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A formative evaluation of potential barriers and facilitators to inform effective implementation of a community-based hypertension care program in rural South Africa: The IMPACT-BP trial

Shafika Abrahams-Gessel [a,1,*], Thabang Manyaapelo [b,1], Nsika Sithole [b], Siphephelo Dlamini [c], Nondumiso Mpanza [b], Samukelisiwe Nxumalo [b], Thabisile Mjilo [b], Joanna Orne-Gliemann [d], Max Bachmann [e], Nombulelo Magula [f], Alison Castle [b,h], Mark J. Siedner [b,f,g,h,1], Thomas Gaziano [a,h,i,1]

[a] Harvard TH Chan School of Public Health, Center for Health Decision Science, 718 Huntington Avenue, Boston, MA 02115, United States
[b] Africa Health Research Institute, 719 Umbilo Road, Durban, R618 to Hlabisa, Somkhele, KwaZulu-Natal, South Africa
[c] Kwazulu-Natal Province, Department of Health, D850 Road, Msiyane Area, Jozini, KwaZulu-Natal 3969, South Africa
[d] University of Bordeaux, National Institute for Health and Medical Research (INSERM) UMR 1219, Research Institute for Sustainable Development (IRD) EMR 271, Bordeaux Population Health Centre, Bordeaux, France
[e] Norwich Medical School, University of East Anglia, Norwich NR47TJ, United Kingdom
[f] Division of Internal Medicine, University of KwaZulu-Natal, Medical School, Private Bag 7, Congella, Durban, KwaZulu-Natal 4013, South Africa
[g] Division of Infectious Diseases, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114, United States
[h] Harvard Medical School, 220 Longwood Avenue, Boston, MA 02115, United States
[i] Division of Cardiology, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115, United States

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ABSTRACT

Background: In rural KwaZulu-Natal Province, South Africa, less than 25 % of persons with hypertension have controlled blood pressure. We conducted a formative evaluation of current clinic-based care to identify barriers and facilitators that could impact effective implementation of a community-based hypertension intervention (IMPACT-BP).

Methods: We conducted individual interviews and group discussions with clinic managers, nurses, community health workers (CHWs), community leaders, and patients to identify barriers and facilitators experienced in clinic-based hypertension care, which could affect the acceptability, feasibility, and implementation of the IMPACT-BP intervention. The Conceptual Model of Implementation Research and the Theoretical Framework of Acceptability guided the design of data collection instruments and analysis. Qualitative data collection was performed by trained social science research assistants, recorded, transcribed, translated, and analyzed using thematic analysis.

Results: Forty-one participants (92 % women) participated in group discussions (n = 32) or individual interviews (n = 9). Barriers to intervention acceptability and feasibility included inadequate levels of staffing, high patient volumes, distrust of CHWs' work at clinics and in the community, and insufficient training and equipment for CHWs. Facilitators included home delivery of medications by CHWs.

Conclusions: Our findings allowed us to identify specific adaptations to the intervention implementation strategy to make the proposed community-based intervention acceptable and feasible in this setting. Adaptations included employing dedicated CHWs and nurses for trial-related activities, developing an expanded CHW training module on hypertension knowledge, teaching CHWs to measure blood pressure and subsequently train patients to do the same, and training CHWs to educate patients about hypertension management.

* Corresponding author.
E-mail address: sabraham@hsph.harvard.edu (S. Abrahams-Gessel).
[1] These authors contributed equally to the manuscript.

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1. Background

Uncontrolled hypertension is one of the greatest risk factors for noncommunicable disease-related morbidity and mortality, including myocardial infarction, stroke, and heart failure (Forouzanfar et al., 2017). In rural KwaZulu-Natal (KZN), South Africa, fewer than one in four persons with hypertension have their condition under control (Wong et al., 2021) and many have limited understanding of their condition (Rampamba et al., 2017). Interventions designed to improve control of hypertension emphasize increasing patient knowledge about their condition and continuous monitoring at regular intervals (Owusu et al., 2018; Rampamba et al., 2019). Primary health centers (PHCs) struggle to encourage patients with hypertension to attend regular follow-up care to achieve control (Siedner et al., 2018). A multi-pronged approach that enhances compliance and support is necessary to improve management of hypertension in this region. A strategy proposed by the South Africa National Department of Health is to improve health system infrastructure to allow for community-based programs that can aid in detection, treatment and care of people with chronic, non-communicable diseases (NCDs) (National Department of Health South Africa, 2022). With this strategy, hypertension management at the community level requires effective, multi-sectoral collaboration between the community, local government health stakeholders, and researchers. Although South African government policies for management of NCDs have been developed with this inclusive approach in mind, its implementation has not yielded the desired results in terms of improved control of NCDs and their risk factors (Ndinda et al., 2018).

Community health workers (CHWs) are key members of the local ward-based primary care clinical outreach teams (OTs) outlined in the national government's re-engineered strategy (Thomas et al., 2021; National Department of Health South Africa and Health Do, 2018) and their role is to provide community-based outreach that links patients to primary care services for the majority of the South African population, which was historically disadvantaged through the unequal distribution of resources under Apartheid (Ataguba et al., 2015; Clarke et al., 2008). Consistent with this national strategy is the provincial KwaZulu-Natal Department of Health's strategic goals to improve control of NCDs and their risk factors through increased screening and treatment in community settings (Health K-NDoP, 2019). The effectiveness of programs that include CHWs as part of the outreach teams to provide home-based care in South Africa has been shown to lead to improvements in maternal, child, (Horwood et al., 2017; Stansert Katzen et al., 2020) and HIV (Thomas et al., 2021) health care delivery but there is no evidence on the impact of improving hypertension control. A recent randomized clinical trial in Argentina demonstrated that CHW-led community-based management of hypertension that combined education, monitoring of blood pressure, and delivery of health messages via SMS significantly improved uncontrolled hypertension (He et al., 2017).

Despite these demonstrated successes, barriers to the optimal delivery of CHW services have been reported. These include lack of support and supervision from other members of primary care clinical outreach teams, insufficient resources to execute their expected functions, inadequate training, and inadequate compensation (Naidoo et al., 2018; Ngcobo et al., 2022; Abrahams-Gessel et al., 2015). These barriers can lead to failures in the implementation of evidence-based public health interventions in South Africa (Klingberg et al., 2021).

Knowledge and skills training of CHWs in the area of NCDs, including hypertension management, have been poor, and, despite the intent, few community-based chronic disease care programs have been converted from the conceptual and pilot phase to routine practice (Sengwana and Puoane, 2004; Tsolekile et al., 2014). A recent process evaluation of the implementation of primary care outreach teams (OTs) in South Africa showed that despite the national strategy of expanding community-based care programs through the primary care OTs and strategic goals to improve NCD and HIV-specific services, there were significant deficits that persisted (Mantell et al., 2022). These gaps were found in areas such as the necessary improvements in training CHWs, providing them with adequate supervision in their delivery of community-based services, integrating CHWs effectively with staff at health facilities, insufficient salaries, and the consistent provision of adequate and functioning equipment.

All these factors ultimately affect the ability of the health system to provide effective community-based programs to manage NCDs. As described in detail elsewhere, the IMPACT-BP trial intervention seeks to address these many challenges by shifting the management of persons with uncontrolled hypertension from the primary health centers to patients' homes through a combination of intervention approaches that include patient self-monitoring, CHW home visits to collect blood pressure (BP) data and provide medications, and remote nursing monitoring and decision making with the support of a mobile health application (Sithole et al., 2023). Training patients to measure their own BP at home will promote self-efficacy and eliminate the need for patients to travel far and spend money to have their BP measured at the health center. Nurses will be empowered to remotely review BP data, current medication use, and history of allergies to make treatment decisions using guidelines-based treatment recommendations generated by the clinical decision support tool in the integrated intervention app. The app uses automated alerts to notify the CHWs when the medications based on the nurse's treatment decision is ready for pickup and delivery to the patient's home. This combination of patient measurement of BP, CHW home visits, transmission of data to the CDS that makes treatment recommendations for nurses, and alerts to notify CHWs to deliver prescribed medications, allow for nurses and CHWs to work efficiently as a team to provide community-based hypertension care using the OT model.

We report the results of a formative evaluation that sought to proactively identify barriers and facilitators currently experienced with clinic-based care that could affect the feasibility, acceptability, and planned implementation strategy for the community-based hypertension management program in the IMPACT-BP trial. This evidence is also intended to inform the design of other community-based chronic disease models of care in similar LMIC settings.

2. Methods

2.1. IMPACT-BP trial intervention

The IMPACT-BP program (Sithole et al., 2023) aims to evaluate a technology-supported, community-based intervention to improve blood pressure control among people with hypertension in the rural district of uMkhanyakude, KwaZulu-Natal province. The overall assessment of the IMPACT-BP trial intervention is comprised of three sequential stages: (1) a formative evaluation of potential barriers and facilitators in current clinic-based care, and evaluating its impact on the feasibility, acceptability, and implementation strategy for the proposed community-based intervention, as reported in this analysis; (2) implementing the intervention in a three-arm parallel group individually randomized control trial to evaluate the effectiveness of the intervention on study outcomes; (3) a post-trial evaluation of the intervention's effectiveness, fidelity, acceptability, sustainability, and cost-effectiveness. The intervention for the trial was designed in collaboration with the KwaZulu-Natal Department of Health and utilizes CHWs to deliver medication and conduct home visits with patients, self-monitoring of blood pressure measurements by patients in their homes using electronic devices, and the use of a linked electronic application by nurses located at PHCs to remotely monitor and manage hypertension. The control arm for the study provided standard of care and, unlike the two intervention arms, did not require participants to measure their own blood pressure at home using an automated blood pressure cuff.

2.2. Design of formative evaluation

We conducted a qualitative study using semi-structured individual interviews and group discussions with key informants in the rural district municipality of uMkhanyakude in KZN. Results of our qualitative assessment are reported as per the Consolidated criteria for reporting qualitative studies (COREQ) checklist (Tong et al., 2007).

2.3. Participant selection

A purposive sample of key stakeholders were invited by study team members to participate in the formative evaluation and the sample was designed to capture feedback from key actors in the communities involved in the delivery (health care workers), facilitation (outreach team leaders, facility managers), and beneficiaries (patients) of the IMPACT-BP intervention. Key informants, invited for individual interviews, were representatives of the KZN Department of Health involved in primary health care delivery programs, a ward councilor, and a traditional community leader. Health care workers (nurses, CHWs, managers) and patients seeking care at local primary health centers (PHCs) in the rural uMkhanyakude District were invited to participate in group discussions facilitated by trained study team members. Health care workers and CHWs, all currently employed by PHCs in the district, were identified through limited employment rosters. Patients were at least 18 years old, diagnosed with uncontrolled hypertension, and attended one of the local PHCs in the district for nurse-supervised treatment.

2.4. Ethics

All those invited to participate had the option to decline without incurring penalties, including loss of employment or demotion, or loss of access to health care services at the PHCs. Those who agreed to participate signed a written informed consent form, prior to participating in any data collection activity. The study protocol was reviewed and approved by the KwaZulu-Natal Department of Health and the University of KwaZulu-Natal Biomedical Research Ethics Committee (BREC; Protocol Number: 00003383/2021) and the Mass General Brigham Institutional Review Board (Protocol Number: 2021P003469). Collected data were securely stored and confidentiality of participants' identities was maintained by using a unique participant ID number.

2.5. Study instruments

We developed semi-structured individual interview guides and group discussion guides using the proposed logic model for the intervention, focusing on the following areas affecting management of hypertension: current challenges with clinic-based care delivery, potential barriers and facilitators for the proposed community-based intervention, and necessary adaptations to the implementation strategy for the intervention.

We also developed these data collection instruments guided by the Conceptual Model of Implementation Research (CMIR) (Proctor et al., 2011) and the Theoretical Framework for Acceptability (TFA) (Sekhon et al., 2017). The CMIR guided the assessment of the acceptability and feasibility of the intervention at the individual (e.g., patients' understanding of hypertension) and organizational levels (e.g., level of resources available at clinics to manage hypertension), as well as the readiness for intervention implementation with specific questions related to the feasibility using available resources (e.g., likely effect of increasing the responsibilities of the CHWs), the acceptability of the intervention to participants, and beliefs about managing hypertension (Supplemental File 1). The TFA supported further refining guide questions by focusing on building trust (e.g., HCWs' beliefs about the patient's ability to participate in managing their hypertension) and engagement with the intervention (e.g., patients measuring their BP at home). The data collection instruments were piloted among the team of social scientists using mock interviews to check the flow of questions and appropriateness of the language.

2.6. Data collection procedures

Prior to data collection, the study team held a series of meetings with DoH officials to review the elements of the proposed intervention and its impact on achieving blood pressure control for participants with hypertension. These meetings allowed the research team to obtain the necessary permissions to access the Department of Health (DoH) facilities, staff and patients for the trial activities. A social scientist with extensive experience in qualitative data collection and analysis (TM) trained a team of three research assistants (RAs) over two weeks to become familiar with the IMPACT BP trial. Key informant interviews were scheduled at the convenience of the participant and conducted by the social scientist and a RA via telephone or in person. The interviews were conducted mostly in isiZulu, with English used intermittently, when necessary. The four GDs were conducted in isiZulu in person by at least two trained RAs: a lead RA facilitating the discussion and the second acting as a rapporteur. The GDs were conducted at a venue that was convenient and accessible for all participants.

All interviews and GDs were digitally recorded, transcribed *verbatim* by translators proficient in isiZulu, and then translated into English for use in the analysis. All transcripts were de-identified to ensure anonymity of the participants.

2.7. Final sample size for analysis

Forty-one persons (3 males) consented to participate in either group discussions (n = 32) or individual informant interviews (n = 9). Most of the participants were between the ages of 40 – 59. Thirteen CHWs, five heath care workers, eight patients with uncontrolled hypertension, and six outreach team leaders (OTLs) participated in group discussions, separated by participant type. Outreach team leaders are typically professional nurses who supervise CHWs in the ward-based primary health care teams that are organized to provide integrated primary care services to individuals, families and households within specified geographic areas. Nine individual interviews (7 females) were conducted with key informants that included district and provincial health officials and community leaders.

Data collection was conducted from January to May 2022.

2.8. Analysis

The analysis and data collection were supervised by a social scientist (TM) and an implementation researcher (SAG). Both the transcriptions and translations were quality checked by a senior RA. The RAs who participated in the interviews summarized the data on the same day to capture the highlights, as did the RAs who acted as rapporteurs during group discussions. The purposeful sampling was designed to collect data from multiple informants directly impacted by primary health care services and thus data saturation was defined as the observed repetition of themes across data collection activities (discussion groups and informant interviews) when rapporteur summaries were reviewed by the discussion group facilitator or interviewer who led the data collection activities. These summaries were also used to check the data quality and consistency of the transcriptions and translations of these activities. A codebook was developed, based on the topics and themes of the interview guides. All transcripts were read, and deductively coded using the data management software NVivo version 12. Recognizing that systems, individuals, and the environment all overlap in both clinic-based and community-based care, we organized the results of this analysis into the three areas of inquiry that guided our data collection (e.g., current challenges with clinic-based care delivery, their potential to serve as either barriers or facilitators for the proposed community-based

intervention, and subsequent adaptations made to the intervention implementation strategy).

The study team met with provincial and district health officials, and community leaders to review the results of the preliminary findings to identify which intervention areas/processes could be feasibly targeted for implementation adaptation, within the framework of current provincial policies to manage chronic conditions. These meetings also established acceptable parameters for adaptations proposed by the study team. Next, the study team finalized adaptations to the target areas/processes to finalize the intervention implementation strategy, as summarized in Table 1. The study team also met with operational team leaders and managers at PHCs to review how to operationalize the proposed adaptations to the intervention implementation to ensure transparency and continued cooperation.

3. Results

3.1. Current barriers in clinic-based hypertension care

Respondents reported having to simultaneously contend with high patient volumes, inadequate staffing, and equipment challenges in hypertension care at the primary health centers (PHCs).

Clinics typically have 120 – 180 patients seeking care daily, often leading to long wait times to see a formally trained health care worker (HCW) for assessment, due to an insufficient number of nurses working at PHCs. In the CMIR framework, the severe lack of trained HCWs is a barrier to feasible clinic-based hypertension management programs.

Although CHWs are meant to be working in the community in the outreach team model for primary care, nurses will engage CHWs in task-sharing measurement of blood pressure to assist them with handling the patient load, despite most CHWs reporting that they only received *ad hoc* training to perform this task. This lack of standardized training in tasks that CHWs are expected to perform on demand leads to a lack of trust between CHWs and their nurse colleagues when viewed through the TFA framework and is also a barrier to the acceptability of the intervention at both the individual and organizational levels in the CMIR framework.

> *". we have never received training about the BP machine, but we were taught by sisters in the mobile clinic, I know because they will allocate me on the BP machine, I know how to read the high and low BP and to see the pulse, but I have never received the training." - GD, CHWs*

> *"I am saying as my colleagues are saying, there was no training that we were called for, I learned alone in the mobile clinic because there was no one who was allocated in the BP machine."* – GD, CHWs

Lack of sufficient, functional equipment at both the health centers and for use in community settings presents a significant barrier to the feasibility and acceptability of interventions when viewed through the CMIR. For example, lack of functional equipment prevents CHWs from effectively monitoring blood pressure in both the primary health centers and in community settings.

> *"The problem that we have is that we do not have a BP machine to check them at home because I am unable to take treatment for her continuously. That is what they [patients] wish for. I will tell her to go to the clinic to check her BP because the clinic does not have a car to go to the community with us [CHWs] to check the granny at home"* - GD, CHWs

The inadequate resources can also lead to CHWs believing that patients often distrust them and have low confidence in the care they provide at patients' homes because patients see their lack of basic supplies as a reflection of the low value assigned to their work.

> *"Sometimes when you go to people's households making your visits, you will find maybe a bedridden person who needs diapers and gloves. You will find that you manage to help her [by bringing the household diapers from the clinic]. They [household] will no longer buy the diapers, they will depend on the clinic whereas we do not get them all the time. In the end*

Table 1
Implementation adaptations applied to the IMPACT-BP intervention in response to qualitative results.

	Level of Evaluation	Target areas/ processes for adaptation	Adaptations made to intervention implementation strategy [Frameworks]
[A] Challenges in the current clinic care system (system and individual)			
• Staff shortages	System Individual	1) Nursing staff responsibilities and ability to supervise CHWs. 2) Shortage of CHWs.	1) Supervision of study CHWs conducting field work performed by nurse managers employed by the study. *[CMIR: acceptability; feasibility; supervision]* 2) After discussions with DoH, the program employed their own CHWs to serve study participants and renamed them community blood pressure monitors (CBPMs). *[TFA: burden; perceived effectiveness]*
• Trust	System Individual	3) Inadequate CHW training to understand background knowledge of hypertension as a disease; no formal training to measure blood pressure BP; lack of proper equipment for blood pressure monitoring	3a) Expanded and implemented current DoH CHW training module on hypertension. *[CMIR: acceptability; feasibility]* 3b) Modified current DoH CHW training module to include training the CBPM to use automated BP cuffs for BP measurement. *[TFA: self-efficacy; perceived effectiveness]*
[B] Potential barriers and facilitators to community-based care			
• Concerns about current CHW workload	System Individual	1) CHW current workload.	1) Established a maximum number of patients to be assigned to each CBPM.
• Insufficient training of CHWs	System Individual	2) Insufficient CHW training	2b) Trained CBPMs to use two different brands of automatic BP cuffs, including calibration and maintenance. 2b) Trained CBPMs to train patients to use the blood pressure cuffs to monitor blood pressure daily.
• CHW concerns about community conditions	System Individual	1) CHW safety; CHW travel distances to patient homes	3a) Used GIS-guided mapping to assign CBPM coverage area. 3b) Defined individual CBPM coverage areas within a reasonable traveling distance from his or her home, within the

(*continued on next page*)

Table 1 (*continued*)

	Level of Evaluation	Target areas/ processes for adaptation	Adaptations made to intervention implementation strategy [Frameworks]
[A] Challenges in the current clinic care system (system and individual)			
			community where the CHW resides.
• Patient challenges	System Individual Environment	3) Patient self-efficacy; patient lack of knowledge to manage their blood pressure	4a) Trained CBPMs to train patients to use the blood pressure cuffs to monitor blood pressure daily. 4b) Developed a comprehensive health education module on BP control to be used by CBPMs in patient homes. Module included information about managing risk factors and the importance of adhering to treatment, as prescribed.

BP: Blood Pressure
CHWs: Community Health Workers
CBPM: Community Blood Pressure Monitor
DoH: Department of Health

they will say that a community care giver [CHW] is not working, she is not giving us what we want, " – GD, CHWs

Participants also reported that standard equipment required for hypertension care, e.g., functioning blood pressure cuffs, are often not available nor functional, making screening and triaging of patients very challenging. This situations presents a serious barrier to effective implementation of interventions at an organizational level in the CMIR framework. It can also lead to patients not trusting the skills of the CHWs working at the health centers and prevent patients from trusting CHWs who provide care, resulting in another barrier to intervention feasibility and acceptability when viewed through the TFA.

"Another thing that is troublesome is our BP reading machines that are always faulty. Some of them are battery used and at times we do not get those batteries because there is no stock available then find that we cannot test patients their blood pressure readings because the machine is not functional. We know that it is important because it would be strange to find that the patient honored their clinic visit and leave feeling a headache, or we hear that they collapsed outside and all that could result from the fact that their vital signs were not taken. Shame, our managers do place orders for new machines, and I will be talking ill of them if I say that they do not however, their orders do not arrive and so such things hinder our work from flowing" – GD, OTLs

This mix of high patient volume, improvised task-sharing with CHWs, inadequate physical equipment resources at PHCs, and variable trust between nurses and CHWs, creates challenging team dynamics for the ward-based primary care outreach teams who provide clinic-based primary care services.

A significant concern of CHWs was that implementation of the intervention would negatively impact their current burden of assigned duties and that the change would not be reflected in their remuneration. Both of these concerns are barriers to the acceptability of the intervention when assessed using the CMIR framework.

Walking is the primary mode of travel for CHWs from their own homes to their patients' households and PHCs and environmental conditions can be unsafe. Those who lived farthest from their assigned households and PHCs are unable to perform outreach services at the same level of efficiency as CHWs whose homes are closer to their designated coverage areas.

Many CHWs reported safety concerns about working in the community.

"How do I go about doing that, on my first visit, maybe I am visiting that area, if you approach someone's household, you salute to that household, when they allow you to enter, sometimes you will find that the family member is in a mental state, and he is carrying a bush knife, the other thing I would like to warn my colleagues about is that we need to be careful of those people like that when entering people's households because there are many people who suffers from that illness" – GD, CHWs

A significant concern of CHWs was that implementation of the intervention would negatively impact teh current burden of duties assigned to CHWs and that the change would not be reflected in their remuneration. The OTLs also noted that CHWs have an expectation of additional compensation when asked to take on additional responsibilities and this was borne out by feedback from CHWs themselves.

"My question is that, if this thing happens, this BP thing, they will say that we must check people at home, are we going to get a raise?" - GD, CHWs

3.2. Perceived barriers and facilitators to community-based care

3.2.1. Engaging patients to be effective partners in managing their hypertension – the interaction of education, lifestyle, and social factors

Nurses and CHWs expressed concern regarding the ability of patients to be effective in managing their own blood pressure (BP). For example, some health workers do not believe that patients understand blood pressure and its effect on health, and they also see health education as a critical tool to overcoming this barrier.

"Yes, so, health education plays a huge role because most of them drink it (treatment) when going to sleep, now they will not sleep at night, that is why they are supposed to be taught that they need to take treatment after breakfast so that you will urinate while you are still up you see. Teach her to understand what they are suffering from, because what is disadvantageous to make BP disease untreatable, people don't understand what BP is" – GD, HCWs

Patients reported their own frustrations with the hypertension care received and felt that they are not given enough information to allow them to better understand their condition or treatment. For example, changes in the physical characteristics of medications (e.g., color and shape of pills) due to prescription changes or medication stockouts confuse patients and they feel that these changes are often poorly communicated to them by health workers. Within the TFA, this undermines an individual's sense of self-efficacy and would likely result in them not accepting the intervention.

"I have experienced and you find that they give us one type of medication and your system gets used to them then, when you go to your next appointment you find that they have changed your pills [generic] to a different kind and so that thing happens repeatedly and it is upsetting to us and to our health [F: oh do they change them?] yes, and when you ask them and tell them that these are not the ones that I am used to they just tell you that it is the same thing but when you look at them you can see that they are not the same, the box and the shape are different [P4: yes, and they tell you that these ones are out of stock, take these ones] and when you start taking the new ones they make you feel tired" – GD, Patients

Healthcare workers also felt that patient preference to use traditional remedies was a barrier to engaging with hypertension care management.

"So other patients are in denial, and they want to continue using traditional herbs and they believe that they will normalize their blood pressure" – GD, OTLs

Patients did report often learning from their peers by sharing alternative (traditional) methods of treatment and recognized that this sometimes did not help with managing their blood pressure.

"It is the Zulu traditional medicines, yes. I remember that it went on to be two people coming to sell and I ended up buying some and I kept sipping and drinking it and, on my next clinic visit they could not detect my blood pressure. They exclaimed when the reading said it was thirty-five and they told me that I was going to die" – GD, Patients

Although patients reported they were aware that diet plays an important role in maintaining good health and in controlling BP, independence and social support impacts their ability to comply with healthcare advice. For example, some were dependent on family members for meal preparation and did not have other sources of social support to arrange for alternative meal preparation.

"I think another issue that can cause this is because sometimes it is our grandchildren who prepare and cook meals at home. They turn to put too much cooking oil. They don't measure oil quantity whereas, we know that you are supposed to measure them with a lid … another thing is mixing soup that they add, and it has lots of salt. We are warned not to use too much salt and my grandchild can prepare a meal in their own style and that can increase blood pressure" - GD, Patients

Outreach team leaders shared concerns that older patients would not be able to handle measuring their own BP due to perceived challenges with technology. The OTLs observed that older patients especially struggle with using cellular phones already and would thus struggle with measuring their own blood pressure using an automated blood pressure cuff.

"*Yes, you see the ones who are in their 70 s or 80 s, they may really struggle with using modern day technology and they may call their children or grandchildren to help them with navigating the system. Some of them can't even dial up numbers when they want to make a phone call and they still require the assistance of the younger generation to dial up for them and their job is holding the phone and so now you can reason how it would be if they have to take their blood pressure reading and they may even not understand how to insert the arm cuff you see that and so how would they be able to send the results back to the clinic automated system"* – GD, OTLs

The CHWs and patients did not express a concern about the use of technology by patients.

3.2.2. Support for care provided by CHWs in community settings

Community health workers reported that patients appreciated having their medications delivered to them at their homes because of the high cost of traveling to the PHCs and thus, the CHWs believed that patients would appreciate the home monitoring of blood pressure embedded in the intervention.

"I can say that it helps them to collect treatment for them because they are reduced. If they take treatment for themselves, they end up not going to the clinic because it is far, and they need transport fee. ……. I am unable to take treatment for her continuously, that is what they wish for. – GD, CHWs

The CHWs also believed that training them to measure blood pressure and equipping them with functioning blood pressure cuffs would increase their credibility with patients in the community.

"They want tangible things, when we are upgraded maybe they will see that this is a real thing and it is going well because we usually carry Vitamin and D worm for babies and the mothers will be happy and if we are carrying the machine, the standard will be high" - GD, CHWs

3.2.3. Lack of support from Outreach Team Leaders for care provided by CHWs in the community

The lack of trust in the work performed by CHWs at health centers can also extend to the work they perform in community settings, further undermining the feasibility of an intervention at the systems level when applying the CMIR, or through lack of trust when applying the TFA. Some CHWs reported that nurses often appear to not trust the ability of CHWs to perform their assigned tasks in patients' homes. The CHWs felt that this was the reason nurses often ignored or discounted the patient information that they provided, or did not value the their patient referrals to the PHCs. This organizational culture in which formally trained health professionals do not trust the work performed by team members without professional training can be a barrier to both the feasibility and acceptability of an intervention, in the CMIR framework, through low uptake by formally trained health professionals.

"I do not know whether they are lazy to write, I do not know, we think that they are lazy to write because they are supposed to write on the referral about how she assisted the client, what she helped the client with, she has seen the client and gave him 1, 2 and 3. I even take a picture using my phone to be sure that the patient was given treatment which shows that the patient went to the clinic and received assistance but the nurse who was assisting the patient did not take the referral. You see, I have a client that I referred last week, she came back and told me that the nurse neglected her when she tried to give her the referral letter, I eventually left the consultation room without the nurse filling in the referral letter" – GD, CHW

"Yes, we come across that challenge because you will find that the nurse will say… how can I put this, I will just say it as it is, sometimes the nurse does not take notice if a patient gives her the referral from a community care giver [CHW]. The nurse would say that she will look it at later, you understand…we report it to our OTL (Outreach Team Leader)… right now it is a bit better because they were able to take the referral letter, (but) there are loopholes here and there" – GD, CHW

3.3. Adaptations to the intervention implementation strategy

Barriers (described above) and facilitators (described below) in both health center and community-based settings were identified using the CMIR and TFA frameworks, at both the individual and health system levels. Facilitators to intervention acceptability and feasibility included the provision of formal training for CHWs to measure blood pressure (BP), CHWs training patients to use automated blood pressure cuffs to measure their own BP at home, and CHW delivery of chronic medications to patients' homes.

After consulting with health officials and clinic managers and reviewing the results of this analysis, the study team designed a set of adaptations to enhance the implementation of the IMPACT-BP intervention prior to starting enrollment. These adaptations are summarized in Table 1.

At the clinic level (systems level factors in the CMIR framework), adaptations focused on alleviating the high patient load on current health care workers, addressing the lack of adequate training of CHWs in blood pressure measurement, and addressing CHW concerns about the community environment in which they provided outreach services. The trial team hired dedicated nursing staff to take on the responsibility of supervising the field work performed by CHWs, which would ordinarily be performed by OTLs.

In consultation with the Department of Health, the trial team hired their own CHWs to perform trial activities in addition to the existing package of services assigned to CHWs by the DoH. The trial team used the DoH hiring criteria, including salary parity, to find suitable candidates. These trial CHWs were assigned the title of Community Blood Pressure Monitor (CBPM), to avoid being confused for DoH CHWs. Community Care Givers (CCGs) is a title that has been used in this setting

previously, hence, some of the participants in this analysis use this title to describe their experiences with CHWs employed by the DoH. The trial team expanded the DoH module on hypertension training to include hypertension-specific educational interventions and training CBPMs to measure blood pressure using two types of electronic blood pressure cuffs. The CBPMs were also trained to provide in-home training to intervention arm patients for measuring their own blood pressure using the automated blood pressure cuff randomly assigned to them for the trial. Collectively, these adaptations were designed to promote self-efficacy among CHWs to execute trial-related tasks and also increased the acceptability of the intervention to CHWs. The training of CHWs and provision of automated blood pressure cuffs were designed to promote trust in the work performed by CHWs for formally trained health professionals on their OTs at the health centers, as well as among the community members that were to be enrolled in the trial.

To address work environment concerns, CBPMs were assigned a maximum of 30 patients to monitor in the community. The coverage area and assigned patient households for a given CBPM was calculated to be within a reasonable walking distance from, and including, the CBPM's own home.

This approach mirrors the approach of the DoH.

Hiring the CBPMs for the trial also allowed the DoH to benefit from expanded coverage of households by CHWs throughout the catchment area.

4. Discussion

In this formative evaluation we learned that community-based programs to manage disease in the primary care outreach team model in rural KwaZulu-Natal are impacted by existing challenges at both individual and organizational factors at primary health care centers (PHCs), as well as cultural and environmental characteristics of the communities themselves. The low number of male health worker participants is consistent with the sex distribution in the South African public health work force, which is approximately 78 % female (Matseke, 2023). The proportion of male respondents among patients is consistent with low health-seeking behaviors for men at primary health centers due to the stigma associated with HIV-infection, as well as not feeling welcome (Chikovore et al., 2016).

We found that current clinic-based care challenges include inadequate staffing levels to match high patient volume, and insufficient training of community health workers (CHWs) to execute their assigned tasks. Current community-based care is hampered by poorly equipped CHWs, insufficient patient knowledge about hypertension, preference for traditional remedies among patients, and lack of social support. Patients appreciate the convenience and cost-saving aspects of CHW monitoring at home but also have a level of distrust of the quality of care provided by CHWs due to their lack of proper training and equipment. Community health workers who are tasked with implementing the community-based model of primary health care described challenges related to a severely under-resourced health system. These include inadequate numbers of CHWs, limited resources for disease management, which hinders performance and reflects poorly on them as providers, safety concerns about community-based work and insufficient or total absence of training in chronic disease care, including hypertension. This combination of factors leads to fractured confidence and complex relationships between CHWs and both their nurse supervisors and their clients.

Proper training of CHWs in the measurement of blood pressure has the potential to overcome multiple barriers observed in this evaluation: improve the effectiveness of task-sharing, reduce the burden on nurses managing high patient volumes at the primary health centers (PHCs), build trust between members of the primary care outreach teams as part of community-based management of hypertension, increase CHWs' sense of self-efficacy, and build trust between CHWs and their patients.

Task-sharing between professional and lay health workers can be effective in interventions to manage BP in LMIC (Anand et al., 2019) and can also alleviate the challenges of high patient volumes in the PHCs. Community health workers can take on the task of measuring BP but training for this task is currently not part of the standard Department of Health (DoH) training curriculum for CHWs, despite CHWs being assigned to manage BP in community settings. Community health workers believe that comprehensive training to measure blood pressure, combined with the provision of functional equipment, would enable them to effectively alleviate patient loads at PHCs and to also provide community-based care for hypertension that is trusted by both patients and other health care workers in the primary care outreach teams. In the PHCs, nurses may trust the BP measurements taken by formally trained CHWs during screening intake and trust that patients with high BP will be correctly triaged during that visit. In community-based management of hypertension, nurses may similarly accept the validity of BP measurements made by properly trained CHWs with functional BP cuffs and use it to manage hypertension. The CHWs may also experience greater self-efficacy in their ability to perform community-based monitoring of patients with hypertension. In response to this critical gap in skills for measuring BP in this setting, we amended the trial implementation plan by expanding the standard DoH training curriculum for our trail CHWs to include measurement of BP with electronic BP cuffs, along with expanded knowledge of hypertension risk factors, treatment adherence, and lifestyle changes. We hypothesize that our expanded training in hypertension knowledge and BP measurement should positively affect the perception of CHW skills by health care workers, thus enhancing the effective implementation of the proposed trial intervention. In addition, based on our observations in this study, training CHWs to measure BP could facilitate building trust with the patient and overcome the observed barrier of patient distrust of CHWs' work due to poor training and lack of equipment. Training CHWs to measure BP would likely have to be performed by nurses and require refresher training to ensure maintenance of the skill, both of which could potentially have a negative impact on the amount of time nurses have to devote to patients. Alternately, at a health systems level, adequate training resources would have to be factored into the overall resource requirements for community-based management of hypertension.

The importance of context has been shown to be a key factor in the design of effective programs that utilize CHWs in LMIC (Scott et al., 2018). In response to concerns about introducing an added workload for current DoH CHWs, we consulted with the DoH and adapted the trial implementation plan by hiring dedicated CHWs for the trial. We used the DoH hiring criteria, salary levels and assigned a trial-specific title - community blood pressure monitors (CBPMs) - to avoid confusion with CHWs already employed by the DoH as part of primary care outreach teams. The CBPMs also performed usual tasks assigned to DoH CHWs, including household registration and profiling of all household members, screening for HIV, and referring patients to the clinics for other health issues, e.g., tuberculosis. We also hired dedicated study nurses to supervise the trial CBPMs to avoid adding to the workload of the DoH nurses who would be managing hypertension of trial participants. The IMPACT-BP intervention app used automated alerts that were dependent on specific actions taken by both CHWs and DoH nurses, to provide virtual supervision of CHWs, supplemented by weekly in-person meetings when CHWs would collect medications to deliver to patients. However, supervision in the health system is not automated or tied to a regular in-person activity that would require the CHW to meet with the DoH nurse at the clinic on a regular basis. Therefore, overall supervision of CHW activities may need to be assigned to a member of the OT that is not the nurse responsible for managing hypertension.

Environmental challenges, including safety concerns, within the communities included in the trial were noted by CHWs in this evaluation and had to be addressed as part of the trial implementation plan. Given that our CBPMs primarily had to walk to households assigned to them in the community, we used geographical information system (GIS) mapping to define CBPM-specific areas within the community to assign

household coverage. The mapping was based on the CBPM's home address and proximity to areas being served by other CBPMs. We also implemented a cap to the number of patients assigned to individual CBPMs at 30, with the expectation that this will mitigate both the added workload and environmental challenges faced by CBPMs when delivering services in this district.

We also observed a set of barriers identified by patients as part of their experience of managing their own high BP: self-efficacy, support structures, and cultural norms. We trained our CBPMs to teach patients to measure their own BP using two automated BP cuffs and this would potentially increase the confidence and self-efficacy of patients for managing their own awareness of their hypertension. Patients reported feeling unsupported by their families in their attempts to manage their blood pressure, especially with meal preparation. Health education equips patients with better knowledge of their condition and can lead to improved outcomes (Paczkowska et al., 2021). The CBPM training was expanded to include an educational module for educating patients about the importance of adhering to treatment and lifestyle recommendations to control BP. When patients are shown to have more confidence in the care they receive, it leads to better outcomes (Owens and Keller, 2018).

In a recent mixed-methods evaluation of community-based interventions for diabetes and hypertension in low resource settings, the interventions did not result in significantly better hypertension management (Flor et al., 2020). The evaluation included two interventions in rural South Africa and India that focused primarily on screening for hypertension and diabetes in community settings using clinic-based primary care teams in which CHWs or lay health workers were responsible for community-based monitoring of hypertension. These interventions found similar barriers (e.g., limited resources to manage hypertension effectively; over-burdened health facilities and staff) and facilitators (e.g., home delivery of chronic medications to patient homes; training CHWs to educate patients about managing their condition) impacting community-based management of hypertension. However, while these programs included individual elements of the IMPACT-BP intervention, it did not combine them into a comprehensive community-based program to manage hypertension. This formative evaluation provides insight into how the combined effects of barriers and facilitators experienced in clinic-based hypertension programs can inform effective implementation of a community-based, integrated, multi-component hypertension management program.

4.1. Strengths and limitations

We identified areas to target to improve the feasibility and effectiveness of the intervention implementation strategy prior to commencing enrollment in the IMPACT BP trial. The inclusion of multiple stakeholders in this analysis and ongoing consultations with the DoH throughout the design and implementation phase of the planned intervention ensured support for the trial and its potential to be scaled, if successful. A noted limitation was that male participation in this formative evaluation was low.

5. Conclusions

This formative evaluation showed that community-based hypertension care in rural South Africa was perceived to be desirable by a wide range of stakeholders. Barriers and facilitators identified in the current experience of clinic-based hypertension management in this study, directly informed the design of proactive adaptations to the planned implementation of the community-based intervention to enhance its feasibility and acceptability to key stakeholders, before commencing enrollment for the IMPACT-BP trial. Adaptations included providing CHWs with comprehensive background education about hypertension, training them to measure blood pressure and to teach patients to use automated blood pressure cuffs, establishing designated coverage areas for CHWs proximate to their own homes, and capping the number of households assigned to them. If the IMPACT-BP intervention is effective in improving hypertension management, it will provide important evidence that multi-component, community-based interventions that proactively identifies adaptations to implementation by reviewing existing barriers and facilitators in community and health center settings, can be effective within the South African model of primary care outreach teams. The final phase of analyzing the overall effectiveness of the IMPACT-BP trial will provide important information about the fidelity, scalability, and cost-effectiveness of multi-component community-based interventions to manage hypertension and potentially other non-communicable diseases.

Authors' contributions

TM, NM, and SAG analyzed and interpreted all the qualitative data. TM, NM, SN, JM, NS, and SD all contributed toward the collection of the data. SAG, TM, JOG, MB, NM, AC, MS and TG all contributed toward the design of the study and data collection. All authors provided input and approved the final manuscript.

CRediT authorship contribution statement

Bachmann Max: Writing – review & editing, Methodology, Investigation, Conceptualization. **Orne-Gliemann Joanna:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Mjilo Thabisile:** Writing – review & editing, Validation, Data curation. **Castle Alison:** Writing – review & editing, Project administration. **Magula Nombulelo:** Writing – review & editing, Conceptualization. **Manyaapelo Thabang:** Writing – review & editing, Writing – original draft, Validation, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Gaziano Thomas:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Abrahams-Gessel Shafika:** Writing – review & editing, Writing – original draft, Validation, Supervision, Methodology, Investigation, Formal analysis, Conceptualization. **Siedner Mark J.:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Dlamini Siphephelo:** Writing – review & editing, Project administration, Data curation. **Sithole Nsika:** Writing – review & editing, Project administration, Data curation. **Nxumalo Samukelisiwe:** Writing – review & editing, Validation, Formal analysis, Data curation. **Mpanza Nondumiso:** Writing – review & editing, Validation, Supervision, Formal analysis, Data curation.

Consent for publication

Not applicable.

Ethics approval and consent to participate

The study protocol was reviewed by the University of KwaZulu-Natal's Biomedical Research and Mass General Brigham's Ethics Committees. This study was approved by the South African Health Products Regulatory Authority (SAHPRA Trial Number: N20211201) and also registered with the South African Clinical Trials Registry (SANCTR Number: DOH-27–112022-4895).

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Declaration of Interest Statement

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Declarations

Not applicable.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ssmhs.2025.100086.

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