

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Tele-Nursing on blood pressure control and Self-care behaviors in patients with chronic hypertension referred to comprehensive urban and rural health service centers in Garmeh- in 2020.

Protocol summary

Study aim

The effect of tele-nursing on blood pressure control and self-care behaviors in patients with chronic hypertension

Design

The present study is a randomized control trial which allocate in control and intervention group. The intervention group will receive the supplementary education on self-care behaviors and blood pressure control within 3 months, while the control group will receive only routine care and training.

Settings and conduct

Cluster sampling will be done in the comprehensive urban and rural health service centers of Garmeh province.

Participants/Inclusion and exclusion criteria

subjects are consist of patients suffer from chronic hypertension who have following criteria: Inclusion Criteria : 1- Being between 30 to 75 years old 2- Being native 3- Access to telephone 4- Confirmed hypertension by a family doctor and having a registered file in the Comprehensive Health Service Center 5- At least 6 months of history of hypertension 6- Taking at least one anti hypertensive drug by the patient 7- Not going under dialysis 8- Not suffering from debilitating disease 9- No cognitive impairment 10- No substance abuse 11- Ability to communicate in Persian 12- Having literacy to read and write Completion of the questionnaire 13- Willingness to participate in the study Exclusion Criteria are include of: 1- suffering from speech and hearing impairment 2- Participating in a similar training course during the last 6 months

Intervention groups

In the intervention group, patients will be given the essential training on self-care behaviors and blood pressure control through tele-nursing technique during 3 months, while the control group will receive standard

treatment.

Main outcome variables

Promoting self-care behaviors and blood pressure control behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201105049279N1**

Registration date: **2020-12-25, 1399/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-25, 1399/10/05**

Update count: **0**

Registration date

2020-12-25, 1399/10/05

Registrant information

Name

Fatemeh Talebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3250 3545

Email address

talebif97@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Tele-Nursing on blood pressure control and Self-care behaviors in patients with chronic hypertension referred to comprehensive urban and rural health service centers in Garmeh- in 2020.

Public title
Effect of Tele- Nursing on blood pressure control and Self-care behaviors

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Being between 30 and 75 years old Indigenous (resident of Garmeh city) Phone access Confirmation of high blood pressure by a family doctor and having a file in the Comprehensive Health Service Center At least 6 months of history of hypertension (duration of the disease is more than 6 months) Taking at least one anti hypertensive drug by the patient Do not have dialysis patients No debilitating disease Lack of cognitive impairment No substance abuse Ability to speak and understand Persian by the patient and her companion Have reading and writing literacy to complete the questionnaire Willingness and satisfaction to participate in the study
Exclusion criteria:
Having speech and hearing impairments Participating in a similar training course during the last 6 months

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **41**

Randomization (investigator's opinion)
Randomized

Randomization description
First, by coin tossing randomly select 5 centers by cluster approach among 10 comprehensive urban health service centers (6 centers) and rural (4 centers). In this way, among the 5 clusters, the samples are randomly divided into two group of control and intervention based on permuted random blocks sampling (urban and rural). That is, we can randomly select samples by making 20 *4 blocks. In this part, we can also choose the two groups of control and intervention by dropping coins.

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 Sabzevar University of Medical Sciences

Street address

Sabzevar, Nuclear Martyrs Boulevard, Above the Unknown Martyrs, Campus of the University of Medical Sciences, Office of the Vice President for Research and Technology

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114 - 9617913

Approval date

2020-12-20, 1399/09/30

Ethics committee reference number

IR.MEDSAB.REC.1399.127

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Blood pressure control

Timepoint

pre and post intervention

Method of measurement

Use of self-care questionnaire and Abbreviated Mental Test(AMTs)

2

Description

self-care behaviors

Timepoint

pre and post intervention
Method of measurement
Self-care behavior control

Secondary outcomes

1

Description

Blood pressure control

Timepoint

Pre and post intervention

Method of measurement

By sphygmomanometer

Intervention groups

1

Description

Intervention group: in the intervention group, in addition to the virtual training session that is held for all research samples, remote nursing (counseling and telephone follow-up) will be performed by researchers for 3 months. In this way, telephone calls are made to follow up blood pressure control and self-care behaviors twice a week in the first month and once a week during the second and third months, with members of the intervention group. The duration of the conversation will be estimated at an average of 15 minutes and the researcher will be able to contact patients during office hours. The content of the conversations included introducing themselves, asking about the general health status of the participants, encouraging them to follow the recommendations and aspects of public and private care, following up on training needs based on their training needs, providing suggested solutions and answering questions. They will be. Phone calls and their content will be recorded for each participant in specific tabs to be re-evaluated in subsequent calls.

Category

Other

2

Description

Control group: During the intervention, the control group will receive standard treatment. This treatment includes medication and training on how to take medication and adhere to a changing diet, lifestyle and physical activity.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive urban and rural health service centers of Garmeh city

Full name of responsible person

Fatemeh Talebi

Street address

parastar Street - between parastar 3 and 5

City

Garmeh

Province

North Khorasan

Postal code

9431644166

Phone

+98 58 3250 3545

Email

Amir.talebi325035@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research and technology of Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshteh Qorat

Street address

Nurse Street - between Nurse 3 and 5

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Garmeh

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Phone

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Email

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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

Deputy of research and technology of Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Fatemeh Talebi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Nurse Street - between Nurse 3 and 5

City

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Postal code

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fatemeh Talebi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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Email

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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

No decision has been made yet

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

Not applicable