12 to 15 clients in each group for six sessions and one session per week that takes about 50 to 70 minutes. Before starting interventions, clients of both groups will complete the social acceptance scale questionnaire of Crowne and Marlowe and chronic social supporting-family scale questionnaire. Moreover, 4 weeks after the last consulting session for each group, questionnaire will be filled by clients of both groups again. General Objectives: Determination of the effect of family consulting on family supporting acceptance in patients under treatment with Methadone Research intervention is group counseling with different matter about treatment and rehabilitation related substance use. Families of inpatient clients in public and private centers (in the first stage of sampling), that their patient had received the final and decisive diagnosis of drug abuse; The patient under treatment with methadone is in consultation phase, at least for 2 months. Including refusal to continue cooperation the related samples will be excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022926844N1**
Registration date: **2016-06-21, 1395/04/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-21, 1395/04/01

Registrant information

Name
Amir Jalali
Name of organization / entity
Kermanshah University of Medical sciences
Country
Iran (Islamic Republic of)
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+98 83 3826 0083
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a_jalali@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermansh University of Medical sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of family counseling on the family support and acceptance among methadone maintenance treatment client referred to addiction management center

Public title
The effect of family counseling on the family support and acceptance of addiction clients under methadone treatment

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria Families of inpatient clients in public and private centers (in the first stage of sampling), that their clients are known case of drug dependent and treated with methadone; The patient under treatment with methadone is in consultation phase, at least for 2 months; Family members are not drug consumer and they live with the patient; The patient is in the 18 to 65 age bond; The patient would have desire and ability to attend the consulting sessions; Presence of at least one member and maximum two members of family in consulting sessions is essential; The patient must not have attend in another similar program; The patient must not have some abnormalities including mental retardation and physical disability such as deadness and blindness؛; The patient must have the ability of reading and writing. Exclusion criteria: Including refusal to continue cooperation and no presence in more than one session.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Ethical committee of kermanshah university of medical sciences

Street address
Shaheid Beheshti .Ave.

City
Kermanshah

Postal code

Approval date
2016-05-11, 1395/02/22

Ethics committee reference number
KUMS.REC.1395.85

Health conditions studied

1

Description of health condition studied
Substance Use

ICD-10 code
F11

ICD-10 code description
Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description
Family acceptance

Timepoint
Before and 4 weeks after intervention

Method of measurement
Maslo and Crawn social acceptance skale

2

Description
Family support

Timepoint
Before and 4 weeks after intervention

Method of measurement
social support in chronic disease - Family scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group received custom and normal clinics' interventions

Category
Lifestyle

2

Description
Intervention groups received group counseling base Michael Frey approach.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
substance use treatment centers of Kermanshah univeristy of medical sciences
Full name of responsible person
Street address
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah university of Medical sciences
Full name of responsible person
Behrouz Hamzeh
Street address
Shaheid Beheshti Ave. Kermanshah
City
Kermanshah
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kermanshah university of Medica Sciences
Full name of responsible person
Behnam Khaledi
Position
Master of science
Other areas of specialty/work
Street address
Nursing and midwifery school - psychiatric nursing department
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Kermanshah
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical sciences
Full name of responsible person
Amir Jalali
Position
PhD
Other areas of specialty/work
Street address
Nrsing and Midwifery school- psychiatric nursing
City
Kermanshah
Postal code
Phone
+98 988338278338
Fax
Email
jalali_amr@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
KUMS
Full name of responsible person
Marjan Yekzaman
Position
Master degree student
Other areas of specialty/work
Street address
City
Postal code
Phone
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty