

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of interactive intervention in the platform of social messengers according to protection motivation theory on medication adherence and blood pressure control in adults with hypertension

Protocol summary

Study aim

The effect of interactive intervention in the platform of social messengers according to protection motivation theory on medication adherence and blood pressure control in adults with hypertension

Design

A randomized, single-blind, parallel-group controlled clinical trial on 142 patients with primary hypertension. Randomization will be done by quadruple block random assignment method.

Settings and conduct

Place Of Study: Comprehensive Health centers under the coverage of Tehran University of Medical Sciences;
Research population: Adults with primary hypertension;
Blinding: Single-Blinded; Blinding description: The statistical analyst will be blinded to the allocation of participants to intervention and control group by providing participant data in coded form (for example: letter A and B)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of primary hypertension; Currently on at least one prescribed blood pressure medication; Literacy (ability to read and write); Ownership and ability to use a smartphone with internet access; Proficiency in using social networking platforms; Active participation in at least one social network.
Exclusion Criteria: Prior participation in similar projects; Current involvement in other research or interventions; Use of special, rare, or costly drugs; Use of injectable blood pressure medication; Presence of sensory disorders (vision, hearing, touch); History of drug addiction; Presence of concurrent diseases

Intervention groups

Intervention group: An interactive intervention based on protection motivation theory will be implemented for 3 months on social messaging platforms for individuals. The control group will receive the usual care. At the end of the

implementation of the program, the content designed based on the protection motivation theory will be provided to the control group.

Main outcome variables

Medication Adherence; Blood pressure control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231202060239N1**

Registration date: **2024-01-14, 1402/10/24**

Registration timing: **prospective**

Last update: **2024-01-14, 1402/10/24**

Update count: **0**

Registration date

2024-01-14, 1402/10/24

Registrant information

Name

Mehdi Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

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051mehdijafari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of interactive intervention in the platform of social messengers according to protection motivation theory on medication adherence and blood pressure control in adults with hypertension

Public title

The effect of interactive intervention taking place in social messenger platforms on medication adherence and blood pressure control

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of primary hypertension by a physician
Minimum use of one anti-hypertensive medication prescribed by a physician
Age between 18 to 65 years
Ability to read and write (being literate)
Possession of a smartphone and ability to use it and access the internet
The ability to use the facilities of social messaging platforms (the person should have the minimum ability to send and receive messages in any possible form (text, voice, etc.)
Have an account in at least one social messaging platform such as Whats App, Telegram, Eitaa, Soroush)

Exclusion criteria:

Participation in previous similar studies
Concurrent involvement in other research or interventions
Use of special or expensive medications
Use of injectable anti hypertensive drugs
Having sensory impairments including vision, hearing, and touch
Addiction to drugs, narcotics
presence of comorbidities (such as diabetes, asthma, cancer, and renal disorders)

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **142****Randomization (investigator's opinion)**

Randomized

Randomization description

Eligible participants will be allocated into two groups: intervention and control, using a block randomization method with a block size of 4. The supervisor will handle the generation of the random sequence and allocation concealment, while the student will conduct the sampling. To maintain concealment, dark envelopes, equal to the sample size, will be used. These envelopes

will contain papers with random sequences. Upon joining the study, each participant will receive an envelope from the researcher. The paper inside the envelope will determine the participant's group assignment.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, only the statistical analyst will not be informed about the allocation of the participants to the intervention and control groups. In this way, the data related to the participants will be delivered to the statistical analyst in coded form (for example, the intervention group with the letter A and the control group with the letter B). After the completion of the data analysis and evaluation of the relevant consequences after the completion of the implementation of the intervention, each code will be finally determined so that after comparing the data, the final result of the effectiveness of the intervention or its absence will be realized.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee, School of Medicine, Tehran University of Medical Sciences

Street address

Ethics Committee, Faculty of Medicine, Poursina St. , Ghods St., Enghelab St.

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1461884513

Approval date

2023-11-29, 1402/09/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.472

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

Primary hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Medication Adherence

Timepoint

Before intervention and 97 days after the intervention

Method of measurement

Hill-Bone Medication Adherence Scale (HB-MAS9) ,Kim et al. 2000

Secondary outcomes

1

Description

Controlled blood pressure: In this study, blood pressure less than 140 mm Hg (systolic) and 90 mm Hg (diastolic) will be considered as controlled blood pressure.

Timepoint

Before implementing the intervention at the beginning of the study (baseline) and then 97 days after the onset of interactive intervention

Method of measurement

In this study, blood pressure measurements will be taken from the participants after they've rested for five minutes in a seated position. A calibrated sphygmomanometer will be used on the patient's right arm for these measurements. This process will be repeated twice, with a 10-minute interval between the measurements.

Intervention groups

1

Description

Intervention group: After establishing communication between the researcher and the people of the intervention group in messengers selected from the previously announced priorities (Soroush, Eitaa, Telegram, WhatsApp), an intervention within 3 months for the people of the intervention group by sending a daily message reminding them to take medicine and a message with multimedia content prepared based on the constructs of the protection motivation theory will be sent on the social messenger platform of their choice. A reminder message to take the medicine according to the list prepared according to the demographic questionnaire (name of the medicine, usual time of taking the medicine) and five minutes before the time of taking the medicine in the corresponding messaging platform with a message containing the name of the medicine, the dose of the medicine, the exact time of taking the medicine and the word "time of taking the medicine" "Your medicine has arrived. Do not delay taking your medicine." Along with the drug usage tips, including: 1) blood pressure control and after taking blood pressure medication, and 2) tips related to the drug used, are sent to the person and they are asked to send a message for feedback and confirmation in case of

taking the drug. They should also declare the use of medication and medication errors in order to register. The people of the intervention group can send their questions to the researcher to be answered in the relevant messengers. A message prepared according to the constructs of the protection motivation theory is also sent one number per day and at a random hour between 10 am and 8 pm. All feedbacks from peoples in the intervention group will be recorded and their questions about the submitted content will be answered. All the questions asked will be recorded and part of the content of the message sent every three days will be non-repeating questions asked by patients and their answers. At the end of each week of the implementation of the intervention, people are requested to send a message to inform the researcher of any change in the type or dosage of the drug used.

Category

Behavior

2

Description

Control group: The people of the control group will also receive the usual care during three months and no intervention will be done. Just to attend for blood pressure measurement, they will receive the same message as the people in the intervention group at the same time and under the same conditions. After 97 days (7 days after the completion of sending the intervention), the people of both groups will come to the center for the final blood pressure measurement and recording, and after the blood pressure control, the medication compliance questionnaire will be provided to both the intervention and control groups for completion. At the end of the implementation of the program, the content designed based on the protection motivation theory will be provided to the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

South Tehran Health Centers

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

Reza Negarandeh

Position

Professor of Nursing Education Department of
Community Health Nursing, School of Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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