Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessing the impact of planned behavior theory oriented intervention on drug adherence in patients undergoing coronary angioplasty

Protocol summary

Study aim
Determining the impact of intervention based on the theory of planned behavior on medication adherence in patients undergoing coronary angioplasty

Design
A randomized controlled trial with two intervention and control groups, with a sample size of 88 patients, is being conducted and Excel's random function is used for randomization.

Settings and conduct
This study was conducted in the cardiology clinic of Khatam Al-Anbia and Mostafa Khomeini Hospitals in Tehran, and eligible patients were included in the study and assigned to the intervention and control groups using a random block method. In both groups, the rate and ratio of drug adherence is measured.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: History of coronary angioplasty, Absence of chronic underlying diseases requiring medication, Age requirement: 18 to 75 years; Exclusion Criteria: Absence of mental health disorders, Not having any illnesses or surgeries that require abstaining from antiplatelet medications.

Intervention groups
Control group: patients who have undergone coronary angioplasty in the past year, in this group, medication compliance is measured and then regular training is provided after angioplasty, and medication compliance is measured again on the 60th day. Intervention group: In this group, medication adherence is measured first, and then, with the cooperation of the patient and the researcher, the barriers to medication adherence in the dimensions of time, place, and method of taking medication are determined, and then a practical plan and strategies to deal with medication adherence barriers are formulated based on the condition of each patient, and in The period of 30 days is reminded. 60 days after the intervention, drug compliance is measured again.

Main outcome variables
The rate and ratio of drug compliance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220814055689N1**
Registration date: **2023-09-03, 1402/06/12**
Registration timing: **retrospective**

Last update: **2023-09-03, 1402/06/12**
Update count: **0**

Registration date
2023-09-03, 1402/06/12

Registrant information

Name
Masoumeh Sherafati
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
2023-07-01, 1402/04/10

Expected recruitment end date
2023-08-22, 1402/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessing the impact of planned behavior theory oriented intervention on drug adherence in patients undergoing coronary angioplasty

Public title
Assessing the impact of planned behavior theory oriented intervention on drug adherence

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
History of coronary angioplasty Positive behavioral intention to take medicine Absence of underlying chronic non-cardiac disease that affects the quality of life. Physical and cognitive ability and independence of medication use. Age requirement:18 to 75 years Literacy for reading and writing
Exclusion criteria:
Lack of mental health Diseases or surgeries that require not taking anti-platelet drugs.

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Using Excel software, 22 blocks of four are formed and in each block, the cells are randomly assigned between control and intervention groups.

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 and Midwifery & Rehabilitation - TUMS
Street address
Room 604, 6th Floor, Tehran University of Medical Sciences Central Building, Qods Intersection, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761

Approval date
2022-10-24, 1401/08/02

Ethics committee reference number
IR.TUMS.FNM.REC.1401.083

Health conditions studied

1

Description of health condition studied
Coronary Angioplasty

ICD-10 code
Z95.5

ICD-10 code description
Presence of coronary angioplasty implant and graft

Primary outcomes

1

Description
The rate of drug adherence after coronary angioplasty

Timepoint
Prior to intervention, 30 days after intervention, and 60 days after intervention.

Method of measurement
The determination of medication adherence level using the Morisky Medication Adherence Scale,

2

Description
The ratio of drug adherence after coronary angioplasty

Timepoint
Prior to intervention, 30 days after intervention, and 60 days after intervention.

Method of measurement
measuring the ratio of medication adherence using the Brazilian Global Evaluation of Medication Adherence (GEMA).

Secondary outcomes

1

Description
The rate of readmission of patients

Timepoint
60 days after intervention.

Method of measurement
Patient information questionnaire

Intervention groups

1

Description

Intervention group: At the patient's first visit to the clinic, after registering their information in the demographic questionnaire, the level and proportion of medication adherence are measured through the utilization of the Moriski questionnaire and the Global evaluation of medication adherence tool.Then, if desired medication adherence is not achieved, with the cooperation of the patient, barriers to medication use in terms of time and place of medication use and method of use are identified, and a practical plan to cope with these barriers is developed based on each patient's problems. A written copy of this plan along with an educational brochure is given to the patient. The importance of proper medication use is also orally taught and a educational brochure is given to patients who have desirable medication adherence. Then, during a 30-days period, this program is executed by phone or in-person reminders to the patient and after 60 days, the level and proportion of medication adherence are measured again. Additionally, during this stage, the rate of re-hospitalization of patients, within a two-month period of program implementation is measured. It should be noted that this intervention focuses on adherence to antiplatelet, statin and aspirin medications.

Category

Treatment - Drugs

2

Description

Control group: In this group, the rate and ratio of drug compliance is measured in the first visit and then common trainings after angioplasty are provided. Again, 60 days later, the rate and ratio of drug compliance will be measured. After the final evaluation, educational pamphlets will be given to the patients of the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-al-anbia and Mostafa Khomeini Hospitals in tehran

Full name of responsible person

Masoumeh Sherafati

Street address

Mostafa Hospital, Italy Street, Felestin Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

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Research and Technology Vice-Chancellor, Central Organization of the University, corner of Quds St., Keshavarz Blvd.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

DR.Elham Navab

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The demographic profile file of the participants, dependent and independent variables, data classification system, codes used in the analysis, clinical study report, informed consent form, statistical analysis map will be shared through the faculty website and email after the study is done.
When the data will become available and for how long
There is no limitation.
To whom data/document is available
Researchers
Under which criteria data/document could be used
For future research and meta-analysis
From where data/document is obtainable
Researcher's email
What processes are involved for a request to access data/document
The request should be sent to email.
Comments