

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of the educational program on mental health literacy of caregivers of psychiatric patients admitted to Ibn Sina Hospital

Protocol summary

Study aim

Determining the effectiveness of educational program on mental health literacy of caregivers of psychiatric patients admitted to Ibn Sina Hospital in Mashhad

Design

Clinical trial with control group, blocked, on 54 patients

Settings and conduct

After reviewing the inclusion criteria, the primary caregivers of individuals with any psychiatric disorder (schizophrenia, bipolar disorder, and major depression) are randomly assigned to the intervention or control group. Then, three sessions of mental health literacy training will be conducted by the psychiatric assistant and under the supervision of psychiatric professors in groups (in groups of 10 to 15 people). In this study, the results evaluator as well as the analyzer are blinded about the type of class held for each group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Be a primary caregiver of the patient for at least 6 months, Does not have acute symptoms of psychiatric disorders, The patient (hospitalized) meets the DSM-5 criteria for schizophrenia, bipolar disorder, or major depression and should not have substance use disorders other than nicotine, Ability to read and write, Signing informed consent form to participate in the study

Intervention groups

Caregivers of psychiatric patients admitted to Ibn Sina Hospital in Mashhad For those entering the intervention group, classes to increase the level of mental health literacy and for those entering the control group, life skills classes are given.

Main outcome variables

Mental health literacy

General information

Reason for update

Completion and revision of inclusion criteria and blinding

Acronym

IRCT registration information

IRCT registration number: **IRCT20211227053550N1**

Registration date: **2022-03-08, 1400/12/17**

Registration timing: **registered_while_recruiting**

Last update: **2026-04-27, 1405/02/07**

Update count: **1**

Registration date

2022-03-08, 1400/12/17

Registrant information

Name

Adeleh Abdolalizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3622 5814

Email address

adeleh137246@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-03, 1400/10/13

Expected recruitment end date

2023-03-04, 1401/12/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of the educational program on mental health literacy of caregivers of psychiatric patients admitted to Ibn Sina Hospital		Other design features	
Public title	The effectiveness of the educational program on mental health literacy of caregivers of psychiatric patients	Secondary Ids	empty
Purpose	Supportive	Ethics committees	
Inclusion/Exclusion criteria	Inclusion criteria: Be a primary caregiver of the patient for at least 6 months Without any acute symptoms of psychiatric disorders Ability to read and write Age between 18-60 The patient (hospitalized) meets the DSM-5 criteria for schizophrenia, bipolar disorder, or major depression and should not have substance use disorders other than nicotine Having informed consent to participate in the study Exclusion criteria:	<u>1</u>	
Age	From 18 years old to 60 years old	Ethics committee	
Gender	Both	Name of ethics committee	Ethics Committee of Mashhad University of Medical Sciences
Phase	N/A	Street address	میدان آزادی، درب شرقی پردیس دانشگاه
Groups that have been masked	No information	City	Mashhad
Sample size	Target sample size: 54	Province	Razavi Khorasan
Randomization (investigator's opinion)	Randomized	Postal code	9138813944
Randomization description	Eligible individuals will enter the study after obtaining informed consent (purpose-based sampling).Individuals randomly (random allocation using dedicated randomization sites such as sealed envelop) into two groups of intervention (three 90-minute group sessions of mental health literacy training at one-week intervals) and control (three 90-minute group sessions with skill training content Of life) will be divided.It should be noted that randomization will be done in blocks using 4 or 6 blocks.After random assignment, the type of group assigned to each person (for example, even and odd numbers) will be written on a sheet of paper, and each sheet will be placed in an envelope in the package.After informing the individuals, if the person (health care provider) is eligible to enter the study, he / she will be asked to complete the informed consent form.Then an envelope will be picked (allocation concealment) and the names and surnames of the people and their contact numbers will be written on it for further coordination and according to the code written in the envelope, the people are placed in one of the two intervention or control groups.	Approval date	2021-12-07, 1400/09/16
Blinding (investigator's opinion)	Not blinded	Ethics committee reference number	IR.MUMS.MEDICAL.REC.1400.620
Blinding description		Health conditions studied	
Placebo	Not used	<u>1</u>	
Assignment	Parallel	Description of health condition studied	Health literacy of caregivers of psychiatric patients
		ICD-10 code	
		ICD-10 code description	
		Primary outcomes	
		<u>1</u>	
		Description	Health literacy of caregivers of psychiatric patients
		Timepoint	Before the classes, at the end of the third session and two months after the end of the sessions, the participants will complete the mental health literacy scale.
		Method of measurement	"Mental Health Literacy Scale"The questionnaire was developed by O'Connor et al. And consists of 35 questions and 6 attributes. These 6 attributes are: 1.Ability to diagnose disorders: It includes 8 questions that are scored using a 4-point Likert scale (very unlikely, unlikely, probable, very probable). 2.Knowledge of risk factors and causes: consists of 2 questions that are scored using a 4-point Likert scale (very unlikely, unlikely, probable, very probable). 3.Knowledge about self-medication: consists of 2 questions that are scored using a 4-point Likert scale (very unhelpful, unhelpful, beneficial, very beneficial). 4.Knowledge of available professional help: consists of 3 questions that are graded using a 4-point Likert scale (very unlikely, unlikely,

probable, very probable). 5. Knowledge of where to look for information: Contains 4 questions that are scored using a 5-point Likert scale (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree). 6. Attitudes about promoting appropriate diagnosis or supportive behavior: includes 16 questions using a 5-point Likert scale (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree) or (definitely willing, probably willing, Neither reluctant nor reluctant, probably reluctant, definitely reluctant) are scored.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For caregivers of people with psychiatric diseases, three sessions of mental health literacy training will be conducted by a psychiatric assistant and under the supervision of psychiatric professors in groups (in groups of 10 to 15 people). Each session lasts 90 minutes. Meetings will be held interactively with questions and answers. The content of the sessions is as follows: The first session (project introduction) Explaining the rules of participation in group meetings (timely attendance at meetings and the need to participate in both sessions), reviewing participants' knowledge about the concept of mental health, mental illness and causes of disorders Mental, explaining the concept of mental health, mental illness and its causes and correcting participants' opinions, examining participants' knowledge about the symptoms of psychiatric disorders and their diagnosis, explaining the signs and symptoms of common and important psychiatric disorders (anxiety, mood, Psychotic). Session 2: Reviewing the topics of the previous session, reviewing people's opinions about the treatment of mental disorders and seeking professional help, explaining about the treatment of mental disorders (medication and psychotherapy), explaining the consequences of not treating mental disorders and the need for help Professional, reviewing individuals' knowledge of how to access and explaining mental health professional assistance. Session 3: Reviewing the topics of the previous session, examining people's opinions about the mentally ill (including their risk, their social and interpersonal skills, and the treatability of the disorder), explaining the stigma of mental disorders, and correcting participants' opinions through Group discussion, summary. At the end of the third session and two months after the end of the sessions, the participants will complete the Mental Health Literacy Scale again.

Category

Lifestyle

2

Description

Control group: کلاس مهارت های زندگی

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Psychiatric Hospital, Mashhad

Full name of responsible person

Adeleh Abdolalizadeh

Street address

Horr Ameli Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9195983134

Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Meshkat

Street address

Azadi Square, east door of the university campus

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Province

Razavi Khorasan

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9177948564

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MDS.Dean@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
Adeleh Abdolalizadeh
Position
Resident of psychiatric
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available