

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A randomized clinical trial comparing the efficacy of cognitive behavioral therapy on drug use control and treatment among women drug users on Maintaining Methadone Therapy (MMT)

Protocol summary

Summary

Objective: The purpose of this study is to determine the impact of a brief cognitive- behavioral therapy on drug control use and treatment among female drug users on Maintaining Methadone Therapy (MMT). The main inclusion and exclusion criteria: Addicted women with age range 18-55 years with a history of at least 3 times drug use during previous month, being on methadone maintenance therapy and without any implications of any severe personality and neurological disorders. Study participants and sample size: Forty women will be selected voluntarily among patients referring to Methadone Maintaining Treatment centers (MMT) and will be divided into two control (n=20) and experimental group (n=20). Design: Proposed intervention will be randomized control trial with random allocation into control and intervention groups. Interventions: A brief cognitive behavioral intervention (one month, one 2-hour session per week) will be used. The study will be conducted at three stages including baseline, intervention and follow up after 3 months. Primary outcome measure: Two groups will be compared regarding the effectiveness of intervention program on reducing relapse rate at three stages.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060621684N2**
Registration date: **2015-08-30, 1394/06/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-30, 1394/06/08

Registrant information

Name

Mahmood AminiLari

Name of organization / entity

Shiraz HIV/AIDS Research Center, Shiraz University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial comparing the efficacy of cognitive behavioral therapy on drug use control and treatment among women drug users on Maintaining Methadone Therapy (MMT)

Public title

The effect of cognitive- behavioural therapy on drug use control and treatment among addicted female

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Being addicted female; being on methadone maintaining therapy for at least 3 months; having a history of relapse during MMT program for at least 3 times over the past one month; completing inform consent; having not a history of severe drug toxicity. Exclusion criteria: Having severe physical and neurological illness; Having severe mental and personality disorders.

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

2-3

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

The Ethics Committee, Shiraz University of Medical Sciences

Street address

7th Floor, Central Building, Shiraz University of Medical Sciences, Zand Ave, Shiraz, Iran

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Postal code

Approval date

2015-06-14, 1394/03/24

Ethics committee reference number

IR.SUMS.REC.1394.45

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F19

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use

Primary outcomes

1

Description

Retention in Methadone Maintenance Treatment without relapse

Timepoint

Before intervention, immediately after intervention, 3 months after intervention

Method of measurement

Opium treatment index; severity of dependence scale; timeline follow back; rapid urine test

Secondary outcomes

1

Description

The trend of reducing in drug use

Timepoint

Before intervention, immediately after intervention, 3 months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Experimental Group: Brief cognitive and behavioural therapy. This guide, reported by Baker et al 2003, details a brief cognitive behavioural intervention specifically designed for regular amphetamine users that may be utilized by practitioners working in a wide range of treatment settings.

Category

Behavior

2

Description

Control Group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Drop in Center, Methadone Maintenance Therapy Center

Full name of responsible person

Hamid Reza Bakhtiyari

Street address

Sang-e Siyah Sector, Gode Araban Street, Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr.Poostfroosh

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7th Floor, Central Building, Shiraz University of Medical Sciences, Zand Ave, Shiraz, Iran

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Shiraz 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

Shiraz HIV/ AIDS Research Center, Shiraz University of Medical Sciences

Full name of responsible person

Mahmood AminiLari

Position

Executive Director

Other areas of specialty/work

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Person responsible for scientific inquiries

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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