

# 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

###### Name

Tahereh Ramezani

###### Name of organization / entity

Kerman University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34331325220

###### Email address

t\_ramezani@kmu.ac.ir

##### 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

Tahereh Ramezani

##### Position

master degree,faculty

##### Other areas of specialty/work

##### Street address

Kerman University of Medical Sciences Campus, beginning around Seven Alavi Garden,

##### City

kerman

##### Postal code

1355376169

##### Phone

+98 34 3132 5700

##### Fax

##### Email

t\_ramezani2kmu.ac.ir

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kmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

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##### Full name of responsible person

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Science  
**Full name of responsible person**  
Tahereh Ramezani  
**Position**  
master degree, faculty  
**Other areas of specialty/work**  
**Street address**  
Kerman University of Medical Sciences Campus ,  
beginning around Seven Alavi Garden, Kerman.  
**City**  
Kerman  
**Postal code**

## 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*