

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of group cognitive behavioral counseling on the self-efficacy and self-perception among methadone maintenance treatment clients.

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 Rasht city, Iran. 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, participants in case group, beside routine interventions that conduct in clinics, will attend in the cognitive behavioral group consulting sessions. Moreover, routine interventions of clinic will be done in control group. Group consulting 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 in both groups will complete the self-efficacy scale questionnaire of Bramson and self-perception scale questionnaire of Dr. Poorhouse. Moreover, 4 weeks after the last consulting session for each group, questionnaire will be filled by clients of both groups again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061626844N3**

Registration date: **2016-07-26, 1395/05/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-26, 1395/05/05

Registrant information

Name

Amir Jalali

Name of organization / entity

Kermanshah University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3826 0083

Email address

a_jalali@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group cognitive behavioral counseling on the self-efficacy and self-perception among methadone maintenance treatment clients.

Public title

The effect of counseling on the self-efficacy and self-perception among methadone maintenance treatment clients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: all clients in public and private centers (in the first stage of sampling) that: the age range is 18 to 65 years; the patient would have desire and ability to attend the consulting sessions; drug use is at least 6 months; at least 1 month of treatment with methadone is

past; the patient must not have attend in another similar program; the patient must not have history of mental illness; the patient must have the ability of reading and writing; the patient must not have some abnormalities including mental retardation and physical disability such as deafness and blindness. Exclusion criteria: refusal to continue cooperation; no presence in more than one session; discontinue the methadone treatment during investigation.

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: **50**

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**

Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shaheid Beheshti

City

Kermanshah

Postal code**Approval date**

2016-06-22, 1395/04/02

Ethics committee reference number

IR.KUMS.REC.1395.219

Health conditions studied**1****Description of health condition studied**

Substance use disorder

ICD-10 code

F10, F11

ICD-10 code description

Mental and behavioural disorders due to use of alcohol, opioids

Primary outcomes**1****Description**

Self efficacy

Timepoint

Before and four weeks after of final session of intervention

Method of measurement

Bramson self efficacy scale

2**Description**

Self perception

Timepoint

Before and four weeks after of final session of intervention

Method of measurement

Pour Hossein self perception scale

Secondary outcomes

empty

Intervention groups**1****Description**

Cognitive behavioral counselling for Intervention group

Category

Lifestyle

2**Description**

Custom intervention due treatment center for control group

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Punlic and Private Centers for Methadone Therapy in Rasht city

Full name of responsible person**Street address****City**

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences, Research deputy

Full name of responsible person

Kourosh Hamzehee

Street address

Research deputy, Kermanshah University of Medical Sciences, Shaheid Beheshti Blvd.

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, Research deputy

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 Medical Sciences

Full name of responsible person

Behnam Khaledi

Position

MSc, Faculty member

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code**Phone**

+98 83 3826 0083

Fax**Email**

bkhaledi@kums.ac.ir

Web page address

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**

School of Nursing and Midwifery, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code**Phone**

+98 83 3826 0083

Fax**Email**

a_jalali@kums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Naseibeh Elahei Poshteh Roudi

Position

Master Student of Psychiatric Nursing

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Kermanshah

City

Kermanshah

Postal code**Phone**

+98 83 3826 1083

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