

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the WHO HEARTS package to improve control of cardiometabolic risk factors in the primary health care system

Protocol summary

Study aim

1- Adaptation and implementation of each of the 6 modules of the HEARTS technical package at the primary health care level. 2- Evaluation of the effectiveness of the implemented package. 3- Determining the effectiveness of interventions on the knowledge, attitude, and practice and health literacy of the studied subjects regarding cardiovascular risk factors, self-care of diabetes, and high blood pressure.

Design

A community-based intervention trial, Two arms parallel group non-randomized trial, in comprehensive health centers

Settings and conduct

This is a community-based study that will be conducted in the following 6 steps: 1. Identifying obstacles and problems 2. Updating Iraper protocols based on the adopted HEARTS package. 3-4. Training and pilot study 5. One-year implementation stage, which will be conducted in comprehensive health centers in Damavand, Shiraz, and Bushehr. In each city, the non-randomly selected centers will be allocated to the intervention and control groups. 6- Evaluating the effectiveness

Participants/Inclusion and exclusion criteria

Eligibility Criteria: Adults aged 30 years or older with a risk of cardiovascular disease/diabetes above 10% or one of the risk factors for diabetes, hypertension, or hyperlipidemia. Exclusion criteria: patients with cardiovascular diseases, pregnant women, patients being treated for an acute illness/medical emergency/patients with an incurable disease.

Intervention groups

Comprehensive health centers in the three cities of Damavand, Shiraz, and Bushehr will be non-randomly assigned to the intervention and control groups. Intervention group: Adopted HEARTS technical package Control group: Current IraPEN program

Main outcome variables

1-Hb A1c 2- Blood Pressure 3. CVD Risk 4- Knowledge, attitude, practice / health literacy

General information

Reason for update

Acronym

IRAN-HEARTS

IRCT registration information

IRCT registration number: **IRCT20221126056612N1**

Registration date: **2022-12-05, 1401/09/14**

Registration timing: **prospective**

Last update: **2023-05-29, 1402/03/08**

Update count: **1**

Registration date

2022-12-05, 1401/09/14

Registrant information

Name

Leila Molaeipour

Name of organization / entity

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Iran (Islamic Republic of)

Phone

+98 21 5683 7552

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the WHO HEARTS package to improve control of cardiometabolic risk factors in the primary health care system

Public title
Effectiveness of WHO HEARTS package in prevention and control of diabetes, hypertension, and hyperlipidemia in primary health care

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Adults aged 30 years or above Those with diabetes, hypertension, or hyperlipidemia or those with CVD/Diabetes risk of 10% or above
Exclusion criteria:
History of cardiovascular diseases Pregnancy Acute illness or medical emergency History of an Incurable disease

Age
From 30 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 1400

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
A community-based intervention trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical

Street address

Research Institute for Endocrine Sciences, No.23, Arabi st, Velenjak

City
Tehran

Province
Tehran

Postal code
1985717413

Approval date
2022-11-09, 1401/08/18

Ethics committee reference number
IR.SBMU.ENDOCRINE.REC.1401.084

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

2

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

3

Description of health condition studied

Heart Disease

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

4

Description of health condition studied

Hemorrhage Stroke

ICD-10 code

I60

ICD-10 code description

Nontraumatic subarachnoid hemorrhage

5

Description of health condition studied

Hemorrhage Stroke

ICD-10 code

I61

ICD-10 code description

Nontraumatic intracerebral hemorrhage

6

Description of health condition studied

Ischemic Stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Hb A1c

Timepoint

0,12 months

Method of measurement

Laboratory - enzymatic assay or using point of care

2

Description

Blood Pressure

Timepoint

0, 12 months

Method of measurement

Mercury or digital sphygmomanometer

3

Description

Knowledge attitude and practice / Health literacy

Timepoint

0, 12 months

Method of measurement

Validated questionnaires for Iranian population

4

Description

Patient satisfaction

Timepoint

0 and 12 months

Method of measurement

Validated questionnaires for Iranian population

5

Description

Health System Staff satisfaction

Timepoint

0 and 12 months

Method of measurement

Validated questionnaires for Iranian population

6

Description

Adherence to treatment

Timepoint

0 and 12 months

Method of measurement

Validated questionnaires for Iranian population

7

Description

Fasting plasma glucose

Timepoint

0 and 12 months

Method of measurement

Enzymatic lab measurements or using point of care

8

Description

Total Cholesterol

Timepoint

0 and 12 months

Method of measurement

Enzymatic lab measurements or using point of care

9

Description

Cardiovascular risk score

Timepoint

0 and 12 months

Method of measurement

CVD risk scoring model

10

Description

Diabetes risk score

Timepoint

0 and 12 months

Method of measurement

Diabetes risk scoring model

Secondary outcomes

1

Description

Taking glucose lowering drugs

Timepoint

0 and 12 months

Method of measurement

Checklist

2

Description

Taking blood pressure lowering drugs

Timepoint

0 and 12 months

Method of measurement

Checklist

3

Description

Taking lipid drugs

Timepoint

0 and 12 months

Method of measurement

checklist

Intervention groups

1

Description

Intervention group: Adopted WHO HEARTS technical package. The HEARTS technical package provides a strategic approach to improving cardiovascular health. It comprises six modules and an implementation guide. This package supports Ministries of Health to strengthen CVD management in primary care and aligns with WHO's Package of Essential Noncommunicable Disease Interventions (WHO PEN). The HEARTS technical package includes the following modules: 1. The Healthy-lifestyle counselling module. This module focuses on the behavioral risk factors and provides information on: tobacco use, unhealthy diet, insufficient physical activity and harmful use of alcohol and also behavioral change, brief interventions for counselling and key points for motivational interviewing. 2. The Evidence-based protocols module uses hypertension and diabetes screening and treatment as an entry point to control cardiovascular risk factors, prevent target organ damage, and reduce premature morbidity and mortality. A comprehensive risk-based approach for integrated management of hypertension, diabetes, and high cholesterol is included in the Risk-based CVD management module. 3. The Access to essential medicines and technology module focuses on access to medicines and basic equipment for CVD management. 4. Risk-based CVD management module helps to identify those who would benefit from lifestyle changes and basic medical treatment to lower blood pressure, cholesterol, and manage diabetes mellitus in an integrated manner. The updated WHO CVD risk prediction charts were developed and presented for 21 global regions to maximize between-region variability and minimize heterogeneity in mortality and major drivers of health outcomes within each region. The charts are intended to allow the introduction of a total risk-stratification approach for management of CVD. They are presented as laboratory-based and non-laboratory-based charts. Laboratory-based algorithms include information on age, sex, smoking status, systolic blood pressure, history or evidence of diabetes mellitus, and the total cholesterol value. In the non-laboratory-based algorithms, body mass index (BMI) is included; information on diabetes mellitus and cholesterol is not necessary for these charts. 5. The Team-based care module uses multidisciplinary teams (which may involve new staff or the shifting of tasks among existing staff). Teams can include patients themselves, primary care physicians, and other allied health professionals, such as nurses, pharmacists, counsellors, social workers, nutritionists, community health workers, or others. Teams reduce the burden on physicians by utilizing the skills of trained health workers. 6. Systems for monitoring module provides a set of indicators on CVD management to allow progress to be monitored. In the current research, initially, the current IraPEN protocols will be adopted based on the HEARTS technical packages by conducting a qualitative study, and then the updated packages will

be applied as an intervention in the intervention group. More information is available at: <https://www.who.int/publications/i/item/9789240001367>

Category

Other

2

Description

Control group: IraPEN programs for cardiometabolic disorders including routine tasks defined for physicians and health-workers in primary health care. In brief, in IraPEN, individuals aged 30 years and older were called for screening of cardiovascular risk factors and calculation of their 10-year CVD risk based on the WHO/ISH risk assessment chart for the Eastern Mediterranean region B, using smoking status, diabetes, systolic blood pressure, total cholesterol and age variables. According to this chart, people were placed in four risk groups as follows: 1. Low risk (less than 10%); care, and risk assessment were followed annually. 2. Medium risk (10 to less than 20%); care, and risk assessment were followed every 9 months. 3. High risk (20 to less than 30%), care, and risk assessment were followed every 6 months. 4. Very High risk (30% and above), care, and risk assessment were followed every 3 months. Meanwhile, all individuals with diabetes, pre-diabetes, hypertension, and hypercholesterolemia are detected, educated, controlled and referred to physicians in systematic and scheduled packages. Follow-up and care of patients with hypertension and diabetes are done every month by Behvarz/health care provider and every 3 months by a physician. For patients with hyperlipidemia, pre-diabetes, and obesity, these follow-ups and care are done every 3 months by Behvarz/health care provider and they are referred to a physician if needed. All follow-ups and care are scheduled and registered through the electronic health information systems. More information is available at: <https://health.sbm.ac.ir/index.jsp?pageid=33694&p=1>

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Damavand

Full name of responsible person

Nahid Navaeyan

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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3

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Ministry of Health and Medical Education
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Leila Molaeipour
Position
Ph.D. Candidate in Epidemiology
Latest degree
Master
Other areas of specialty/work
Epidemiology
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Specialist

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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 current research is a community-based study. The extensive data collected in this study is registered in a national health information system and is confidential, and it is not possible to be shared.

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The results of this study will be published as a scientific paper.

When the data will become available and for how long

After completing the study

To whom data/document is available

Access to the documents will be with the permission of the Research Institute for Endocrine Sciences of Shahid Beheshti University of Medical Sciences.

Under which criteria data/document could be used

Access to the documents will be with the permission of the Research Institute for Endocrine Sciences of Shahid Beheshti University of Medical Sciences.

From where data/document is obtainable

Research Institute for Endocrine Sciences of Shahid Beheshti University of Medical Sciences

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

Official letter to the Research Institute for Endocrine Sciences of Shahid Beheshti University of Medical Sciences

Comments