

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The effect of adjustment Additive Salt with a medical salt shaker on Blood Pressure and 24-Hour Urine Sodium in pre-hypertensive persons

#### Protocol summary

##### Study aim

Determining the effect of adjusting salt addition using a medical salt shaker on blood pressure and 24-hour urine sodium in prehypertension

##### Design

Clinical trial with control and intervention groups, double-blind, randomized, on 70 patients

##### Settings and conduct

A clinical trial with a double-blind and randomized control group on 70 people from Rahnan, Khadijah Kobri and Amirhamzeh health centers.

##### Participants/Inclusion and exclusion criteria

entry criteria 1- Reading and writing literacy . 2- Living in Isfahan (being available) 3- People who are 20-65 years old. and have the ability to perform their daily activities alone. 4- The participants should be of both sexes (non-pregnant women). 5- Having a systolic blood pressure of 120-139 and a diastolic blood pressure of 80-89. Non-entry criteria Having even one occasion of systolic blood pressure above 14 in previous visits to the doctor

##### Intervention groups

In this study, a medical salt shaker was provided to the intervention group, how to use it and they were also taught how to follow a low salt diet along with it, and in three stages before the start of the intervention. Two weeks and one month after the intervention, blood pressure and 24-hour urine sodium laboratory index were measured in two stages before and after the intervention in two intervention groups. The only difference between the control group and the intervention group is not having a medical salt shaker.

##### Main outcome variables

Independent variable: medical salt tank, Dependent variable: 24-hour urine sodium laboratory index and blood pressure changes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220815055699N1**  
Registration date: **2023-06-29, 1402/04/08**  
Registration timing: **retrospective**

Last update: **2023-06-29, 1402/04/08**

Update count: **0**

##### Registration date

2023-06-29, 1402/04/08

##### Registrant information

##### Name

Zahra Shokrani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2016-11-20, 1395/08/30

##### Actual recruitment start date

2016-10-22, 1395/08/01

##### Actual recruitment end date

2016-11-20, 1395/08/30

##### Trial completion date

2017-01-20, 1395/11/01

##### Scientific title

The effect of adjustment Additive Salt with a medical salt shaker on Blood Pressure and 24-Hour Urine Sodium in pre-hypertensive persons

**Public title**

Effect of medical salt shaker on blood pressure and urinary sodium

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

1- Reading and writing literacy . 2- Not having a speech disorder or hearing disorder . 3- Living in Isfahan (being available). 4- People who are 20-65 years old. and have the ability to perform their daily activities alone. 5- People who have not used other educational methods and complementary medicine such as massage therapy in the previous three months to control their blood pressure. 6- The participants should be of both sexes (non-pregnant women). 7- The patients should be interested in participating in the study. 8- According to the patient, a history of severe mental stress in six months do not have a past (such as death of relatives and separation from spouse) and are not under severe stress at the time of conducting the research. 9- Having a systolic blood pressure of 120-139 and a diastolic blood pressure of 80-89. 10- Do not participate in another blood pressure control program. 11- People who, according to their health record, have mental retardation, blindness, deafness, or an active mental illness (schizophrenia) , bipolar disorder and depression) are not severe. 12- People who are not addicted to narcotics, painkillers and psychotropic drugs. 13- People who do not have chronic pain syndromes.

**Exclusion criteria:**

Not having enough motivation to cooperate in the plan and comply with the things taught. People who had a systolic blood pressure of 14 or higher even once in previous visits to the doctor. Cases of excessive fluid accumulation in the body such as cirrhosis, etc., use of diuretic drugs, active bleeding or severe sweating.

**Age**

From **20 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **70**

Actual sample size reached: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

By the researcher's colleague, the words intervention and control were written on cards with the same number of samples and put in a bag, and each of the research units randomly took out one of the cards from the bag and thus was placed in the intervention or test group. they got. After the samples with the characteristics of the research units were selected, both groups participated in the training session related to proper diet

and the proper diet training pamphlets were given to both groups. And the intervention group participated in the adjustment program of added salt using the daily salt measurement tool. It should be noted that the training session was held by the researcher.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The researcher's colleague put the samples into two intervention and control groups, and the samples and the researcher did not know about this issue

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of isfahan University of Medical Sciences

**Street address**

Hazar Jarib St., Isfahan University of Medical Sciences and Health Services

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**Postal code**

81746-73461

**Approval date**

2016-10-22, 1395/08/01

**Ethics committee reference number**

ir.mui.rec.1395.3.600

**2****Ethics committee****Name of ethics committee**

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## Health conditions studied

### 1

#### Description of health condition studied

Prehypertension

#### ICD-10 code

I10-I15

#### ICD-10 code description

Hypertensive diseases

## Primary outcomes

### 1

#### Description

Blood pressure and 24-hour urine sodium

#### Timepoint

Before the start of the intervention Two weeks and one month after the start of the intervention

#### Method of measurement

Mercury sphygmomanometer and 24-hour urine test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

For the intervention group, an educational session was held with the content of explaining the nature of hypertension disease, symptoms of the disease, classification, cause of occurrence and modifiable and non-modifiable risk factors, etc., the importance of how to use a proper diet and the components of the food pyramid, the DASH food pattern, the amount salt, fruits and vegetables, and at the end of the meeting, their questions were answered, and pamphlets containing the training materials, 24-hour urine collection containers, and a medical salt box were provided to each person in the intervention group by the researcher's colleague. The people of the intervention group were emphasized to use only medical salt shakers to add salt to their food. Before the intervention and two weeks and one month after the intervention, their blood pressure was measured, and before and after the intervention, the 24-hour urine sodium of the subjects was measured

#### Category

Lifestyle

### 2

#### Description

Control group: For the control group, like the intervention group, an educational session was held, with the content of explaining the nature of hypertension, symptoms, classification, cause of occurrence, modifiable and non-modifiable risk factors, etc., the importance of how to use a proper diet and the components of the pyramid.

food, the DASH food pattern, the amount of salt consumed and fruit and vegetables, and at the end of the meeting, their questions were answered, and pamphlets containing the taught materials and 24-hour urine collection containers were delivered. And before the start of the intervention, two weeks and one month After the intervention, their blood pressure was measured, and before and after the intervention, the 24-hour urine sodium of the subjects was measured.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khadijah Kobri Clinic, Rahnan Clinic and Amir Hamzeh Clinic

##### Full name of responsible person

Zahra shokrani

##### Street address

Allay120/amirkabir street

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##### Phone

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Vice President of Research and Technology

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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

Esfahan 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**  
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Esfahan University of Medical Sciences  
**Full name of responsible person**  
Zahra shokrani  
**Position**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Yes - There is a plan to make this available  
**Study Protocol**  
No - There is not a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
No - There is not a plan to make this available  
**Clinical Study Report**  
No - There is not a plan to make this available  
**Analytic Code**  
No - There is not a plan to make this available  
**Data Dictionary**  
Undecided - It is not yet known if there will be a plan to  
make this available  
**Title and more details about the data/document**  
Demographic information, blood pressure and urinalysis  
results can be shared  
**When the data will become available and for how  
long**  
Access starts one month after results are published  
**To whom data/document is available**  
Researchers working in academic and scientific  
institutions and students  
**Under which criteria data/document could be used**  
There are no special conditions  
**From where data/document is obtainable**  
Shokrani@gmail.com  
**What processes are involved for a request to access**

**data/document**

Within one month from the time of application  
**Comments**