Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating a multidimensional intervention on increasing medication adherence in the elderly with hypertension

Protocol summary

Study aim
Determining the effect of the multidimensional method on increasing medication adherence in the elderly with hypertension.

Design
The clinical trial consists of a control group and parallel groups. It is a triple-blind, randomized, Phase 2 trial involving 80 patients. A black bag (containing the names of individuals eligible for the study) was used for randomization.

Settings and conduct
Baqiyatallah University of Medical Sciences. Training along with the presentation of a pamphlet with the content of blood pressure and its complications, drug compliance and its effects, the role of the provided medicine box Installing the software on the elderly person's phone, teaching how to use it and how to record blood pressure daily to the patient and his companion Providing education tailored to the elderly A triple blind method in the form of not providing training to the control group

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 60 years and older, Definite diagnosis of hypertension, Ability to read and write in Persian, Possession of a smartphone and the ability to use it. Exclusion criteria: Lack of willingness to participation, Significant and impactful life changes resulting in high physical and psychological stress, Participant's death.

Intervention groups
Instruction in two sessions Application of Installed application, Providing medicines orginizer

Main outcome variables
Medication compliance; blood pressure level; frequency of visits to the emergency room due to uncontrolled blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230228057572N1**
Registration date: **2023-09-26, 1402/07/04**
Registration timing: **retrospective**

Last update: **2023-09-26, 1402/07/04**
Update count: **0**

Registration date
2023-09-26, 1402/07/04

Registrant information

Name
Omid Nademi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8126 3296

Email address
omid_nademi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2023-08-22, 1402/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating a multidimensional intervention on increasing medication adherence in the elderly with hypertension

Public title
Investigating the effect of combined intervention including medication box, education and medication reminder software on increasing medication compliance and blood pressure control in the elderly

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age 60 years and older Willingness to cooperate in the study Definitive diagnosis of high blood pressure based on the doctor's opinion Ability to read and write in Persian Lack of simultaneous participation in similar interventions Sign the informed consent form to participate in the research Having a smart mobile phone and being able to use it

Exclusion criteria:
Reluctance to continue participation after choosing the person The impossibility of completing the research instrument in the pre-test and post-test stages Major changes affecting a person's life resulting in high physical and mental stress (such as the death of relatives and friends, severe physical and mental illness, divorce, etc.) Death of the contributor

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
For the selection of samples, simple random sampling method will be used. Initially, all patients eligible for the study at Baqiyatallah Hospital and its affiliated clinic will be chosen, and their names will be placed in equal-sized pieces of paper inside a black bag. After shaking the bag, the first name will be randomly and completely blindly drawn, and assigned to the control group. Then, the next name will be selected by replacing the drawn name back into the bag, and placed in the intervention group. This process will continue until each group reaches the predetermined size. It should be noted that each name can only be selected once. If a name is drawn again, it will be returned to the bag."

Blinding (investigator's opinion)
Triple blinded

Blinding description
In the present study, allocation to control and intervention groups will be done blindly and randomly. Also, participants will be unaware of their group type. Data collection will also be done blindly by a nurse expert apart from the research team. The data analysis will be hidden related to the control and intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Baqiyatallah Hospital

Street address
Baqiyatallah Hospital, No. 204, Mollasadra Ave., Vanak Sqr

City
Tehran

Province
Tehran

Postal code
1435915371

Approval date
2023-07-31, 1402/05/09

Ethics committee reference number
IR.BMSU.BAQ.REC.1402.034

Health conditions studied

1

Description of health condition studied
High blood pressure

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Medication compliance

Timepoint
Measurement of high blood pressure at the beginning of the study (before the start of the intervention) and one month after the start of the intervention

Method of measurement
Moriski medication adherence questionnaire

Secondary outcomes

1

Description
Blood pressure
Timepoint
Before starting the study and after completing the intervention
Method of measurement
Standard sphygmomanometer

Intervention groups

1

Description
Intervention group: general training in plain language with a pamphlet with the content of blood pressure and its side effects, medication compliance and its effects, training on installing the medication reminder software designed by the research team on the elderly person's phone and how to use it for the patient and his companion. Providing specific training needs identified and with formats suitable for the elderly
Category
Prevention

2

Description
Control group: The control group will not receive any intervention during the study.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Omid Nademi
Street address
South Sheikh Bahai St, Mollasadra St, Vanak Square
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8126 3990
Email
omid_nademi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr. Mehdi Jafari-Oori
Street address
South Sheikh Bahai St, Mollasadra St, Vanak Square
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8755 5501
Email
m.jafarioori@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Omid Nademi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
South Sheikh Bahai St, Mollasadra St, Vanak Square
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8126 3990
Fax
Email

omid_nademi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Omid Nademi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Fax

Email
omid_nademi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
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Fax

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omid_nademi@yahoo.com

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
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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Study data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
No special conditions are required

From where data/document is obtainable
Omid Nademi 00989122258420

What processes are involved for a request to access data/document
The access period starts 6 months after the results are published

Comments