

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the sustainable effect of self-care educational intervention on diet quality to reduce the risk of cardiovascular diseases in chronic patients.

Protocol summary

Study aim

Determination the sustainable effect of self-care educational intervention on diet quality to reduce the risk of cardiovascular diseases in chronic patients of Saravan city in 2023.

Design

Among the 4 comprehensive urban health service centers in Saravan, 2 centers will be selected as intervention centers and 2 centers will be selected as controls. Then, 57 people from each center will be randomly selected from the list of chronic blood pressure patients (19 people), diabetes (19 people) and obesity (19 people) and will be included in the study.

Settings and conduct

Treatment of Saravan city, comprehensive urban health service centers

Participants/Inclusion and exclusion criteria

People must be 18 years old or older. Participants should be able to read and write. Participants must be residents of Saravan city. People in comprehensive health service centers should have health records. Participants should not have cardiovascular disease

Intervention groups

Holding training sessions to strengthen self-care in food quality

Main outcome variables

Increasing the quality of the diet

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230612058460N1**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

Hossien Izadirad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3372 5403

Email address

izadi111389@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-21, 1402/03/31

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the sustainable effect of self-care educational intervention on diet quality to reduce the risk of cardiovascular diseases in chronic patients.

Public title

the sustainable effect of self-care educational intervention on diet quality to reduce the risk of cardiovascular diseases in chronic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

People must be 18 years old or older. Participants should be able to read and write. Participants must be residents of Saravan city. People in comprehensive health service centers should have health records. Participants should not have cardiovascular diseases.

Exclusion criteria:

People with mental and psychological problems People with less than 6 months of residence in Saravan

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **230**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the 4 comprehensive urban health service centers in Saravan, 2 centers will be selected as intervention centers and 2 centers will be selected as controls. Then 57 people from each center will be randomly selected from the list of chronic blood pressure patients (19 people), diabetes (19 people) and obesity (19 people) and will be included in the study.

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

Ethics committee of zahedan University of Medical Sciences

Street address

Imam Bakhsh St. 5- School of Nursing

City

ZAHEDAN

Province

Sistan-va-Balouchestan

Postal code

9891915399

Approval date

2023-05-27, 1402/03/06

Ethics committee reference number

IR.ZAUMS.REC.1402.099

Health conditions studied

1

Description of health condition studied

Self-care educational intervention - Diet quality - Cardiovascular diseases

ICD-10 code

Z60.8

ICD-10 code description

Other problems related to social environment

Primary outcomes

1

Description

Diet quality

Timepoint

6 months

Method of measurement

Assessment tool of healthy Eating Index-2015

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, the educational content will be prepared based on the guidelines of the Ministry of Health, articles and authentic books and educational booklets. The subjects of the educational sessions will include the recognition of chronic diseases, the importance of diet and self-care in preventing chronic diseases, adherence and following dietary guidelines, developing a low-salt diet, limiting alcohol consumption, maintaining a low-fat diet. In this research, visual educational materials including videos, photos, and illustrated pamphlets will be used, as well as interactive exercises where participants can share their experiences and learn how to act by observing others. The face validity of the educational materials will be determined in a review by a panel of ten experts consisting of doctors, nutritionists, nurses, health educators and patients. Training sessions will be held by health experts in comprehensive health service centers. The time of each session is approximately between 50 and 60 minutes, and each time groups of up to 10 people will participate in it. At the beginning of the study, control group patients will receive four training sessions on four consecutive days. Then, a one-hour training session will be held every 3 months until the end of the study in order to follow up and strengthen nutritional self-care behaviors, which will be a total of six training sessions

during the project period

Category

Prevention

2**Description**

Control group: no intervention is done in the control group.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Saravan

Full name of responsible person

Hossien Izadirad

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Azadi St. - Health and treatment network

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Nur Mohammad Bakhshani

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Dr. Hasabi Square - Zahedan University of Medical Sciences campus

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9816743463

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zaums.research@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Hossien Izadirad

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Hossien Izadirad

Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable