Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of family psychoeducational on family caregiver Burden, Anexiety, Stress and Depression

Protocol summary

Summary

Objective: This randomized controlled trial evaluated the effectiveness of a group psycho-educational program on caregivers of mental disorders. Hundred family caregivers of patients with Schizophrenia and mood disorders that attending in Noor hospital, affiliated to Isfahan Behavioral Sciences Research Center, were the study population. In this study, Caregiver is one who is a member of the family (parents, children,..) and has the most frequent contact with the patients, helps to support the patient financially, has most frequently been collateral in the patients' treatment . The psycho-educational intervention that was used in this research consisted of four consecutive weekly sessions providing information about patients disorder process, teaching symptom management, teaching caregiver self care, discussing psychosocial issues, providing mutual support to one another, teaching them to monitor their own feelings, teaching coping skills and problem solving and it was offered in a group format. It was used because group education programs have been widely recommended as a valuable strategy to deliver support and information to family caregivers. The program followed up for a period of 3 months and caregiver burden was assessed by using the Zarit Burden Interview (ZBI).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804272200N1**
Registration date: **2009-09-09, 1388/06/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-09-09, 1388/06/18

Registrant information

Name
Saeid Pahlavanzadeh

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Behavioral Sciences Research Center of Isfahan University of Medical Sciences

Expected recruitment start date

2008-01-02, 1386/10/12

Expected recruitment end date

2008-07-17, 1387/04/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of family psychoeducational on family caregiver Burden, Anexiety, Stress and Depression

Public title

Family Caregivers of Mental Disorders

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Family member who is main caregiver at home. 2- aged at least 16 years. 3- being

able to make a good communication. 4- being able to complete questionnaire. Exclusion Criteria: 1-Not participate in family education about mental disorders and caring of them. 2- Do not have any history of identified somatic and mental disorder and hospitalization.

Age
From **16 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan Behavioral Sciences Research Center

Street address
Noor Medical Center, Hasht Behesht, Ostandari Street

City
Isfahan

Postal code

Approval date
2008-04-15, 1387/01/27

Ethics committee reference number
24/11/4/12

Health conditions studied

1

Description of health condition studied
Schizophrenia Spectrom

ICD-10 code
F20,F21,F2

ICD-10 code description
Schizophrenia, schizotypal and delusional disorders

2

Description of health condition studied
mood disorders

ICD-10 code
F30,F31,F3

ICD-10 code description
Mood [affective] disorders

Primary outcomes

1

Description
family caregiver burden

Timepoint
three months after the end of study

Method of measurement
questionnaire

2

Description
Anxiety

Timepoint
at the end of study & three months later

Method of measurement
questionnaire

3

Description
Depression

Timepoint
at the end of study & three months later

Method of measurement
questionnaire

4

Description
Stress

Timepoint
at the end of study & three months later

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: The psycho-educational intervention that was used in this research consisted of four consecutive weekly sessions providing information about patients disorder process, teaching symptom management, teaching caregiver self care, discussing psychosocial issues, providing mutual support to one another, teaching them to monitor their own feelings, teaching

coping skills and problem solving and it was offered in a group format.

Category

Behavior

2

Description

Control: routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor Medical Center affiliated to Isfahan University of Medical Sciences

Full name of responsible person

Street address

Noor Medical Center , HASHT BEHESHT, Ostandari Street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Abbas Atari , Dean of Behavioral Sciences Research Center

Street address

Office of BSRC, Noor hospital

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences

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

Isfahan University of Medical Sciences

Full name of responsible person

Saeid Pahlavanzadeh

Position

MSc , Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mohsen Yazdani

Position

MSc and Faculty member

Other areas of specialty/work

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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