Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of a Lifestyle Educational Intervention on Self-Care Behaviors in Patients with Hypertension: Application of the Continuous Care Model

Protocol summary

Study aim

Determining the effect of a lifestyle educational intervention on self-care behaviors in patients with hypertension: application of the Continuous Care Model

Design

A concealed, randomized, single-blind, controlled trial with a parallel group design of 88 patients with primary hypertension, enrolled by cluster randomization with lottery and individual selection by random number table, and followed for the non-pharmacological study period.

Settings and conduct

This cluster-randomized trial in Qom health centers allocates four centers (clusters) by lottery to intervention or control (two centers each). The intervention group receives lifestyle education in four phases (orientation, sensitization, control, evaluation); the control group receives routine care. Eligible lower-quartile self-care hypertension patients are randomly selected after cluster allocation. Outcomes are measured at pre-intervention, immediately post, and three months post; participants and providers are unblinded, but assessors and analysts are blinded.

Participants/Inclusion and exclusion criteria

Eligibility criteria included adults aged 30–65 with primary hypertension, at least one year of disease history, and an active SIB record. After screening, participants with lower self-care scores who provided consent were enrolled. Exclusion criteria:conditions affecting participation, concurrent trials, and safety or logistical limitations

Intervention groups

ntervention group: Participants receiving a lifestyle-based educational intervention grounded in the Continuous Care Model, based on the findings of the descriptive–analytical phase to improve self-care behaviors. Control group: Participants receiving routine care provided by comprehensive health service centers without receiving the study educational intervention.

Main outcome variables

Mean score of self-care behaviors based on the standardized self-care questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260526069537N1**
Registration date: **2026-05-31, 1405/03/10**
Registration timing: **prospective**

Last update: **2026-05-31, 1405/03/10**
Update count: **0**

Registration date

2026-05-31, 1405/03/10

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-10, 1405/03/20

Expected recruitment end date

2026-09-11, 1405/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of a Lifestyle Educational Intervention on Self-Care Behaviors in Patients with Hypertension: Application of the Continuous Care Model

Public title

Lifestyle Education for Blood Pressure Control Using the Continuous Care Model

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being classified among participants with lower self-care scores according to the criterion defined in the study. Willingness to participate in the interventional phase of the study. Providing written informed consent for participation in the interventional phase of the study.

Exclusion criteria:

Presence of physical or psychological conditions affecting participation in the educational program concurrent participation in other clinical trials safety or logistical limitations as determined by the investigator .

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Cluster randomization with simple random allocation will be used in this study. The unit of randomization will be the selected Comprehensive Health Service Centers, and each center will be considered as a cluster. Block randomization, stratified randomization, and other quasi-random methods will not be used in this study. Upon completion of the descriptive analytical phase, four selected centers will enter the intervention phase. A numerical identifier will be assigned to each center, and the identifiers will be written on identical and indistinguishable slips of paper. The slips will then be placed in a sealed container by an individual independent of the research team, and two identifiers will be randomly drawn. The centers corresponding to these two identifiers will be allocated to the intervention group, while the remaining two centers will be allocated to the control group. Accordingly, the random allocation sequence for assigning clusters to the study groups will be generated. All data from the descriptive analytical phase, including self-care scores, will be collected prior to the randomization process. Therefore, researchers will not be aware of the future allocation of centers to the study groups at the time of baseline data collection. Following cluster allocation, eligible participants for the intervention phase will be identified based on the self-care scores recorded during the descriptive–analytical phase. For this purpose, self-care scores within each center will be ranked separately, and individuals whose scores fall within the lower quartile of the self-care score distribution in the same center will be considered eligible for inclusion in the intervention phase. Subsequently, 44 participants will be selected from the eligible individuals in each group using a random number table generated by SPSS version 27. To ensure allocation concealment, generation of the random sequence and allocation of centers to the study groups will be performed by an individual independent of the research team, and the allocation results will be kept by that individual until the group assignment process has been finalized. In addition, the outcome assessor and the data analyst will be blinded to group allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

To reduce bias in this study, blinding will be implemented at the level of outcome assessors and data analysts. Outcome assessors responsible for post-intervention data collection will not be aware of the allocation of clusters to the intervention and control groups. In addition, the data will be provided to the statistical analyst in a coded form, and the analyst will also be blinded to group identities. Due to the educational nature of the intervention and the cluster design of the study, blinding of participants, clinical caregivers, and intervention implementers will not be feasible.

Placebo

Not used

Assignment

Parallel

Other design features

This study will be conducted in three phases.In the first phase, a descriptive–analytical cross-sectional study will be performed among 573 patients with primary hypertension to determine the status of self-care behaviors, self-efficacy, and lifestyle dimensions, as well as to identify the predictors of self-care behaviors.In the second phase, a lifestyle-based educational package will be developed based on the findings of the first phase, a review of relevant scientific literature, and expert opinions, within the framework of the Continuous Care Model (CCM). If self-efficacy or any of the lifestyle dimensions are not identified as significant predictors of self-care behaviors in the first phase, those variables will not be incorporated into the educational content.In the third phase, a randomized controlled trial (RCT) will be conducted among 88 patients with primary hypertension (44 participants in the intervention group and 44 participants in the control group). Participants will be selected from individuals whose self-care scores fall within the lower quartile of the self-care score distribution identified in the first phase. The lifestyle-based educational intervention, developed according to

the Continuous Care Model, will be implemented, and its outcomes will be evaluated immediately after the intervention and again three months later.The main innovation of this study is the integration of lifestyle education with the Continuous Care Model and the development of an educational intervention based on the identified needs of patients with hypertension. In addition, the study investigates the predictive role of self-efficacy and lifestyle dimensions in self-care behaviors. The Continuous Care Model consists of four stages: orientation, sensitization, control, and evaluation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tarbiat Modares University

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Approval date
2026-05-27, 1405/03/06

Ethics committee reference number
IR.MODARES.REC.1405.031

Health conditions studied

1

Description of health condition studied
Essential Hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Mean score of self-care behaviors based on the standardized Hypertension Self-Care Profile questionnaire

Timepoint
Before the intervention (pre-test), immediately after the intervention, and three months after the intervention

Method of measurement
Standardized Hypertension Self-Care Profile questionnaire

Secondary outcomes

1

Description
Mean systolic blood pressure

Timepoint
Before the intervention, immediately after the intervention, and three months after the intervention

Method of measurement
Standard mercury sphygmomanometer in millimeters of mercury

2

Description
Mean diastolic blood pressure

Timepoint
Before the intervention, immediately after the intervention, and three months after the intervention

Method of measurement
Standard mercury sphygmomanometer in millimeters of mercury

Intervention groups

1

Description
Intervention group: Intervention Group: Participants in this group will receive a lifestyle-based educational program within the framework of the Continuous Care Model (CCM). The educational content will be developed based on the findings of the descriptive–analytical phase of the study, the identified predictors of self-care behaviors, a review of relevant scientific literature, and expert opinions.The Continuous Care Model consists of four stages: Orientation, Sensitization, Control, and Evaluation. These stages will be implemented continuously and systematically with the aim of initiating, strengthening, and maintaining self-care behaviors among patients with primary hypertension.Orientation Stage:In this stage, an initial relationship will be established between the researcher, the patient, and, whenever possible, one family member. The objectives of the study, the importance of hypertension control, the role of self-care in preventing disease complications, and the patient's role in the educational program will be explained. In addition, educational needs, existing problems in disease management, patients' expectations, and potential barriers to self-care will be identified and assessed.Sensitization Stage:During this stage, the main lifestyle-based educational intervention will be delivered. The educational content will be developed according to the findings of the first phase of the study and may include proper medication adherence, healthy nutrition, salt reduction, regular physical activity, weight management, stress management, smoking cessation, home blood pressure monitoring, and other self-care-related factors. Educational activities will be conducted individually and in groups using methods such as

lectures, face-to-face education, group discussions, question-and-answer sessions, and active patient participation. Educational materials may include educational booklets, pamphlets, presentation slides, educational images and infographics, multimedia files, and other appropriate educational resources tailored to participants' needs. Whenever possible, a family member will also be encouraged to participate in the educational sessions.Control Stage:In order to reinforce and maintain self-care behaviors, continuous follow-up of participants will be carried out during this stage. Follow-up activities will include regular telephone calls, educational and reminder messages, answering participants' questions, and identifying and addressing potential barriers to implementing the educational recommendations. Adherence to the recommended self-care behaviors will be assessed, and appropriate feedback will be provided. Whenever feasible, family members will also be involved in the follow-up process to enhance social and family support for the patient.Evaluation Stage:In this stage, the effectiveness of the educational program will be assessed. Data collected during the descriptive–analytical phase will be considered as baseline (pre-test) measurements. Subsequently, study outcomes including self-care behaviors, self-efficacy, lifestyle dimensions, and blood pressure will be measured immediately after the intervention and again three months after completion of the intervention and compared with baseline values.The duration of the educational program and the number of educational sessions will be determined based on the final intervention package developed during the second phase of the study. Nevertheless, all educational activities and follow-up procedures will be implemented within the framework of the Continuous Care Model and under the supervision of the principal investigator.

Category

Lifestyle

2

Description

Control group: Participants in the control group will not receive any lifestyle-based educational intervention or Continuous Care Model-based educational program during the study period. They will continue to receive only the routine services provided by Comprehensive Health Service Centers. These services include routine hypertension care, periodic medical visits, standard educational activities routinely offered by the health centers, usual follow-up services within the healthcare system, health recommendations, and prescribed pharmacological treatments provided by their treating physicians.Participants in the control group will be assessed according to the same schedule as the intervention group with respect to the study outcomes, including self-care behaviors, self-efficacy, lifestyle dimensions, and blood pressure. Data collected during the descriptive analytical phase of the study will be considered as baseline (pre-test) measurements for this group. Follow-up assessments will be conducted immediately after completion of the intervention period and again three months after the end of the intervention.To ensure ethical considerations, after completion of the study and data collection, all educational materials developed for the intervention group, including educational booklets, pamphlets, and other educational resources, will also be provided to participants in the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

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Sponsors / Funding sources

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Grant name
Not applicable - Self-funded
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Personal funding (Self-supported)
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

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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
Due to the sensitive nature of participants' personal information and the principle of confidentiality in clinical research, anonymized individual participant data (IPD) from this study will not be made available to other researchers or the public.
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