

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effect of Mindfulness-Based Intervention on Perceived Stress, Perception of Disease and Control Source in Patients with Acute Coronary Syndrome Admitted to Hospital

Protocol summary

Study aim

Determining the Effectiveness of Mindfulness-Based Intervention on Perceived Stress, Perception of Disease and Control Source in Patients with Acute Coronary Syndrome

Design

Controlled randomized clinical trial. Blinding will not be done in this study.

Settings and conduct

Study setting will be Chamran Medical Center of Isfahan and sample size will be 76 subjects (38 in each group)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with acute coronary syndrome by the cardiologist based on clinical and para-clinical diagnosis Non-inclusion criteria: Having any diagnosed mental disorder; Co-morbid acute somatic disorders; Having any problems that interfere with communication and participation in the intervention

Intervention groups

Intervention group: Patients with acute coronary syndrome who will receive an intervention consisting of a 6-session program focusing on mindfulness techniques and their application to improve control over body and mental status. Control group: Patients with acute coronary syndrome who are receiving routine care and do not participate in similar programs until the completion of the study.

Main outcome variables

Perceived stress; Perception of disease; Locus of control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160927030002N2**
Registration date: **2019-04-30, 1398/02/10**

Registration timing: **prospective**

Last update: **2019-04-30, 1398/02/10**

Update count: **0**

Registration date

2019-04-30, 1398/02/10

Registrant information

Name

Mousa Alavi

Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2640-06-21, 2019/03/31

Expected recruitment end date

2640-11-21, 2019/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Mindfulness-Based Intervention on Perceived Stress, Perception of Disease and Control Source in Patients with Acute Coronary Syndrome Admitted to

Hospital

Public title

Effectiveness of Mindfulness-Based Intervention on Mental Health in Patients with Acute Coronary Syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with acute coronary syndrome by the cardiologist based on clinical and paraclinical diagnosis. The samples are willing to participate in the study. Subjects are aware of current conditions and type of illness. Research samples are from patients aged 35-70. Participants have full vigilance and awareness of time, place and person, and don't have any mental disabilities, significant cognitive or physical problems that prevent their participation in meetings. Don't have any malignancy and mental disorders such as psychosis. Living in Isfahan. Research samples do not have a history of attending psychotherapy training sessions or similar studies over the past year. Don't have any systemic diseases such as cancers and stroke. Literacy to read and write. Have complete satisfaction to participate in the research project (identified by clinical interviewing and taking history). Patients have full vigilance, acceptable hearing and speech ability.

Exclusion criteria:

Having any diagnosed mental disorder. Co-morbid acute somatic disorders. Having any problems that interfere with communication and participation in the intervention.

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is done in convenience form. Then, the names of the patients for whom a definite diagnosis of heart disease was given and those who have inclusion criteria are listed and then randomly assigned to two groups of intervention and control using SPSS software.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib street,

City

Isfahan

Province

Isfahan

Postal code

81745-319

Approval date

2019-03-18, 1397/12/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.491

Health conditions studied

1

Description of health condition studied

Perceived stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

2

Description of health condition studied

Perception of Disease

ICD-10 code

R44.9

ICD-10 code description

Unspecified symptoms and signs involving general sensations and perceptions

Primary outcomes

1

Description

Perceived Stress

Timepoint

Three steps before, immediately and one month after the intervention

Method of measurement

Perceived Stress Scale

2

Description

Perception of Disease

Timepoint

Three steps before, immediately and one month after the intervention

Method of measurement

Illness Perception Questionnaire

3

Description

Locus of Control

Timepoint

Three steps before, immediately and one month after the intervention

Method of measurement

Rotter's Locus of Control Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Six sessions of Mindfulness-based treatment plan will be implemented according to the Kabat-Zinn Protocol (Kabat-Zinn, Massion et al., 1992). 45-minute sessions once a week (for 6 sessions), in the morning shift, and from 9:00 to 10:00 AM, will be held.

Category

Rehabilitation

2

Description

Control group: Includes a group of patients similar to those in the intervention group who receive routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Gholamreza Masomi

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Moshtagh Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Tahereh Changiz

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Grant name

Thesis

Grant code / Reference number

IR.MUI.RESEARCH.1397.491

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

Yes

Title of funding source

Isfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Mousa Alavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

All data is shared upon request.

When the data will become available and for how long

Sharing time will be started 6 months after publication of paper

To whom data/document is available

For researchers and institutions upon request

Under which criteria data/document could be used

Use of data for research purposes is allowed.

From where data/document is obtainable

Asked by e-mail at the following address

m_alavi@nm.mui.ac.ir

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

The applicant must submit a Letter of Approval for the research project.

Comments