Clinical Trial Protocol
Iranian Registry of Clinical Trials
01 Feb 2021

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: Does 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)
Phone
+98 31 3792 7607
Email address
ghezelbash@nm.mui.ac.ir

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
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
Isfahan
Postal code
18599748
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
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
Street address
Nursing and Midwifery Faculty, Isfahan University of Medical Sciences, Hezarjerib Ave., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7565
Email
ghezelbash@nm.mui.ac.ir

Person responsible for updating data

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
Street address
Nursing and Midwifery Faculty, Isfahan University of Medical Sciences, Hezarjerib Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
simagh1396@gmail.com

Person responsible for scientific 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
Street address
Nursing and Midwifery Faculty, Isfahan University on Medical Sciences, Hezarjerib Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
ghezelbash@nm.mui.ac.ir

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