

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of emotion regulation program on social skills and perceived social stigma in patients with mood disorders

Protocol summary

Study aim

Determining the effect of emotion regulation program on social skills and perceived social stigma in patients with mood disorders

Design

This study is a clinical trial with a control group and it is performed on 60 samples that were placed in two groups of 30 people, control and test, using a simple random method. Randomization in this study is done using spss

Settings and conduct

The research environment is Khurshid and Farabi hospitals in Isfahan. The sample of our study will be patients diagnosed with depressive and bipolar mood disorders hospitalized in these centers. The adjustment program sessions will be conducted in 6 sessions of 30-45 minutes and in the form of groups of eight to ten patients for the intervention group and three times a week, by the student and with the supervision and accompaniment of the supervisor in the classroom of the department.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being hospitalized with a diagnosis of one of the depressive disorders, bipolar by a psychiatrist, being at least 18 years old Non-entry criteria: patient's unwillingness to continue attending, absence of more than two sessions, acute phase of the patient, causing any physical problem or discomfort to the patient.

Intervention groups

Intervention group: The sessions of the emotion regulation program will be conducted in 6 sessions of 30-45 minutes for the intervention group and three times a week in the classroom of the department. Control group: They will not receive any training program and at the end, the content of the sessions will be provided to the members of the control group

Main outcome variables

social skills and perceived social stigma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039321N5**

Registration date: **2024-02-04, 1402/11/15**

Registration timing: **prospective**

Last update: **2024-02-04, 1402/11/15**

Update count: **0**

Registration date

2024-02-04, 1402/11/15

Registrant information

Name

sima ghezelbash

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7607

Email address

ghezelbash@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-05-20, 1403/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of emotion regulation program on social skills and perceived social stigma in patients with mood disorders	
Public title	The effect of emotion regulation program on social skills and perceived social stigma
Purpose	Education/Guidance
Inclusion/Exclusion criteria	
Inclusion criteria:	1. Diagnosed with one of the depressive disorders, bipolar, recorded by a psychiatrist in the patient's file. . The patient has passed the acute period of his illness, was in a relatively stable condition when entering the study, and was hospitalized in a non-acute ward In bipolar patients, the patient should not be in the mania phase . Patients should be in the adult age group (over 18 years old) The patient is willing to participate in the study The patient should not suffer from cognitive disorders at the same time - which cause learning disorders. (It is clear according to the documents of the case). Not suffering from mental retardation (it is clear according to the documents of the case) The patient should not be affected by the side effects of drug and non-drug treatment The patient has not experienced stressful events such as divorce and loss of loved ones during the last six months . The patient has not participated in interventions similar to the intervention of this study at the same time or recently The patient has relative and higher vision (it is clear by examining the mental status examination form recorded in the patient's file by the researcher). The patient should be able to speak Persian and be literate in reading and writing (able to complete the questionnaires). The patient and his accompanying person should have access to a smartphone and the Internet and should be familiar with the ITA messenger program, so that if they are unable to attend the third stage of the questionnaires one month after the end of the intervention, they can In this way, he communicated with them (in order to complete the questionnaire one month after the intervention, when the patient was probably discharged from the hospital). The patient does not have a recent history of substance abuse.
Exclusion criteria:	1) The unwillingness of the patient or his family to continue their presence in the study. 2) absence of more than two patient sessions from the intervention sessions 3) Return of the patient to the acute period of the disease 4) Transferring the patient to another hospital or dying during the study 5) causing any physical problem or discomfort, as a result of which the sample is no longer able to continue participating in the study.
Age	From 18 years old
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	Generating random samples in spss statistical software: Transform; compute variables; random numbers (RV-UNIFORM(min,max)) The sampling method is based on available sampling and random allocation of samples using spss statistical software. In this way, for the samples, based on the determined sample size, we will consider numbers from 1 to 60, then with the help of spss software and according to the mentioned route, we will randomly allocate 30 people in each of the test and control groups.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee in Research Faculty of Nursing, Management and Rehabilitation - Isfahan University
Street address	Isfahan University of Medical Sciences ,Isfahan ,Iran
City	Isfahan
Province	Isfahan
Postal code	8174673461
Approval date	2024-01-13, 1402/10/23
Ethics committee reference number	IR.MUI.NUREMA.REC.1402.170
Health conditions studied	
<u>1</u>	
Description of health condition studied	depressive disorders
ICD-10 code	F32
ICD-10 code description	Major depressive disorder, single episode

2

Description of health condition studied

bipolar disorders

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

The score of social skills in Riggio and Kanari social skills questionnaire

Timepoint

The beginning of the study (before the intervention), immediately after and one month after the educational program

Method of measurement

Riggio and Kanari social skills questionnaire

2

Description

Perceived social stigma score from the Michael King Stigma Questionnaire

Timepoint

The beginning of the study (before the intervention), immediately after and one month after the educational program

Method of measurement

Michael King Stigma Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The sessions of the emotion regulation program will be conducted by the researcher in groups of 8-10 patients three times in the classroom of Khurshid and Farabi Hospital in Isfahan in 6 sessions of 30-45 minutes. The content of these sessions is based on a training booklet that provides the patients with a summary of the discussed training in the form of a training booklet. In addition, the educational content of the sessions will be transmitted through group discussions, lectures, questions and answers, and presentation of videos and slides.

Category

Other

2

Description

Control group: They do not receive any educational program and only participate in two sessions of

introduction and discussion.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

Atefe Azimi

Street address

Farabi Specialized and Subspecialized Hospital, Arghwaniye Blvd., Mushtaq 3rd St., Isfahann ,Iran

City

Isfahan

Province

Isfahan

Postal code

81551-13153

Phone

+98 31 3795 2000

Email

farabi@mui.ac.ir

2

Recruitment center

Name of recruitment center

Khorshid hospital

Full name of responsible person

Atefe Azimi

Street address

khoshid medical educational research complex ,Governorate Street ,Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81458-33117

Phone

+98 31 3222 2127

Email

Nour@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

Street address

Nursing and Midwifery Faculty., Isfahan University of Medical Sciences., Hezerjerib Ave

City

isfahan

Province
Isfahan

Postal code
81746-73461

Phone
+98 31 3668 8138

Email
research@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
Atefe Azimi

Position
Master's student in psychiatry

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezarjerib Ave., Isfahan, Iran

City
Isfahan

Province
Isfahan

Postal code
8174673461

Phone
+98 31 3792 7565

Email
atefe.azimi.nk76@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Atefe Azimi

Position
Master's student in psychiatry

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Isfahan University Of Medical Sciences, Hezar-Jerib Ave., Isfahan, IR Iran.

City
isfahan

Province
Isfahan

Postal code
8174673461

Phone
+98 31 3792 7565

Email
atefe.azimi.nk76@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Sima Ghezelbash

Position
Faculty member- instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Isfahan University Of Medical Sciences, Hezar-Jerib Ave., Isfahan, IR Iran.

City
Isfahan

Province
Isfahan

Postal code
8174673461

Phone
+98 31 3792 7565

Email
ghezelbash@nm.mui.ac.ir

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

Not applicable
Data Dictionary
Not applicable