

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparative study of using drug reminder cards with telephone follow-up on drug adherence of the elderly with hypertension

Protocol summary

Study aim

Comparative study of using drug reminder cards with telephone follow-up on drug adherence of the elderly with hypertension referred to comprehensive health service centers in Rafsanjan in 1401

Design

Control group with two parallel groups, randomized by minimization, sample size of 40 people per group

Settings and conduct

The reminder card is designed by the researcher and provided to the first intervention group. Phone Reminder Telephone Call is performed in pre-coordinated times in the second intervention group. Control group does not intervene

Participants/Inclusion and exclusion criteria

Inclusion criteria Seniors 60 to 75 years old Suffering from high blood pressure according to the doctor's opinion Taking antihypertensive drugs Ability to read and write Not suffering from Alzheimer's and other types of dementia Physical ability (movement-vision-hearing) to take medicines independently Not using other types of drug reminders Exclusion criteria being admitted to the hospital Change in the mental state and alertness of a person due to a disease such as CVA Unwillingness to continue participating in the study Failure to answer the phone more than twice Failure to attend the health center once a month

Intervention groups

Control Group, routine care for blood pressure treatment will be done in accordance with the routine of comprehensive health services centers. The drug card intervention group, weekly medication cards will be designed and provided to the patient. The telephone tracking group follows the researcher how to take medications through telephone calls.

Main outcome variables

medication adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160503027736N6**

Registration date: **2022-10-04, 1401/07/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-04, 1401/07/12**

Update count: **0**

Registration date

2022-10-04, 1401/07/12

Registrant information

Name

shahin heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 5351

Email address

sh.heidari@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-03, 1401/04/12

Expected recruitment end date

2022-11-03, 1401/08/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of using drug reminder cards with telephone follow-up on drug adherence of the elderly with hypertension

Public title

Comparative study of using drug reminder cards with telephone follow-up on drug adherence of the elderly with hypertension

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Seniors 60 to 75 years old suffering from high blood pressure according to the doctor's opinion taking antihypertensive drugs being able to read and write not suffering from Alzheimer's and other types of dementia physical ability (movement-vision-hearing) to take medicines independently Not using other types of drug reminders

Exclusion criteria:

being admitted to the hospital Change of mental state and alertness of a person due to a disease such as CVA Unwillingness to continue participating in the study Failure to answer the phone more than twice Failure to attend the health center once a month

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization by minimization method: in this method, initially, the patients will categorize based on key variables, include gender and scores of Morisky medication adherence scale-8. Afterwards, from the patients who will meet the inclusion criteria, the first participant will place in the intervention or control group by coin flip, and other participants will allocate to the study group with lower total of variables. The following table is used as a randomization tool: Variables Category : Intervention group (pill card) * Intervention group (phone call)*Control group morrisky medication adherence scale-8(MMAS-8) score A score of 0 to 6 is adherence Score 8 to 6 Moderate adherence A score 8 high adherence sex: female male

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

Research Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Nurse Street, College of Nursing and Midwifery

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2022-06-22, 1401/04/01

Ethics committee reference number

IR.RUMS.REC.1401.063

Health conditions studied

1

Description of health condition studied

Drug adherence in the elderly with high blood pressure

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Drug adherence in the elderly with high blood pressure

Timepoint

At the beginning of sample collection, one, two, three months after the start of the intervention

Method of measurement

Morisky medication adherence questionnaire, demographic information questionnaire, pill counting form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Medication reminder card. Weekly drug reminder cards are designed by the researcher and given to the patient according to the review of the

available texts and booklets and based on the drugs used by the patient. Considering that the intervention lasts for 3 months, 12 cards are designed for each person over time and according to the changes in the drugs used. The information on these cards includes the name of the drug, a clear color picture of the pill, the number of pills per dose, the reason for using it with a color picture (for example, the picture of a sphygmomanometer for antihypertensive medicine), the time/time of using the medicine using the picture or The pictograph will be the time of day and night (morning, noon, night, bedtime). Two copies of each reminder card are given to the patient and it is recommended to place each one in the most visible places. (For example, on the refrigerator door, inside the bedroom or on the prayer mat...)

Category

Behavior

2**Description**

Intervention group: Telephone call group. The researcher keeps track of how the drugs are taken through phone calls. In this way, the nurse calls all the people at the pre-arranged time and reminds them of the name of the medicine, the dose of the medicine, the time of taking the medicine and the considerations when taking the medicine. The duration of the conversation is considered to be 5 to 10 minutes on average for each person, which varies based on the needs and educational questions of the patients. The phone call time will be set between 8:00 am and 8:00 pm with the agreement of the patients. The call schedule is provided to the patient in writing. The number of phone calls to follow up adherence to medication will be 2 times a week in the first month and once a week during the second and third months. If the first call is missed, the second call will be made on the same day. If the second call is also missed, the last call will be made the next day. Telephone follow-up is done for 3 months based on studies (33, 34).

Telephone conversations will be recorded in the set form.

Category

Behavior

3**Description**

Control group: In the control group, routine blood pressure treatment activities and care will be performed according to the routine of comprehensive health service centers.

Category

Other

Recruitment centers**1****Recruitment center**

Name of recruitment center
health service centers

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rafsanjan 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

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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

There is no further information.

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable