Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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
Iranian Institute of Information Science and Technology
Street address
No. 1090, slamic Revolutionary Street. Palestine crossroads
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Province
Tehran
Postal code
13157731314
Approval date
2016-10-30, 1395/08/09
Ethics committee reference number
۲۲۶۷۴۳۸

Health conditions studied

1

Description of health condition studied
Mitral valve prolapse syndrome
ICD-10 code
134.1
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

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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
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Associate professor

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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