Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of mental health literacy promotion program on emotional regulation strategies, social health and perceived stress of family caregivers of patients with chronic psychiatric disorders

Protocol summary

Study aim

Determining the effect of mental health literacy promotion program on emotional regulation strategies, social health and perceived stress of chronic psychiatric family caregivers in Isfahan

Design

Clinical trial, with control group, without blinding, random allocation, sample size of 60 people. Statistical software will be used to randomly assign members to groups.

Settings and conduct

Farabi and Khurshid hospitals in Isfahan. Random sampling and based on the entry criteria, filling out the questionnaire by the samples before, immediately after and one month after the last intervention session, providing training in 6 sessions and one session every week, providing training in an intensive session for the control group after the implementation of the follow-up

Participants/Inclusion and exclusion criteria

Having a desire to enter the study, having a history of hospitalization in the past year or current hospitalization, the presence of a diagnosed psychiatric disorder in the patient, at least 6 months have passed since the onset of the disease, not experiencing an unfortunate accident during the past six months, not having a history of drug use. Drugs or alcohol, no history of psychiatric diseases, being literatePersian language .

Intervention groups

In this study, we have two intervention and control groups. In the intervention group, the mental health literacy promotion program will be presented in 6 sessions. The control group does not receive training. To compensate for the control group's deprivation of education, after the implementation of the follow-up one month after the last intervention session, educational content will be presented to the control group in one session in an intensive form.

Main outcome variables

emotional regulation strategies, social health, perceived stress

General information

Reason for update

Acronym

MHL

IRCT registration information

IRCT registration number: **IRCT20160927030002N3**
Registration date: **2023-03-19, 1401/12/28**
Registration timing: **prospective**

Last update: **2023-03-19, 1401/12/28**
Update count: **0**

Registration date

2023-03-19, 1401/12/28

Registrant information

Name

Mousa Alavi

Name of organization / entity

Department of Psychiatric Nursing, Nursing and Midwifery Care

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7588

Email address

m_alavi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of mental health literacy promotion program on emotional regulation strategies, social health and perceived stress of family caregivers of patients with chronic psychiatric disorders

Public title
Investigating the effect of mental health literacy promotion program on emotional regulation strategies, social health and perceived stress
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The participants should be willing to participate in the study. The patient has a history of being hospitalized in a psychiatric ward for the past year or is currently hospitalized in a psychiatric ward. The patient is suffering from a psychiatric disorder diagnosed by a psychiatrist, and his hospitalization in the psychiatric department is not solely due to substance abuse. At least 6 months have passed since the onset of the disease of the sick member of the participants' family. The participants have not experienced an unfortunate incident or severe stress such as the death of a loved one or divorce, etc. during the last six months. The participants should not have a history of using drugs or alcohol. The participants should not have a history of psychiatric diseases, which led to drug use or hospitalization in the psychiatric ward. The participants must be literate in reading and writing and understand the Persian language. The participant is solely responsible for the care of a sick family member.
Exclusion criteria:
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method is based on available sampling and random allocation using spss software; In this way, by referring to the files of patients who are currently hospitalized or have a history of hospitalization in psychiatric wards, we will find the samples for our study that meet the criteria for entering the study by sampling method; Then the samples will be assigned number 1-60 and using spss software we will randomly assign numbers 1-60 in two test and control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
In this study, the samples are randomly divided into intervention and control groups, the intervention group receives mental health literacy training, but the control group does not receive training.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Faculty of Nursing, Management and Rehabilitation of Isfahan University of Medic
Street address
Hezar Jarib St. Isfahan University of Medical Sciences. Building number 3. medical School. Ground Floor. Medical ethics group.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-03-05, 1401/12/14
Ethics committee reference number
IR.MUI.NUREMA.REC.1401.170

Health conditions studied

1

Description of health condition studied
Chronic psychiatric diseases such as schizophrenia, depression and bipolar
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Emotion regulation strategies
Timepoint
The beginning of the intervention (before the start of the intervention). Immediately after the last intervention session, one month after the last intervention session
Method of measurement
Gross and Jan's emotion regulation strategies

questionnaire

2

Description
Social health
Timepoint
The beginning of the intervention (before the start of the intervention). Immediately after the last intervention session, one month after the last intervention session
Method of measurement
Keyes Social Health Questionnaire

3

Description
Perceived stress
Timepoint
The beginning of the intervention (before the start of the intervention). Immediately after the last intervention session, one month after the last intervention session
Method of measurement
Cohen's Perceived Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Training to improve mental health literacy will take place during 6 sessions as follows: First session: Improving the knowledge of family caregivers about mental health. The second session: improving communication skills with the patient and the community. The third session: teaching strategies to reduce the stigma of the disease and negative attitudes to family caregivers. Fourth session: Training of family caregivers in the field of their own needs and those of people with mental disorders. Fifth session: Training of family caregivers in the field of patient rights and strategies for seeking help. Sixth session: introduction of supportive interventions to improve the mental health of the patient and family.
Category
Other

2

Description
Control group: There is no intervention in this group. The members of this group will fill the relevant questionnaires at the same time as the intervention group before the intervention, immediately after and one month after the intervention, and after the end of the intervention to compensate for the deprivation of this group from training. provided, after completing the follow-up and filling of the questionnaires, training will be provided to them in an intensive session.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
Mousa Alavi
Street address
Third Mushtaq St. Arghavanieh Blvd. Farabi Specialized and Subspecialized Hospital
City
اصفهان
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3531 2020
Email
m_alavi@nm.mui.ac.ir

2

Recruitment center
Name of recruitment center
Khurshid Hospital
Full name of responsible person
Mousa Alavi
Street address
Ostandari Street. Next to Shahid Dast Ghaib Blvd. Khurshid Hospital.
City
اصفهان
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3222 2127
Email
m_alavi@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mojgan Mortazavi
Street address
Hezar Jarib St. Isfahan University of Medical Sciences and Health Services. Building No. 4- University Research and Technology Vice-Chancellor
City
Esfahan
Province

Isfehan
Postal code
8174673461
Phone
+98 31 3792 8134
Email
research@nm.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mousa Alavi
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nursing and Midwifery Care Research Center, School of Nursing and Midwifery, Isfahan University of M
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7588
Fax
+98 31 3792 7588
Email
m_alavi@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zeynab Pirallahi
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Hezar Jarib St. School of Midwifery Nursing
City
Isfahan
Province
Isfehan
Postal code
8174683461
Phone
+98 31 3792 3876
Email
zeynabpirallahi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mousa Alavi
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nursing and Midwifery Care Research Center, School of Nursing and Midwifery, Isfahan University of M
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7588
Fax
+98 31 3792 7588
Email
m_alavi@nm.mui.ac.ir

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

Undecided - It is not yet known if there will be 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

After deidentifying people, a part of the data, such as information related to the results of the scores of emotion regulation strategies questionnaires, social health and participation perception stress participants in two control and test groups before and after the implementation of the intervention without specifying the identity of the informants and the information will be presented in the form of general statistical results.

When the data will become available and for how long

1 month after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Having a valid certificate of activity in the mentioned organization

From where data/document is obtainable

Musa Alavi 09138936489. Faculty of Midwifery Nursing, Isfahan. mousa_alavi@yahoo.com Zainab Pirollahi 09190521377. Isfahan Midwifery Nursing School. zeynabpirallahi@gmail.com

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

The applicant first applies through email, in the next step, if there is no response, she communicates through the contact number, and if she does not receive a response, the request for information is made in person.

Comments