

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effectiveness of mindfulness-based cognitive-behavioral therapy on social anxiety, cognitive flexibility and happiness in patients with coronary heart disease

Protocol summary

Study aim

treatment

Design

The experimental (n = 15) and control (n = 15) groups were selected by convenience and simple random sampling.

Settings and conduct

Research method: semi-experimental type with a pre-test, post-test design with a control group. The statistical population is all patients with coronary heart disease referred to Heshmat Hospital in Rasht city, who referred to this hospital in July and August 1400. The tool for collecting materials and information was scanning authentic books and articles, as well as referring to authentic sites, and in order to collect data, the students' adaptation questionnaire was used by Dennis and Vanderwaal (2010), the Oxford happiness questionnaire and the social anxiety questionnaire of Conor et al. 2000) was used.

Participants/Inclusion and exclusion criteria

Entry criteria: the person must be suffering from coronary heart disease; the person must be a resident of Rasht city; the person must be interested in participating in this research. Exclusion criteria: not being able to read and write; taking psychiatric drugs.

Intervention groups

After the pre-test (questionnaire), the MBCT training protocol in 8 sessions of 90 minutes is provided as an audio file to the experimental group, which is based on the 8-week MBCT program for adults, and at the end, members will be re-evaluated by a questionnaire.

Main outcome variables

Cognitive flexibility; social anxiety; happiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210824052280N1**

Registration date: **2022-10-17, 1401/07/25**

Registration timing: **retrospective**

Last update: **2022-10-17, 1401/07/25**

Update count: **0**

Registration date

2022-10-17, 1401/07/25

Registrant information

Name

Reyhane Darrudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3387 6158

Email address

reyhane72azar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of mindfulness-based cognitive-

behavioral therapy on social anxiety, cognitive flexibility and happiness in patients with coronary heart disease

Public title

The effect of mindfulness on social anxiety, cognitive flexibility and happiness

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The person must have coronary heart disease. The person must be a resident of Rasht. The person must be interested in participating in the research.

Exclusion criteria:

Inability to read and write. Taking psychiatric drugs.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is a simple randomization. The study has two groups and from the beginning it is agreed that odd numbers will be given to the intervention group and even numbers will be given to the control group. Then, using random numbers table, the relevant numbers are extracted, each number is written on a card and placed in an envelope, and the envelopes are sealed, and the patient's number is written on each envelope, and the first patient who enters the study Envelope number 1, patient number 2, envelope number 2 and so on will be given. Finally, people in two intervention groups (15 people) and control group (15 people) will enter the research.

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 Lahijan Azad University

Street address

Health Building 7, Kamranieh, Talshan

City

Rasht

Province

Guilan

Postal code

4193168619

Approval date

2021-09-08, 1400/06/17

Ethics committee reference number

IR.IAU.LIAU.REC

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

Coronary heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

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

Cognitive flexibility score in Dennis and Vanderwaal's cognitive flexibility questionnaire

Timepoint

Before and after the intervention

Method of measurement

Cognitive flexibility questionnaire of Dennis and Vanderwaal

2**Description**

Oxford happiness questionnaire score

Timepoint

Before and after the intervention

Method of measurement

Oxford Happiness Questionnaire

3**Description**

Conover's Social Anxiety Questionnaire

Timepoint

Before and after the intervention

Method of measurement

Conover's Social Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group receives cognitive behavioral therapy based on mindfulness. The therapy sessions are as follows: each session lasts for 45 minutes and two sessions per week during four consecutive weeks for a total of eight sessions. The content of the interventions of each session is as follows: First session: physical examination training and focus on short breathing, reading and meditation reflection, breathing exercise training and doing it, breathing exercise assignment, notes of emotions during exercise. The second session: practicing thoughts and feelings, people's feedback from the practice, getting to know how to relax. The third session: conscious movement, meditation and checking the body, discovering the experiences of thoughts and creating images and feelings of the present. The fourth session: practice of seeing and hearing, meditation and understanding the present moment, practice with sitting meditation. The fifth session: Reviewing the exercise and examining its effects on the body; Three-minute breathing exercise. Sixth session: training in body scanning technique, searching for physical senses (hearing and taste), observing opposite thoughts and alternative views. Seventh session: Observing the creation of alternative thoughts and views, making a list of energizing (creating a sense of pleasure and mastery) and boring activities. 8th session: body inspection meditation, final meditation, review of the entire course.

Category

Treatment - Other

2

Description

Control group: In this study, people in the control group do not receive any intervention and it is created only for the purpose of comparison to determine the effectiveness of the treatment used in the intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Heshmat Educational & Remedial Center

Full name of responsible person

Dr. Rasoul Yousefi

Street address

Bayani Street

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Rasht

Province

Guilan

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413955588

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heshmat@gums.ac.ir

Web page address

https://heshmat.gums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Lahijan Branch

Full name of responsible person

Gholamreza Vaghar Lahiji

Street address

East Kashif Street, the end of Shaghayegh Street

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3951544169

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Email

info@liau.ac.ir

Web page address

http://www.liau.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University, Lahijan Branch

Proportion provided by this source

100

Public or private sector

Private

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

Mohammad.Mahdi Pasandideh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Assistant professor

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

Psychology

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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

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 general specifications such as information about the main outcome are shared.

When the data will become available and for how long

The access period begins three months after the publication of the results

To whom data/document is available

The use of the results is free for the public, and it is also available to all researchers in the research field under study.

Under which criteria data/document could be used

Its use is unrestricted, citing the source.

From where data/document is obtainable

Islamic Azad University Lahijan branch

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

Refer to the Open University Branch Library, Theses section

Comments