Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of a Psychosocial Support Program on Perceived Stress and Social Support and Quality of Life of Family Caregivers of Patients with Mental Disorders

Protocol summary

Study aim

Investigate the effect of a psychosocial support program on perceived stress and social support and quality of life of family caregivers of patients with mental disorders

Design

The present study is a clinical trial that was performed on 72 persons in two groups of intervention and control and in three stages with pre-intervention test, immediately after and one month after intervention.

Settings and conduct

Environment in the study is Noor Hospital in Isfahan, which has psychiatry departments. The sample of this study is the main caregivers of male and female patients with psychiatric disorders referred to psychiatric wards. The psychosocial support program sessions will be conducted twice a week by the researcher by conducting six 90-minute training sessions twice a week in the classroom of Noor Hospital. Summaries of the training discussed will be provided to caregivers as a training booklet.

Participants/Inclusion and exclusion criteria

A family caregiver is considered as the main caregiver of the patient The patient's family caregiver is interested in the study and is satisfied Caregiver only cares a person with chronic disease in the family Export: A history of psychiatric disorders diagnosed for caregiver by a psychiatrist who has led to medication or hospitalization Concurrent or previous participation in similar training programs

Intervention groups

Intervention group: Support programs sessions will be held in 6 sessions of 90 minutes twice a week. Control group: Ddoes not receive any training program and only participates in two session of introduction and discussion with each other about the family's problems.

Main outcome variables

Perceived Stress Scores in Cohen' Perceived Stress Scale ; Score of Perceived Social Support in Zimet's Multidimensional Scale of Perceived Social Support ; Score of Quality of Life in World Health Organization Quality of life questionnaire - Brief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039321N2**
Registration date: **2019-09-17, 1398/06/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-17, 1398/06/26**
Update count: **0**

Registration date

2019-09-17, 1398/06/26

Registrant information

Name

sima ghezelbash

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of a Psychosocial Support Program on Perceived Stress and Social Support and Quality of Life of Family Caregivers of Patients with Mental Disorders

Public title

The Effect of a Psychosocial Support Program on Perceived Stress and Social Support and Quality of Life

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

A family caregiver is considered as the main caregiver of the patient and has all the responsibilities of the patient The caregiver is responsible for the patient suffering from a severe mental disorder (such as schizophrenia, mood disorders, anxiety disorders and etc) and does not mean substance abuse Can speak, read and write in Persian The patient's family caregiver is interested in the study and is satisfied The patient has a mental disorder diagnosed by a psychiatrist which can be evaluated by assessing the patient's records (referring to a case or summary records of the hospitalization) Caregiver only cares a person with chronic disease in the family

Exclusion criteria:

A history of psychiatric disorders diagnosed for caregiver by a psychiatrist who has led to medication or hospitalization (determined by asking the family) Having experienced severe stress such as the death of loved ones or divorces over the past 6 months Concurrent or previous participation in similar training programs (any research project similar to the present study)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

They are placed in one of the intervention or control groups with the help of simple randomization method. The randomization tool in this study is a sealed envelope.

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 Isfahan University of Medical Sciences

Street address

Vice chancellery for research affairs, Isfahan University of Medical Sciences., Hezarjerib Ave., Isfahan city

City

Isfahan

Province

Isfehan

Postal code

۸۱۷۴۶۷۳۴۶۵

Approval date

2019-08-13, 1398/05/22

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.231

Health conditions studied

1

Description of health condition studied

Perceived Stress

ICD-10 code

F43

ICD-10 code description

Reaction to severe stress, and adjustment disorders

2

Description of health condition studied

Perceived Social Support

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Quality of Life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Perceived Stress Scores in Cohen' Perceived Stress Scale

Timepoint

The beginning of the study (before the intervention), immediately after and one month after the educational program

Method of measurement
Cohen's Perceived Stress Scale

2

Description
Score of Perceived Social Support in Zimet's Multidimensional Scale of Perceived Social Support
Timepoint
The beginning of the study (before the intervention), immediately after and one month after the educational program
Method of measurement
Zimet's Multidimensional Scale of Perceived Social Support

3

Description
Score of Quality of Life in World Health Organization Quality of life questionnaire - Brief
Timepoint
The beginning of the study (before the intervention), immediately after and one month after the educational program
Method of measurement
World Health Organization Quality of life questionnaire - Brief

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Psychosocial support programs sessions will be held in 6 sessions of 90 minutes twice a week in the classroom rooms of the Nour Hospital in Isfahan by a researcher in a group way for caregivers in groups of 5 to 15. The contents of these training sessions are based on an educational booklet. Educational materials are provided to caregivers as a handbook. Additionally, the training content of the sessions will be communicated through group discussions, lectures, questions and answers, and presentation of films and slides.
Category
Other

2

Description
Control group:Does not receive any training program and only participates in two session of introduction and discussion with each other about the family's problems.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Nour and Ali Asghar Hospital
Full name of responsible person
Reyhane Haji Sadeghian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Sima Ghezelbash

Position
Faculty Member

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable