

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The Effectiveness of group Dialectical Behavior Therapy in reducing symptoms of panic and depression in patients with Mitral valve prolapse syndrome

Protocol summary

Study aim

Efficacy of dialectical behavior therapy on decreasing depression and panic attacks

Design

A clinical trial is a quasi-experimental pretest-posttest with a control group. Community-based and pragmatic research with parallel groups. Samples included 16 women who were randomly assigned into two groups of 8, and one-way blindness was performed on the samples.

Settings and conduct

The present research is based on the effect of psychological interventions on cardiovascular diseases. The study was applied research in the city of Mashhad.

Participants/Inclusion and exclusion criteria

Entry requirements: 1- Subjects are female. 2- Diagnosis of mitral valve prolapse syndrome is diagnosed by a cardiologist. 3- Having a minimum age of 18 and a maximum of 50 years. 4. Not having a particular disease. 5. No use of psychoactive drugs Non-arrival conditions:1. Having secondary heart disease 2. Having family and professional problems

Intervention groups

Dialectic Behavioral Therapy has four therapeutic strategies, attention awareness, distress tolerance, interpersonal self-efficacy and emotional regulation. Each of these strategies has behavioral techniques and exercises that will allow one to control and adjust his painful thoughts and feelings.

Main outcome variables

Reduce symptoms of depression and panic attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180702040310N1**

Registration date: **2018-07-17, 1397/04/26**

Registration timing: **retrospective**

Last update: **2018-07-17, 1397/04/26**

Update count: **0**

Registration date

2018-07-17, 1397/04/26

Registrant information

Name

Masood Salehi

Name of organization / entity

University of Ferdosi Mashhad

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-04-13, 1394/01/24

Expected recruitment end date

2015-06-09, 1394/03/19

Actual recruitment start date

2015-04-18, 1394/01/29

Actual recruitment end date

2015-06-09, 1394/03/19

Trial completion date

empty

Scientific title

The Effectiveness of group Dialectical Behavior Therapy in reducing symptoms of panic and depression in patients with Mitral valve prolapse syndrome

Public title

Efficacy of dialectical behavior therapy on depression and panic attacks

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All female patients with mitral valve prolapse syndrome in Mashhad city Having no secondary heart disease

Exclusion criteria:

Having ages under 18 and over 50 Having mental illness Having family and professional problems

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **18**

Actual sample size reached: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Because the participants had a specific heart disease. In the first step, an easy sampling method was used to select individuals. In the second stage, a simple sampling method was used to accommodate the subjects in the experimental and control groups. In the third stage, a number was assigned to the participant from 1 to 16. In the fourth stage, individuals with the odd number in the experimental group and those with a pair number in the control group were placed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants were randomly assigned to two groups, but they were not told which group they were. In addition, each group was formed on separate days. Participants were also told to not be in any way connected with the other group's participants.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

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Technology

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13157731314

Approval date

2016-10-30, 1395/08/09

Ethics committee reference number

۲۲۶۷۳۳۸

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

Mitral valve prolapse syndrome

ICD-10 code

I34.1

ICD-10 code description

Floppy mitral valve syndrome

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

the score Depression, Anxiety and Stress . Scoring Panic Attacks

Timepoint

The variables of depression and panic attacks were measured at the beginning of the study and before the intervention and at the end of the intervention.

Method of measurement

Inventory, Beck Depression, Anxiety and Stress. Albanian Panic Attack Questionnaire

Secondary outcomes

empty

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

Intervention group: Using the skills of mindfulness, emotion regulation, distress tolerance, interpersonal and self-efficacy for 10 sessions of 75 minutes."Control group": no drug treatment. Non-use of psychological treatments. 10 sessions of 75 minutes and group discussions related to the physical and psychological problems caused by the disease.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical Psychology Clinic of Ferdowsi University

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Ferdowsi

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The University of Ferdowsi

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

The University of Ferdowsi Mashhad

Full name of responsible person

Mohaamad Javad Asgari Ebrahimabad

Position

Associate professor

Latest degree

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Other areas of specialty/work

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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

Not applicable

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