

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of family-centered empowerment program on depression, anxiety and stress among patients with obsessive-compulsive disorder and their caregivers' burden

Protocol summary

Study aim

To Determine The Effect of family-centered empowerment program on depression, anxiety and stress among patients with obsessive-compulsive disorder and their caregivers' burden.

Design

Semi-experimental research with pretest-post test design with control group in waiting list and one month follow-up of intervention and control group

Settings and conduct

After sampling and Assigning 25 patients in both Intervention and control groups ,Eight 60-minute training sessions and twice a week were held for the intervention group at Faculty of Nursing and Midwifery Nasibe(Sari).The content of the training sessions focused on increasing awareness of obsessive-compulsive disorder and familiarity with negative emotions and management.The training was conducted by a psychiatrist nurse as a lecture, question and answer, and a booklet.During this period, no intervention was performed for the control group.After one month of telephone follow up for the Intervention group, two groups again were evaluated.The questionnaires of this research included: Depression , Anxiety and Stress Scale , Maudsley Obsessive Compulsive Inventory, Zarit Caregiver Burden Questionnaire and General Health Questionnaire (GHQ-12).

Participants/Inclusion and exclusion criteria

Inclusion Criteria Included :Early diagnosis of Obsessive-Compulsive Disorder , At least 18 years of Age -The absence of psychosis and major depression and exclusion criteria included : having a physical illness (deaf, blind, motor disability) and mental retardation - Those who do not fully complete the questionnaire -those who do not attend the two-sessions of the training session

Intervention groups

25 Patient with Obsessive-Compulsive Disorder

Main outcome variables

depression - anxiety - stress - caregiver burden

General information

Reason for update

Acronym

بررسی تاثیر اجرای برنامه توانمندسازی خانواده محور بر میزان افسردگی ، اضطراب واسترس بیماران وسواس جبری و بار مراقبتی مراقبین آنها

IRCT registration information

IRCT registration number: **IRCT20171203037723N1**

Registration date: **2018-12-03, 1397/09/12**

Registration timing: **retrospective**

Last update: **2018-12-03, 1397/09/12**

Update count: **0**

Registration date

2018-12-03, 1397/09/12

Registrant information

Name

Hamideh Azimi Lolaty

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7343

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2018-07-22, 1397/04/31
Actual recruitment start date
2018-05-20, 1397/02/30
Actual recruitment end date
2018-08-20, 1397/05/29
Trial completion date
2018-10-22, 1397/07/30

Scientific title

The effect of family-centered empowerment program on depression, anxiety and stress among patients with obsessive-compulsive disorder and their caregivers' burden

Public title

The effect of family-centered empowerment program on depression, anxiety and stress among patients with obsessive-compulsive disorder and their caregivers' burden.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Initial diagnosis of OCD by a psychiatrist
The desire to participate in the study
Having at least 18 years of age
Spent at least six months from the time of diagnosis
Absence of psychotic disorders
Lack of major depression
Lack of physical illness (Deaf, blind, Disability Movement)and mental retardation

Exclusion criteria:

patients and their caregivers who do not attend two sessions of training sessions
Do not answer the questionnaire questions completely
Do not cooperate in carrying out assignments

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**
More than 1 sample in each individual
Number of samples in each individual: **2**
A person with a family member
Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

central headquarters of Mazandaran University of Medical Sciences and Health Services , the beginning of Valiasr highway , Sari

City

sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR. MAZUMS.REC.1397.1504

Health conditions studied

1

Description of health condition studied

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Depression score > = 14

Timepoint

Before Intervention - After Intervention - One Month After Intervention

Method of measurement

Depression, anxiety stress scale (DASS)

2

Description

- Caregiving Score > = 30

Timepoint

Before Intervention - After Intervention - One Month After Intervention

Method of measurement

Zarit caregivers burden

3

Description

Anxiety score > = 10

Timepoint

Before Intervention - After Intervention - One Month After Intervention

Method of measurement

Depression, anxiety stress scale (DASS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group : Each patient will attend in Educational sessions with a family member. Eight Educational sessions will be held twice a week for one month. The sessions focused on obsessive-compulsive disorder and its treatment, the importance of family role and familiarity with negative emotions and their management. The lecture and question and answer method and the slideshow will be used.

Category

Other

2

Description

Control group: Each patient will be accompanied by a family member in the research. The control group will receive routine center care and will not attend in Educational sessions. The control group will complete only the questionnaires.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghban Specialist Clinic (Tuba)

Full name of responsible person

Hamideh Azimi Lolaty

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Sari City, Khazar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Azimi Lolaty

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Amir Mazandarani Blvd. Vesal Shirazi Ave.-Nasibe Nursing and Midwifery Faculty

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Azimi Lolaty

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

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When the data will become available and for how long

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To whom data/document is available

.....

Under which criteria data/document could be used

.....

From where data/document is obtainable

.....

What processes are involved for a request to access data/document

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Comments