Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
I10-115
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
Rrasht
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

Other areas of specialty/work

Street address
Rasht. namjoo street

City
Rasht

Postal code
41498-35951

Phone
+98 13 3354 8578

Fax
-

Email
r.aghebati44097@yahoo.com

Web page address
-

Person responsible for scientific inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences

Full name of responsible person
Roghaye Aghebati

Position
Health education and health promotion student

Other areas of specialty/work

Street address
Rasht, namjo street

City
Rasht

Postal code
41498-35951

Phone
+98 13 3354 8578

Fax
-

Email
raghebati44097@yahoo.com

Web page address
-

Person responsible for updating data

Contact

Name of organization / entity
Guilan University of Medical Science

Full name of responsible person
Roghaye Aghebati

Position
Health education and health promotion student

Other areas of specialty/work

Street address
Rasht .namjo street

City
Rasht

Postal code
4149835951

Phone
+98 13 3354 8578

Fax
-

Email
r.aghebati 44097@yahoo.com

Web page address
-

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