Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Name of organization / entity
Zahedan University of Medical Sciences
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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
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Baharan Psychiatric Hospital, Imam Khomeini Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Latest degree

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Other areas of specialty/work

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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