Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 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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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)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target 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.
City
Tehran
Province
Tehran
Postal code
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
Mohammad Reza Salmani Nadushan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Keshavarz Blvd., corner of Quds St., Central Organization of the University, 6th floor of Research and Technology Vice-Chancellor

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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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Position

Msc student of Community Health Nursing / Tehran University of Medical sciences

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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