

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison effect of telephone versus face to face counseling on the quality of life of patients with hypertension

Protocol summary

Study aim

Determination effect of telephone with face to face counseling on the quality of life in patients with hypertension

Design

A clinical trial study of three groups and multi-center. Sample size is determined based on pilot study. Randomization is based on random numbers table.

Settings and conduct

The city of Esfarayen has two comprehensive health centers and a total of nine health centers. Persons aged 40 to 60 years who are referred to these bases are selected based on cluster sampling and randomly selected

Participants/Inclusion and exclusion criteria

Inclusion criteria were at least 140 systolic blood pressure and diastolic blood pressure of 90, age 40 to 60 years and Exclusion criteria unwillingness to continue cooperation, Participate in previous telephone counseling, participate in previous counseling more than 3 hours

Intervention groups

In the first group, telephone counseling is performed once a week and the duration of each phone call is between 20-25 minutes and the duration of the intervention is three months. The second group is face-to-face counseling once a week and the time of each session is between 30-35 minutes and the duration of the intervention is three months.

Main outcome variables

Determining the quality of life before and after the intervention using the sf-36 questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141222020394N5**

Registration date: **2018-12-24, 1397/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-24, 1397/10/03**

Update count: **0**

Registration date

2018-12-24, 1397/10/03

Registrant information

Name

Mahbobeh Firooz

Name of organization / entity

Mashhad Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 58 3723 2650

Email address

mahbobehfirooz@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chanveller for Research esfarāyen univercity of Medical Sciences

Expected recruitment start date

2018-12-20, 1397/09/29

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of telephone versus face to face counseling on the quality of life of patients with hypertension

Public title

Effectiveness of telephone versus face to face counseling on the quality of life hypertension patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Able to communicate and is fluent in Persian At least one year has passed since the history of hypertension The age is between 40 and 60 years old Echocardiography is normal

Exclusion criteria:

Underlying disease other than hypertension The patient dont tends to continue this study

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

PASS software

Blinding (investigator's opinion)

Single blinded

Blinding description

Samples are taken from a multi healthcare centers. Each center is considered to be an intervention to blind the samples. Each sample contains one code, numbers: one, four, seven, and et al, for telephone counseling, numbers two, five, eight and et al, related to face to face counseling and numbers three, six, nine, and et al, related Will be to the control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Esfarāyen Faculty of Medical Sciences

Street address

Imam Reza Street

City

Esfarayen

Province

North Khorasan

Postal code

76981-96618

Approval date

2017-01-03, 1395/10/14

Ethics committee reference number

IR.ESFARAYENUMS.REC.1395.18

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

Hypertension

ICD-10 code

I15

ICD-10 code description

Secondary hypertension

Primary outcomes**1****Description**

Quality of life

Timepoint

before intervention, three months after intervention

Method of measurement

SF36 Quality of life questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Telephone counseling is performed once a week and the duration of each phone call is between 20-25 minutes and the duration of the intervention is three months.

Category

Prevention

2**Description**

Face-to-Face counseling once a week and the time of each session is between 30-35 minutes and the duration of the intervention is three months

Category

Prevention

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

Malek Afzali Comprehensive Health Center

Full name of responsible person

Arezoo Kamizi

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2**Recruitment center****Name of recruitment center**

Shahid Shokoohi Comprehensive Health Center

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

Esfarāyen Faculty 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**

Esfarāyen Faculty of Medical Sciences

Full name of responsible person

Mahbobeh firooz

Position

Master of sciences in nursing

Latest degree

Master

Other areas of specialty/work

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Latest degree

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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

No - There is not 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

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

Title and more details about the data/document

The results will be informed public in the form of articles published in the journals

When the data will become available and for how long

after publish of the article

To whom data/document is available

All members of society

Under which criteria data/document could be used

To apply appropriate training method to patients with hypertension

From where data/document is obtainable

To medical science databases or journal page

What processes are involved for a request to access data/document

In an email to the author's documentation will be provided

Comments