Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 2026

• Effects of educational intervention strategies based on self-care health literacy hypertensive patients with limited health literacy: An Application of Health Belief Model

Protocol summary

Summary

• The purpose of this quasi-experimental study to determine the effect of education based on Health Belief Model on self-care behaviors among hypertensive patients with limited health literacy. Study design: randomized in two groups. Study population: patients with hypertension with limited health literacy. Inclusion criteria: the health record in the health center; at least 6 months of diagnosis is past ; has read and write ; lack of symptoms, hypertension (heart attacks, strokes, kidney disease and eye blood pressure) ; willingness to participate in the study. Exclusion criteria: participate in training sessions for more than one session ; complications during the study. Sample size: 100 patients (each n = 50). Interventions: A Case Study after inviting of patients with limited health literacy, pre-test in both groups carried out from the intervention group, patients are invited to participate in 4 sessions (within 2 weeks) participate. The training program based on health belief model and focus groups and educational comics will be designed and proposition leaves. 1 and 3 months after the end of the program from both groups were tested and the results will be compared. Measuring variables are: 1) self-care, 2) awareness 3) health belief model 4) health literacy. The main outcomes of the study: self-care behaviors and awareness is increased.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011731999N1**
Registration date: **2017-01-25, 1395/11/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-25, 1395/11/06

Registrant information

Name
Azam Larki
Name of organization / entity
Bushehr University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 61 3290 4230
Email address
a.larki@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research of Bushehr University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

• Effects of educational intervention strategies based on self-care health literacy hypertensive patients with limited health literacy: An Application of Health Belief Model

Public title

• Educational program on self-care behaviors influence

blood pressure.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the health record in the health center; at least 6 months of diagnosis is past ; has read and write ; lack of symptoms, hypertension (heart attacks, strokes, kidney disease and eye blood pressure) ; willingness to participate in the study. Exclusion criteria: participate in training sessions for more than one session ; complications during the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

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

Bushehr University of Medical Sciences

Street address

Bushehr. Rishehr

City

Bushehr

Postal code

Approval date

2016-12-19, 1395/09/29

Ethics committee reference number

IR.BPUMS.REC.1395.128

Health conditions studied

1

Description of health condition studied

hypertansion

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

2

Description of health condition studied

hypertansion

ICD-10 code

I15

ICD-10 code description

Secondary hypertension

Primary outcomes

1

Description

self-care bihaviors

Timepoint

Before the intervention, 1 and 3 months after intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

awareness

Timepoint

Before the intervention, 1 and 3 months after intervention

Method of measurement

questionnaire

2

Description

Perceived susceptibility

Timepoint

Before the intervention, 1 and 3 months after intervention

Method of measurement

questionnaire

3

Description

Perceived severity

Timepoint

Before the intervention, 1 and 3 months after intervention

Method of measurement

questionnaire

4

Description

Perceived benefits

Timepoint

Before the intervention, 1 and 3 months after intervention

Method of measurement

questionnaire

5

Description

Perceived barriers

Timepoint

Before the intervention, 1 and 3 months after intervention

Method of measurement

questionnaire

6

Description

self efficacy

Timepoint

Before the intervention, 1 and 3 months after intervention

Method of measurement

questionnaire

7

Description

Guide for action

Timepoint

Before the intervention, 1 and 3 months after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

A Case Study after inviting of patients with limited health literacy, pre-test in both groups carried out from the intervention group, patients are invited to participate in 4 sessions (within 2 weeks) participate. The training program based on health belief model and focus groups and educational comics will be designed and proposition leaves. 1 and 3 months after the end of the program from both groups were tested and the results will be compared.

Category

Lifestyle

2

Description

The control group received routine care clinics.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Healthy Heart Clinic on Tir 7

Full name of responsible person

Zinat Sarkhosh

Street address

Bushehr. Sangi

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Assistant Bushehr University of Medical Sciences

Full name of responsible person

Afshin Ostovar

Street address

Salman Farsi street, Bahmani, Bushehr, Iran

City

Bushehr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Assistant Bushehr 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

Bushehr University of Medical Sciences

Full name of responsible person

Mahnush Reisi

Position

Department of Health Education and Health Promotion

Other areas of specialty/work

Street address

Salman farsi Street, Bahmani, Bushehr

City

Bushehr

Postal code

Phone
+98 77 3332 2081
Fax
Email
mr_reisi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Mahnush Reisi
Position
Department of Health Education and Health Promotion
Other areas of specialty/work
Street address
Salman farsi,Bahmani street,Bushehr.
City
Bushehr
Postal code
Phone
+98 77 3332 2081
Fax
Email
mr_reisi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Azam Larki
Position
Post Graduate student Bushehr University of Medical Sciences
Other areas of specialty/work
Street address
Bahmani,Slman farsi street,Bushehr
City
Bushehr
Postal code
Phone
+98 61 3290 4230
Fax
+98 61 3333 5200
Email
azam.larki69@gmail.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