Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 2026

The effect of mobile educational application on adherence to treatment and blood pressure in the elderly with hypertension

Protocol summary

Study aim

Determining the effect of mobile educational application on adherence to treatment and its consequences on blood pressure in the elderly with hypertension of the Retired Cultural Center

Design

This study is a randomized clinical trial with a control group that was conducted to determine the effect of mobile educational application on adherence to treatment and its consequences on blood pressure in 54 elderly people with hypertension in the retired cultural center of Neishabour. In order to randomly assign individuals to the two groups and ensure the balance of the number of individuals in the groups, the block randomization method was used.

Settings and conduct

The research took place in the Neishabour Cultural Retirees Education Center, which includes an organization in Neishabour city.

Participants/Inclusion and exclusion criteria

Elderly 70 to 60 years according to WHO guidelines No history of psychological disorders based on AMT questionnaire No history of attending similar training sessions for at least 6 weeks Take anti-hypertensive drugs based on your doctor's diagnosis Member of Neishabour Retired Cultural Association Has a smartphone with Android operating system The ability to use mobile phones and educational applications that were objectively examined by the researcher in the first session. Primary hypertension based on physician diagnosis for at least 6 weeks

Intervention groups

Intervention group: Patients with hypertension referred to the Neishabour Cultural Retirees Center who were trained. Control group: The patient with hypertension referred to the Cultural Retirees Center of Neishabour city who met the inclusion criteria.

Main outcome variables

Adherence to treatment; Hypertension

General information

Reason for update

Due to presence of some mistakes in the initial registration of information and re-examination by the supervisors, we decided to correct them. Inclusion criteria: The reason for updating the information in this section was the misspelling of some inclusion conditions. Total sample size: The reason for updating this section was a mistake in recording study information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200618047824N1**
Registration date: **2020-11-29, 1399/09/09**
Registration timing: **retrospective**

Last update: **2021-03-24, 1400/01/04**
Update count: **2**

Registration date

2020-11-29, 1399/09/09

Registrant information

Name

Danial Baghei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4334 5243

Email address

dbaghei@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-06, 1399/03/17

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

2020-06-06, 1399/03/17

Actual recruitment end date

2020-08-05, 1399/05/15

Trial completion date

2020-08-05, 1399/05/15

Scientific title

The effect of mobile educational application on adherence to treatment and blood pressure in the elderly with hypertension

Public title

The effect of mobile educational application on adherence to treatment and blood pressure in the elderly

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly 60 to 70 years according to WHO guidelines No history of psychological disorders based on AMT questionnaire No history of attending similar training sessions for at least 6 weeks Take anti-hypertensive drugs based on your doctor's diagnosis Member of Neishabour Retired Cultural Association Has a smartphone with Android operating system The ability to use mobile phones and educational applications that were objectively examined by the researcher in the first session. Primary hypertension based on physician diagnosis for at least 6 weeks

Exclusion criteria:

Having vision, hearing or any illness that prevents the use of smartphones Having a history of psychological disorders based on AMT questionnaire

Age

From **60 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected consecutively from the retirees of the Neyshabour Cultural Association based on the inclusion criteria. In order to randomly assign people to two groups and ensure the balance of the number of people in the groups, the block randomization method was used. In this study, blocks with quadruple sizes were created. Random sequences were generated using the www.sealedenvelope.com website. Dark envelopes were used to conceal the allocation. Equivalent to the calculated sample size (n = 54), a dark envelope was prepared and the envelopes were numbered from 1 to 54 and the name of the desired group (control or intervention) was placed inside each envelope according to the random sequence created.

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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina Avenue, Qods Street, Enqelab Square, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2020-02-12, 1398/11/23

Ethics committee reference number

IR.TUMS.FNM.REC.1398.175

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Adherence to treatment

Timepoint

At the beginning of the study (before the intervention) and after the end of the study (after the last session of the intervention)

Method of measurement

40-item questionnaire on adherence to treatment in chronic diseases developed by Madanloo et al. (2013)

Secondary outcomes

1

Description
Hypertension
Timepoint
At the beginning of the study (before the intervention) and after the end of the study (after the last session of the intervention)
Method of measurement
Use a sphygmomanometer

Intervention groups

1

Description
Intervention group: The intervention for the intervention group was performed in the form of 6 absentee sessions: The first session: stating the objectives, explaining the mobile health training program, the content of the training sessions (training chart), how to communicate with the researcher to answer questions and resolve ambiguity. Session 2: Definition of hypertension, symptoms, complications and methods of treatment and control. Session 3: Lifestyle and include proper diet for hypertensive patients. Session 4: Lifestyle and include adequate exercise, sleep and rest for hypertensive patients. Session 5: Lifestyle and includes the effect of stimulants such as tea, caffeine and coffee on blood pressure and the harms of smoking and alcohol consumption for hypertensive patients. Session 6: Lifestyle and stress management in hypertensive patients.
Category
Lifestyle

2

Description
Control group: Patients with hypertension referred to the Cultural Retirees Center of Neishabour city who met the inclusion criteria. This group is not specially trained by researchers.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Neishabour Cultural Retirees Education Center
Full name of responsible person
Danial Baghei
Street address
Neishabour - Resalat Blvd. - Resalat Sharghi 16 - No. 200
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Danial Baghei
Position
Msc
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Phone
+98 51 4334 5243

Fax

Email
dbaghei@razi.tums.ac.ir

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
The data obtained from this project will eventually be reported as standard and general, and reporting personal information by individuals does not seem necessary.

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

Statistical Analysis Plan
Yes - There is 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
No - There is not a plan to make this available

Title and more details about the data/document
Demographic information and information about the main outcome of this project can be shared.

When the data will become available and for how long
Start of access period 1 year after printing the results

To whom data/document is available
The data of this project can be shared by all aspiring researchers working in academic and scientific institutes.

Under which criteria data/document could be used
Appropriate scientific use of the data of this study in order to improve the quality of similar studies is unimpeded.

From where data/document is obtainable
The data of the present research is possible by announcing the request via email Nikpeyma@yahoo.com and also danial.baghei@gmail.com.

What processes are involved for a request to access data/document
After confirming the eligibility of the person requesting the information, the data will be sent as soon as possible via the above emails.

Comments