Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Supportive Education Based on the Neuman Systems Model on Anxiety Levels and Coping Strategies in Patients with Myocardial Infarction

Protocol summary

Study aim
Determining the Effect of Supportive Education Based on the Neuman Systems Model on Anxiety Levels and Coping Strategies in Patients with Myocardial Infarction

Design
This RCT at Mostafa Khomeini Hospital will enroll 70 MI patients randomized via block randomization (using permuted block randomization on block size=4) to intervention or control groups. Blinding will be applied to the outcome assessors who will evaluate anxiety and coping strategy outcomes. Data will also be analyzed by an independent researcher unaware of group assignments.

Settings and conduct
This RCT at Mostafa Khomeini Hospital will randomize eligible MI patients into intervention (12 sessions: 2 in-person, 10 remote via WhatsApp/Telegram/phone) or control groups. Blinded evaluators will assess outcomes. The hybrid delivery method ensures feasibility for post-MI patients with mobility limitations.

Participants/Inclusion and exclusion criteria
Diagnosis of myocardial infarction (MI) by the treating physician, age between 35 and 70 years, and no known psychotic disorders. No acute pain and ejection fraction (EF) above 30%. Have access to online messaging services Exclusion criteria include unwillingness to continue participation, incomplete questionnaire responses, development of another cardiac condition or deterioration of the patient's health for any reason that increases anxiety, and absence more than one educational session.

Intervention groups
Intervention group receives 12 weeks of Neuman Systems Model-based education (12 sessions: 1 assessment, 3 structured, 8 supportive on stress reduction, relaxation, family support, and coping strategies tailored to individual needs) via online/phone platforms. Control group receives standard post-discharge care (routine follow-ups, pamphlets) without educational intervention.

Main outcome variables
anxiety, coping strategy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241109063649N1**
Registration date: **2025-08-02, 1404/05/11**
Registration timing: **prospective**

Last update: **2025-08-02, 1404/05/11**
Update count: **0**

Registration date
2025-08-02, 1404/05/11

Registrant information

Name
Sahar Abdoli

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2025-11-22, 1404/09/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Supportive Education Based on the Neuman Systems Model on Anxiety Levels and Coping Strategies in Patients with Myocardial Infarction

Public title
"How Supportive Education Can Help Heart Attack Patients Manage Anxiety and Cope Better: A Study Based on the Neuman Systems Model."
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of myocardial infarction (MI) by the treating physician age between 35 and 70 years no known psychotic disorders No acute pain ejection fraction (EF) above 30% Have access to online messaging services
Exclusion criteria:
unwillingness to continue participation incomplete questionnaire responses development of another cardiac condition or deterioration of the patient's health for any reason that increases anxiety absence more than one educational session.
Age
From **35 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be selected using an accessible sampling method and divided into test and control groups through permuted block randomization with blocks of four. The blocks include the following sequences: 1. IICC, 2. ICIC, 3. ICCI, 4. CCII, 5. CICI, and 6. CIIC, where the letter 'I' represents 'Intervention' (training) and the letter 'C' represents 'Control.' To conceal the generated sequences, six identical envelopes will be prepared, each containing a block of four letters (either 'C' or 'I'). These envelopes will be placed in identical packets. The first patient will then be asked to randomly select one of these six envelopes. Once the envelope is chosen by the individual, it will be opened, and the four-letter sequence inside will be recorded. This sequence will determine the order of the first four participants, with the individual being assigned the first to fourth positions based on randomization. The envelope will then be resealed and removed from the set until the remaining five envelopes are selected and the process is completed. The fifth patient will again be given the remaining envelopes to randomly select one, determining the sequence for the next set of participants. This method will be repeated for all samples to ensure proper randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding will be applied to the outcome assessors who will evaluate anxiety and coping strategy outcomes. Data will also be analyzed by an independent researcher unaware of group assignments.
Placebo
Not used
Assignment
Parallel
Other design features
This RCT at Mostafa Khomeini Hospital will enroll 70 MI patients randomized via block randomization (using permuted block randomization on block size=4) to intervention or control groups. Blinding will be applied to the outcome assessors who will evaluate anxiety and coping strategy outcomes. Data will also be analyzed by an independent researcher unaware of group assignments.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethic committee of ilam university of medical sciences
Street address
Ilam, Banganjab, Boulevard-e Pajoohesh, Campus of Ilam University of Medical Sciences
City
Ilam
Province
Ilam
Postal code
6939177143
Approval date
2024-12-24, 1403/10/04
Ethics committee reference number
IR.MEDILAM.REC.1403.176

Health conditions studied

1

Description of health condition studied
Myocardial Infarction
ICD-10 code
I21
ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI)

myocardial infarction

2

Description of health condition studied
Generalized anxiety disorder
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Coping strategy
Timepoint
3 months
Method of measurement
Lazarus and Folkman Coping Strategies Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Participants in the intervention group will receive supportive education based on the Neuman Systems Model over a period of 12 weeks. The program includes a total of 12 sessions: one introductory session for assessment and interview, three structured educational sessions focusing on anxiety, defense mechanisms, family support, and stress coping strategies, eight follow-up supportive sessions tailored to the individual needs of the participants. Sessions 1 and 12 will be conducted in person in the hospital's educational room, while sessions 2–11 will be held remotely through online messaging platforms (e.g., WhatsApp, Telegram) or via telephon
Category
Prevention

2

Description
Control group: Participants in the control group will not receive any structured educational intervention. They will receive routine post-discharge care provided by the hospital, including standard clinical follow-up and general informational pamphlets about heart health from the cardiology unit. No specific training or supportive sessions will be provided to this group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mostafa Khomeinin Hospital, Ilam University of Medical Sciences, Ilam, Iran
Full name of responsible person
Sahar Abdoli
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banganjab, main campus, Ilam University of Medical Sciences, Ilam, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Deputy for Research, Dr. Naser Abasi
Street address
Banganjab, Boulevard-e Pajoohesh, Ilam University of Medical Sciences Campus, Ilam, Iran
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Grant name
Grant code / Reference number
1403.176
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam 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
Ilam University of Medical Sciences

Full name of responsible person
Sanaz Aazami

Position
Associated Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Position
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Other areas of specialty/work
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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
"The study involves participant information, and ethical approval does not permit the sharing of individual participant data, even in deidentified form. There is no further information."

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The personal data will be shared after deidentification, and the data related to anxiety levels and coping strategies will be shared without including any identifying information or names.

When the data will become available and for how long
Access to the data will begin 6 months after the publication of the results.

To whom data/document is available
"The study data and documents will be available to all researchers, including those affiliated with academic, scientific, and industrial institutions, provided that requests are submitted along with a detailed research proposal and valid ethical approval."

Under which criteria data/document could be used
All requests will be reviewed by the research team and the study's ethics committee. The final decision

regarding access to the data rests with the research team. The data will be available for 2 years after the request, after which a new request will be required. Confidentiality: Recipients of the data are obligated to maintain confidentiality and are prohibited from sharing the information with unauthorized individuals or organizations.

From where data/document is obtainable

Applicants can request documents or data through the following methods: Submitting a request via email: Email address: aazami-s@medilam.ac.ir

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

The applicant must submit their request along with a research proposal and valid ethical approval via email. The request must include the following information: Full name of the applicant Organizational affiliation Purpose of the data request Brief description of the research proposal Request Review: The request will be reviewed by the research team of the study. This process usually takes between 2 to 4 weeks. If additional information is required, this timeframe may be extended. Data Submission: After completing the above steps, the requested data or documents will be provided to the applicant via email or a secure download link. This step typically takes 1 to 2 business days.

Comments