Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 trail. 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

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Name of organization / entity
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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
Isfehan
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
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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
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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