

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the Effectiveness of unified for transdiagnostic Psychotherapy and Mindfulness-Based Cognitive Therapy on Emotional Regulation, Distress Tolerance, Anxiety sensitivity and Rumination in Heart Disease patients with Type D Personality

Protocol summary

Study aim

Determining the difference in the effectiveness of mindfulness-based cognitive therapy and unified transdiagnostic psychotherapy on improving emotional regulation, promoting disturbance tolerance, reducing anxiety sensitivity and rumination in cardiac patients with D personality.

Design

The clinical trial has a control group, with parallel groups, not blinded and non-random assignment of people to groups. Phase 1 on 60 patients.

Settings and conduct

Among the heart patients of Simorgh Heart Clinic in Mashhad, 60 people with personality type D will be selected and placed in 3 research groups. All 3 groups are measured before, after and 2 months after the implementation of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: obtaining the required cutoff score in questionnaire D, not participating in concurrent psychotherapy sessions, not having a clinical diagnosis similar to other disorders, not having a history of hospitalization and episodes of psychosis... Exclusion criteria: sudden occurrence of trauma, bereavement, severe recurrence of heart disease.

Intervention groups

The intervention groups include integrated metadiagnostic group (20 people), cognitive therapy group based on mindfulness (20 people) and control group (20 people).

Main outcome variables

2 independent changes (treatment method) (treatment method) (psychological treatment study and transdiagnostic treatment) and four dependent variables (emotion regulation, disturbance tolerance and treatment of a worry and thought disorder)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231209060306N1**

Registration date: **2024-01-03, 1402/10/13**

Registration timing: **prospective**

Last update: **2024-01-03, 1402/10/13**

Update count: **0**

Registration date

2024-01-03, 1402/10/13

Registrant information

Name

masume bigonah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 558 2396

Email address

masoomehbigonah@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparison of the Effectiveness of unified for transdiagnostic Psychotherapy and Mindfulness-Based Cognitive Therapy on Emotional Regulation, Distress Tolerance, Anxiety sensitivity and Rumination in Heart Disease patients with Type D Personality
Public title	Comparison of the Effectiveness of unified for transdiagnostic Psychotherapy and Mindfulness-Based Cognitive Therapy on Emotional Regulation, Distress Tolerance, Anxiety sensitivity and Rumination in Heart Disease patients with Type D Personality
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Obtaining the required cutoff score in the personality questionnaire D Existence of heart disease Non-participation in concurrent psychotherapy sessions and no history of more than three treatment sessions in the person's history. Not having the same clinical diagnosis with substance withdrawal disorders, dementia, depression disorder and adjustment disorder based on Ballinger's and expert diagnosis. Minimum middle school literacy. Not taking medical drugs at the same time and drug abuse and addiction Not having a history of hospitalization and episodes of psychosis Minimum age of 40 and maximum of 70 years
Exclusion criteria:	Absence of more than two sessions in therapy sessions. Sudden occurrence of trauma, bereavement and adjustment problems for people during the time period of the sessions Severe recurrence of heart disease. Failure to carry out relevant instructions and exercises in meetings.
Age	From 40 years old to 70 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Specialized committee of ethics in biomedical research of Torbete Jam University
Street address	Islamic azad university of torbate jam
City	Torbate jam
Province	Razavi Khorasan
Postal code	9188754575
Approval date	2023-04-26, 1402/02/06
Ethics committee reference number	IR.IAU.TJ.REC.1402.002
Health conditions studied	
1	
Description of health condition studied	Heart disease
ICD-10 code	
ICD-10 code description	
Primary outcomes	
1	
Description	Emotion regulation
Timepoint	The beginning of the intervention (before starting the treatment) and the last session of the study and for follow-up after one month
Method of measurement	Cognitive emotion regulation questionnaire (Garnefsky et al, 2001)
2	
Description	Confusion tolerance
Timepoint	The beginning of the intervention (before starting the treatment) and the last session of the study and for follow-up after one month
Method of measurement	Tolerance questionnaire by Simmons and Gaher (2005)
3	
Description	

Anxiety Sensitivity

Timepoint

The beginning of the intervention (before starting the treatment) and the last session of the study and for follow-up after one month

Method of measurement

Rees and Patterson Anxiety Sensitivity Questionnaire (1985)

4

Description

Rumination

Timepoint

The beginning of the intervention (before starting the treatment) and the last session of the study and for follow-up after one month

Method of measurement

Nolen-Hoeksma questionnaire (1991)

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: this group will receive cognitive behavioral therapy based on mindfulness, which is designed based on the protocol of Segal and Teasdel (2002) in 8 sessions of 90 minutes.

Category

Behavior

2

Description

The second intervention group: this group will receive integrated metadiagnostic treatment according to the protocol of Barlow et al. (2012) in 10 sessions of 60 minutes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Simorgh Heart Clinic, Mashhad

Full name of responsible person

Dr.Javad Ramezani

Street address

Imam Reza Hospital Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Javad Nik Andish

Street address

Kilometer 10 Torbate Jam Road, Islamic Azad University, Torbat Jam Branch

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Province

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Nikandis_s@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

50

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

Islamic Azad University

Full name of responsible person

Masoome Bigonah Rudmajani

Position

Phd Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"There is no further information".

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data, such as the information related to the main outcome, can be shared. Study protocol, statistical analysis, report of research findings can be published

When the data will become available and for how long

Access starts after the end of research and publication of articles

To whom data/document is available

All students and professors and those interested in the field of health psychology

Under which criteria data/document could be used

Expansion of existing therapeutic areas in psychology

From where data/document is obtainable

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

Apply by email

Comments