

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The effect of cognitive-behavioral intervention on the burden and quality of life in drug dependence caregivers referred to the Shahid Modarres Hospital in 2016

#### Protocol summary

##### Summary

The aim of this study was to improve the care givers burden and quality of life on families of drug dependence. This study is a clinical trial, randomized, parallel, double-blind study. In this study, 64 family caregivers of drug dependence who are eligible for inclusion criteria through convenience sampling and randomly divided into two groups and the control group have 8 session intervention. Having at least one drug dependence persons and the ability to participate in the training sessions are the most important criteria to enter the study. If for some reason more than one session of training sessions to care for his absence will be removed. The Zarit questionnaire caregiver burden and World Health Organization Quality of Life Questionnaire of 26 questions (WHOQOL-BREF) is completed by both groups in three stages: before, immediately after and one month after the intervention. By comparing the results of this study at the end, we can measure the effect of cognitive-behavioral intervention on burden and quality of life caregivers and if it was effective, the education can be used.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017011431927N1**

Registration date: **2017-02-11, 1395/11/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-02-11, 1395/11/23

##### Registrant information

##### Name

Maryam Faghih

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 214 2075

##### Email address

mfaghih@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2016-06-21, 1395/04/01

##### Expected recruitment end date

2016-08-21, 1395/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of cognitive-behavioral intervention on the burden and quality of life in drug dependence caregivers referred to the Shahid Modarres Hospital in 2016

##### Public title

The effect of cognitive-behavioral intervention on the burden and quality of life in drug dependence caregivers referred to the Shahid Modarres Hospital in 2016

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: family caregiver to be considered as

primary care and all have to assume his responsibilities; the family have a mental and physical ability to take care of drug dependent persons; wishing to participate in the stud; be able to communicate and follow the rules of the training session; only care chronic condition like drug dependent in the family; able to speak, read and write in Persian language; psychiatric drug and no drug is not consumed; in family training sessions (any other research project in the field) have not participated in the past; care for person of drug dependence who range in age from 18-60 years Drug dependent persons and at least once a history of hospitalization due to drug dependence disorder have; drug dependent persons is not affected with any disease (physical disabilities, mental, etc.). Exclusion criteria: family caregiver are not want to continue to participate in the training session; there is any problem, so be careful not to be able to continue to participate in the study; look out for a maximum of two sessions of the training sessions absence; the physical and psychological problems in family caregivers who can not presence in the meetings.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

School of Nursing and Midwifery, Isfahan University of Medical Sciences

**Street address**

Hezar jarib street, Azadi Sq

**City**

Esfahan

**Postal code****Approval date**

2016-02-21, 1394/12/02

**Ethics committee reference number**

IR.MUI.REC.1394.3.974

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

Drug dependence

**ICD-10 code**

F10-19

**ICD-10 code description**

Mental and Behavioral Disorders due to use of alcohol,opioids,cannabis;sedatives, hypnotics, anxiolytics,cocaine,other stimulants, including caffeine,hallucinogens,nicotine,inhalants and other psychoactive substances and multiple drug use

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

Caregiver burden

**Timepoint**

Before the intervention, after the intervention, one month after the intervention

**Method of measurement**

Zarit caregiver burden Questionnaire

**Secondary outcomes****1****Description**

Quality of Life

**Timepoint**

Before the intervention, after the intervention, one month after the intervention

**Method of measurement**

World Health Organization Quality of Life Questionnaire of 26 questions (WHOQOL-BREF)

**2****Description**

Quality of Life

**Timepoint**

Before the intervention, after the intervention, one month after the intervention

**Method of measurement**

World Health Organization Quality of Life Questionnaire of 26 questions (WHOQOL-BREF)

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

Researcher set her intervention based on cognitive-behavioral intervention program such as a supportive

intervention in 8 sessions (on average) 90 minute classes for drug dependence are family members who are qualified to do.

**Category**

Other

**2****Description**

the control group will participate in 3 sessions that organized by fellow researcher, and they will discuss and share their experiences

**Category**

Other

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

Shahid Modarres Hospital

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

Shahid Modarres Hospital, 18 km of road Isfahan, Najaf Abad (beginning Goldasht)

**City**

Najaf Abad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Ashraf Kazemi

**Street address**

Hezar jarib St, Azadi Sq

**City**

Isfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan 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**

Isfahan University of Medical Science

**Full name of responsible person**

Saied Pahlavanzadeh

**Position**

Master of Science in Psychiatric Nursing / Registered Psychiatric Nursing and Midwifery Faculty

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

Isfahan University of Medical Sciences, Hezar jarib St, Azadi Sq

**City**

Shahin Shahr

**Postal code****Phone**

+98 31 3668 7124

**Fax****Email**

pahlavanzadeh@nm.mui.ac.ir;

sharife\_mousavi@nm.mui.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences, School of Nursing and Midwifery

**Full name of responsible person**

Maryam Faghieh

**Position**

Bachelor of Nursing / Psychiatric Nursing Graduate Student

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

Shahin Shahr, Attar St.

**City**

Shahin Shahr

**Postal code**

8316633646474

**Phone**

+98 913 214 2075

**Fax****Email**

mfaghieh@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Isfahan University of Medical Sciences, School of Nursing and Midwifery

**Full name of responsible person**

Maryam Faghieh

**Position**

Bachelor of Nursing / Psychiatric Nursing Graduate Student

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**Street address**

Shahin Shahr, Attar St.

**City**

Isfahan

**Postal code**

**Phone**

**Fax**

**Email**

mfaghhih@nm.mui.ac.ir

**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*