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STUDY PROTOCOLS

Effectiveness of m-health technology-enabled physical activity program on physical activity adoption and adherence in people with hypertension in India: A randomized controlled trial protocol

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Abstract

Background: Exercise and medication have similar benefits in reducing blood pressure (BP); however, hypertension management initiatives primarily focus on medicines. This is due to scarce research on the effectiveness of implementation strategies for optimal exercise adoption and adherence. Smartphones were found to be effective in delivering hypertension care and increase exercise adherence. Despite this, only a small number of research projects in India have used smartphones as a strategy for managing hypertension.

Methods: We hypothesized that smartphone application-based care would lead to higher exercise adherence among adults (30–79 years) with hypertension compared to those who receive usual care. It will be a multicentric, randomized controlled, parallel-design, superiority clinical trial. The outcome assessor and data analyst will be blinded to group allocation. Participants in the intervention group will receive mobile application-based care for 6 weeks. Participants in the usual care group will receive a standard intervention. Both groups will receive the same number of follow-ups.

Results: The primary outcome is the difference in the proportion of people adherent to the recommended level of physical activity evaluated using an exercise adherence rating scale in the intervention group and the control group. Exercise adoption will be measured as the percentage of eligible participants in each study setting willing to initiate the exercise program. The secondary outcome includes differences in systolic and diastolic BP and self-management (evaluated using the Hypertension Self-Care Profile). The trial outcome will be accompanied by a process evaluation.

Conclusions: This research will inform about the comparative effectiveness of conventional and m-health interventions for exercise adoption and adherence in people with hypertension in resource-constrained settings.

KEYWORDS

hypertension, low- and middle-income countries, m-health, physical activity adherence

Clinical trials registry- India (CTRI): CTRI/2023/05/052359 (on 08/05/2023).

Key points

- Less than one-fifth of the Indian population with hypertension had their blood pressure under control due to inadequate access to healthcare and poor treatment adherence.
- Exercise has similar effectiveness at lowering BP as the majority of antihypertensive drugs.
- Lack of implementation strategies has led to structured exercise not being evaluated as extensively as antihypertensive medications.
- Smartphones could be a potential tool for improving healthcare access and self-management of hypertension in resource constraint settings like India.

1 | INTRODUCTION

The burden of hypertension has doubled over the past three decades worldwide with increasing prevalence in low- to middle-income countries (LMICs).[1,2] This is alarming because hypertension accounts for almost half of the heart disease or stroke-related deaths.[3] In LMICs, despite the availability of evidence-based treatment, hypertension management is poor due to low rates of awareness, treatment, and control.[4] In India, nearly a quarter (24.2%) of the population has hypertension, with prevalence higher among males (24.0%) than females (21.0%).[5,6] However, over two decades, less than half of the population with hypertension (46.8%) knew about having high blood pressure (BP), and less than one-fifth (17.5%) had their BP under control.[5]

Several initiatives have been taken to address low control rates of hypertension. A population-level hypertension program called the "India Hypertension Control Initiative" was conducted in 26 districts across five Indian states in their primary care clinics. In that program, control in BP averaged 43% among half-million individuals with hypertension.[7] However, this program and others like mPower Heart, SMART Health India, and m-Wellcare projects were carried out in public healthcare facilities thereby restricting its reach to almost 80% of the population with hypertension who might seek treatment in the private healthcare sector.[8–11] The Mumbai hypertension project is an initiative conducted in the private healthcare sector, but its impacts were confined to the program's participants rather than the population with hypertension.[12]

Inadequate access to healthcare services and poor adherence to recommended treatment are two of the main factors linked to poor control of BP.[5,7,13] People with limited access have been forced to travel great distances to reach government healthcare facilities, wait longer to receive treatment there, endure poor communication and counseling from healthcare providers, or choose to pay more for suboptimal care at private healthcare facilities.[11,14–17] On the other hand, people's dearth of awareness about hypertension, the fact that hypertension is asymptomatic, a lack of exercise, a higher intake of salt, and so on, contribute to poor treatment adherence.[18] Therefore, the control of hypertension in India requires an organized care delivery approach that focuses on the unmet needs of those who experience it.

According to a meta-analysis consisting of more than 350 randomized controlled trials (RCTs), exercise (–8.96 mmHg, 95% confidence interval [CI]: –10.27 to –7.64) and medicine (–8.80 mmHg, 95% CI: –9.58 to –8.02) have similar benefits in reducing systolic blood pressure in people with hypertension.[19] Despite this, hypertension care delivery initiatives predominantly focus on pharmacological treatment and patient education.[19] These findings are attributed to scarce evidence related to the effectiveness and comparative effectiveness of implementation strategies for optimal exercise adoption and adherence.[19]

Implementation of hypertension care using smartphones is found to be effective and considered to be one of the strategies to improve adherence to treatment.[20,21] Access to mobile phones is continuously increasing with more than 50% of the Indian population owning it.[22]

Despite this level of penetration of mobile phone services, a promising tool for healthcare access as well as self-management, only a handful of research initiatives have utilized it.[20,23]

Therefore, this research will be carried out to inform about the comparative effectiveness of a conventional and an m-health strategy for exercise adoption and adherence in people with hypertension. This research will also address the barriers related to accessing hypertension care and exercise adherence by focusing on a smartphone-enabled self-management intervention.

1.1 | Objectives

The primary objective of this study is to determine: The effectiveness of mobile application-based care in increasing exercise adherence in people with hypertension (HTN) as compared with usual care.

The secondary objectives are: (1) to determine the effectiveness of the mobile application-based care as compared with usual care on self-management, diastolic blood pressure (DBP), and systolic blood pressure

(SBP); and (2) to collaboratively involve people with hypertension as research partners in the trial.

2 | METHODS

2.1 | Study design

It will be a multicenter randomized controlled, parallel-design, superiority clinical trial (Figure 1). Participants will be randomized to either the mobile application-based care or usual care. Reporting the protocol is done according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[24]

2.2 | Setting

People with hypertension receiving care in tertiary care hospitals and the physiotherapy department of the Anand and Kheda districts of Gujarat state will be assessed for eligibility (Supporting Information: Appendix 1).

2.3 | Eligibility

2.3.1 | The following criteria must be met by all trial participants

(1) Male and female of 30–79 years of age.[3,25,26] (2) SBP ≥ 140 mmHg and/or DBP ≥ 90 mmHg.[27] (3) People with hypertension who have been prescribed antihypertensive medicine though they may or may not have adhered to the prescription. (4) People with hypertension or their caregivers who have used an android-based smartphone for the past ≥ 1 year.

2.3.2 | Exclusion criteria

Known or suspected complications of hypertension (i.e., myocardial infarction, cerebrovascular stroke, heart failure, or kidney failure). (2) Known or suspected physical limitation(s) rendering them incapable of performing the requested level of physical activity. (3) Current participation in a structured physical activity

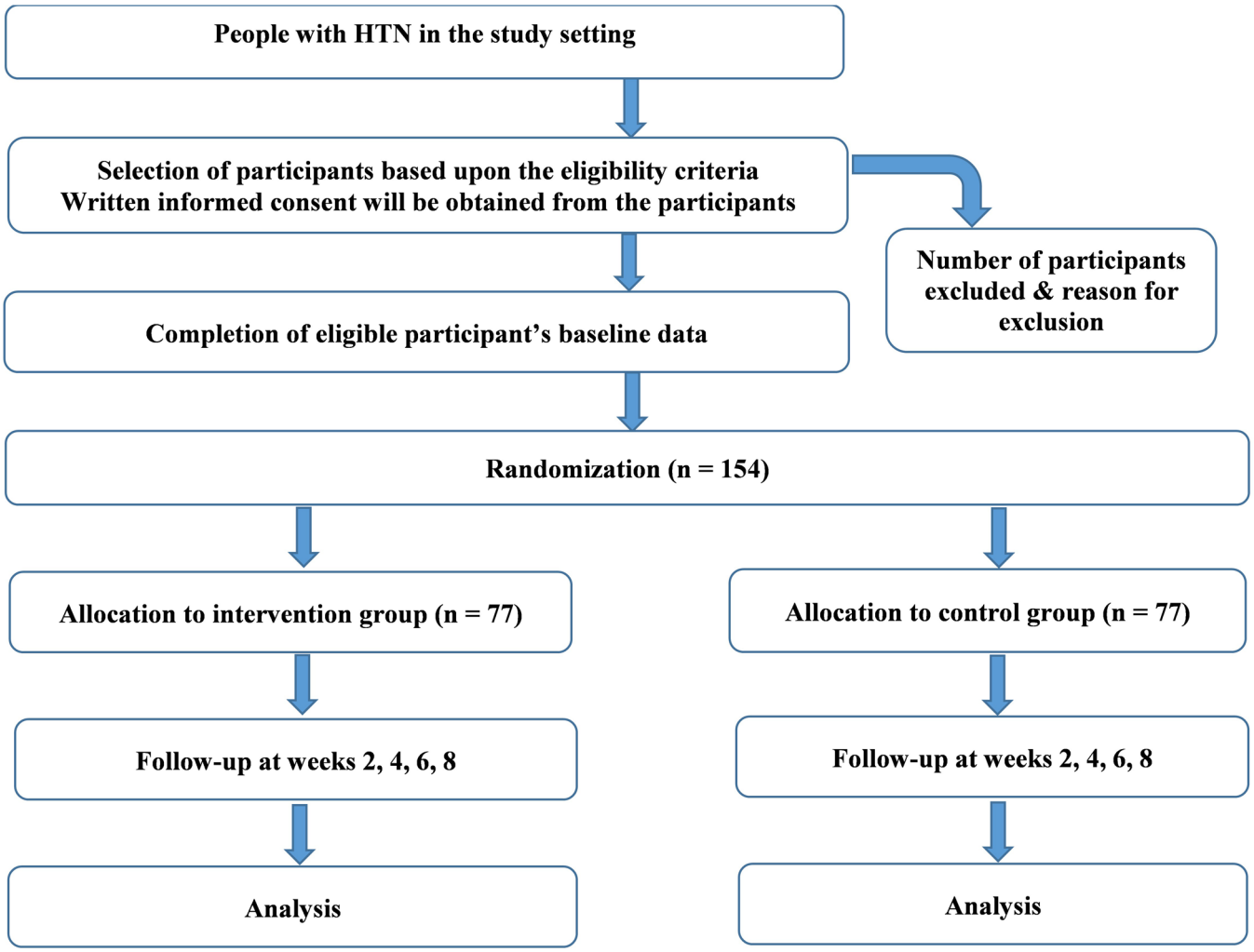

FIGURE 1 Planned flow of participants through the trial.

program. (4) People who cannot consent due to lack of mental capacity.

2.4 | Recruitment procedure

Figure 1 includes information on the recruitment procedure.[28] A study information letter will be given to the individual who may be eligible. In the letter, the research team informs people with hypertension that they will be contacted to discuss participation and provides information about the study's protocols. The written informed consent will be procured by a physiotherapist from the eligible individuals during the consultation.

2.5 | Sample size

G*Power (version 3.1.9.7) was utilized to perform the priori power analysis to compute the required sample size. With an initial total sample size of 128 (64 + 64), factoring in a 20% dropout rate, the adjusted total sample size will be 154 (77 + 77). A sample size of 154 people with hypertension, 77 in each group, is sufficient to find a clinically important difference of 20% (p1:0.28 and p2:0.08)[29–31] between groups for improving exercise adherence using a two-tailed Fisher's exact test of proportions between two groups with 80% power, allocation ratio of 1:1 and a 5% level of significance.

2.6 | Randomization procedure

Random sequencing of participants will be done using https://www.randomizer.org/ by an investigator with no clinical involvement in the trial. Random assignment of the participants into two groups (77 in each) will be performed via a central randomization method. A physiotherapist who is trained by the primary investigator in the recruitment, participant's education, mobile application installation, and data collection procedure will telephone a contact who will be independent of the recruitment process for allocation consignment. A bachelor's degree in physiotherapy will suffice for the data collector. The outcome assessor (exercise adherence and self-management) and data analyst will be blinded to group allocation.

The criteria for withdrawal from the study and unblinding after recruitment include: (1) Lack of interest to continue the participation in the study determined by telephonic communication established at every 2 weeks interval. (2) Hospital admission due to hypertensive emergencies that is, due to acute myocardial infarction, neurological deficit, pulmonary edema or renal failure. (3) Death of the participant.

2.7 | Details of intervention and control group

The intervention description and replication (TIDieR) template is utilized to describe the intervention and control group conditions.[32] Training session(s) will be conducted to train a physiotherapist to collect participants' data and to deliver interventions to both the groups. At the time of recruitment, baseline details such as the socio-demographics (i.e., age, gender, etc.), risk factors of hypertension, previous m-health experience, self-management skills, preferred days and time to exercise, BP value and type of medication prescribed will be recorded for participants of both the groups (Supporting Information: Appendix 2).

2.7.1 | Control group: Usual care group (UC)

Participants in this group will receive Usual care and education regarding hypertension self-management.

UC

Participants will be prescribed antihypertensive medication as well as be appraised about their BP value.

Education regarding hypertension self-management

A physiotherapist will educate participants about hypertension self-management using a manual based on the recommendations of the International Society of Hypertension (ISH) "ISH 2020 Global Hypertension Practice Guidelines."[27] There will be a single session provided at the time of trial entry. Participants will be encouraged to perform 30–40 min of moderately intense activity for at least 5 days per week in a home/community setting as per the recommendation of American College of Sports Medicine (ACSM-2018).[33]

2.7.2 | Intervention group: Mobile application-based hypertension care (MA)

Participants randomized to the MA group in addition to the usual care will be provided with mobile application-based care for 6 weeks. It will include: (1) consultation and training to use the mHealth application; (2) provision of mHealth intervention for self-managing hypertension.

Consultation and training to use the m-health application

At the time of recruitment, a 6-min walk test (6MWT) will be performed, based upon which the walking speed of the participant will be calculated. It provides an estimate to the participant of the distance required to cover during the training session.[34] A physiotherapist

will teach participants to measure and record their pulse rate, level of exertion, walk distance, and duration.

The physiotherapist will install the mobile application on the phones of the participants. The physiotherapist will provide them with at least one mobile application familiarization session. They will be invited to utilize the application in the presence of the physiotherapist, and if any problems occur, then it will be rectified. When participants access and use all components of the mobile application-based intervention at least once without assistance, they will be regarded to have received enough training.

Provision of m-health intervention for self-managing hypertension

Participants will be prescribed a structured exercise program (Table 1) according to the guidance of the ACSM.[33] This trial offers a walking program to the participants because an aerobic exercise like walking is extensively studied in people with hypertension.[19] To encourage adherence, participants will be offered the choice to perform continuous or interval walking in their homes or community dwellings. Every day, participants will have to walk for 30–40 min at least 5 days a week at a moderate intensity. In this trial, the intensity of walking will be determined using the Gellish et al. maximum heart rate method (MHR = 207 – [0.7 × age]).[35] Some people with hypertension who received a prescription for beta-blockers may metabolize the medication differently, resulting in a different response of heart rate to exercise. For these people, the rate of perceived exertion scale (RPE) will be used to guide the walking intensity. The walking session will include a 10-min warm-up and cool-down period. The walking duration will increase by 10 min upon completion of the second week of the trial program.

The foundation of the trial is the mobile application and the gaps in the usual care which it will address are as follows.

Shortfall of healthcare workforce[3]. Relationships with healthcare providers are a key factor affecting adherence to prescribed care.[18] However, healthcare providers have inadequate time to communicate with people with hypertension due to a higher workload.[3,31] So, the mobile application in this trial, enabled with a decision support system, will provide targets and recommendations for hypertension care and an exercise plan concurrent with current guidelines for people with hypertension. It will register and record a person's health data for decision-making, tracking, and follow-ups. These application functions will assist by shifting some of the patient management tasks from the healthcare provider and provide accessible, evidence-based care to the people with hypertension.

Advice for lifestyle modification. Limited time to communicate with patients makes it quite challenging for the healthcare provider to discuss measures required to modify patient lifestyle.[3,31] Therefore, there is a need to provide evidence-based information about hypertension and lifestyle modification through alternative methods. So, the mobile application in this trial provides guideline-recommended information to improve awareness among people with hypertension and their families in the local language to assist in modifying one's lifestyle.

Adherence support. By employing patient-centered care, adherence to self-management and hypertension management techniques can be significantly improved.[36] In this trial, the primary focus of the mobile application is on individuals with hypertension and their families, who constitute the target users. These users will gain access to pertinent information concerning hypertension and effective lifestyle modifications. Furthermore, the application will play a pivotal role in delivering timely notifications and reminders, thereby facilitating the incorporation of a recommended exercise regimen into their routine. To ensure consistent adherence to exercise programs, the application will also provide a mechanism for tracking progress. This will be accomplished by periodically prompting users to provide feedback on their adherence level using the Exercise Adherence Rating Scale (EARS), a standardized assessment tool. These EARS responses will be collected every 2 weeks, offering a comprehensive view of the users' commitment to the exercise regimen.

TABLE 1 Exercise program.

Location	Weeks	Weekly sessions	Walk duration (mins)	Intensity	Mode of exercise
Home/community based	1–2	At least 5	Total time: 30–40 Training: continuous or interval (*each interval session of at least 10)	MHR: 64%–76% and RPE: 12–13	Walking at 80%–90% speed of 6MWT
	3–6	At least 5	Total time: 40–50 Training: continuous or interval (*each interval session of at least 10)	MHR: 64%–76% and RPE: 12–13	Walking at 80%–90% speed of 6MWT (Distance increased by 45–55 m)

Abbreviations: 6MWT, 6-min walk test; MHR, maximum heart rate; RPE, rate of perceived exertion.

2.7.3 | Follow-up

Participants of both groups will receive the same number of appointments and follow-ups. They will receive a phone call from a physiotherapist at the end of the 2nd, 4th and 6th week following group allocation. For participants in the intervention group who missed reporting the duration and distance of a walk for two or more sessions, an additional phone call will be placed to document the reasons for a missed session(s) or cessation of the program. Maximum follow-up of the participants will be limited to 8 weeks.

2.7.4 | Adverse event

Participants will be provided with a list of termination criteria for exercise and possible symptoms that, if they materialize, must immediately report to the physiotherapist. They will be transferred to a tertiary care hospital for further assessment and management. Once the event(s) have been documented, participants will be unblinded and removed from the study.

Participants will be encouraged to contact their physician related to their pharmacological management during the trial. Prescription of a new drug(s), participation in a behavior therapy program(s), or an initiation of an additional structured physical activity program apart from the current program requested in this trial will lead to the exclusion of the participants from the study. Table 2 displays the study participants' schedule and time commitment based on the SPIRIT statement.[24]

2.8 | Outcome measures

2.8.1 | Primary outcome measure

Exercise adherence

It refers to the degree to which trial participants comply with the prescribed exercise program.[37] Self-reported measures of adherence such as questionnaires, diaries, tally counters, and visual analog scales were commonly used in a home-based setting. These measures, however, did not undergo extensive psychometric testing.[38,39]

In our study, EARS developed by Newman-Beinart et al.[40] will be used as a measure of exercise adherence. The EARS asks about the recommended exercise (Section A: five-item), rates exercise adherence (Section B: six-item) and investigate reasons for nonadherence (Section C: 10-item). Test–retest reliability for EARS is 0.94, and its internal consistency is 0.81. EARS is evaluated using a Likert scale (completely agree to completely disagree) and a higher overall result indicates better adherence to the advised exercise. Its total score (Sections B and C) ranges from 0 to 64. The score on the six-item adherence scale ranges from 0 to 24. The cut-off score is 17, participants are deemed to have adhered to the recommended exercise program if they get an average score above 17 out of 24 on a six-item adherence scale.[29,41]

Exercise adoption

Exercise program adoption is essential to exercise adherence; it will be quantified as the percentage of eligible participants in each study setting who are eager to start the exercise program. The reasons that led to the adoption—or lack thereof—of the exercise program will be inquired from the participants.[42,43]

2.8.2 | Secondary outcome measures

Self-management

Self-management is "actions directed toward oneself or the environment to regulate one's functioning in the interest of one's life, integrated functioning, and well-being."[44] Hypertension self-management is a comprehensive approach inclusive of adherence to prescribed medication and multiple lifestyle behaviors such as physical activity, moderation in salt intake, consumption of fatty foods, management of body weight, alcohol consumption, and smoking cessation. It also includes regular follow-ups with doctors, BP monitoring, and stress management.

The commonly used tools to measure hypertension self-management include the Morisky scale and the Hill-Bone Adherence Scale. However, these scales focus on medication adherence. The Hypertension Self-Care Profile (HBP-SCP) tool, assessing various facets of hypertension self-management, will be employed in our trial to evaluate hypertension self-management.[45] It is a self-administered questionnaire with three sections: behavior, self-efficacy, and motivation. Each section has 20 items and is graded using a Likert scale (never to always) with scores ranging from 20 to 80. The overall summated score ranges from 60 to 240, with the high score suggesting a high level of self-care behavior, motivations, and self-efficacy related to hypertension.

SBP and DBP

It will be assessed using a sphygmomanometer as per the recommendation of ISH.[27]

The exercise adherence rating scale and the hypertension self-care profile will be translated into Gujarati using the forward and backward translation process of World Health Organization (WHO).[46]

2.8.3 | Process outcome

Process evaluation includes fidelity assessment of technology-based intervention. A retrospective analysis will

TABLE 2 Schedule of study participants' enrollment, assessment and interventions.

	STUDY PERIOD								
	Enrolment	Allocation	Post-allocation						Close- out
TIMEPOINT** Week	-1 to 0	0 to 1	1 ± 2 days	2 ± 2 days	3 ± 2 days	4 ± 2 days	5 ± 2 days	6 ± 2 days	7 ± 2 days	8 ± 2 days
ENROLMENT										
Eligibility screen	X									
Informed consent	X									
Allocation		X								
INTERVENTION										
[Intervention A- usual care]			◆	—	—	—	—	◆		
[Intervention B- mobile application based care]			◆	—	—	—	—	◆		
ASSESSMENTS										
Baseline variables	X									
Measurement of systolic and diastolic blood pressure	X							X		X
Hypertension Self-Care Profile (HBP-SCP)	X							X		X
Exercise Adherence Rating Scale(EARS)				X		X		X		X
Intention, Attitude, Acceptance, Adoption & satisfaction towards mobile application`								X		X

be carried out following the approach suggested by Dabbs et al.[47] The delivery of the intervention and how well it was received will be evaluated as part of the fidelity evaluation. This will be done by observing a random 10% of the participants' training session videos. Additionally, it will inquire about participants' attitudes toward, acceptance of, intention to use, and adoption of the mobile application as well as their satisfaction with the training process to use it. Exercise adherence will be tracked in this study using EARS, walk distance logs, and phone follow-up logs.

2.9 | Patient and public involvement

Discussion regarding the possible roles of people with hypertension at the different stages of projects that is, development of the study information letter for the participants, manual to provide education on hypertension self-management, development of the mobile application, translation of the outcome measures, and in the dissemination of study findings will be conducted prospectively using the involvement matrix. The discussion will also be conducted retrospectively to understand whether the conferred roles were carried out satisfactorily.[48]

3 | DATA ANALYSIS

Data entry will take place in a predefined data dictionary and the validity of data entry will be assessed using the proofreading data method. Data will be analyzed using the intention-to-treat principle. The "last value carried forward" method will be applied to the missing observations. Password-protected files will be used to store the data. On a reasonable request, data will be available from the primary investigator.

3.1 | Primary analysis

To analyze the categorical and continuous data, SPSS (version-23) will be utilized. Descriptive statistics will be used to express demographics and outcomes. A test for normality will be used to analyze the distribution of data. The differences in exercise adherence rate (obtained using exercise adherence rating scale) of participants in intervention and control groups will be analyzed using Fisher's exact test. The establishment of appropriate power by sample size allows for the detection of a difference of five points on the exercise adherence rating scale between participants in the intervention and control group.

3.2 | Secondary analysis

The differences in self-management of hypertension (obtained using HBP-SCP) and in BP (systolic and diastolic) among participants in intervention and control groups will be analyzed using Fisher's exact test.

For each study setting, exercise adoption will be expressed as a percentage of eligible participants who are willing to participate in the study.

The covariates of exercise adherence (age, gender, education, self-efficacy, and baseline SBP)[21] will be adjusted. Accounting for the differences in the variables between the groups at trial entry to determine their influence on exercise adherence, a multivariate regression analysis will be used.

A sensitivity analysis will be performed to determine the main outcome of exercise adherence. The observed effect of the intervention will be subject to a sensitivity analysis to determine how changing the threshold (i.e., a 5.5-point difference in exercise adherence rating scale score across groups) affects the result. A subgroup analysis will be performed to investigate whether treatment effect varies among young (30–44 years old), middle (45–64 years old), and older (65–79 years old) adults.[49]

All statistical tests will be two-tailed. The statistical inference will be based on 95% confidence intervals and *p*-values (≤0.05).

4 | ETHICS AND DISSEMINATION

This study was approved by the Institutional Ethics Committee of the first author's affiliated university. Our results will be presented at conferences and/or published in a research journal as part of our dissemination strategy. The findings will also be presented at stakeholder meetings with administrators, academicians, researchers, and clinicians who manage hypertension. The main outcomes of this study will be shared in the form of infographics across social media websites.

5 | STRENGTH AND LIMITATIONS OF THE STUDY

The benefit of this study is that it will offer mobile application-based therapies, thereby removing the location and temporal constraints associated with outpatient hypertension care. To help people manage their blood pressure, it will also offer a guideline-based decision-support system. This study also has several limitations. The main limiting factor in this study is that it will be conducted in one region of India; hence the result of this trial may not be generalizable to the entire Indian population. The intervention requires owning a smartphone, which is increasing rapidly in India, and more than half of its population owns a smartphone. It also requires mobile literacy. Although HBP-SCP will ask about adherence to prescription medication, this short-term intervention primarily focuses on nonpharmacological management. The application will be used after the person is diagnosed with hypertension, which requires the availability of healthcare professionals at the clinical site. In a clinical context, offering the mobile application for hypertension self-management by the healthcare provider to the patients will also pose an operational challenge due to time constraints.

6 | IMPLICATIONS

The trial strategy will provide people with limited resources and access to healthcare. Clinically, mobile applications will provide guideline-based decision-support systems and a task-sharing approach. It will also act as a repository for patient health information. If the strategy is determined to be efficient and effective, the public healthcare system may adopt it.

AUTHOR CONTRIBUTIONS

The research study was conceptualized and the draft protocol was prepared by Vidhi Thakar under the guidance of V. Prakash. The development of background, design of the trial, and anticipated trial results were all developed by Vidhi Thakar, Sureshkumar Kamalakannan, and V. Prakash. The manuscript was written by Vidhi Thakar, and it was reviewed by V. Prakash and Sureshkumar Kamalakannan. All the authors have read and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest. No specific grants from funding agencies in the public, commercial, or not-for-profit sectors were received for this research.

DATA AVAILABILITY STATEMENT

The data that supports the findings of this study is available from the corresponding author upon reasonable request.

ETHICS STATEMENT

This study was approved by the Institutional Ethics Committee of Charotar University of Science and Technology (CHA/IEC/ADM/23/04/410).

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REFERENCES

1. Zhou B, Carrillo-Larco RM, Danaei G, et al. Worldwide trends in hypertension prevalence and progress in treatment and control from 1990 to 2019: a pooled analysis of 1201 population-representative studies with 104 million participants. *Lancet*. 2021;398(10304):957-980. doi:10.1016/S0140-6736(21)01330-1
2. Mills KT, Bundy JD, Kelly TN, et al. Global disparities of hypertension prevalence and control: a systematic analysis of population-based studies from 90 countries. *Circulation*. 2016;134(6):441-450. doi:10.1161/CIRCULATIONAHA.115.018912
3. Jeemon P, Séverin T, Amodeo C, et al. World heart federation roadmap for hypertension: a 2021 update. *Global Heart*. 2021;16(1):63. doi:10.5334/gh.1066
4. Geldsetzer P, Manne-Goehler J, Marcus ME, et al. The state of hypertension care in 44 low-income and middle-income countries: a cross-sectional study of nationally representative individual-level data from 1·1 million adults. *Lancet*. 2019;394(10199):652-662. doi:10.1016/S0140-6736(19)30955-9
5. Koya SF, Pilakkadavath Z, Chandran P, et al. Hypertension control rate in India: systematic review and meta-analysis of population-level non-interventional studies, 2001–2022. *Lancet Reg Health*. 2023;9:100113. doi:10.1016/j.lansea.2022.100113
6. International Institute for Population Sciences (IIPS) and ICF. *International Institute for Population Sciences National Family Health Survey (NFHS-5), 2019-21 India: Volume I*. IIPS; 2021. Accessed February 23, 2023. https://dhsprogram.com/pubs/pdf/FR375/FR375.pdf
7. Kaur P, Kunwar A, Sharma M, et al. The India hypertension control initiative–early outcomes in 26 districts across five states of India, 2018–2020. *J Hum Hypertens*. 2022;37:560-567. doi:10.1038/s41371-022-00742-5
8. Ajay VS, Jindal D, Roy A, et al. Development of a smartphone-enabled hypertension and diabetes mellitus management package to facilitate evidence-based care delivery in primary healthcare facilities in India: the mpower heart project. *J Am Heart Assoc*. 2016;5:e004343. doi:10.1161/JAHA.116.004343
9. Praveen D, Patel A, McMahon S, et al. A multifaceted strategy using mobile technology to assist rural primary healthcare doctors and frontline health workers in cardiovascular disease risk management: protocol for the SMARTHealth India cluster randomised controlled trial. *Implement Sci*. 2013;8:137. doi:10.1186/1748-5908-8-137
10. Prabhakaran D, Jha D, Prieto-Merino D, et al. Effectiveness of an mHealth-Based electronic decision support system for integrated management of chronic conditions in primary care: the mWellcare cluster-randomized controlled trial. *Circulation*. 2019;139(3):380-391. doi:10.1161/CIRCULATIONAHA.118.038192
11. Engelgau MM, Karan A, Mahal A. The economic impact of non-communicable diseases on house-holds in India. *Global Health*. 2012;8:9. doi:10.1186/1744-8603-8-9
12. Hegde A, Patel H, Laxmeshwar C, et al. Delivering hypertension care in private-sector clinics of urban slum areas of India: the Mumbai hypertension project. *J Hum Hypertens*. 2022;37:767-774. doi:10.1038/s41371-022-00754-1
13. Busingye D, Arabshahi S, Evans RG, et al. Factors associated with awareness, treatment and control of hypertension in a disadvantaged rural Indian population. *J Hum Hypertens*. 2017;31(5):347-353. doi:10.1038/jhh.2016.85
14. Atun R, Jaffar S, Nishtar S, et al. Improving responsiveness of health systems to non-communicable diseases. *Lancet*. 2013;381:690-697. doi:10.1016/S0140-6736(13)60063-X
15. Babu V, Sahu S, Kanungo S. Hypertension control status and quality of care for hypertension among patients availing treatment from private sector: a cross-sectional study in urban field practice area of JIPMER, Puducherry. *J Family Med Prim Care*. 2019;8:72-76. doi:10.4103/jfmpc.jfmpc_248_18
16. Balarajan Y, Selvaraj S, Subramanian S. Health care and equity in India. *Lancet*. 2011;377:505-515. doi:10.1016/S0140-6736(10)61894-6
17. Perera M, de Silva CK, Tavajoh S, et al. Patient perspectives on hypertension management in health system of Sri Lanka: a qualitative study. *BMJ Open*. 2019;9(10):e031773. doi:10.1136/bmjopen-2019-031773
18. Gupta S, Dhamija JP, Mohan I, Gupta R. Qualitative study of barriers to adherence to antihypertensive medication among rural women in India. *Int J Hypertens*. 2019;2019:5749648. doi:10.1155/2019/5749648
19. Naci H, Salcher-Konrad M, Dias S, et al. How does exercise treatment compare with antihypertensive medications? A network meta-analysis of 391 randomised controlled trials assessing exercise and medication effects on systolic blood pressure. *Br J Sports Med*. 2019;53(14):859-869. doi:10.1136/bjsports-2018-099921
20. Cavero-Redondo I, Saz-Lara A, Sequí-Dominguez I, et al. Comparative effect of eHealth interventions on hypertension management-related outcomes: a network meta-analysis. *Int J Nurs Stud*. 2021;124:104085. doi:10.1016/j.ijnurstu.2021.104085
21. Collado-Mateo D, Lavín-Pérez AM, Peñacoba C, et al. Key factors associated with adherence to physical exercise in patients with chronic diseases and older adults: an umbrella review. *Int J Environ Res Public Health*. 2021;18(4):2023. doi:10.3390/ijerph18042023
22. India Cellular and Electronic Association. *Contribution of smartphones to digital governance in India*. Accessed February 24, 2023. https://icea.org.in/blog/wp-content/uploads/2022/06/ICEA-Digital-Governance-in-India-Report-2020.pdf
23. Hearn J, Ssinabulya I, Schwartz JI, Akiteng AR, Ross HJ, Cafazzo JA. Self-management of non-communicable diseases in low- and middle-income countries: a scoping review. *PLoS One*. 2019;14(7):e0219141. doi:10.1371/journal.pone.0219141
24. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-207. doi:10.7326/0003-4819-158-3-201302050-00583
25. Roth GA, Mensah GA, Johnson CO, et al. Global burden of cardiovascular diseases and risk factors, 1990–2019. *J Am Coll Cardiol*. 2020;76(25):2982-3021. doi:10.1016/j.jacc.2020.11.010
26. Murray C, Aravkin AY, Zheng P, et al. Global burden of 87 risk factors in 204 countries and territories, 1990–2019: a systematic analysis for the global burden of disease study 2019. *Lancet*. 2020;396(10258):1223-1249. doi:10.1016/S0140-6736(20)30752-2
27. Unger T, Borghi C, Charchar F, et al. 2020 international society of hypertension global hypertension practice guidelines. *J Hypertens*. 2020;38(6):982-1004. doi:10.1097/HJH.0000000000002453
28. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c869. doi:10.1136/bmj.c869
29. de Lira MR, de Oliveira AS, França RA, Pereira AC, Godfrey EL, Chaves TC. The Brazilian Portuguese version of the exercise adherence rating scale (EARS-Br) showed acceptable reliability, validity and responsiveness in chronic low back pain. *BMC Musculoskelet Disord*. 2020;21(1):294. doi:10.1186/s12891-020-03308-z
30. Anjana RM, Pradeepa R, Das AK, et al. Physical activity and inactivity patterns in India—results from the ICMR-INDIAB study (Phase-1) [ICMR-INDIAB-5]. *Int J Behav Nutr Phys Act*. 2014;11(1):26. doi:10.1186/1479-5868-11-26
31. Das H, Moran AE, Pathni AK, Sharma B, Kunwar A, Deo S. Cost-effectiveness of improved hypertension management in India through increased treatment coverage and adherence: a mathematical modeling study. *Global Heart*. 2021;16(1):37. doi:10.5334/gh.952
32. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and

replication (TIDieR) checklist and guide. *BMJ*. 2014;348:g1687. doi:10.1136/bmj.g1687
33. Riebe D, Ehrman JK, Liguori G, Magal M, eds. ACSM's guidelines for exercise testing and prescription. *American College of Sports Medicine*. 10th ed. Wolters Kluwer; 2018:397.
34. Chandrasekaran B, Reddy KC. Six-minute walk test as a guide for walking prescription for patients with chronic obstructive pulmonary diseases. *Ind J Respirat Care*. 2018;7:73-76. doi:10.4103/ijrc.ijrc_19_17
35. Gellish RL, Goslin BR, Olson RE, McDonald A, Russi GD, Moudgil VK. Longitudinal modeling of the relationship between age and maximal heart rate. *Med Sci Sports Exercise*. 2007;39(5):822-829. doi:10.1097/mss.0b013e31803349c6
36. Lasco G, Mendoza J, Renedo A, et al. Nasa Dugo ('It's in the Blood'): lay conceptions of hypertension in the Philippines. *BMJ Glob Health*. 2020;5(7):e002295. doi:10.1136/bmjgh-2020-002295
37. Whellan DJ, O'Connor CM, Lee KL, et al. Heart failure and a controlled trial investigating outcomes of exercise TraiNing (HF-ACTION): design and rationale. *Am Heart J*. 2007;153(2):201-211. doi:10.1016/j.ahj.2006.11.007
38. Nicolson PJA, Hinman RS, Wrigley TV, Stratford PW, Bennell KL. Self-reported home exercise adherence: a validity and reliability study using concealed accelerometers. *J Orthop Sports Phys Ther*. 2018;48(12):943-950. doi:10.2519/jospt.2018.8275
39. Bollen JC, Dean SG, Siegert RJ, Howe TE, Goodwin VA. A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. *BMJ Open*. 2014;4:e005044. doi:10.1136/bmjopen-2014-005044
40. Newman-Beinart NA, Norton S, Dowling D, et al. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the exercise adherence rating scale (EARS). *Physiotherapy*. 2017;103(2):180-185. doi:10.1016/j.physio.2016.11.001
41. Adhikari SP, Dev R, Shrestha JN. Cross-cultural adaptation, validity, and reliability of the Nepali version of the exercise adherence rating scale: a methodological study. *Health Qual Life Outcomes*. 2020;18(1):328. doi:10.1186/s12955-020-01588-6
42. Glasgow RE, Harden SM, Gaglio B, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health*. 2019;7:64. doi:10.3389/fpubh.2019.00064
43. Kwan BM, McGinnes HL, Ory MG, Estabrooks PA, Waxmonsky JA, Glasgow RE. RE-AIM in the real world: use of the RE-AIM framework for program planning and evaluation in clinical and community settings. *Front Public Health*. 2019;7:345. doi:10.3389/fpubh.2019.00345
44. Orem DE. *Concepts of Practice*. 3rd ed. McGraw-Hill; 1985.
45. Han H-R, Lee H, Commodore-Mensah Y, Kim M. Development and validation of the hypertension self-care profile: a practical tool to measure hypertension self-care. *J Cardiovasc Nurs*. 2014;29(3):E11-E20. doi:10.1097/JCN.0b013e3182a3fd46
46. World Health Organization. *WHODAS 2.0 Translation Package (version 1.0) Translation and Linguistic Evaluation Protocol and Supporting Material [Internet]*. WHO; 2010. Accessed February 24, 2023. https://terrance.who.int/mediacentre/data/WHODAS/Guidelines/WHODAS%202.0%20Translation%20guidelines.pdf
47. DeVito Dabbs A, Song MK, Hawkins R, et al. An intervention fidelity framework for technology-based behavioral interventions. *Nurs Res*. 2011;60(5):340-347. doi:10.1097/NNR.0b013e31822cc87d
48. Smits DW, van Meeteren K, Klem M, Alsem M, Ketelaar M. Designing a tool to support patient and public involvement in research projects: the involvement matrix. *Res Involv Engagem*. 2020;6:30. doi:10.1186/s40900-020-00188-4
49. Zhao Y, Ni Q, Zhou R. What factors influence the mobile health service adoption? A meta-analysis and the moderating role of age. *Int J Inf Manag*. 2018;43:342-350. doi:10.1016/j.ijinfomgt.2017.08.006

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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