

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Effectiveness of family psychoeducational on family caregiver Burden, Anxiety, 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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Iran (Islamic Republic of)

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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, Anxiety, 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 Spectrum

##### **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****Street address**

Mental Health Nursing Department, Nursing & Midwifery School, Isfahan University of Medical Sciences

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University of Isfahan

**Full name of responsible person**

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**Position**

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