

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of quality of life therapy on stress, burden and life satisfaction in family caregivers of addicts

Protocol summary

Study aim

Determining the effect of quality of life therapy on stress, psychological burden and family satisfaction of addicts referring to Zahedan Psychiatric Hospital in 2018

Design

In this study, 80 family caregivers of addicts referred to Zahedan Psychiatric Hospital who have entrance requirements are selected and divided into two groups of intervention and control in simple random order.

Settings and conduct

Both intervention and control groups performed pretest tests by completing psychological burden, stress and life satisfaction questionnaires. The intervention group will receive 7 sessions of quality of life therapy education based on the content specified in the hospital's educational class.

Participants/Inclusion and exclusion criteria

Career Entry Criteria: A member of the family who has all the health, medical, care and support responsibilities of the patient, Having a minimum degree of guidance, Resident in Zahedan City, The carer is the only caregiver of a patient. Addict entry criteria: The primary and primary diagnosis of drug dependence, Absence of psychiatric disorders, Having a minimum age of 20 and a maximum of 50 years, Life in the family Watch out for departure criteria: An extreme incident one month before the time of the study, having acute psychological problems and addiction

Intervention groups

The intervention group will receive 7 sessions of quality of life therapy within one day, 90 minutes, and based on specified content. Four weeks after the end of the intervention, the post-test will be performed. The control group does not receive counseling and training during this period. And the educational content will be provided to the family carers of the control group.

Main outcome variables

burden, stress and life satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160924029954N11**

Registration date: **2018-09-04, 1397/06/13**

Registration timing: **prospective**

Last update: **2018-09-04, 1397/06/13**

Update count: **0**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name

Ali navidian

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2482

Email address

alinavidian@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-11, 1397/06/20

Expected recruitment end date

2018-11-11, 1397/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of quality of life therapy on stress, burden and life satisfaction in family caregivers of addicts

Public title

The effect of quality of life therapy on burden in family caregivers of addicts

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

A member of the family who has all the health, medical, care and support responsibilities of the patient. Having a minimum degree of middle school Resident in Zahedan City The carer is the only caregiver of a patient

Exclusion criteria:

having acute psychological problems and addiction a mishap one month before the study

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were randomly assigned into two intervention and control groups and the randomized sealed envelope was used.

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

Ethics committee of Zahedan University of Medical Sciences & Health Services

Street address

Administrative Complex of Zahedan Medical Science Campus, Persian Gulf Blvd, Dr. Hesabi Square, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.ZAUMS.REC.1397.194

Health conditions studied

1

Description of health condition studied

Psychiatric condition of addict carers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

subjective burden

Timepoint

Before intervention and one month after intervention

Method of measurement

Burden questionnaire

2

Description

Stress

Timepoint

Before intervention and one month after intervention

Method of measurement

Stress Beck Questionnaire

3

Description

Life satisfaction

Timepoint

Before intervention and one month after intervention

Method of measurement

Life satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive 7 sessions of quality of life therapy within one day, 90 minutes, and based on the specified content.

Category

Other

2

Description

Control group: Control group: During this period, the control group does not receive any counseling and training. At that same interval, the post-test intervention group is also done. Educational content will be provided to the family carers of the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Psychiatric Hospital

Full name of responsible person

Zahra Karimi

Street address

Baharan Psychiatric Hospital, Imam Khomeini Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nour Mohammad Bakhshani

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Zahra Karimi

Position

Master Student in Psychiatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Faculty of Nursing Midwifery, Mashahir Square,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ali Navidian

Position

Ph.D.

Latest degree

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Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participants information is confidential

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

En the method of implementation of the plan is explained in the thesis

When the data will become available and for how long

The post-graduation study protocol is described in the thesis

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

The thesis is explained

What processes are involved for a request to access data/document

There is no plan to publish it

Comments