

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of self-care blended education on treatment adherence in hypertensive patients

Protocol summary

Study aim

Effect of Combined Self-Care Training on Adherence to Therapy in Patients Afflicted with High Blood Pressure Admitted to Shahin Dezh Hospital, in 2016

Design

A clinical trial with a sample size of 60 people with a control group, randomized with lottery method

Settings and conduct

The study was conducted in a clinic of Shahin Dezh Hospital in an educational intervention for test group for the duration of 4 weeks

Participants/Inclusion and exclusion criteria

Not having a high blood pressure above 110/180, or any evidence of an emergency, stroke or myocardial infarction in the past six months; Complications of illness and hospitalization

Intervention groups

Patients with high blood pressure were evaluated in both control and intervention groups. Educational intervention was conducted for the intervention group for 4 weeks. The control group received routine training. The data gathering tool was a follow-up questionnaire that was completed for both groups before and after intervention.

Main outcome variables

Adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160220026662N2**

Registration date: **2018-09-03, 1397/06/12**

Registration timing: **retrospective**

Last update: **2018-09-03, 1397/06/12**

Update count: **0**

Registration date

2018-09-03, 1397/06/12

Registrant information

Name

Nader Aghakhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-20, 1396/02/30

Expected recruitment end date

2017-07-06, 1396/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of self-care blended education on treatment adherence in hypertensive patients

Public title

The effect of blended education on treatment adherence

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

At least the reading and writing skills Absence of a sick person or a close relative of his relatives in the healthcare team Not having malignant disease or mental illness according to file information Having aged 20 to 65

years old Having a blood pressure higher than 90/140 and less than 110/180 Being treated for at least six consecutive months without diabetes or chronic kidney disease Not having a high blood pressure above 110/180, or any evidence of an emergency, stroke or myocardial infarction in the past six months Lack of unstable angina, grade 3 or 4 heart failure, serious liver or kidney disease, and pregnancy

Exclusion criteria:

Cancellation of the continuation of the study for any reason (lack of cooperation or death) Lack of access by phone and telephone with the patient and his family while conducting research Complications of illness and hospitalization

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomized randomization by lottery method

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

Ethics committee of Urmia University of medical Sciences

Street address

Orjhans Ave, Resalat Blvd

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urmia

Province

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Postal code

5714783734

Approval date

2017-04-19, 1396/01/30

Ethics committee reference number

Ir.Umsu.rec.1396.30

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Treatment adherence

Timepoint

Measure the grade of adherence to the treatment before the intervention and 2 weeks after the intervention

Method of measurement

Adherence to treatment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Educational intervention is based on the implementation of combined education including educational videos, pamphlets, lectures, and group discussions

Category

Prevention

2

Description

Control group: Provide routine training

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Shahin Dezh Hospital

Full name of responsible person

Zahra Rahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Uremia University of Medical Sciences

Full name of responsible person

Rahim Begaye

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Pardis Nazlou, 11 km of Nazlou Road

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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

Vice Chancellor for Research of Uremia 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

Oroumia University of Medical Sciences

Full name of responsible person

Zahra Rahimi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available