Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 Siences

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 Siences

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 Siences

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 Siences

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 Sience

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 Siences, 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 Faghih

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

mfaghih@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 Faghih

Position

Bachelor of Nursing / Psychiatric Nursing Graduate Student

Other areas of specialty/work
Street address
Shahin Shahr, Attar St.
City
Isfahan
Postal code
Phone
Fax
Email
mfaghih@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