

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of acceptance and commitment therapy on stigma and family functioning of patients with mental disorders

Protocol summary

Study aim

Determining the effect of acceptance and commitment therapy on stigma and family functioning of patients with mental disorders

Design

The present study is a randomized clinical trial without blinding.

Settings and conduct

The present study is a randomized clinical trial without blinding. 60 family members of patients with mental disorders will participate in this study. The location of the study will be the psychiatric department of Vali Asr Hospital affiliated to Fasa University of Medical Sciences.

Participants/Inclusion and exclusion criteria

In present study 60 family members of patients with mental disorders will participate in this study. Inclusion criteria include: Willingness to participate in the study and having at least one year of experience in caring for patients with mental disorders, and exclusion criteria include the absence of family members for more than two sessions in training sessions and unwillingness to continue participating in the study for any reason.

Intervention groups

For the intervention test group, the educational program will be implemented in the form of 6 sessions of 60 minutes each session and two days a week for 3 weeks. Lectures, group discussions, questions and answers, and brainstorming methods are used in the training sessions by a psychologist who has already completed the training course. In this research, the general treatment guide based on acceptance and commitment will be used. Acceptance and commitment therapy is a psychotherapy technique that promotes acceptance of negative thoughts, feelings, and events. In fact, this psychotherapy technique encourages a person to consciously participate in activities. The control group will not receive the training intervention, but they will be given the training package.

Main outcome variables

stigma and family functioning of patients with mental disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044802N10**

Registration date: **2023-09-14, 1402/06/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-14, 1402/06/23**

Update count: **0**

Registration date

2023-09-14, 1402/06/23

Registrant information

Name

Mostafa Bijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5331 5012

Email address

bizhani_mostafa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2023-12-11, 1402/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of acceptance and commitment therapy on stigma and family functioning of patients with mental disorders

Public title

Investigating the effect of acceptance and commitment therapy on stigma and family functioning of patients with mental disorders

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study Having at least one year of experience caring for patients with mental disorders

Exclusion criteria:

Absence of family members for more than two sessions in training sessions Unwillingness to continue participating in the study for any reason

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

60 cards are placed in a sealed envelope. 30 cards will be labeled A (intervention group) and 30 cards will be labeled B (control group). Then, the members of the families participating in the study are asked to take one of the cards. People who take card A will be in the intervention group and people who take card B will be in the control group.

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 Fasa University of Medical Sciences

Street address

Fars province, Fasa city, Ibn Sina square. Fasa University of Medical Sciences. Fasa Iran

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2023-07-30, 1402/05/08

Ethics committee reference number

IR.FUMS.REC.1402.061

Health conditions studied**1****Description of health condition studied**

Mental disorders

ICD-10 code

F99

ICD-10 code description

Unspecified mental disorder

Primary outcomes**1****Description**

stigma

Timepoint

Before, immediately and one month after the educational intervention

Method of measurement

Shamsaei et al.'s stigma questionnaire

2**Description**

Family functioning

Timepoint

Before, immediately and one month after the educational intervention

Method of measurement

Epstein et al.'s family function assessment questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For the intervention test group, the educational program will be implemented in the form of 6 sessions of 60 minutes each session and two days a week for 3 weeks. Lectures, group discussions, questions

and answers, and brainstorming methods are used in the training sessions by a psychologist who has already completed the training course. In this research, the general treatment guide based on acceptance and commitment will be used. Acceptance and commitment therapy is a psychotherapy technique that promotes acceptance of negative thoughts, feelings, and events. In fact, this psychotherapy technique encourages a person to consciously participate in activities. The training sessions include the first session of familiarization and training regarding treatment based on acceptance and commitment, the second session of creating flexible patterns of behavior through value-oriented encounter, the third session of moving towards a valuable life with an accepting and observant self, the fourth session of ways to respond to thoughts Disturbing and stressful, the fifth session is self-awareness and self-control behaviors, the sixth session is setting goals based on values and taking effective measures to achieve those goals and stay on the path of values.

Category

Behavior

2

Description

Control group: The control group will not receive the training intervention, but they will be given the training package

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Fasa Hospital

Full name of responsible person

Mostafa Bijani

Street address

Fars province, Fasa city, Ibn Sina square. Fasa University of Medical Sciences. Fasa Iran .

City

Fasa

Province

Fars

Postal code

7461686688

Phone

+98 917 330 8451

Email

bizhani_mostafa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Akbar Farjad Far

Street address

Fars province, Fasa city, Ibn Sina square. Fasa University of Medical Sciences. Fasa Iran

City

Fasa

Province

Fars

Postal code

7461686688

Phone

+98 912 176 9752

Email

farhad_2020@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bijani

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Fars province, Fasa city, Ibn Sina square. Fasa University of Medical Sciences. Fasa Iran .

City

Fasa

Province

Fars

Postal code

7461686688

Phone

071-53350994-6

Email

bizhani_mostafa@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bijani

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Fars province, Fasa city, Ibn Sina square. Fasa University of Medical Sciences. Fasa Iran .

City

Fasa

Province

Fars

Postal code

7461686688

Phone

071-53350994-6

Email

bizhani_mostafa@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bijani

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Fars province, Fasa city, Ibn Sina square. Fasa University of Medical Sciences. Fasa Iran .

City

Fasa

Province

Fars

Postal code

7461686688

Phone

071-53350994-6

Email

bizhani_mostafa@yahoo.com

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After completing the study and publishing the results, researchers can send their request to the responsible author to use the results of this study

When the data will become available and for how long

After completing the study and publishing the results

To whom data/document is available

After completing the study and publishing the results, researchers can send their request to the responsible author to use the results of this study

Under which criteria data/document could be used

After completing the study and publishing the results, researchers can send their request to the responsible author to use the results of this study

From where data/document is obtainable

corresponding author: Mostafa Bijani

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

After completing the study and publishing the results, researchers can send their request to the responsible author to use the results of this study

Comments