

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Street address

Department of Health Education and Health Promotion, Daneshgah Street, between Daneshgah 16-18

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Phone

+98 51 3893 9832

Email

Peymann@mums.ac.ir

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.

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Phone

+98 51 3180 1337

Email

tafaghodim@mums.ac.ir

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

Street address

Department of Health Education and Health Promotion, between 16th and 18th Daneshgah, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3854 4643
Email
tavakkolisb2@mums.ac.ir

Person responsible for scientific 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
Street address
Department of Health Education and Health
Promotion, Daneshgah Street, between Daneshgah
16 -18
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 3007
Email
tavakkolisb2@mums.ac.ir

Person responsible for updating data

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
Street address
Department of Health Education and Health
Promotion, Daneshgah Street, between Daneshgah
16 -18
City
Mashhad
Province
North Khorasan
Postal code
9138813944
Phone
+98 51 3841 3007
Email
tavakkolisb2@mums.ac.ir

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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