

# 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

#### City

Rasht

#### Province

Guilan

#### Postal code

413955588

#### Phone

+98 13 3366 3070

### Email

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

#### City

Lahijan

#### Province

Guilan

#### Postal code

3951544169

#### Phone

+98 13 4222 9074

#### 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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East Kashef St.

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

Islamic Azad University

**Full name of responsible person**

Reyhane Darrudi

**Position**

Collegian

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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**Province**

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**Postal code**

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**Phone**

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**Fax****Email**

Reihane72azar@gmail.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**

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**