Clinical Trial Protocol
Iranian Registry of Clinical Trials
15 Oct 2019

The effect of self management program on control of disease and self efficacy in hypertensive patients

Protocol summary

Summary
The aim of this study is to investigate the effect of self management program on self efficacy and control of disease in hypertensive patients. This is a semi-experimental clinical trial on 150 patients were recruited from health centers affiliated to Tehran University of Medical Sciences which have been sampled simply and randomized divided in to experimental and control groups. The control group received only routine visits, while the experimental group in addition to receiving usual care, will participate in self management program. then encouraged to accomplish self management program and followed up by telephone weekly for 8 week. At the end of fourth week, blood pressure measured in experimental and control groups. Then at the end of eighth week, the appointment, Blood pressure is measured, and questionnaire related to self efficacy and disease control in both control and experimental groups are completed and be compared.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201105314443N3
Registration date: 2012-04-18, 1391/01/30
Registration timing: registered_while_recruiting

Last update:
Update count: 0
Registration date
2012-04-18, 1391/01/30

Registrant information

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Recruitment status
Recruitment complete
Funding source
Tehran University Of Medical Sciences

Expected recruitment start date
2011-09-23, 1390/07/01
Expected recruitment end date
2012-09-22, 1391/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of self management program on control of disease and self efficacy in hypertensive patients

Public title
The effect of self management program on hypertensive patients control

Purpose
Supportive

Inclusion/Exclusion criteria
An inclusion criteria: tend to have participated in the study; 69-30 years old ;There Hypertension the mild and moderate (180-140mmhg systolic blood pressure and diastolic blood pressure between 110 to 90), which is confirmed by medical experts; not at the stage of acute disease; The ability to have a conversation in Farsi; read and write ; to establish direct telephone contact with the patient's home is there; difficulties in communication (hearing, etc.) is not; Hard and the underlying disease is not terminal: Such as metastatic cancer, kidney failure); Exclusion criteria: the patient dies during the study; stage of disease is acute and severe

Age
From 30 years old to 69 years old

Gender
Both

Phase
N/A

Groups that have been masked
None
Sample size
Target sample size: 160

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Tohid Square
City
Tehran
Postal code
14159
Approval date
2011-07-28, 1390/05/06
Ethics committee reference number
14159

Health conditions studied

1
Description of health condition studied
primary hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1
Description
control of disease
Timepoint
before and after intervention
Method of measurement
control of disease questionnaire

Secondary outcomes

Intervention groups

1
Description
The control group received only usual care included drug therapy and advise to low salt and low fat regime
Category
Treatment - Other

2
Description
In experiment group, in addition to receiving the usual care group will participate in self management program. self management program with a day 4-hour workshop shall be conducted with patients with primary hypertension, in its first workshop and its objectives are described and will interact with participant ( formation of patient-provider partnership skill). Then educational materials about the nature of the disease, hypertension, risk factors, complications and control procedures, and complications of drug therapy (medical management areas), strengthening behavior and changes in health behavior (role management areas) and methods of stress reduction and management emotions such as anger, fear and despair, and ... (emotional management) by the researcher to speak at 100 minutes in two 50-minute rest period between the two lectures will be presented in 15 minutes. The second part of workshop, which takes 2 hours, will designed Scenarios in relation to situations where patients with hypertension, may be faced with it, and discussion in small groups, patient information used in the workshop and Finally, is characterized by the correct way to handle situations designed to strengthen problem-solving skills, decision making skills. Also in workshop in the correct way to measure blood pressure, patients are taught and practiced and will ensure that the patient is taught how to correctly measure your blood pressure. The intervention focused on increasing acceptance of diet, nutrition, weight loss, reduced sodium intake, regular physical activity of moderate (walking every day) and smoking cessation and medication regimen is adhered.
Category
Rehabilitation

Recruitment centers

1
Recruitment center
Name of recruitment center
Health Center Of Tehran University Of Medical Sciences

Full name of responsible person
Omolhoda Kaveh Savadkooh

Street address
Tohid square, Faculty of Nursing and Midwifery

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University Of Medical Sciences

Full name of responsible person
Mr Dr Photoohi, University Research Assistant

Street address
Ghods street

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Tehran

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Tehran 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty