

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the effect of one-way and interactive SMS reminder on adherence to treatment regimen in the elderly with hypertension

Protocol summary

high blood pressure control; Improving adherence to drug therapy

Study aim

to compare the effect of one-way and interactive SMS reminders on medication compliance in the elderly with hypertension.

Design

A randomized clinical trial, without blinding, on the elderly with high blood pressure under oral drug treatment, selecting 114 patients with easy primary sampling based on the purpose and dividing into three equal groups of 38 people randomly.

Settings and conduct

The study was done without blinding in Shahrekord blood pressure clinic. After completing the initial forms and the questionnaire, the average sitting and lying blood pressure are recorded. A text message is sent to the intervention groups daily for a month. Unlike group 1, group 2 is able to send messages. Group 3 do not receive messages and cannot send messages. The blood pressure of the three groups will be measured one and two months later and the questionnaire will be completed again.

Participants/Inclusion and exclusion criteria

Entry criteria: having a mobile phone and the ability to read text messages, consent, diagnosis of hypertension, age 60 years and older, taking oral hypertension medication Exclusion criteria: taking blood pressure injection drugs, having coronary artery disease, chronic kidney disease, controlled hypertension during previous visits, participation in other research projects.

Intervention groups

The one-way interactive group (1) receives a daily text message after completing the treatment compliance questionnaire and blood pressure measurement for one month. One and two months later, blood pressure is measured and the questionnaire is completed. Two-way interactive group (2) can send SMS in addition to receiving SMS. Control group (3) do not receive messages and cannot send SMS.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231122060136N1**

Registration date: **2023-12-27, 1402/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-27, 1402/10/06**

Update count: **0**

Registration date

2023-12-27, 1402/10/06

Registrant information

Name

Nasrin Malekmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3452 3853

Email address

nasrin215malekmohammadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of one-way and interactive SMS reminder on adherence to treatment regimen in the elderly with hypertension

Public title

The effect of SMS on the use of blood pressure medication in the elderly with high blood pressure

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Having a mobile phone and the ability to read text messages Willingness to cooperate in the study Diagnosis of hypertension Age 60 years and older Taking at least one medication to control hypertension

Exclusion criteria:

Use of blood pressure injection drugs Having coronary artery disease chronic kidney disease Having controlled hypertension during previous visits Participation in other research projects

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

114 selected samples are divided into 3 groups of 38 people, one-way, two-way and control interaction with the help of random allocation software. In this software, numbers between 1 and 114 are entered and then selected by this program in groups of 9. The first 9 numbers are in the one-way interaction group, the second 9 numbers are in the two-way interaction group, and the third 9 numbers are in the control group, and this is repeated again, and at the end, the remaining 6 numbers are grouped in pairs and in the same order in Groups are placed.

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 Shahid Sadoughi University of Medical Sciences, Yazd

Street address

No. 31, 75 Alley, West Saadi , Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8817845645

Approval date

1981-08-11, 1360/05/20

Ethics committee reference number

IR.SSU.REC.1402.079

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I15.8

ICD-10 code description

Secondary hypertension, unspecified

Primary outcomes

1

Description

The treatment adherence score is based on Morisky questionnaire, whose total score range is between 0 and 8. The lower the score, the more people will adhere to medication.

Timepoint

Completing the questionnaire at the beginning of work and two months after

Method of measurement

Morisky questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The one-way interaction group, after completing the treatment compliance questionnaire and blood pressure measurement, will receive daily text messages for one month. One and two months later, blood pressure is measured and the questionnaire is completed again.

Category

N/A

2**Description**

Intervention group: The two-way interaction group will receive a daily SMS after completing the treatment compliance questionnaire and blood pressure measurement for one month. In addition to receiving text messages, this group can also send text messages to the researcher. One or two months later, the blood pressure will be measured and the questionnaire will be completed again.

Category

N/A

3**Description**

Control group: In the control group, the treatment compliance questionnaire is completed and initial blood pressure is measured. This group does not receive messages during the study and cannot send SMS. One and two months later, blood pressure is measured and the questionnaire is completed again.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahrekord blood pressure clinic

Full name of responsible person

Nasrin Malekmohammadi

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Email

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

Yazd University of Medical Sciences

Full name of responsible person

Yazd University of Medical Sciences

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No. 31, 75 Alley, West Saadi St

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

No

Title of funding source

Yazd University of Medical Sciences (Faculty of Nursing and Midwifery)

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**

Yazd University of Medical Sciences

Full name of responsible person

Nsirin Malekmohammadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Nasrin Malekmohammadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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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

Information about the main outcome or similar

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

For all

Under which criteria data/document could be used

Yazd University of Medical Sciences website Personal email: nasrin215malekmohammadi@gmail.com Phone 09132815336

From where data/document is obtainable

Yazd University of Medical Sciences website Personal email: nasrin215malekmohammadi@gmail.com Phone 09132815336

What processes are involved for a request to access data/document**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Nasrin Malekmohammadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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