

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of Telehealth program on health literacy and self-care behaviors in patients with hypertension at risk of peripheral artery diseases

Protocol summary

Study aim

Determining the effect of remote health program on health literacy and self-care behaviors in patients with high blood pressure at risk of peripheral artery disease.

Design

This study is a randomized controlled clinical trial using remote communication technology

Settings and conduct

The current research will be conducted on patients aged 45 to 95 years with high blood pressure diagnosed by a cardiologist at Shahid Rahimi Hospital in Khorramabad.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Has a record of hospitalization in Shahid Rahimi Hospital Information and written consent to participate in the study (30) Participants are at risk of peripheral artery diseases based on a special nomogram (minimum initial blood pressure increase of 140/90) (5). Have a smart phone or laptop Age between 45 and 95 years based on nomogram (36) The patient or caregiver should be literate (37) Have the ability to use smart phones and social networks (39) Diagnosis of high blood pressure by a cardiologist Exit criteria: Reluctance to continue cooperation in the study (39) Death of the patient (40) Having hearing and speech problems (12) Participation in other educational and rehabilitation programs (40) Hospitalization during the study (38) Suffering from other vascular diseases such as Raynaud's, lupus or vasculopathy Existence of psychiatric diseases (28) Absence of more than one meeting (14) Having chronic diseases and limitations in self-care ability (38) Changing mobile phone number and not informing (37) Having a blood pressure crisis (110/180) The need for vascular reconstruction through surgery Aortic aneurysm or vascular thrombosis

Intervention groups

Hypertensive patients at risk of peripheral artery disease

Main outcome variables

Increasing health literacy and self-care behaviors in hypertensive patients at risk of peripheral artery disease

General information

Reason for update

Acronym

آموزش سواد سلامت و رفتارهای خودمراقبتی از راه دور

IRCT registration information

IRCT registration number: **IRCT20230409057867N1**

Registration date: **2025-06-04, 1404/03/14**

Registration timing: **retrospective**

Last update: **2025-06-04, 1404/03/14**

Update count: **0**

Registration date

2025-06-04, 1404/03/14

Registrant information

Name

Farhad Falah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3326 3663

Email address

farhadfalah1367@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-10, 1402/02/20

Expected recruitment end date

2023-07-11, 1402/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Telehealth program on health literacy and self-care behaviors in patients with hypertension at risk of peripheral artery diseases

Public title

The effect of Telehealth program on health literacy and self-care behaviors in patients with hypertension at risk of peripheral artery diseases

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with hypertension Has a record of being admitted to Shahid Rahimi Hospital in Khorram Abad

Exclusion criteria:

Age less than 45 years Unwillingness to participate in the study

Age

From **45 years** old to **95 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each person or person caring for the patient was considered as a sample

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of samples in study groups is done by random block method. Then, by random block method, they are placed in 2 study groups in a balanced way. It should be noted that the volume of each block is 4 items, so that 6 different combinations of 4 blocks (AABB, ABAB, BBAA, BAAB, ABBA, BABA) are created and randomly selected by placing the blocks. are selected

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 Lorestan University of Medical Sciences and Health Services

Street address

University of Medical Sciences, Shahid Anoushirvan Rezaei Square, Moalem St., Lorestan, Khorram Abad

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2023-04-09, 1402/01/20

Ethics committee reference number

IR.LUMS.REC.1400.22510

Health conditions studied**1****Description of health condition studied**

Peripheral artery disease

ICD-10 code

(I00-I99)

ICD-10 code description

IX Diseases of the circulatory system

Primary outcomes**1****Description**

Increasing health literacy and self-care ability in patients with arterial vascular disease and the presence of risk factors such as blood pressure, smoking, improper diet and low activity

Timepoint

Before studying and after studying

Method of measurement

with Montazeri et al.'s health literacy questionnaire and Han et al.'s self-care questionnaire

Secondary outcomes**1****Description**

Increasing patient self-care

Timepoint

Before and after study

Method of measurement

The 20-item instrument has 4-point Likert responses: always (score 4), often (score 3), sometimes (score 2) and rarely or never (score 1), with the total score varying between 20 and 80, and obtaining a higher score means

more self-care. Is. Items 12 and 13 have reverse scoring

Intervention groups

1

Description

Control group: During the training period, this group was independent from the intervention group and will only receive routine treatment according to the previous roll

Category

Lifestyle

2

Description

Intervention group: This group will receive training on health literacy and self-care behaviors continuously and in two months through the remote network.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahimi Khorramabad Hospital

Full name of responsible person

Farhad Falah

Street address

Phase 2 of Army Coy, Shahab 5 East

City

Khorramabad

Province

Lorestan

Postal code

4736814949

Phone

+98 916 669 7718

Email

farhadfalah1367@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

tahare toulabi

Street address

University of Medical Sciences, Shahid Anoushirvan Rezaei Square, Moalem St., Lorestan, Khorram Abad

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khorrabad

Province

Lorestan

Postal code

6813833946

Phone

Email

publicrelation@iums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

University of Medical Sciences

Proportion provided by this source

1

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

farhad falah

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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toulabi_t@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

tahare toulabi

Position

college professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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nurse

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To protect the privacy of the participants

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

The data will be stored in a file and the results will be published at the end of the study

When the data will become available and for how long

4 months

To whom data/document is available

Research team

Under which criteria data/document could be used

With the aim of improving and making patients aware of health-threatening conditions and lifestyle changes

From where data/document is obtainable

Research team

What processes are involved for a request to access data/document

After conducting the study and statistical analysis and recording the data, I will publish the data with the privacy of the participants and the consent of the groups

Comments