Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of salt intake reduction and socioeconomic determinants on cardiovascular diseases and hypertension in the Shahrekord PERSIAN cohort in Chaharmahal and Bakhtiari province, Iran

Protocol summary

Study aim
Determining the effectiveness of educational intervention to reduce salt intake on systolic and diastolic blood pressure

Design
a community trial.

Settings and conduct
A village-based cluster randomized controlled trial will be conducted in the first part of the study. Villages in Ardal County, Chaharmahal and Bakhtiari Province will be randomly selected. Out of the 20 target villages, the villages will be divided into two intervention and control groups. Ten villages will be randomly selected as the intervention group to reduce salt consumption and ten villages as the control group. The interventions will occur over 2 months (8 weeks, one 1.5-hour session each week, and a total of 8 group discussion sessions with the village people and a team of nutritionists, health educators, cardiologists, and epidemiologists).

Participants/Inclusion and exclusion criteria
People who participated in the Shahrekord Cohort Study and have a registration code.

Intervention groups
Among the 20 target villages of the cohort study in Ardal County, Chaharmahal and Bakhtiari Province, the villages will be divided into two intervention and control groups. Ten villages will be randomly selected as the intervention group to reduce salt consumption and ten villages as the control group.

Main outcome variables
The primary outcome will be the change in the proportion of people with controlled blood pressure (BP <140/90 mmHg) from baseline. BP outcomes include changes in systolic blood pressure (SBP), diastolic blood pressure (DBP)

General information

Reason for update

Acronym
SH

IRCT registration information
IRCT registration number: **IRCT20140901019002N2**
Registration date: **2025-05-18, 1404/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-18, 1404/02/28**
Update count: **0**

Registration date
2025-05-18, 1404/02/28

Registrant information

Name
Ali Ahmadi

Name of organization / entity
SKUMS

Country
Iran (Islamic Republic of)

Phone
+98 38 1333 0065

Email address
ahmadi@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-30, 1404/02/10

Expected recruitment end date
2025-05-31, 1404/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of salt intake reduction and socioeconomic determinants on cardiovascular diseases and hypertension in the Shahrekord PERSIAN cohort in Chaharmahal and Bakhtiari province, Iran

Public title
Salt and hypertention
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The rural community of Ardel County, which is part of the Persian Shahrekord Future Cohort Study population, registered in the enrollment phase.
Exclusion criteria:
Not being a member of the Shahrekord group
Age
From **30 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **340**
Randomization (investigator's opinion)
Randomized
Randomization description
Among the 20 target villages of the cohort study in Ardal County, Chaharmahal and Bakhtiari Province, the villages will be randomly divided into two intervention and control groups. Ten villages will be randomly selected as the intervention group (receiving education and information) to reduce salt consumption and ten villages will be selected as the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
During the study, none of the participants, evaluators, interventionists, or health staff involved in the trial knew who was in 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
دانشگاه علوم پزشکی شهرکرد
Street address
سعدی 17
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815918459
Approval date
2022-04-19, 1401/01/30
Ethics committee reference number
IR.SKUMS.REC.1401.015

Health conditions studied

1

Description of health condition studied
hupertention
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Systolic and diastolic blood pressure
Timepoint
Before and after the intervention (8 weeks after the intervention)
Method of measurement
Blood pressure monitor

Secondary outcomes

1

Description
Lipids and salt intake
Timepoint
Before and after the intervention
Method of measurement
Laboratory and food frequency and cohort study

Intervention groups

1

Description
Intervention group:
Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Rural health homes and comprehensive health centers in Ardal

Full name of responsible person
Ali Ahmadi

Street address
17 sadi

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815918459

Phone
+98 38 3333 3448

Email
aliahmadi2007@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Dr. Seyed Mohammad Omrani

Street address
Kashani

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815874119

Phone
+98 38 3333 0062

Email
omranism@skums.ac.ir

Web page address
https://research.skums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahre-kord University of Medical Sciences

Proportion provided by this source
50

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
Shahre-kord University of Medical Sciences

Full name of responsible person
Ali Ahmadi

Position
Proffesor

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

Street address
17 Sadi

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815918459

Phone
+98 38 3333 3448

Email
ahmadi@skums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Arsalan Khaledifar

Position
professor

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

Street address
kashani

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815874119

Phone
+98 38 3333 0064

Email
khaledifar@skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Ali Ahmadi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

17 Sadi

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815918459

Phone

+98 38 3333 3448

Email

ahmadi@skums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After the work is completed, except for identity information, the rest of the data can be shared.

When the data will become available and for how long

after one year

To whom data/document is available

There is no limit.

Under which criteria data/document could be used

For joint work and scientific collaboration with other researchers

From where data/document is obtainable

Executive and office

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

Responses will be made within two months of receiving the email and request for collaboration.

Comments