

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effectiveness of motivational interviewing among non-adherence hypertensive patients in Palestine: a cluster randomized control trial

Protocol summary

Study aim

To improve the adherence of hypertension treatment among hypertension patients in Gaza.

Design

Two arm parallel group randomized controlled trial with non blinded behavioral change counseling and outcome assessment

Settings and conduct

Hypertension patients attending ten governmental primary health centers in Gaza strip will be assessed for antihypertensive medication adherence (AMA). Five centers will be the control. Other five centers will have behavioral counseling about AMA. Three motivational interviewing (MI) sessions will be done to improve adherence. AMA will be reassessed after intervention in both control and intervention centers. Not blinded trial.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Palestinian resident who received his usual care in government primary health center, aged 18 years or older with confirmed diagnosis of hypertension, and taking at least one antihypertensive medication.

Exclusion Criteria: Have a diagnosis of cognitive impairment or serious medical condition as determined by their primary care physician or unable to provide informed consent or refuse to participate.

Intervention groups

Intervention group: patients randomized to this group will receive their usual hypertension medications plus behavioral counseling about medication adherence. A standardized structured adherence script will be used to improve self-efficacy and intrinsic motivations. This is proposed to be done through monthly motivational interviewing session for three months. Control group: patients randomized to this group will receive their usual hypertension medications only.

Main outcome variables

Primary outcome: Antihypertensive medication adherence score change. Secondary outcomes: within-patient changes in blood pressure and within-patient

score changes in self-efficacy and intrinsic motivation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180705040352N1**

Registration date: **2018-09-13, 1397/06/22**

Registration timing: **prospective**

Last update: **2018-09-13, 1397/06/22**

Update count: **0**

Registration date

2018-09-13, 1397/06/22

Registrant information

Name

Khalid Khadoura

Name of organization / entity

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Palestine, State of

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-30, 1397/07/08

Expected recruitment end date

2019-01-15, 1397/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of motivational interviewing among non-adherence hypertensive patients in Palestine: a cluster randomized control trial

Public title

Effect of motivational sessions in improving hypertension medication adherence

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Palestinian resident who received his usual care in government primary centers Age 18 years or older Confirmed diagnosis of hypertension Taking at least one antihypertensive medication

Exclusion criteria:

Have a diagnosis of cognitive impairment or serious medical condition as determined by their primary care physician Unable to provide informed consent or refuse to participate

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **364**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization is two stages cluster random sampling, stratified simple random sampling and systematic random sampling. Unit of randomization in stratified simple random is cluster. Unit of randomization in systematic random sampling is individual.

Randomization strata is each governorate as one strata Tools will be used in Randomization is table of random numbers. Random sequences is built by selecting two centers from each governorate (strata), so selecting two tickets from pot containing all centers in each strata will be done, then sampling fraction will be calculated to recruit a proportion of the patients from each center. A list of all patients in the center will be prepared, then random number table will be used to select the first patient. Allocation concealment is not carried out.

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 Tehran University of Medical Sciences

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Approval date

2018-03-18, 1396/12/27

Ethics committee reference number

IR.TUMS.SPH.REC.1396.4828

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

Antihypertensive medication adherence

Timepoint

Before intervention and after one month from completing the intervention

Method of measurement

Morisky medication adherence scale (MMAS-8).

Secondary outcomes

1

Description

Within-patient difference in blood pressure

Timepoint

Before intervention and one month after intervention

Method of measurement

Sphygmomanometer

2

Description

Within-patient difference in self-efficacy

Timepoint

Before intervention and one month after intervention

Method of measurement

Self-efficacy scale

3

Description

Within-patient difference in intrinsic motivation scores

Timepoint

Before intervention and one month after intervention

Method of measurement

Intrinsic motivation scale by Treatment Self-Regulation Questionnaire (TSRQ)

Intervention groups

1

Description

Intervention group: hypertensive patients receive both usual care of hypertension plus motivational interviewing for three months in primary health centers which was randomly allocated to be intervention centers.

Participants in each intervention group will attend three motivational interviewing (MI) sessions which will be conducted monthly for three months. The initial session will be individual session may need about 20 minutes by trained research assistants (RA) with the aid of a standardized structured adherence counseling script.

Two follow-up sessions will be done by group discussion sessions to discuss treatment adherence by lifestyle modification (e.g. salt intake, physical exercise, smoking cessation) and to let patients share their experiences.

The time expected nearly 20-30 minutes for each. RA will work as a facilitator to manage the first session and highlights the importance of lifestyle modification. In the second session the RA will provide some strategies to achieve lifestyle modification. The individual MI sessions comprises of the following sequential steps: 1. Assess the patient's motivation and confidence: The trained RA will assesses motivation and confidence with the following questions: a. On a scale of 1 to 10 (10 is the highest), how motivated/interested are you in taking your blood pressure medication as prescribed? b. On a scale of 1 to 10 (10 is the highest), assuming you want to, how confident are you that you can take your blood pressure medication as prescribed? 2. Elicit barriers, concerns and positive self-motivational statements: depending on the patient's response to the motivation/confidence questions above, the RA then will ask the patient the following questions: a. Why did you not choose a lower number, like a 1 or 2? (this elicits positive motivational statements). b. Why did you not choose a higher number (this elicits barriers) or what will it take to get you to a 9 or 10? 3. Summary of pros and cons: The RA next will summarize the patient's pros and cons, and asks if there was anything else that she/he wanted to add. Provide menu of options: If barriers were presented, the RA then will prompt the patient to offer solutions. After the patient will exhaust her/his own

solutions (or in the event that none were offered), the RA will seek permission to list other solutions "that have worked for other people". 4. Assess patient's values and goals: Patients will asked to complete a values-clarification list to help link their medication adherence and health to other core values and life goals. This helps to create ambivalence between current behavior and goals and values. Patients will be asked to sort a list of approximately 29 values in terms of personal importance and to select around 5 that are most important. Then they will be asked to briefly discuss why the values/goals selected are important to them and then they will explore what connection if any, they will see between their current health behavior and their ability to achieve these goals or live out these values. Alternatively, the RA may ask how changing their health behavior may be related to these goals or values. 5. Clarify contract and global summary: The interview, when appropriate, ends with a behavioral contract for the patient to try at least one of the solutions offered. Again the RA summarizes what was agreed upon and incorporates patients' suggestions.

Category

Behavior

2

Description

Control group: hypertensive patients receive usual care of hypertension in governmental primary health centers which will be randomly allocated to be control centers.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Remal primary health center

Full name of responsible person

Khaleel Seiam

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Recruitment center

Name of recruitment center

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Full name of responsible person

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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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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

Sponsor: country of origin

Country of origin

IR

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

Khalid Jamal Khadoura

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified individual participant data in this study would be available to other researchers after publication of the results.

When the data will become available and for how long

When summary data are published

To whom data/document is available

For people working in academic institutions

Under which criteria data/document could be used

For academic purposes, criteria will be decided by researchers later.

From where data/document is obtainable

Tehran University of Medical Sciences and authors.

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

Email correspondent author researcher and explain the need.

Comments

Tehran University of Medical Sciences agreement must be obtained as well.