Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 2026

Effect of a Physicians Communication Skills Training on Health Outcomes and HealthLiteracy Among Hypertensive Patients: a Randomized Controlled Trial

Protocol summary

Study aim

Evaluation of the effectiveness of physician communication training on level of patient' health literacy skills and hypertension outcome among patients with uncontrolled blood pressure.

Design

A randomized controlled trial method was used to enroll 242 hypertensive patients and 35 physicians from healthcare clinics in the Mashhad, Iran. All participants received a code, then, they were randomly divided into two control and intervention groups. Multiple statistical analysis were used to assess whether the physician training improved physicians-patient's communication skills, hypertension outcomes, self- efficacy, and patient medication adherence after intervention.

Settings and conduct

The study population was women and men who referred to health centers in Mashhad, Iran. 6 Clinics were randomly assigned (as the unit of randomization) to either usual care control (n = 3 clinics) or the training intervention (n = 3).

Participants/Inclusion and exclusion criteria

They have uncontrolled blood pressure, age 18 or older, could speak and read Farsi، able to give informed consent, did not suffered an acute-myocardial infarction or had kidney disease and other health impairments

Intervention groups

All participants were allocated into an educational intervention group and control group. In intervention group, the educational intervention was conducted based on the potential communication gaps with focus on Health Literacy in Practice (HLP) strategies. The control group did not receive any intervention education.

Main outcome variables

Hypertension outcomes; physicians-patient's communication skills; Self- efficacy; patient medication adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160710028863N24**
Registration date: **2018-04-04, 1397/01/15**
Registration timing: **prospective**

Last update: **2018-04-04, 1397/01/15**
Update count: **0**

Registration date

2018-04-04, 1397/01/15

Registrant information

Name

Nooshin Peyman

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 502 6195

Email address

peymann@mums.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2634-11-22, 2013/09/01

Expected recruitment end date

2635-11-19, 2014/08/28

Actual recruitment start date

2634-11-22, 2013/09/01

Actual recruitment end date

2634-12-22, 2013/10/01

Trial completion date

empty

Scientific title
Effect of a Physicians Communication Skills Training on Health Outcomes and HealthLiteracy Among Hypertensive Patients: a Randomized Controlled Trial

Public title
Effect of a Physicians Communication Skills Training on Health Outcomes Among Hypertensive Patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
All eligible patients included if they had to be have uncontrolled blood pressure prescribed at least one antihypertensive medication during the past three months were age 18 or older could speak and read their native language in Iran (Persian)

Exclusion criteria:
They were unable to give informed consent had suffered an acute-myocardial infarction or had kidney disease had visual impairment, mental disturbance illiteracy, and upper limb disability

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **940**
Actual sample size reached: **242**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random sampling was used to select eligible patients with hypertension from the six primary care clinics in Mashhad, Iran. Health secretaries provided different lists of patients and all the patients are assigned number. The researcher then used tables of random number to select each number of the patients. 940 patients with hypertension were randomly screened, of whom 698 were excluded for several reasons such as they did not meet the inclusion criteria. Of the final 242 enrolled patients enrolled for the initial study were randomly assigned to intervention (n= 121) and control groups (n=121).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
.

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences Research Committee

Street address
Daneshgah Street, between Daneshgah 16 -18

City
Mashhad

Province
Razavi Khorasan

Postal code
91388-13944

Approval date
2634-11-22, 2013/09/01

Ethics committee reference number
IR.MUMS.REC.1392.125

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension, high blood pressures associated with health literacy and health outcome

Primary outcomes

1

Description
hypertension outcomes (SBP and DBP)

Timepoint
The beginning of the study (before the intervention), after intervention, and six months after the intervention

Method of measurement
Automated blood pressure monitor

2

Description
patient’s Health literacy skills

Timepoint
The beginning of the study (before the intervention), after intervention, and six months after the intervention

Method of measurement
International questionnaire of Health Literacy in Practice (HLP) strategies

Secondary outcomes

1

Description
self-efficacy
Timepoint
The beginning of the study (before the intervention), after intervention, and six months after the intervention
Method of measurement
The International chronic disease self-efficacy Questionnaire

2

Description
Patient's medication adherence
Timepoint
The beginning of the study (before the intervention), after intervention, and six months after the intervention
Method of measurement
The Adult Primary Care Questionnaire was used to assess medication adherence.

Intervention groups

1

Description
Intervention group: physicians-patient’s training to address key disparities based on Health Literacy in Practice (HLP) strategies among hypertensive patient
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
six government primary care clinics
Full name of responsible person
Dr Nooshin Peyman
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Department of Health Education and Health Promotion, Danshgah Street, between Daneshgah 16-18
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi (Pharm.D, Ph.D)
Street address
Mashhad University of Medical Sciences International Office, Administration Center (Qoreishi Building), Daneshgah St.
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Seyedeh Belin Tavakoly Sany
Position
Academic Staff
Latest degree
Ph.D.
Other areas of specialty/work
Environmental Health
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Potential data is sharable after distinguishing people

When the data will become available and for how long
Start the access period one month after the publication of result

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Data is sent through an official request and by email

From where data/document is obtainable
Dr Nooshin Peyman Peymann@mums.ac.ir

What processes are involved for a request to access data/document
Data is sent through an official request and by email

Comments
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