STUDY PROTOCOL

Effectiveness of community-based intervention using PATCH on disease perception, empowerment, and self-care in hypertension: a community trial protocol

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Abstract

Background Hypertension plays a significant role in the global burden of cardiovascular diseases. The planned approach to community health (PATCH), as a community-based framework, highlights community participation in decision-making. This study aimed to determine the effectiveness of a community-based intervention using the PATCH on disease perception, empowerment, self-care behaviors, and blood pressure in patients with hypertension.

Methods This study will be a parallel randomized community trial. Twelve comprehensive rural health service centers (CRHSCs) are randomly selected as clusters. A total sample size of 428 individuals (214 in the intervention group and 214 in the control group) with hypertension covered by CRHSCs will be selected through cluster random sampling.

The PATCH framework, developed by the Centers for Disease Control, will be employed to organize the community and empower it to address the issue in the intervention group. The control group will receive only the routine programs provided by the health system.

Three months after the intervention, the outcome of hypertension perception will be assessed via the Disease Perception Questionnaire developed by Kamran et al., and empowerment will be measured via the Perceived Control Scale designed by Israel. Six months after the intervention, self-care behaviors will be evaluated through the Self-Care Behavior Assessment Questionnaire created by Han et al., and blood pressure will be assessed using a standard sphygmomanometer. Data analysis will be conducted via SPSS software version 20, which applies univariate and multivariate linear regression tests.

Discussion The protocol aligns with health policies in the domain of noncommunicable diseases, emphasizing sustainable and participatory approaches. If proven effective, the findings can be utilized in educational programs and policymaking efforts, paving the way for the broader implementation of community-based interventions. Moreover, this framework can empower social groups to take an active role in combating noncommunicable diseases, and if effective, its application could yield long-term health benefits for individuals and communities.

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Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	Effectiveness of Community-Based Intervention Using PATCH on Disease Perception, Empowerment, and Self-Care in Hypertension: A Community Trial Protocol
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Role of sponsor {5c}	The role of the funders is to keep track of the research planning and execution. Study funders have no role in the study design, collection, management, analysis, and interpretation of data; the writing of the report; or the decision to submit the report for publication.

Introduction

Background and rationale {6a}

Hypertension is a chronic noncommunicable disease that is frequently asymptomatic [1, 2] and is commonly referred to as the "silent killer" [3, 4]. The increasing average age and rates of obesity within both developed and developing countries have contributed to the growing occurrence of hypertension as a significant health concern [5].

According to the Global Burden of Disease (GBD) study, hypertension is widely recognized as the primary risk factor for mortality on a global scale [6] and is responsible for an estimated 10.4 million deaths annually [7]. The economic impact of hypertension and cardiovascular diseases accounts for half of the total economic burden of diseases [1], and it is projected that hypertension-related fatalities, along with their complications, will surpass 23.6 million by the year 2030 [8].

High blood pressure has been the second most important determinant of disease burden in Iran since the 1990s [9]. The reported prevalence ranges from 25 to 35% among adults, affecting approximately 10 million individuals [5, 10].

Given the slow progression of hypertension disease [11], increased emphasis on self-care and blood pressure management becomes imperative. In conjunction with conventional treatments, lifestyle modifications are highlighted as effective strategies for the prevention and control of hypertension. Currently, only 37% of patients achieve the recommended blood pressure levels, despite the availability of effective treatments. Therefore, lifestyle modifications, such as increased physical activity and dietary adaptations, have proven effective in reducing blood pressure among hypertensive patients, even without medication, and are often recommended as the initial step in blood pressure management [12].

In developing countries, approximately 639 million individuals are affected by limited healthcare resources and inadequate self-care practices.

Traditional approaches to blood pressure control are more focused on self-care education. Such interventions have demonstrated limited sustainability, and the design of related studies has not generated a high level of evidence [13–15]. Alternatively, a community-based approach (such as PATCH), which focuses on strengths and resources within communities, fosters equitable participation, enhances capacity building, and promotes sustainable actions at both the individual and societal levels, which proves to be more promising [16, 17]. A study by Schwalm et al. indicated that community-based approaches can significantly improve health outcomes for individuals with hypertension by involving local health workers and community members in care delivery [18]. Similarly, studies conducted in various settings have shown the effectiveness of community-based interventions for health-related outcomes in people living with hypertension in low- and low- to middle-income countries {Nyame, 2024 #234}. Furthermore, community engagement not only improves disease management but also fosters a supportive environment for patients, leading to better adherence to treatment protocols [19].

The planned approach to community health (PATCH), as a community-based framework, aims to increase community engagement and empowerment in designing, implementing, and evaluating health promotion programs. Within the empowerment process, individuals are encouraged to participate in decisions affecting their health and gain individual and collective power [20]. Among the prominent features of this approach are active community engagement in the planning process, community mobilization, and relationships within and between communities [21]. PATCH was developed and introduced by the Centers for Disease Control and Prevention (CDC) in collaboration with local and state health departments and community groups [22]. Previous studies have applied the PATCH framework in urban settings [21, 23]. In this study, this approach will be used for social mobilization in rural settings by forming health promotion committees and self-help groups at the village level, establishing intra- and intergroup communication, and implementing interventions.

The formation of committees and working groups constitutes the first stage of the approach, namely, community mobilization, through which the established structures can actively participate in community-based planning (Fig. 1) [21]. In rural areas, due to their smaller populations and greater homogeneity, people tend to exhibit better cooperation across various aspects, leading to a greater likelihood of self-help group formation and participation {Daniel, 2024 #241}.

Planning based on the PATCH framework is not directed by an external health expert; its impact within
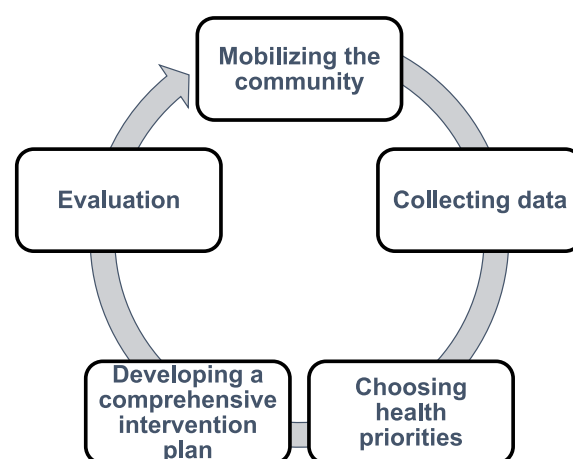

Fig. 1 Stages of the Planned Approach to Community Health (PATCH) [21]

the community is likely to be more sustainable than interventions planned solely by specialists via a top-down approach. Increased participation in the various stages of the needs assessment, design, and implementation of the intervention cultivates a sense of ownership within the community, which contributes to the sustainability of the intervention's effects {de Sá, 2024 #237}.

One of the crucial components of self-care is illness perception. Illness perception pertains to the beliefs that patients hold regarding their illness, which can influence their adherence to treatment and psychological well-being. The perception of illness can impact patients' ability to engage in self-care and comply with therapy [24]. Although research has been conducted in this area, further studies are needed to explore the development and impact of community-based interventions on disease perception and self-care [25]. Some studies have reported negative perceptions among patients with hypertension towards their condition, which holds significance for their adaptation and self-care behavior improvement [26].

Considering the relationships between illness perception and empowerment [24], empowerment and self-care behaviors [27], and self-care behaviors and hypertension [28], as demonstrated in various studies, a conceptual framework for this study has been proposed (Fig. 2).

Given the sedentary and mechanized lifestyles of individuals and the increasing prevalence of hypertension, the focus of interventions related to self-care in hypertension education and the relative lack of a community-based health promotion approach [25, 29], the necessity for the current study is becoming more apparent. By employing this method and utilizing PATCH as a theoretical framework, harnessing the potential of
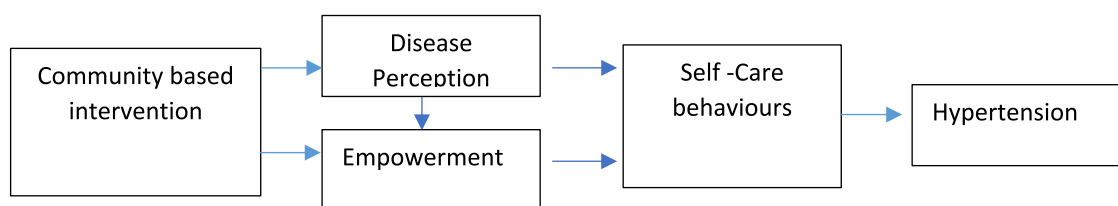
Fig. 2 Conceptual framework of the study

self-help groups, and implementing a community trial with a control group, this study seeks to bridge the current research gap. The novelty of this study lies in its use of a community-based and participatory approach, which has been less explored in the context of hypertension management. Unlike the community-based approaches employed in previous interventions, which have focused primarily on educational methods [13–15], the PATCH framework emphasizes community capacity building, empowerment, and participatory problem solving.

While many studies have focused on individual dimensions such as self-care behaviors or illness perceptionperceptions [13, 18, 30, 31], this study addresses empowerment at both the individual and community levels. Community empowerment is achieved through the establishment of health promotion councils and self-help groups, which foster a sense of ownership and sustainability in behavior change interventions. Furthermore, most studies have applied the PATCH framework in urban settings [21, 23]; this study provides valuable insights into the effectiveness of community-based interventions in rural areas with unique cultural and social characteristics.

Implementing the proposed protocol from this study has the potential to empower individuals and groups and increase their involvement in community-based noncommunicable disease interventions.

Objectives {7}

This study aims to determine the effectiveness of community-based interventions using a PATCH framework for improving disease perception, empowerment, self-care behaviors, and blood pressure in patients with hypertension.

The hypothesis is that community-based interventions lead to improvements in disease perception, empowerment, and self-care behaviors and a reduction in average systolic and diastolic blood pressure in the intervention group compared with the control group.

Trial design {8}
This study utilizes a community-based intervention in the form of a parallel randomized community trial.

Methods: participants, interventions and outcomes
Study setting {9}
The community consists of individuals diagnosed with hypertension (systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg) who are covered by CRHSCs in Babol County, Iran. This county is located in the northern region of Iran, within Mazandaran Province, and is the most populous in the province. It comprises six districts, seven cities, and 673 villages. According to the 2016 census, the population of this county was 531,930, with 250,217 individuals residing in urban areas and the remaining 281,713 individuals living in rural areas.

The villages in this county do not differ significantly in terms of ethnicity, culture, or economic status and are relatively similar to each other. On the basis of screening conducted in this county in 2019, 107,835 individuals (48.96%) out of the screened population above 30 years old (220, 241) were found to have hypertension or prehypertension [32], and their information has been registered in the health information system of the Ministry of Health and Medical Education (MOHME). Among the 27 CRHSCs in Babol County (27 clusters), 12 CRHSCs (12 clusters) were selected through simple random sampling. In the next stage, one health house is randomly selected from all the health houses covered by each CRHSC (12 health houses from 12 CRHSCs).

The required sample size will be randomly selected from the list of patients diagnosed with hypertension in the "SIB" system on the basis of inclusion and exclusion criteria in each health house separately (criteria mentioned in the eligibility criteria section). The SIB system refers to the Integrated Health System, which is the most recently developed electronic health records system in Iran. The system officially started operating in February 2016 with the goal of unifying health-related data and offering healthcare services within health programs across the country.

Eligibility criteria {10}

Individuals who are diagnosed with hypertension, have a systolic blood pressure equal to or greater than 140/90 mmHg without the use of medication, who are literate, who are covered by the CRHSCs under the supervision of the Health Deputy of Babol University of Medical Sciences (BUMS), and who are registered in the SIB system as patients with hypertension are eligible to participate in the study.

Who will provide informed consent? {26a}

Informed consent form

The researcher (HH) will present the study and explain the process of completing the informed consent form. The participants will subsequently complete and confirm the informed consent form, which is available in the Farsi language and adapted to be culturally appropriate.

No biological samples will be collected for research purposes; therefore, additional consent from participants will not be needed.

Additional consent provisions for the collection and use of participant data and biological specimens {26b}

This is not applicable. No biological samples will be collected for research purposes; hence, additional consent from the participants will not be needed.

Interventions

Explanation for the choice of comparators {6b}

From the 27 CRHSCs (clusters), 12 centers (clusters) are randomly selected using simple random sampling. Next, one health house will be randomly selected through simple random sampling from all health houses covered by each comprehensive rural health service center (12 health houses from 12 CRHSCs). A block randomization protocol (generated by random allocation software with block sizes of four) will be used to allocate health houses to the intervention and control groups. No interventions will be administered to the control groups during the study. Patients will receive routine care provided by health centers throughout the trial. At the end of the study, a self-care educational package for hypertension patients will be given to each center in the control group.

Intervention description {11a}

In this study, a PATCH framework was employed to increase capacity and improve self-care behaviors in patients with hypertension. This approach emphasizes community participation and empowerment at various stages, including problem identification, capacity assessment, solution finding, implementation, and evaluation. Individuals affected by hypertension play a role in problem solving. The primary objective of this approach is to systematically empower community members to analyze and address their health concerns.

In each village, a health promotion council consisting of community leaders is established. With the coordination of this council, training and facilitation for self-help groups will be conducted by community health workers from selected CRHSCs. After 18-member self-help groups are formed, capacity building within these groups is led via self-care guidelines developed by the Health Education and Promotion Office of the MOHME for community health workers (members of the village who provide primary health care services).

This capacity-building activity focuses on self-care topics related to hypertension. The key feature of community-based intervention with a PATCH framework, in addition to the participatory nature of the planning process, is the formation of social networks and the fostering of communications. In this study, this approach effectively mobilizes the community through the establishment of health promotion committees and self-help groups at the village level and encourages communication within and between them, facilitating interventions at these levels. The establishment of committees and working groups is indeed the initial stage of community mobilization.

Intervention procedure

The design of the community-based intervention with a community health planning approach will consist of the following six stages:

(1) Community mobilization
(2) Data collection
(3) Problem analysis and prioritization
(4) Program development
(5) Implementation
(6) Evaluation

(1) Community mobilization

   The establishment of health promotion councils has been observed in chosen specific villages. These councils are formed through correspondence with the appropriate district offices and garnering support within each village. Council members include researchers, health workers from the health house, the resident physician, the village headman, the religious leader, an elder and trustee of the village, health volunteers, and health ambassadors (family members who act as intermediaries between the community and the country's health network).

An introductory and informative session will be conducted, followed by a 1-day meeting in which the researcher (HH) will present and engage in question-and-answer sessions on topics such as the community-based intervention method, healthy behaviors, social determinants of health, hypertension, the importance of self-care, the nature and significance of the PATCH, the stages involved, as well as planning in self-help groups and the importance of their involvement in self-care programs.

This committee is responsible for monitoring and coordinating the activities of the self-help groups, receiving relevant reports, and providing feedback every month or as per their preference. Furthermore, concerning nonbehavioral (social) determinants that impact self-care in hypertension patients and extend beyond the scope of the health sector, the members of the Health Promotion Council play a crucial role as decision-makers.

On the basis of these influencing determinants, recommendations for activities such as health exhibitions, healthy food festivals, campaigns, sports competitions, family walks, the provision of financial resources, social support, license issuance, and inviting notable individuals by self-help groups can be proposed. Depending on their jurisdiction, the members of the Health Promotion Council contribute to the implementation of such activities in the action plans of self-help groups.

In this study, considering the sample size in each village, two self-help groups of 18 people were formed. Various self-care activities tend to have a greater impact when conducted interactively or within a group context. Consequently, self-care programs often involve "group interaction" through self-help groups. The primary function of self-help groups is to provide "mutual assistance," which involves offering social support among individuals who share a common problem or concern. In this study, the self-help group members were individuals with hypertension who were motivated to manage or prevent complications associated with their condition.

The potential benefits of self-help groups in reducing individuals' stress levels and mitigating the impact of stress on depressive symptoms are significant from both social and psychological standpoints. This psychological aspect acts as a mediator in the intervention's effects on improving self-care behaviors and abilities. These self-help groups engage in

planning activities to identify determinants that influence self-care behaviors, implement interventions, and evaluate health promotion activities related to hypertension self-care. The collaboration with the village health promotion council ensures the effective implementation of these activities.

With respect to group dynamics, the facilitator provides a comprehensive presentation of the definition of a group, the stages of group evolution, and strategies for maintaining group dynamics. This presentation spans a day during which participants gain insights into the different stages of group development and acquire skills to manage challenges that arise in these stages. To collect participants' feedback on strategies for maintaining group dynamics, brainstorming and visualization as a mind map will be used.

(2) Data collection

To identify the reasons for not adopting self-care behaviors and to facilitate these behaviors, brainstorming sessions will be conducted within self-help groups to explore barriers and facilitators (both behavioral and nonbehavioral). During a 1-day training session, participatory methods such as cause–and–effect analysis via fishbone diagrams and mind mapping will be employed. These groups have become empowered to recognize the issue of hypertension and its influencing factors, as well as propose self-care solutions on the basis of the identified factors.

(3) Problem analysis and prioritization

To determine and prioritize the reasons for not adopting self-care behaviors and how to facilitate these behaviors, the change matrix is utilized. The capacities of villages and districts to provide services related to self-care in hypertension, such as healthcare centers, active groups, and charities, will be identified by self-help groups with the assistance of the Village Health Promotion Council via a resource mapping approach.

(4) Program development

The action plans will be developed in collaboration with the Village Health Promotion Council to promote health activities in areas such as stress management, increasing physical activity and weight loss, improving nutrition, self-monitoring of blood pressure, and regular medical check-ups, on the basis of the most common determinants among villages.

(5) Implementation

Training sessions will be conducted for community health workers on the basis of the self-care and

self-help group guidelines developed by the Office of Health Education and Health Promotion of the MOHME in the field of hypertension management. The educational content included facilitating self-help groups, understanding hypertension, and self-care methods. These training sessions, which will be led by the researcher, will be conducted over a 2-day workshop utilizing lectures and participatory methods (discussion and sharing experiences) to improve their knowledge and perceptions of the disease.

Community health workers with a minimum of 2 years of work experience undergo training provided by the research team (EJ and HH) in a workshop. After the training, they are expected to correctly answer more than 80% of the self-care exam questions prepared by the MOHME. An action plan for self-care will be developed and implemented on the basis of defined activities, roles, and responsibilities. For activities beyond health behavior-related determinants, the Health Promotion Council will be involved in the implementation process.

Notably, all the processes, such as coordination, implementation, conducting meetings, organizing training courses, providing training on the use of various blood pressure monitors, and measuring and recording blood pressure, as well as administering questionnaires, will be closely supervised by the researchers (HH and EJ). During this period, the control group will receive only routine healthcare programs.

(6) Evaluation

Three months after the intervention commences, disease perception and empowerment will be assessed as primary outcomes for all individuals enrolled in the study, including both the intervention and control groups. Additionally, 6 months after the intervention begins, secondary outcomes, including self-care behaviors related to blood pressure and participants' blood pressure, will be evaluated.

Criteria for discontinuing or modifying allocated interventions {11b}

The criteria for study exit include individuals' dissatisfaction with ongoing participation in the study, migration, or death.

Strategies to improve adherence to interventions {11c}

A community-based approach will be implemented to enhance the capabilities and improve the self-care behaviors of patients with hypertension. The primary objective of this approach is to systematically empower individuals within the community to analyze and propose solutions to their health issues, thereby promoting the sustainability of the intervention and fostering commitment to it. The establishment of self-help groups and capacity building within these groups encourages their engagement in the programme and mutual support in self-care activities.

The presence of a health promotion council consisting of stakeholders also facilitates the organization of self-help group sessions and ensures the continuity of activities. Health ambassadors, who have previously undergone comprehensive self-care training, including hypertension self-care, will be utilized to ensure participants' adherence to follow-up interventions and provide support for their ongoing activities at home through weekly telephone calls during the intervention period.

Relevant concomitant care permitted or prohibited during the trial {11d}

Participants in the control group of the study have been registered in the MOHME SIB system as individuals with hypertension, and they also receive routine care similar to that of the intervention group, which does not pose any hindrance. Any changes in the type and dosage of medications during the intervention period will be taken into account during the analysis of the results.

Provisions for post-trial care {30}

After the study, each center in the intervention group, if interested, may continue to engage in the self-help groups established for ongoing self-care programs. They may also avail themselves of the services provided by the Health Promotion Council regarding self-care activities.

Outcomes {12}

This study focuses on four main outcome variables: the perception of hypertension, empowerment, self-care behaviors, and blood pressure. The primary outcomes include the perception of hypertension and empowerment, whereas the secondary outcomes include self-care behaviors and blood pressure.

The perception of hypertension will be measured via instruments developed by Kamran et al. [26]. Before and 3 months after the intervention.

Empowerment will be assessed via the perceived control scale developed by Israel [33] and validated by Asadi et al. [34]. Before and 3 months after the intervention.

Self-care behaviors will be measured via the Self-Care Behavior Assessment Questionnaire for Hypertensive Patients (HTN-SCP), which was developed by Han et al. [35] and validated by Ghanei et al. [36] before and 6 months after the intervention. The blood pressure of individuals will also be measured before and 6 months

after the intervention via the Zenith Med Model ZTH 5001 standard mercury sphygmomanometer, whose accuracy has been verified via calibration equipment.

Participant timeline {13}

The participation of individuals in this study will commence in March 2024 and continue until August 2024. The final report and knowledge translation activities will be undertaken after March 2025. This manuscript has been prepared following the SPIRIT reporting guidelines (Table 1).

Sample size {14}

The study includes CRHSCs in rural areas of Babol County that provide care for individuals diagnosed with hypertension. The information of these individuals is recorded in the MOHME SIB system as hypertensive patients. The required sample size will be randomly selected from the list of hypertensive patients in the SIB system separately at each health center. A total of 428 individuals are considered as the sample size, with 36 individuals in each cluster, taking into account the 12 clusters (CRHSCs).

The intervention will be implemented at the CRHSC level, with two self-help groups for hypertensive patients in each cluster. The sample size was calculated on the basis of the primary outcome of the study, which was the reduction in blood pressure in the target group. Previous studies (Delavari et al.) [37] were consulted to determine the mean reduction in blood pressure based on interventions for blood pressure control, with a mean and standard deviation of 148.45 ± 12.32 for the control group and 142.59 ± 11.56 for the intervention group (effect size 0.49). Considering a 95% confidence level and 90% study power, the required sample size was calculated via G Power software version 3, assuming a two-sided hypothesis. The required sample size was determined to be 178 individuals, with 89 individuals in each group. The sample size is calculated via the following formula:

$$ n = \frac{\left(S_1{}^2 + S_2{}^2\right)\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)2}{(\overline{X_1} - \overline{X_2})2} $$

However, considering the cluster sampling method in the first stage, a design effect of two was applied to detect any potential effect, resulting in a sample size of 356 individuals (178 individuals in each group). Furthermore, considering the longitudinal nature of this study and the 6-month follow-up period, a maximum sample dropout rate of 20% was assumed, which was added to the final sample size. Therefore, a total of 428 individuals (214 individuals in each group) were included in the final sample size, with 36 individuals per cluster.

Recruitment {15}

In this study, cluster random sampling was employed. Cluster sampling is a probability sampling method commonly used for studying large populations, especially

Table 1 Timeline of the effects of a community trial using a planned approach to community health (PATCH) on disease perception, empowerment, and self-care behaviors in patients with hypertension

	STUDY PERIOD				
	Enrolment	Allocation	Postallocation		Close-out
TIMEPOINT**	$-t_1$	t_0	t_1	t_2	t_3
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Questionnaire completion	X				
Allocation and randomization		X			
INTERVENTIONS:					
Intervention (first 3 months)			X		
ASSESSMENTS:					
Baseline assessment: Demographic information (Demographic questionnaire) + Blood pressure (Zenit Mod standard dial sphygmomanometer model ZTH 5001) + Disease perception (hypertension perception scale) + Empowerment (Perceived control scale: Multiple Levels of Empowerment Indices) + Self-care behaviors (HTN-SCP)		X			
Assessment (T1): Disease perception (hypertension perception scale) + Empowerment (Perceived control scale: Multiple Levels of Empowerment Indices)				X	
Assessment (T2): Self-care behaviors (HTN-SCP) + Blood pressure (Zenit Mod standard dial sphygmomanometer model ZTH 5001)					X

those that are geographically dispersed. In cluster sampling, researchers divide a population into smaller groups known as clusters [38]. Each CRHSC is considered a cluster. From the 27 CRHSCs in Babol County (27 clusters), 12 centers (12 clusters) were randomly selected via simple random sampling [39]. Then, one health center will be randomly selected from all the health centers covered by each CRHSC, resulting in the selection of 12 health centers from 12 CRHSCs (flowchart of study) (Fig. 3).

Notably, the villages included in the study receive services from different health centers, and because of the distance between the villages, the likelihood of information contamination is minimal.

Assignment of interventions: allocation
Sequence generation {16a}
To allocate health centers to the intervention and control groups, a blocked randomization protocol will be used. This protocol is generated via random allocation software with blocks of four. In this study, the intervention and control groups were selected from different villages.

Concealment mechanism {16b}
In this study, there was no concealment mechanism (blinding).

Implementation {16c}
In the design of this research (a parallel-group randomized controlled community trial), adherence to the CONSORT 2010 checklist criteria was followed to increase the accuracy of design and study reporting [40]. Intervention studies are classified into various categories, and one type of classification divides these studies into clinical trials and field trials on the basis of randomization units. If randomization is performed on patients, the study is referred to as a clinical trial, and if it is conducted on healthy individuals, it is referred to as a field trial [41, 42]. When randomization is based on populations or groups of populations, allocating different populations to groups is termed a community trial. In the parallel design, individuals are randomly assigned to either the intervention or control group and remain in these groups until the end of the study [43].
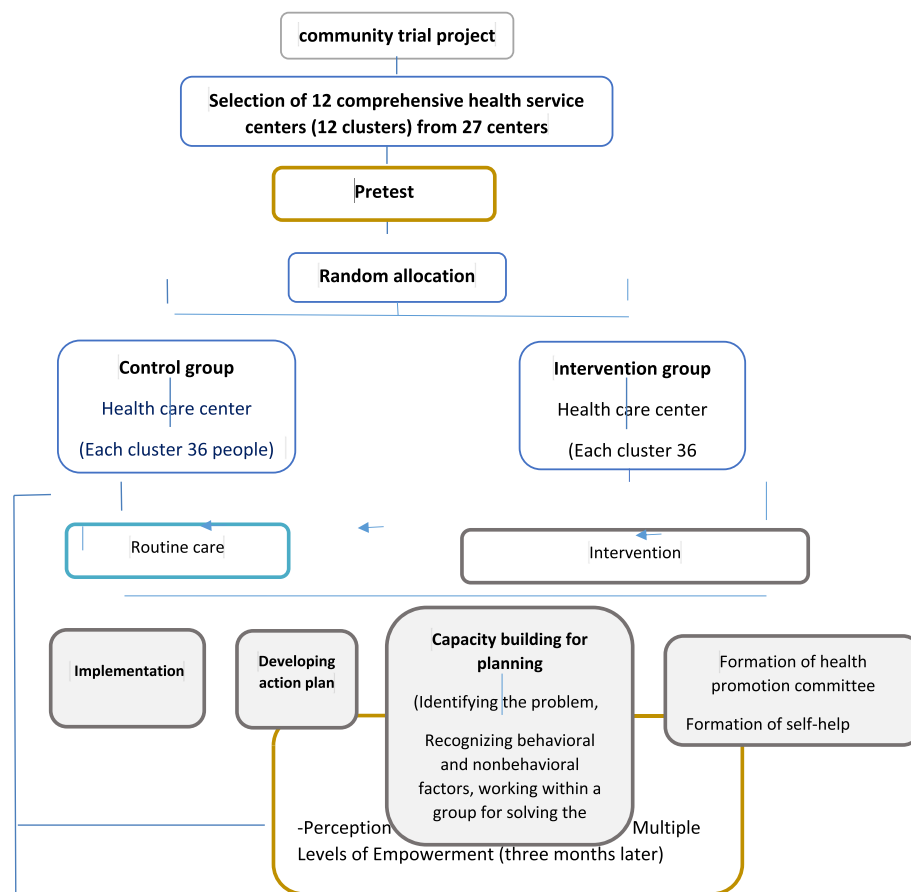

Fig. 3 Flowchart of the study

Assignment of interventions: blinding

Who will be blinded {17a}
In this study, there was no blinding.

Procedure for unblinding if needed {17b}
Blinding is not applicable in this study because clusters are simultaneously allocated to two groups. Simultaneous allocation does not affect the behaviors of units or outcomes. With respect to interventions, we are obliged to identify interventions for CRHSCs.

A unique numerical code is assigned to each created random sequence. Upon entry of each center into the study, by contacting the study epidemiologist, the group to which the individual belongs will be disclosed. The name of the center, along with the assigned code and the type of intervention received, will be registered and maintained by the study epidemiologist, who has access to the randomization chain. Healthcare workers will be invited to participate in the study.

Data collection and management

Plans for assessment and collection of outcomes {18a}
Data collection will take place in three stages:

(1) Before the intervention (using questionnaires including demographic information, the perception of hypertension, the perceived control scale items: multiple levels of empowerment indices, self-care behaviors in hypertensive patients, and a tool to measure blood pressure)

(2) Three months after the intervention (using a questionnaire to assess the perception of the disease and multiple levels of empowerment indices);

(3) Six months after the intervention (using a questionnaire to assess self-care behaviors in patients with hypertension and blood pressure measurement tools);

Data collection tools

(1) Demographic Information Questionnaire: This questionnaire includes age (in years), sex (male/female), marital status (single/married/never married/divorced/widowed), level of education (high school and lower/diploma/university degree), occupation (worker/employee/self-employed/retired/housewife/student/unemployed), economic status (family income does not cover living expenses/family income partially covers living expenses/family income fully covers living expenses), duration of hypertension diagnosis (in months), family history

of hypertension (yes/no), and type and dosage of antihypertensive medication used.

(2) Blood pressure (systolic and diastolic) will be measured via a standard analog sphygmomanometer (Zenith Med Model ZTH 5001, manufactured in Switzerland), the accuracy of which has been verified and confirmed via a calibration device.

The blood pressure of individuals is measured under standard conditions in a quiet room at an appropriate temperature from the person's right arm while seated and relaxed. The measurement is taken in such a manner that the individual has not consumed coffee, tea, alcohol, or smoke for at least 30 min prior; their bladder is empty, they are not fasting, and they have rested for 5 min before the blood pressure measurement without speaking.

(3) Hypertension Perception Questionnaire: This tool, developed by Kamran et al. [26] in Iran, consists of 14 questions. It is based on a Likert scale with four options (completely agree, agree, disagree, and completely disagree), where each item is scored from 1 to 4 on the basis of the response. Items 1, 3, 7, and 12 in this tool are reverse-scored. The score range is from 14 to 56. A higher score indicates a more accurate perception of the disease.

(4) Perceived Control Scale: Multiple levels of empowerment indices: This tool was developed by Israel [33] and validated by Asadi et al. [34]. The Persian version comprises 11 items rated on a Likert scale from 1 to 4, representing completely disagree (1 point), somewhat disagree (2 points), somewhat agree (3 points), and completely agree (4 points). The scale measures empowerment at the organizational, individual, and community levels, with items 1 to 4 assessing organizational-level empowerment; items 5 and 6 assessing individual-level empowerment, and items 8 to 11 assessing community-level empowerment. Scores range from 11 to 44, with higher scores indicating greater empowerment (perceived control). This tool possesses the ability to demonstrate intervention effects on empowerment across various individual, organizational, and community levels.

(5) The Self-Care Behavior Assessment Questionnaire for Hypertensive Patients

HTN-SCP was developed by Han et al. [35] at Johns Hopkins University. Validation in the Persian language was conducted by Ghanei et al. [36]. This tool consists of 20 items focused on the self-care behaviors of hypertensive patients, such as adherence to a low-fat and low-sodium diet, abstinence from alcohol and smoking, blood pressure self-monitoring, weight control, regular

physician visits, and stress reduction. Responses are rated on a 4-point Likert scale ranging from "always" (score of 4) to "rarely/never" (score of 1). The questionnaire comprises 20 items with responses on a 4-point Likert scale, including always (score of 4), often (score of 3), sometimes (score of 2), and very little/never (score of 1). The scoring for questions 12 and 13 is reversed so that it always corresponds to a score of 1, and very little or never corresponds to a score of 4. Thus, individuals can score between 20 and 80, where higher scores indicate better self-care behaviors.

Plans to promote participant retention and complete follow-up {18b}

In this study, two self-help groups were selected in each village, with each group comprising 18 individuals. The presence of interpersonal interaction and mutual support within these self-help groups promotes better adherence to self-care decisions and program participation, leading to improved outcomes. The self-help groups receive education on group dynamics, and participants' opinions on strategies to maintain group dynamics and their commitment to the program are also gathered.

Public and patient involvement

The participation of patients and village health promotion councils in the research process is integrated at the following stages to improve the quality of study design and implementation, better understand community needs, and develop sustainable solutions:

(1) Participation in protocol design:
– Patients with hypertension, as primary representatives of the target group, and members of the village health promotion councils were invited during the early stages of protocol design. By sharing their experiences and needs, they contributed to identifying and analyzing key issues related to self-care and community-based strategies.
(2) Participation in implementation:

– During the study's implementation, patients serve as active members of self-help groups. Their roles include problem analysis, suggesting solutions, participating in educational sessions, and collaborating in the execution of the action plan.
– Community members, as part of village health promotion councils, play a vital role in planning self-help group activities and providing feedback.

(3) Evaluation and monitoring

– Patients and members of village health promotion councils will share their opinions on the study's implementation process and the effectiveness of the interventions.
– This feedback will be used to refine processes and enhance the impact of interventions.

Data management {19}

All data, including informed consent forms, demographic characteristics, perceptions of hypertension, Perceived Control Scale items (Multiple Levels of Empowerment Indices), and a self-care questionnaire for hypertension, will be collected online via a platform called "Porsline," which is similar to SurveyMonkey. The collected data were exported to Excel and analyzed via SPSS software.

Confidentiality {27}

All information obtained from participants will be treated as confidential, and the researcher will take all necessary measures to ensure the confidentiality of the entrusted data. Research data will be stored via unique study identification codes for each participant. The key to the identification code list will only be accessible to the research team throughout the study. Therefore, the privacy of participants will be fully protected.

Plans for collection, laboratory evaluation, and storage of biological samples for genetic or molecular analysis in this trial/future use {33}

There will be no laboratory testing or storage of biological samples for genetic or molecular analysis in this study.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

For statistical analysis, after the data are collected and to ensure the accuracy of entry, descriptive data will be reported via indices such as the mean, standard deviation, and number/percentages. To make decisions regarding statistical tests, the normality of the data will first be assessed via the Kolmogorov–Smirnov test. If the data are normally distributed, parametric tests will be employed. To compare the desired outcomes between groups, a paired sample t test will be used to examine the relationship between quantitative variables under two dependent conditions, and the independent samples t test will be used for two independent conditions.

Furthermore, to investigate the relationship between two categorical variables, the chi-square test will be used, and if the conditions for the chi-square test are not met, Fisher's exact test will be applied. To compare the means

of a quantitative variable in more than two dependent conditions, repeated-measures ANOVA will be utilized.

The Pearson correlation coefficient will be used to assess the linear correlation between quantitative variables, and linear regression (both univariate and multivariate) will be employed after checking the necessary assumptions to investigate the main study variables in the presence of all variables in the study. A multivariate analysis will be conducted to control for confounding variables. In this analysis, standardized and unstandardized regression coefficients and 95% confidence intervals are provided. All analyses will be performed via SPSS version 20, and a significance level of 0.05 will be considered for all analyses.

Interim analyses {21b}

Interim analysis was not planned in this study. Assessing the effects of interventions requires long-term follow-up and the collection of comprehensive data. Hence, the study is designed to ensure a complete evaluation of the intervention at the end of the 6-month period. Interim analyses could lead to premature or incorrect interpretations of the data and reduce the possibility of observing the long-term effects of the intervention.

Frequent or interim analyses could also result in early termination of the study on the basis of incomplete or short-term data. This is particularly important in studies focused on behavioral changes and the gradual effects of the intervention. The final analysis at the designated time ensures that all effects of the intervention, especially its long-term impacts, are examined and that the findings are scientifically and practically valid. Given the long-term nature of the intervention, measuring the true effects requires sufficient time. Furthermore, practical applications of the findings necessitate a complete cycle of intervention to obtain valid and usable data for health policy-making. Additionally, considering the study design and sample size, interim analyses may increase the likelihood of a Type I error (increased probability of false positive results).

Conditions such as patient safety or immediate intervention effects might necessitate interim analyses; however, such issues are not relevant in this study. The intervention in this study was educational and participatory in nature and did not involve any invasive or pharmacological methods. Therefore, there is no need for early termination to ensure participant safety. Regarding the nature of the intervention, this research is based on the PATCH, which requires full community involvement throughout the study. Early termination could undermine participation and program outcomes and prevent the achievement of the study's long-term goals.

Methods for additional analyses (e.g., subgroup analyses) {20b}

Subgroup analysis involves determining the demographic characteristics (age, sex, marital status, education, occupation, and economic status) of individuals with hypertension in both the intervention and control groups. It also includes assessing the correlation between the mean score of disease perception and the mean score of empowerment and self-care behaviors before and 6 months after the intervention.

Methods in analysis to handle protocol nonadherence and any statistical methods to handle missing data {20c}

Intention-to-treat analysis (ITT) will be used. Additionally, the multiple imputation method is employed to handle missing data.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

The author may provide the complete protocol. Relevant information and data throughout the study will be made available upon request.

Oversight and monitoring
Composition of the coordinating center and trial steering committee {5d}

The structure for managing and overseeing the study is as follows:

(1) Coordinating center

The main coordinating center for this study is located at the Health Deputy of Babol University of Medical Sciences.

Composition: This includes the Principal Investigator, Project Manager, and Research Assistants.

Roles and responsibilities.

– Executing and organizing daily study activities.
– Coordinating among participating centers and providing guidance for proper protocol implementation.
– Monitoring data collection, ensuring the completion of information forms, and ensuring data quality.
– Managing financial resources and required equipment.
– Providing periodic reports to the study steering team and other oversight committees.

(2) Project Management Group (PMG)
   Composition: This group consists of the Principal Investigator, advisors, and other key executive members of the study.
   Roles and responsibilities.

– Overseeing daily study activities and data collection.
– Resolving operational issues and ensuring adherence to the timeline.
– Holding monthly meetings to review study progress and identify challenges.

(3) Trial Steering Group (TSG)
   Composition: This committee includes senior researchers, subject matter experts, and representatives from relevant stakeholders in The Research Deputy of TUMS.
   Roles and responsibilities.

– Supervising the overall study progress to ensure protocol adherence with scientific and ethical standards.
– Approving protocol changes if necessary.
– Providing strategic recommendations to address major issues.
– Conducting quarterly meetings to review the overall progress of the study and provide reports.

(4) Daily Support Groups
   Composition: These groups include health staff at rural centers, health workers, health ambassadors, and facilitators of self-help groups.
   Roles and responsibilities.

– Providing operational and educational support to participants.
– Facilitating group sessions.
– Assisting with intervention implementation and completing questionnaires.
– Monitoring protocol adherence at the local level. Meetings and timelines.
– aProject Management Group holds monthly meetings.
– Trial steering group meeting every 3 months.
– Daily support groups submit daily reports to the coordinating center.
– Periodic reports are sent to the coordinating center and the ethics committee.

Composition of the data monitoring committee, its role and reporting structure {21a}

The main coordinating center, located at the Health Deputy of Babol University of Medical Sciences, will oversee data monitoring. Auditors will adhere to a monitoring plan to ensure that the clinical trial is conducted and that the data are generated, documented, and reported following the protocol and legal requirements.

Adverse event reporting and harms {22}

Considering the nature of public health interventions, the health of the participants in this study was not at risk, and no harm was anticipated. We have explicitly stated in the informed consent form that if any unexpected harm occurs during or after the study as a result of participation, the research team members will be responsible for the treatment of side effects and their associated costs. Throughout the study, all adverse events, whether related or unrelated to the intervention, will be documented by the study team according to the predetermined timeline. An assessment of the cause will be conducted for all collected adverse events, and each event will be reported separately. Adverse events will be reported via the MedDRA (Medical Dictionary) classification.

Frequency and plans for auditing trial conduct {23}

The auditing of trial conduct will be carried out by the project management group (PMG) and the trial steering group (TSG). These teams will operate as follows:

• Project Management Group (PMG)

  The PMG comprises the principal investigator, consultants, and other key members of the study team. Monthly meetings are held to facilitate planning, monitor data collection throughout the study period, evaluate study progress, identify potential challenges, and implement appropriate solutions.
• Trial Steering Group (TSG)
  The TSG consists of senior researchers, specialized consultants, and representatives of stakeholders associated with the project at the Research Deputy of TUMS. The group convenes quarterly to ensure that the study adheres to scientific standards and ethical principles, reviews overall study progress, addresses operational considerations, and makes strategic decisions to overcome challenges.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

Any significant changes in the implementation method of the project that may affect the potential benefits, safety, and physical or mental well-being of the participants will be noted.

Processes for notifying and documenting protocol changes

In case of any changes to the study protocol, the following processes will be implemented to ensure proper notification and documentation:

(1) Notifying Sponsor and Funder.

The proposed protocol changes will first be communicated to the study sponsor and funder for their review and approval.

(2) Principal Investigator Notification.
Once approved, the Principal Investigator (PI) will be responsible for informing all participating centers about the changes.

(3) Submission of Revised Protocol.
The revised protocol will be recorded in the Investigator Site File for official documentation.

(4) Documentation of Deviations.
Any deviation from the original protocol will be thoroughly documented via a breach report form, detailing the reasons, specifics, and potential impacts of the deviation on the study.

(5) Clinical Trial Registry Update.
Approved protocol changes will be updated in the Clinical Trial Registry to maintain transparency and public awareness.

(6) Ethics Committee Notification.
Any major change that could affect participant rights or safety will be submitted to the Ethics Committee for review and approval before implementation.

These processes ensure that all protocol changes are meticulously documented and appropriately communicated to stakeholders and relevant authorities, maintaining the integrity and transparency of the study.

Dissemination plans {31a}

We intend to present the findings of this study to key stakeholders at national and international seminars and publish them in reputable journals. The results will be made available to decision-makers in the field of noncommunicable diseases at the ministry level, as well as to community participants in the villages. The dataset will be accessible upon request. Additionally, a copy of the thesis will be provided to the Deputy of Health at BUMS.

A summary of the results will also be provided to the participants upon request.

Discussion

The increasing prevalence of chronic diseases represents a major challenge that healthcare professionals must address. The lifestyle and behavior of individuals significantly affect the occurrence and severity of such diseases. According to the Global Burden of Disease (GBD) study, hypertension is the leading risk factor for cardiovascular diseases and mortality worldwide [6]. Previous studies conducted on community-based interventions have yielded positive results; however, these studies focused specifically on hypertension self-care behaviors or illness perceptions at the individual level [13, 18, 30, 31], whereas this study addresses outcomes such as empowerment at both the individual and community levels.

A notable difference between our protocol and previous protocols [14, 44, 45] is the lack of planning frameworks and behavior change theories in the intervention design, which can be crucial.

The perception of the disease, awareness of its contributing factors [26], and self-care [14] play significant roles in controlling hypertension. The community-based approach stands as one strategy that can assist the community in comprehending the determinants involved in hypertension and empower them to control it. The PATCH, as a community-based framework, highlights community participation in decision-making. It focuses on identifying needs, setting priorities, developing an implementation plan, and evaluating the plan to ensure effectiveness [46]. Previous studies have applied the PATCH framework in urban settings [21, 23]. This study provides valuable insights into the effectiveness of community-based interventions in rural areas with unique cultural and social characteristics.

Unfortunately, interventions aimed at bolstering self-care in hypertension patients have primarily taken the form of educational initiatives [13–15], with less consideration given to the promotion aspect and community-based approach. The extent to which these interventions can influence the self-care behaviors of the community and empower them to impact the factors affecting hypertension remains unclear. Consequently, this research aims to assess the effectiveness of a community-based intervention utilizing a PATCH framework on patients' perceptions of hypertension, empowerment, self-care behaviors, and blood pressure.

Given the severe short- and long-term consequences of hypertension for individuals, families, and society, the findings of this research have practical implications for the educational and operational planning of CRH-SCs, hospitals, hypertension control centers, and patient

associations, particularly in prevention, control, and treatment areas.

Community-based intervention using the PATCH approach has the potential to address existing gaps in the prevention and control of hypertension at the community level. Hypertension is identified as one of the main priorities of the National Health Program in Iran. The Comprehensive National Plan for the Prevention and Control of Noncommunicable Diseases and their Risk Factors{Peykari, 2017 #238} emphasizes the strategy of community participation in health promotion activities. This study protocol aligns with overarching health policies and emphasizes sustainable and participatory approaches. Furthermore, considering that sociocultural contexts and community needs are important in managing hypertension, as cultural practices influence dietary habits, physical activity levels, and perceptions of health{Miezah, 2024 #236}, the PATCH framework, owing to its emphasis on community needs assessment and its engagement of community members in the design and implementation of interventions, is more aligned with the needs and culture of the community.

If proven effective, the findings can be incorporated into educational programs and policy efforts, paving the way for the widespread implementation of community-based interventions. Furthermore, this framework can empower social groups to play an active role in combating noncommunicable diseases. If effective, its application could provide long-term health benefits to individuals and communities.

There are several challenges in the implementation of community-based programs. Mobilizing the community in the initial stages can be problematic because of low interest and participation among community members. To overcome these barriers, strategies such as leveraging the influence of the Village Health Promotion Council and conducting communication activities are essential. Additionally, sustaining participation throughout the intervention period can be challenging. Regular follow-ups, offering incentives to increase participation, and fostering a sense of ownership among community members can be beneficial. Furthermore, health beliefs and behaviors may vary widely among individuals within the community. To address this, within the PATCH, the needs assessment and prioritization process considers the majority's perspective. Additionally, feedback mechanisms during needs assessment and problem-solving sessions ensure that the intervention is adapted to the diverse needs of individuals.

Trial status

This study was registered as a randomized clinical trial in the Iranian Registry of Clinical Trials (IRCT) with the registration number IRCT20231213060354N1 on December 24, 2023. The recruitment of participants for this study is expected to commence in March 2024 and continue until August 2024. The current version and date of the protocol are as follows: last updated on February 11, 2024.

Abbreviations
BUMS   Babol University of Medical Sciences
CRHSC   Comprehensive Rural Health Service Center
GBD   Global Burden of Disease
MOHME   Ministry of Health and Medical Education
PATCH   Planned Approach to Community Health
PI   Principal Investigator
SPSS   Statistical Product and Service Solutions
TUMS   Tehran University of Medical Sciences

Data Availability {29}
To protect confidentiality, participant data cannot be shared publicly. However, the dataset used or analyzed during the current study will be available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate {24}
This study was approved by the Ethics Committee of Tehran University of Medical Sciences (TUMS) with the ethics code IR.TUMS.SPH.REC.1402.245. Informed consent will be obtained from all participants before they participate in the study.

Consent for publication {32}
The protocol does not include any details related to images or videos of specific individuals. Owing to the community-based nature of the research process and community ownership in the research process, images will be captured by the research team and, with their consent, included in the study report.

Competing interests {28}
The authors declare that they have no competing interests.

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