

# 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

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

#### 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

#### 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

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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

##### Street address

Shahid Fahmideh Ave., Jilard, Damavand.

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##### Province

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1985717413

##### Phone

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**Email**  
ndavood@yahoo.com

## 2

### Recruitment center

**Name of recruitment center**  
Shiraz  
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Fariba Moradi Ardakani  
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## 3

### Recruitment center

**Name of recruitment center**  
Bushehr  
**Full name of responsible person**  
Razia Hajioni  
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Bushehr Health Center, Salh Abad Ave., Bushehr  
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## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**  
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Alireza Mahdavi  
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armahdavi@yahoo.com

**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**  
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**Full name of responsible person**  
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**Latest degree**  
Master  
**Other areas of specialty/work**  
Epidemiology  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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Associate Professor  
**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

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**Street address**

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**City**

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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**