

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

A clinical trial study on intervention based on the theory of planned behavior on improving self-care behavior of patients with hypertension in two intervention and control groups with blood pressure control.

Protocol summary

Summary

Objective: Mean score of the planned behavior theory structures in patients with hypertension in intervention and control groups will be determined and compared. The difference between the mean performance score of following diet plan and structural theory and physical activity and using drug after the intervention will be determined. Design: This study will be conducted as controlled trial. The intervention group will consist of patients with hypertension and its history at least a year that will refer to centers No. 14 in Rasht. The control group will be the patients to be selected in centers No. 13 in Rasht. Setting and conduct: The tool to be used will be a questionnaire including demographic information, and questions related to the control of blood pressure history, and questions about the planned behavior theory including persons' attitude on hypertension, mental norm and perceived behavioral control and intention of conducting behavior to control blood pressure. To assess the nutritional information, FFQ 148 will be used. Inclusion criteria: People with hypertension; people living in health centers of rural areas; Having history of hypertension during the previous one year; age above 45 years until 65 years old; patient's participation with satisfaction. Exclusion Criteria: Patient's withdrawal from going on; A patient's life-threatening event or death during conducting program; Changing patient's inhabitant to outside of research area. Intervention: Executing educational program by the researcher in the intervention group. Main outcome measures: The aim will be designed to promote and expand self-care behaviors in controlling blood pressure as the primary outcome variable.

General information

Acronym

Full blood pressure patients self-care

IRCT registration information

IRCT registration number: **IRCT2016011622984N1**

Registration date: **2016-01-16, 1394/10/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-16, 1394/10/26

Registrant information

Name

Fardin Mehrabian

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 133335415

Email address

mehrabian@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial study on intervention based on the theory of planned behavior on improving self-care behavior of patients with hypertension in two intervention and control groups with blood pressure control.

Public title

Effects of intervention based on the theory of planned behavior on improving self-care behavior in hypertension patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: People with high blood pressure; People living near health centers of rural areas and having a medical record in the health house; History of hypertension during one year ago; Age above 45 years old and below 65 years old; Patient's participation in research with his (her) satisfaction. Exclusion criteria: Patient's withdrawal from the study whenever s(he) wants, if (s)he does not want to continue; A life-threatening event or death during conducting intervention programs for patients;

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Choose a health center in the center of the quota by random selection of patients in each health center is a table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Rasht, in front of stadium Azodi

City

Rasht

Postal code

4149835951

Approval date

2014-08-19, 1393/05/28

Ethics committee reference number

4930231618

Health conditions studied

1

Description of health condition studied

hypertention

ICD-10 code

I10-I15

ICD-10 code description

Essential (primary) hypertension Incl.: High blood pressure Hypertension (arterial)(benign)(essential)(malignant)(primary)(systemic) Excl.: involving vessels of: brain (I60-I69) eye (H35.0) -

Primary outcomes

1

Description

hypertention

Timepoint

before and 2.5 months after the educational intervention

Method of measurement

Manual gearboxes

Secondary outcomes

1

Description

average structures perceived behavioral theory

Timepoint

Before and 2.5 month after intervention

Method of measurement

The questionnaire was created by the researcher

2

Description

average physical activity

Timepoint

Before and 2.5 month after intervention

Method of measurement

GPAC Questionnaire

3

Description

average use a drug

Timepoint

Before and 2.5 month after intervention

Method of measurement

The questionnaire was created by the researcher

4

Description

average food intake and the DASH diet group

Timepoint

Before and 2.5 month after intervention

Method of measurement

FFO Questionnaire

Intervention groups

1

Description

" Intervention group: three educational sessions will be held separately in three different topics, and teaching aids and CD s and pamphlets related to the same session will be used. The overall aim of the first session: To increase patients' awareness of hypertension and familiarity with examining the current situation in their behaviors associated with blood pressure control Session period: 45 minutes Educator: researcher The overall aim of the second session: The patients' familiarity with the outcomes of their lifestyle modification as the main solution to promote self-care behaviors with an emphasis on the structure of the perceived behavioral control in high blood pressure control The overall aim of the third session; Familiarity with diet plan used in patients with hypertension and to determine and change their attitude toward the use of this diet plan in order to promote appropriate nutritional behavior. The main aim of the study is that a program is designed to promote and expand self-care behaviors in controlling blood pressure as the primary outcome variable. Educational content of sessions includes general information on high blood pressure (definition, symptoms, complications, prevention and treatment) and an emphasis on self-care behaviors in controlling high blood pressure, such as physical activity, proper nutrition and the use of medication. . Educational materials including pamphlets and posters and educational CD will be used in each session. Educational methods used in the sessions will be as a combination of lecture, question and answer, group discussion and brainstorming."

Category

Lifestyle

2

Description

"control group: In the control group, no educational intervention performed by the researcher. The control group did not receive any intervention by the researcher and the 2.5 month training package that was given to the intervention group was the control group "

Category

Lifestyle

Recruitment centers

1

Recruitment center**Name of recruitment center**

Urban and rural 13 health centers in Rasht

Full name of responsible person

Roghaye Aghebati

Street address

No. 96 Alley Bahonar, Street Babaei, Blvd Eftekhari, Rasht, Gilan Awards

City

Rasht

2

Recruitment center**Name of recruitment center**

Urban and rural 14 health centers in Rasht

Full name of responsible person

Roghaye Aghebati

Street address

No. 96 Alley Bahonar, Street Babaei, Blvd Eftekhari, Rasht, Gilan Awards

City

Rasht

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for research of guilan University of Medical Sciences

Full name of responsible person

Dr Mehrabian

Street address

Namjoo street.

City

Rasht

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Roghaye Aghebati

Position

Health Education & health promotion Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty