

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of education based on the protection motivation theory and theory of planned behavior on the adherence to dietary approaches to stop hypertension

Protocol summary

Study aim

The comparative study of the effect of education based on the protection motivation theory and theory of planned behavior on the adherence to dietary approaches to stop hypertension (DASH) among prehypertension patients

Design

Clinical trials with control group, randomized. Sample size: 150 subjects in total, 50 sample per groups.

Settings and conduct

Pretest and post test three months after the completion of training sessions. Three 60-minute sessions of training with group discussion method, lecture and distribution of booklet and pamphlet based on the theory of planned behavior and protection motivation theory were implemented on two groups of intervention separately. Blood pressure and food program were compared before and after intervention in the three groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Average SBP during two measurements within two minutes must be in the range of 120 to 139 or average DBP must be in the range of 80 to 89 Consent to participate in the study. Exclusion criteria: Pregnancy Disease such as kidney failure and cancer Not regular attendance in class.

Intervention groups

First intervention group: A diet was received and three 60-minute sessions of training based on the theory of planned behavior were implemented. Second intervention group: A diet was received and three 60-minute sessions of training based on the protection motivation theory were implemented. Control group: Received a diet plan.

Main outcome variables

Hypertension, Food intake

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130707013891N2**

Registration date: **2019-03-26, 1398/01/06**

Registration timing: **retrospective**

Last update: **2019-03-26, 1398/01/06**

Update count: **0**

Registration date

2019-03-26, 1398/01/06

Registrant information

Name

Saeed Dashti

Name of organization / entity

Faculty of Health, Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

2018-06-22, 1397/04/01

Scientific title

The effect of education based on the protection motivation theory and theory of planned behavior on the adherence to dietary approaches to stop hypertension

Public title

The effect of education based on the protection motivation theory and theory of planned behavior on the adherence to dietary approaches to stop hypertension

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

average SBP during two measurements within two minutes must be in the range of 120 to 139 or average DBP must be in the range of 80 to 89 Not having diabetes. Consent to participate in the study.

Exclusion criteria:

During the study, the patient is complications heart attack or stroke. not regular attendance in class.

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **150**Actual sample size reached: **150****Randomization (investigator's opinion)**

Randomized

Randomization description

Random assignment of the patients into two intervention groups Patients are randomly divided into two groups and a control group with a table of random numbers (a random number table is a collection of numbers that are generated without a specific pattern or order and completely randomized, then samples are randomly selected by Randomizer software.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees1**Ethics committee****Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Bahonar Square, Yazd, Central Organization of Shahid Sadoughi University of Yazd Medical Sciences and Health Services

City

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8916978477

Approval date

2016-11-05, 1395/08/15

Ethics committee reference number

IR.SSU.SPH.REC.1395.103

Health conditions studied1**Description of health condition studied**

Prehypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes1**Description**

Hypertension

Timepoint

Before the intervention, and 3 months after intervention

Method of measurement

hypertension high blood pressure according to the millimeters Mercury with the use of digital indicator

Secondary outcomes1**Description**

Food intake

Timepoint

Before the intervention, and 3 months after intervention

Method of measurement

3-day food records.

Intervention groups1**Description**

Control group: Received a meal plan.

Category

Lifestyle

2

Description

First intervention group: A diet was received and three 60-minute sessions of training based on the theory of planned behavior were implemented.

Category

Lifestyle

3

Description

Second intervention group: A diet was received and three 60-minute sessions of training based on the protection motivation theory were implemented.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Delkhah Health Center

Full name of responsible person

Dashti Saeid

Street address

No.21,Motehari Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mirzaei Masoud

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dashti Saeid

Position

Phd. Student

Latest degree

Master

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

Mazloomi sayed saeed

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

Health Promotion

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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

No more information.

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

No - There is not 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