

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effects of emotion regulation training on stress, anxiety , depression and resiliency among caregivers family of patients with schizophrenia.

Protocol summary

Summary

This study is an interventional study. The goal of study is determining the effect of emotion regulation training on the stress, anxiety, depression and resiliency caregiver's family of patients with schizophrenia. Inclusion criteria are, Both sexes, Patients who were hospitalized more than once, mental health of caregiver, Direct communication with the patient , and exclusion criteria are, caregivers less than 15 years old; Absence of more than 2 sessions in the curriculum. The population of the study is the caregiver's family of patients with schizophrenia that refer to Psychiatric Hospital Shahid Beheshti, affiliated to Kerman University of Medical Sciences. The sample size is, 70 caregiver, and randomly are divided, one experimental group and one control group (each group of 35 people). The intervention is caregiver's education. The duration of the study is 6 months(onset:2017-09-06). Before the training, DASS21 and Resiliency questionnaires is given two groups. Then experimental group is placed under training for 8 sessions of 60 minutes, and the control group does not receive any training. After the training sessions, the questionnaires are complete by two groups. The outcome of this research is the effect of training on the degree of stress, anxiety, depression and resiliency in caregivers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061733997N2**

Registration date: **2017-08-16, 1396/05/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-16, 1396/05/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology kerman university of medical science

Expected recruitment start date

2017-09-06, 1396/06/15

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of emotion regulation training on stress, anxiety , depression and resiliency among caregivers family of patients with schizophrenia.

Public title

The effects of emotion regulation training on stress, anxiety , depression and resiliency among caregivers family of patients with schizophrenia .

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria : Both sexes; Patients who were hospitalized more than once; mental health of caregiver; Direct communication with the patient; and exclusion criteria: caregivers less than 15 years old; Absence of more than 2 sessions in the curriculum.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

The participants, are assigned randomly block, into two groups of control and intervention (each group of 35 samples).

Secondary Ids**1****Registry name**

no

Secondary trial Id

no

Registration date

empty

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

Vice Chancellor for Research and Technology, Ethics committee of kerman University of Medical Science

Street address

-Deputy of Research and Technology of Kerman University of Medical Sciences-Vice Chancellor for Research, Street Ibn Sina, Tahmasebabad Crossroads-

City

Kerman

Postal code

۷۶۱۸۷۴۷۶۵۳

Approval date

2010-06-10, 1389/03/20

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2**Description of health condition studied**

Stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

3**Description of health condition studied**

Depression

ICD-10 code

F31.9

ICD-10 code description

Bipolar affective disorder, unspecified

4**Description of health condition studied**

Resiliency

ICD-10 code

F99-F99

ICD-10 code description

Unspecified mental disorder

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

depression, anxiety, stress, resiliency

Timepoint

before and after education

Method of measurement

questionner

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

depression, anxiety, stress, resiliency

Timepoint

before and after education

Method of measurement

questionnaire

Intervention groups

1

Description

The experimental group will complete the questionnaires before the curriculum, and they will place under the emotion regulation training for 8 sessions of 60 minutes. The relevant training is done by the psychologist. Teaching is delivered as a lecture, a question and answer, as well as a training booklet. Session 1: Communicating and Conceptualizing and the need to use of regulation excitement training, Session 2: awareness of positive threats and types, Session 2: awareness of negative threats and types, Session 4: accepting positive excitement, Session5: accepting negative excitement, Session 6: re-evaluating and expressing positive emotions, Session 7: re-evaluating and expressing negative emotions, Session 8: Summing up the training sessions and asking questions and completing the questionnaires.

Category

Treatment - Drugs

2

Description

The control group will complete the questionnaires before the curriculum, but they do not receive any training, and after completing education course, they will complete the questionnaires again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahide Beheshti Psychiatric Hospital in Kerman

Full name of responsible person

Street address

Shahide Beheshti Psychiatric Hospital, Gomhoori Boulevard-

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, kerman University of Medical Science-

Full name of responsible person

Abbas Pardakhty

Street address

Vice Chancellor for Research and Technology of Kerman University of Medical Sciences , Street Ibn Sina,Tahmasebad Crossroads.

City

kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research and Technology, kerman University of Medical Science-

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

kerman University of Medical Science

Full name of responsible person

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Position

master degree,faculty

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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