Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of an Evidence-Based Hypertension Self-Care Intervention Developed Using Intervention Mapping versus Usual Care on Self-Care, Self-Efficacy, and Quality of Life among Hospital Employees with Hypertension: A Randomized Controlled Trial

Protocol summary

Study aim

To evaluate the effect of an evidence-based Hypertension Self-Care Intervention Map on self-care behaviour, self-efficacy, and quality of life among hospital employees with essential hypertension in Baghdad.

Design

Two-arm, parallel-group, open-label randomized controlled trial with 120 participants, 60 per group. Individual block randomization will be stratified by hospital in a 1:1 ratio, with both groups represented at both centers.

Settings and conduct

The trial will be conducted in two Baghdad hospitals. After consent and baseline assessment, participants will be randomized within each hospital. Trained nurses will deliver the intervention separately from controls. Outcomes will be reassessed after 45 days. The study is open-label, with coded data.

Participants/Inclusion and exclusion criteria

Full-time hospital employees aged 30–65 years with physician-diagnosed essential hypertension for at least six months, receiving treatment, able to communicate in Arabic, and providing written consent. Physicians, nurses, those unable to complete study procedures, those planning to leave the hospital, and those withdrawing consent will be excluded.

Intervention groups

The intervention group will receive the Hypertension Self-Care Intervention Map plus usual care through approximately six nurse-led sessions over 45 days, practical activities, and follow-up messages. The control group will receive usual care only and may receive educational materials after post-test data collection.

Main outcome variables

Self-care behaviour and self-efficacy measured with the Arabic Hypertension Self-Care Profile, and quality of life measured with the Arabic World Health Organization Quality of Life-Brief Version, at baseline and post-test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260611069749N1**
Registration date: **2026-07-09, 1405/04/18**
Registration timing: **prospective**

Last update: **2026-07-09, 1405/04/18**
Update count: **0**

Registration date

2026-07-09, 1405/04/18

Registrant information

Name
Lubna Al-sbehat
Name of organization / entity
Tarbiat Modares University
Country
Iran (Islamic Republic of)
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+98 939 794 9175
Email address
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-01, 1405/06/10

Expected recruitment end date

2026-11-30, 1405/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of an Evidence-Based Hypertension Self-Care Intervention Developed Using Intervention Mapping versus Usual Care on Self-Care, Self-Efficacy, and Quality of Life among Hospital Employees with Hypertension: A Randomized Controlled Trial

Public title

Effect of a Hypertension Self-Care Program on Self-Care and Quality of Life among Hospital Employees with High Blood Pressure

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Hospital employee aged 30 to 65 years. Physician-confirmed diagnosis of essential hypertension for at least six months. Full-time employment in one of the selected study hospitals. Receiving hypertension management through medication, lifestyle recommendations, or both. Ability to communicate in Arabic. Voluntary willingness to participate and ability to provide written informed consent.

Exclusion criteria:

Employment as a physician or nurse. Severe acute physical illness that prevents participation in the study. Severe mental illness or cognitive impairment that prevents questionnaire completion or participation in the intervention. Baseline inability to complete the questionnaires or study procedures. Planned resignation, retirement, transfer from the selected hospital, or prolonged absence during the study period.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

After confirmation of eligibility, obtaining written informed consent, and completion of the baseline assessment, participants within each hospital will be randomly allocated to the intervention or control group using hospital-stratified block randomization with a 1:1 allocation ratio. The unit of randomization will be the individual participant, not the hospital or work unit. A separate randomization sequence will be generated for each hospital using a reproducible computerized random-number procedure. Participant identification codes rather than names will be used in the allocation list. The randomization list will be kept separate from recruitment and baseline data-collection records. Group assignment will be revealed only after the participant has completed the baseline assessment, thereby maintaining allocation concealment until assignment.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This trial constitutes the fourth and final evaluation stage of a multiphase mixed-methods study. The Hypertension Self-Care Intervention Map will be developed through the integration of quantitative and qualitative findings using the Intervention Mapping framework. During the trial stage, participants will be randomized individually within each hospital using hospital-stratified block randomization; therefore, both intervention and control participants will be represented at each hospital. The hospitals will serve as study sites and stratification factors rather than units of randomization. Outcomes will be assessed at baseline and after completion of the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr Bridge, Jalal Al Ahmad Highway, Tehran, Iran

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Tehran

Province

Tehran

Postal code

14115-111

Approval date

2026-02-07, 1404/11/18

Ethics committee reference number

IR.MODARES.REC.1404.242

2

Ethics committee

Name of ethics committee

Research Ethics Committee of the Iraqi Ministry of Health

Street address

Iraqi Ministry of Health, National Centre for Training and Human Development, Baghdad, Iraq

City
Baghdad
Postal code
10047
Approval date
2026-04-22, 1405/02/02
Ethics committee reference number
Decision No. 52/2026

Health conditions studied

1

Description of health condition studied
Essential (primary) hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Hypertension self-care behaviour score
Timepoint
At baseline before randomization and after completion of the 45-day intervention period.
Method of measurement
Measured using the Arabic-adapted 19-item Hypertension Self-Care Profile Self-Care Behaviour Scale. Each item is scored from 1 (rarely or never) to 4 (always), giving a total score ranging from 19 to 76. Higher scores indicate more frequent hypertension self-care behaviours.

2

Description
Hypertension self-care self-efficacy score
Timepoint
At baseline before randomization and after completion of the 45-day intervention period.
Method of measurement
Measured using the Arabic-adapted 19-item Hypertension Self-Care Profile Self-Efficacy Scale. Each item is scored from 1 (not confident) to 4 (very confident), giving a total score ranging from 19 to 76. Higher scores indicate stronger self-efficacy for performing hypertension self-care behaviours.

Secondary outcomes

1

Description
Quality-of-life domain scores
Timepoint
At baseline before randomization and after completion of the 45-day intervention period.
Method of measurement
Measured using the validated Arabic version of the World Health Organization Quality of Life–Brief Version questionnaire. The questionnaire contains 26 items: two general items and 24 items distributed across four domains: physical health, psychological health, social relationships, and environment. Items are scored on a five-point scale. Items 3, 4, and 26 are reverse-scored. Domain scores are calculated and transformed according to the instrument scoring manual, with higher scores indicating better quality of life.

Intervention groups

1

Description
Intervention group: Participants will receive the Hypertension Self-Care Intervention Map in addition to usual care. The program will include approximately six group sessions, each lasting 45–60 minutes, delivered over a 45-day period by trained nurse educators and/or trained facilitators. The sessions will address hypertension knowledge, medication adherence, healthy diet and salt reduction, physical activity, blood pressure monitoring, stress management, self-efficacy, goal setting, and problem solving. Interactive methods will include group discussion, demonstration, role play, peer support, practical exercises, and guided goal setting.
Category
Behavior

2

Description
Control group: Participants allocated to the control group will continue to receive usual care during the study period and will not receive the structured Hypertension Self-Care Intervention Map sessions during the intervention period.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghazi Al-Hariri Hospital for Surgical Specialties
Full name of responsible person
Lubna Al-Sbehat
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Bab Al-Muadham, Baghdad, Iraq
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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

Name of organization / entity
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https://en-med.modares.ac.ir

Grant name
No external grant

Grant code / Reference number
Not applicable

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tarbiat Modares University

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
Tarbiat Modares University

Full name of responsible person
Lubna Al-Sbehat

Position
PhD Student in Nursing

Latest degree
Master

Other areas of specialty/work
Nursing

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Person responsible for scientific inquiries

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Full name of responsible person
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Associate Professor

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Ph.D.

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Person responsible for updating data

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Position

PhD Candidate in Nursing

Latest degree

Master

Other areas of specialty/work

Nursing

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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

Deidentified individual participant data will not be shared because the study involves sensitive health-related data from patients with hypertension recruited from specific hospital settings. Even after deidentification, there may be a risk of indirect identification. Data sharing is also limited by the informed consent conditions, ethical approvals, and institutional regulations. Only aggregated results will be reported in publications and academic outputs.

Study Protocol

No - There is not 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

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The statistical analysis plan and the blank informed consent form will be shared. These documents will not include identifiable participant information or individual participant-level data.

When the data will become available and for how long

The documents will become available after publication of the main study results or completion of the doctoral dissertation, whichever occurs first, and will remain available for five years.

To whom data/document is available

The documents will be available to qualified researchers affiliated with academic or research institutions upon reasonable request.

Under which criteria data/document could be used

Requests must include a clear academic or scientific purpose and must comply with ethical approvals, participant confidentiality, and institutional regulations. The documents may be used for scientific research, methodological reference, or research planning only.

From where data/document is obtainable

Requests should be submitted by email to the principal investigator at lubna.alsbehat@modares.ac.ir. Requests may be reviewed in consultation with the study supervisor and Tarbiat Modares University.

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

The applicant should submit a written request specifying the requested document, scientific purpose, institutional affiliation, and planned use. The research team will review the request and, if approved, provide the documents electronically.

Comments

No deidentified individual participant data will be shared.