

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of two methods of teach back and motivational interview on the therapeutic regimen adherence in patients with hypertension

Protocol summary

Study aim

"determine Comparing the effect of two methods of teach back and motivational interview on the therapeutic regimen adherence in patients with hypertension"

Design

In this study, 81 patients with hypertension who visit the Shaheed Mofateh Clinic in Yasuj and have the inclusion criteria will be selected. Participants will be randomly allocated in two groups of intervention and control, and a code will be assigned for each participant.

Settings and conduct

Shahid Mofateh medical Clinic of Yasuj City

Participants/Inclusion and exclusion criteria

Inclusion criteria: Acquire undesirable score (less than 50 percent of 100 percent of two scales diet, exercise and medicines) follow the questionnaires from people diet that they afflicts with hypertension Exclusion criteria: Participation in the training course on blood pressure in the last 6 months History of chronic diseases including chronic kidney disease, chronic renal parenchymal, renal artery stenosis, history of nephrectomy, renal surgery

Intervention groups

Teach back intervention group: Intervention group1: The tutorial will be run using the teach-back method. Educational content will be taught to the patient by a face-to-face researcher in plain language without the use of medical terminology. The patient is then asked to express the educational content in his / her own language. If the patient does not understand correctly, the content will be re-educated. Motivational interview intervention group: the group intervention will be performed in 8-12 people groups. A total of 5 interview sessions will be held within 2 months for each group with a duration of 60 to 90 minutes for each session.

Main outcome variables

Adherence to the treatment regimen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180711040430N1**

Registration date: **2019-01-08, 1397/10/18**

Registration timing: **retrospective**

Last update: **2019-01-08, 1397/10/18**

Update count: **0**

Registration date

2019-01-08, 1397/10/18

Registrant information

Name

Maryam Alishapour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 2223 4115

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-15, 1397/06/24

Expected recruitment end date

2018-11-15, 1397/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of two methods of teach back and motivational interview on the therapeutic regimen adherence in patients with hypertension

Public title

Comparing the effect of two methods of teach back and motivational interview on the therapeutic regimen adherence in patients with hypertension

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Literacy Hearing and speaking ability At least 6 months passed of hypertension diagnosis Diagnosis of primary hypertension by the physician Consent to participate in the study Age of 35 to 60 years' old

Exclusion criteria:

Participation in the training course on blood pressure in the last 6 months History of chronic diseases including chronic kidney disease, chronic renal parenchymal, renal artery stenosis, history of nephrectomy, renal surgery, endocrine diseases including pheochromocytoma and Cushing's syndrome Taking contraceptive pills 6 months before the intervention

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated in two groups of intervention and two group control, and a code will be assigned for each participant

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of yasouj University of Medical Sciences

Street address

Management of medical science.,Vice President of Research and Technology,University of Medical Sciences.,Blvd martyr Motahhari.,Yasouj

City

Yasouj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591994799

Approval date

2018-09-08, 1397/06/17

Ethics committee reference number

IR.YUMS.REC.1397.075

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

therapeutic regimen adherence

Timepoint

Before the intervention, two months after the intervention

Method of measurement

Using the questionnaire of adherence of hypertensive patients to treatment regimen

2

Description

Blood pressure

Timepoint

Before the intervention, two months after the intervention

Method of measurement

Manometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Teach Back method for three sessions of an hour each The tutorial will be run using the teach-back method. Educational content will be taught to the patient by a face-to-face researcher in plain

language without the use of medical terminology. The patient is then asked to express the educational content in his / her own language. If the patient does not understand correctly, the content will be re-educated .

Category

Behavior

2

Description

Intervention group: In this study, motivational interviewing in the intervention group runs in the fifth sessions. the structure of weekly meetings extracted from a motivational interviewing group intervention book with a five-session structure. Contents of the Motivational interviewing session: • First session (dating): A group norms and processes, facilitates the philosophy, practice of freedom, the exercise of Dimensions of behavior influence, the exercise of change cycle assessment of commitment and confidence. • Second session (emotion): Feelings Practice identifying, practicing and perfecting the exercise of influence dimension and emotional dimension and homework. • The third session (positive and negative aspects of behavior and change): Practice of brainstorming of Short-term and long-term profit and losses, Practice of complete table of the positive and negative aspects, describe and Practice of corrective options and alternatives one. • Fourth session (values): Definition of values, Practice of identifying and prioritizing notch values, practice to define values and value-behavior consistency. • Fifth session (closing Landscape): Summarizing and concluding of previous training Sessions in a Landscape practice and preparation for the start of behavior change programs.

Category

Behavior

3

Description

Control group: patients will not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofatheh Yasuj medical Clinic

Full name of responsible person

Soheila zabolipour

Street address

St Shahid Mohammad Montazeri., Yasouj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology, Yasouj University of Medical Sciences

Full name of responsible person

Hossein Mari Oryad

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Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, Shahid Motahary Blvd. Yasuj

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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

Vice-chancellor for Research the Technology, Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Maryam Ali Shapour

Position

Master student of Medical-Surgical nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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

Triages that began to fall ill on January 11, 1397 should have a release plan when registering their study protocol.

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

No - There is not a plan to make this available