Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Transitional Care Pathway on HealthCare Seeking Behaviors, Treatment Adherence, and Care Transition in patients with Acute Coronary Syndrome

Protocol summary

Study aim

Determining the effect of transitional care pathway on health care seeking behaviors, treatment adherence and care transition in patients with acute coronary syndrome.

Design

Clinical trial with control group, with parallel groups, blinding of analyst and allocator, randomized, on 70 patients. Closed-envelope randomization.

Settings and conduct

This randomized controlled clinical trial will be conducted on 70 patients with acute coronary syndrome hospitalized in Imam Reza Hospital in Mashhad, who meet the criteria for entering the research and will be included in the study through available sampling. The participants in the research will be randomly assigned to one of the two control or intervention groups. Patients in the control group will receive standard care, but in the intervention group, in addition to the usual interventions, interventions related to the transitional care pathway will be implemented. Questionnaires related to health care-seeking behaviors, and treatment adherence at the beginning of hospitalization and one month later, and the care transition measure one week after discharge, will be completed by phone and online. Finally, the data will be analyzed by statistical tests. In this study, blinding of the analyst and allocator is done.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age more than 18 Consent to participate in the study Hospitalization with diagnosis of acute coronary syndrome The ability to communicate verbally Exclusion criteria: Unstable clinical condition of the patient

Intervention groups

In the intervention group, in addition to routine care, patients will also receive the transitional care pathway interventions. In the control group, in addition to routine care, participants will receive standard care designed based on Tuna et al.

Main outcome variables

Health care seeking behaviors; Treatment Adherence; Care transition Measure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220130053882N2**
Registration date: **2023-08-09, 1402/05/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-09, 1402/05/18**
Update count: **0**

Registration date

2023-08-09, 1402/05/18

Registrant information

Name

AmirReza JamshidBeigi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Transitional Care Pathway on HealthCare Seeking Behaviors, Treatment Adherence, and Care Transition in patients with Acute Coronary Syndrome

Public title

Investigating the effect of transitional care pathway on the outcomes of patients with acute coronary syndrome

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 18 years Consent to participate in the study Hospitalization with diagnosis of acute coronary syndrome (diagnosis confirmed by doctor) Ability to communicate verbally

Exclusion criteria:

Instability of the patient's clinical condition

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to prevent the dissemination of information, the method of randomization is time block method. In this way, sampling in the intervention and control groups will be done in the middle of the week. In this way, the first group will be randomly selected by lottery, then the patients who meet the criteria for entering the study will be included in the intervention or control group in the middle of the week. Randomization is such that first a random sequence will be generated for 8 weeks by Randomizer.org and this sequence will be kept in a sealed envelope. At the beginning of each week, the door of the envelope is opened and based on the code in the envelope, all the patients of that week are assigned to the intervention or control group.

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

Research Ethics Committees of School of Nursing & Midwifery, Mashhad University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Doctor's Crossroad, Ibn Sina Street, Mashhad University of Medical Sciences , Khorasan Razavi, Iran

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Postal code

9176943314

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.058

Health conditions studied

1

Description of health condition studied

Angina pectoris

ICD-10 code

I20

ICD-10 code description

Angina pectoris

2

Description of health condition studied

Acute myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

Questionnaire score of health care seeking behaviors

Timepoint

At the time of hospitalization and one month later

Method of measurement

A researcher-made questionnaire of health care seeking behaviors

2

Description
Questionnaire score of treatment adherence
Timepoint
At the time of hospitalization and one month later
Method of measurement
Ziyai et al. treatment adherence questionnaire

3

Description
Questionnaire score of Care Transition
Timepoint
one week after discharge
Method of measurement
Care Transition Measure (CTM-15)

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, patients will receive interventions related to the transitional care pathway in addition to routine care after the need for assessment performed by the "Cardiac Disease Need Assessment Form". Interventions of transitional care pathway, which includes care interventions and education, and based on the review of reliable sources and the use of experts' opinions, will begin from the time of admission (emergency/CCU) for the patient after the illness, and according to the time of patient care, during hospitalization (emergency/CCU/I/post-angio). after discharge (telephone or online follow-up at home) will continue. The care and content of this program is provided by the researcher and through oral explanation and presentation of pamphlets, and includes things that use patient hospitalization (such as pain relief, rhythm and hemodynamic monitoring, introduction of the care team, ward and hospital, assessment of patient needs, etc.), treatment of diseases, activity, etc.), discharge time (such as self-care training and monitoring of complications, recognition of danger signs, bathing, prayer, smoking, rest, activity, tests, periodic check-ups, care of devices (such as ICD), coordination with cardiac rehabilitation program, etc.) After discharge, home care is done by phone or online (such as patient status, answering questions, checking side effects, medication side effects, taking medications, observing activity level and diet, rehabilitation status, monitoring ACS side effects, etc.). The frequency of follow-up of patients at home will be once a week by phone and online, and during this period, patients can ask their questions to the researcher. At the time of discharge, the patient will be asked how to communicate online and the communication received (Soroush, Eeta, Gap, Telegram, WhatsApp, etc.).
Category
N/A

2

Description
Control group: Among the control group, the participants will receive standard care designed based on Tuna et al. research in addition to routine care, which includes planned discharge training as well as a manual prepared by the researcher. In the educational program planned for this group, the definition of heart attack, symptoms, treatment goals and risk factors are presented. The training program also contains information about the importance of exercise and nutrition. The training is simple and understandable and the patient is allowed to ask his questions.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Amirreza Jamshidbeigi
Street address
Imam Reaz hospital, Ibn Sina Blvd, Mashhad, Razavi Khorasan Province, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Qayour
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University St., Mashhad, Razavi Khorasan Province, Iran
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amirreza Jamshidbeigi

Position

MSc. Medical Surgical Nursing student ,Student Research Committee, Faculty of Nursing and Midwifery,

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available