Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Nov 2026

The effect of running the wellness tours on CABG patients' physical activity & diet

Protocol summary

Study aim
The effect of running the wellness tours on CABG patients' physical activity & diet

Design
Controlled field trial with pre-test and post-test, parallel groups, double-blind, randomized, phase 2 on 60 patients, randomization by sealed envelope method

Settings and conduct
People with a history of open heart surgery, performed in Mellat Park, Mashhad

Participants/Inclusion and exclusion criteria
Inclusion: Heart patients with a history of open heart surgery within 1 to 4 months of surgery. Exclusion: Other heart patients and people with underlying diseases

Intervention groups
The intervention group will go to Mellat Park with the research team, and the researcher will explain the wellness tour program, disease, risk factors, medication regimen, and warning signs for 15 to 20 minutes. The patients' pulse and baseline blood pressure will be measured. After controlling baseline symptoms, physical activity will be performed according to the American Heart Association protocol, including a 5 to 10 minute warm-up, 30 to 35 minute walk with at least a 20 percent increase in pulse, then a 10 to 15 minute cool-down process to return to baseline pulse, then recommendations for better exercise and danger signs will be taught to the subjects. Subsequently, a discussion will be held regarding the subjects' questions regarding the educational materials provided. Then, a lunch package will be provided to them along with diet education for heart patients based on the American Heart Association protocol. The samples will complete weekly physical activity and diet questionnaires, and after 4 weeks, the questionnaires will be collected to evaluate the results. The control group will not receive any intervention, and the ongoing methods will be performed routinely in the third phase of rehabilitation for them.

Main outcome variables
Physical activity , diet

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251210068272N1**
Registration date: **2026-02-04, 1404/11/15**
Registration timing: **retrospective**

Last update: **2026-02-04, 1404/11/15**
Update count: **0**
Registration date
2026-02-04, 1404/11/15

Registrant information
Name
Ali Geraylou
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
2026-01-05, 1404/10/15
Expected recruitment end date
2026-01-21, 1404/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of running the wellness tours on CABG patients' physical activity & diet

Public title
The effect of running the wellness tours on CABG patients' physical activity & diet

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
All patients who had undergone coronary artery bypass surgery and who had been 1 to 4 months post surgery.

Exclusion criteria:

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 60 people will be randomly assigned to two groups of 30 people each, with random blocks of 4 people each, approved by the randomization site, in two intervention and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The sealed envelope method is used to conceal allocation. In this way, the random sequence is written on small pieces of paper and kept in a sealed envelope. Each time a person enters the study, the envelope is opened, and based on its code, they are assigned to the intervention or control group.

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
6th floor, Sahar Complex, Khodadadi 1 alley, Mohammadie 2 street, Mashhad, Iran

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Province
Razavi Khorasan

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9186352915

Approval date
2025-09-30, 1404/07/08

Ethics committee reference number
IR.MUMS.NURSE.REC.1404.072

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Graft

ICD-10 code
Z50

ICD-10 code description
Encounter for other specified postprocedural aftercare

2

Description of health condition studied
Wellness Tour

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Surgical Follow up Care

ICD-10 code

ICD-10 code description

4

Description of health condition studied
Cardiac Rehabilitation

ICD-10 code

ICD-10 code description

5

Description of health condition studied
physical Activity

ICD-10 code

ICD-10 code description

6

Description of health condition studied
Diet Adherence

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The number of minutes of physical activity based on the International Physical Activity Questionnaire
Timepoint
Measurement of minutes of physical activity before the start of the intervention, 7, 14, 21, and 28 days after the intervention.
Method of measurement
International Physical Activity Questionnaire

2

Description
Diet score based on the Cardiovascular Diet Checklist
Timepoint
Measurement of dietary score before the intervention, 7, 14, 21, and 28 days after the intervention
Method of measurement
Cardiovascular Diet Checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: On a certain morning, the research team, along with a nurse and a doctor equipped with a first aid kit and basic and advanced resuscitation equipment, will go to Mellat Park with the research units in the intervention group, and the researcher will provide the necessary explanations about the Tourtendres program that will be held for 3 to 4 hours. The disease, risk factors, medication regimen, and warning signs that require a visit to the doctor will be explained within 15 to 20 minutes. The patients' pulse and baseline blood pressure will be measured. After controlling baseline symptoms, physical activity according to the American Heart Association protocol includes a 5 to 10 minute warm-up (walking at a slow pace), a 30-35 minute walk with at least a 20 percent increase in pulse, then returning to baseline pulse within 10 to 15 minutes. A cooling process (slowing down, then stretching) will be performed, and then recommendations regarding exercise and danger signs (signs that exercise should be stopped if observed) will be taught to the subjects. Subsequently, a discussion will be held regarding the questions of the individuals regarding the educational materials provided. Then, a lunch package will be provided to them along with training related to the diet of heart patients based on the American Heart Association protocol (appropriate and healthy foods, harmful foods, daily required amount, proper cooking method, and nutritional recommendations). At the end, the materials file will be given to the individuals, and a question and answer session will be held regarding the presented program. The intervention group was trained in terms of observing self-care behaviors and completed weekly questionnaires on physical activity and diet, and after 4 weeks, the questionnaires will be collected to evaluate the results.
Category
Lifestyle

2

Description
Control group: The control group does not receive any intervention, and the ongoing procedures are routinely performed for them in the third phase of rehabilitation (follow up training).
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Hoseynikhah's office
Full name of responsible person
Ali Geraylou
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2

Recruitment center
Name of recruitment center
Dr. Moeunipour's office
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
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Shahid Dr. Kharazmi Educational Complex, Ferdowsi University, Mashhad, 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

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Name of organization / entity
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Ali Geraylou
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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
Due to the confidentiality of personal information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available