

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Self-Awareness Skills on Stigma in Family Caregivers of Patients with Bipolar Disorder type 1

Protocol summary

Study aim

The effect of self-awareness skills on stigma in family caregivers of patients with bipolar disorder type 1

Design

A clinical trial with a control group with parallel groups randomized by block method is conducted on 49 samples.

Settings and conduct

In Ibn Sina Hospital of Mashhad, intervention is held in the form of educational sessions

Participants/Inclusion and exclusion criteria

Entry criteria for caregivers: first-degree relative of the patient who is the main caregiver of the patient. High school education, living in Mashhad and Iranian nationality, age at least 18 and at most 60 years old, no physical, hearing and visual impairments, no known mental disorders and no drug use in this context, no experience of another crisis such as divorce and Death of loved ones in the last six months, lack of medical education. Criteria for the admission of patients: Confirmation of a patient with type 1 bipolar disorders by a psychiatrist, at least six months have passed since the diagnosis of the disease, and have a history of at least one previous hospitalization in a psychiatric hospital.

Intervention groups

After determining the subjects and completely identical conditions, the pre-test will be performed for the test and control groups. The training of self-awareness skills will be done in a group for a period of 4 weeks, twice a week in 8 sessions of 35 minutes. Also, one month after the end of the intervention, the control group will be invited to participate in the self-awareness training session.

Main outcome variables

In the control group, it is expected that our intervention will reduce the stigma score and also they will behave carefully in dealing with everyday life issues.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231014059720N1**

Registration date: **2023-10-30, 1402/08/08**

Registration timing: **prospective**

Last update: **2023-10-30, 1402/08/08**

Update count: **0**

Registration date

2023-10-30, 1402/08/08

Registrant information

Name

Amir Fallah Moghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4444 1942

Email address

fallahamir1992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-14, 1402/09/23

Expected recruitment end date

2024-01-13, 1402/10/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Self-Awareness Skills on Stigma in Family Caregivers of Patients with Bipolar Disorder type 1

Public title

The Effect of Self-Awareness Skills on Stigma in Family Caregivers of Patients with Bipolar Disorder type 1

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Entry criteria for caregivers: first-degree relative of the patient who is the main caregiver of the patient. High school education living in Mashhad and Iranian nationality age at least 18 and at most 60 years old no physical, hearing and visual impairments no known mental disorders and no drug use in this context no experience of another crisis such as divorce and Death of loved ones in the last six months lack of medical education Criteria for the admission of patients: Confirmation of a patient with type 1 bipolar disorders by a psychiatrist at least six months have passed since the diagnosis of the disease and have a history of at least one previous hospitalization in a psychiatric hospital.

Exclusion criteria:

to be absent in one of the training sessions After completing the training process, the main caregiver of the patient experiences such things as divorce or the death of a loved one until the post-test During the research, participate in another educational program in this field.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **49**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked In order to randomly assign patients to study subjects while ensuring equal numbers in study groups, random permutation block method is used. For this purpose, blocks with sizes 2 and 4 are used, and a random list will be created through the website <https://www.sealedenvelope.com>.

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 Mashhad University of Medical Sciences

Street address

No.31,27th Salman Farsi Ave.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9657134991

Approval date

2023-10-08, 1402/07/16

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.082

Health conditions studied

1

Description of health condition studied

Bipolar type 1

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

The effect of self-awareness skill training on the stigma of family caregivers

Timepoint

before and one month after the end of the intervention

Method of measurement

Ritscher et al.'s internal stigma questionnaire of mental patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The study population is the caregivers of patients with bipolar disorder type 1 hospitalized in the educational or therapeutic adult departments of Ibn Sina Hospital. Caregivers of patients who are interested in participating in the research will be invited. Then, a meeting will be held to state the objectives of the study, informed and written consent will be obtained from the caregivers of the patients, and they

will be asked to complete the demographic checklist and the standard questionnaire of internal stigma of psychiatric patients by Ritscher et al. The sample size has been calculated by considering 20% attrition for the group of 49 people. The intervention group will undergo self-awareness training for 4 weeks in the form of two 35-minute sessions per week (8 sessions), which are as follows. The intervention is taken from the book Life Skills Training authored by Hamed Barabadi, and in each session, first a brief explanation about the activity that is to be done, and then homework is completed in the classroom and at home. The assignments are classified as the mentioned items. 1- Definition of self-awareness 2- Definition of real self and ideal self 3- Emotions and its components 4- Self-image 5- Self-esteem 6- Trophy of victory 7- Filling placards of success 8- Introducing sources of self-awareness. After one month of the intervention, the questionnaires will be completed again by this group.

Category

Other

2

Description

Control group: In the control group, after filling the relevant questionnaire, they do not receive any intervention and they only receive the usual interventions of the hospital, and after our interventions are completed and the questionnaire form is completed by the intervention group, the control group is invited to act after one month. come to receive the interventions taken from the life skills training book in one session.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Hospital, Mashhad

Full name of responsible person

Saeed Vaghee

Street address

Educational complex of Shahid Dr. Kharazmi, university campus, east gate of Ferdowsi University of Mashhad, Azadi Square, Khorasan Razavi

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9137913199

Phone

+98 51 3859 1511

Email

VagheeS@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeed Vaghee

Street address

Educational complex of Shahid Dr. Kharazmi, university campus, east gate of Ferdowsi University of Mashhad, Azadi Square, Khorasan Razavi

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nms.pr@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Saeed Vaghee

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Educational complex of Shahid Dr. Kharazmi, university campus, east gate of Ferdowsi University of Mashhad, Azadi Square, Khorasan Razavi

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Saeed Vaghee
Position
Associate professor
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Saeed Vaghee
Position
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Latest degree
Master
Other areas of specialty/work
Nursery
Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Its main implications are shared

When the data will become available and for how long

The access period starts one year after the results are published

To whom data/document is available

It is accessible to all people

Under which criteria data/document could be used

The person to whom the data is sent must have a university degree in psychiatry or psychology and for what purpose he requests this information.

From where data/document is obtainable

09050476711 Fallah Moghaddam Amir

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

An email will be sent to him during a phone call with the number 09050476711, and after his request, information will be sent to him through the given email within a month.

Comments