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 compromises 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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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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https://www.tums.ac.ir/faculties/msahrai?lang=en&display=mysite
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
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Full name of responsible person
Khalid Jamal Khadoura
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Person responsible for updating data

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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.