

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Maryam Faghih

Position

Bachelor of Nursing / Psychiatric Nursing Graduate Student

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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