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Protocol for a controlled before-after quasi-experimental study to evaluate the effectiveness of a multi-component intervention to reduce gaps in hypertension care and control in low-income communes of Medellin, Colombia

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ABSTRACT

Introduction Research on public health interventions to improve hypertension care and control in low-income and middle-income countries remains scarce. This study aims to evaluate the effectiveness and assess the process and fidelity of implementation of a multi-component intervention to reduce the gaps in hypertension care and control at a population level in low-income communes of Medellin, Colombia.

Methods and analysis A multi-component intervention was designed based on international guidelines, cross-sectional population survey results and consultation with the community and institutional stakeholders. Three main intervention components integrate activities related to (1) health services redesign, (2) clinical staff training and (3) patient and community engagement. The effectiveness of the intervention will be evaluated in a controlled before-after quasi-experimental study, with two deprived communes of the city selected as intervention and control arms. We will conduct a baseline and an endline survey 2 years after the start of the intervention. The primary outcomes will be the gaps in hypertension diagnosis, treatment, follow-up and control. Effectiveness will be evaluated with the difference-in-difference measures. Generalised estimation equation models will be fitted considering the clustered nature of data and adjusting for potential confounding variables. The implementation process will be studied with mixed methods. Implementation fidelity will be documented to assess to which degree the intervention components were implemented as intended.

Ethics and dissemination The study protocol has been approved by the Ethics Research Committee of Metrosalud in Colombia (reference 1400/5.2), the Medical Ethics Committee of the Antwerp University Hospital (reference 18/40/424) and the Institutional Review Board of the Antwerp Institute of Tropical Medicine (reference 1294/19). We will share and discuss the study results with the community, institutional stakeholders and national health policymakers. We will publish them in national and international peer-reviewed scientific journals.

Trial registration number NCT05011838.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We respond to exhortations to rigorously evaluate multi-component interventions to improve hypertension care and control in low-income and middle-income countries.
⇒ The planned intervention is based on formative research and inspired by guidelines from international hypertension care initiatives and has been adapted to the local environment with the participation of all relevant stakeholders.
⇒ We employ a controlled before-after quasi-experimental study design.
⇒ We will rely on quantitative outcomes and qualitative process assessments, and combine effectiveness and implementation fidelity indicators to better inform subsequent adaptation and scaling up.
⇒ The intervention will be implemented in a low-income area of an industrialised city in a middle-income country, and results may not be generalisable to upper-class urban zones or underserved rural settings.

INTRODUCTION

Non-communicable diseases accounted for 73.5% of global deaths in 2017.[1] Their incidence is disproportionately increasing in low/middle-income countries (LMICs),[2] and they constitute the first cause of mortality and disability in the Americas region, generating at least 5.5 million deaths each year.[3] Notwithstanding, most Latin American and Caribbean health systems provide inadequate

chronic disease management.[4] Globally, only about one in ten people with chronic conditions are successfully treated.[5] Moreover, most out-of-pocket health payments and catastrophic expenditures are related to such conditions.[6 7]

Uncontrolled hypertension is the main modifiable risk factor for cardiovascular diseases (CVDs) and is associated with more than 10 million deaths worldwide each year.[8] Almost 75% of people suffering from hypertension live in LMICs, where disease awareness is low, and healthcare access is limited.[9 10] High disease prevalence and poor hypertension control are pivotal factors in the rising epidemic of CVDs in LMICs,[11] where they mainly strike the working-age population and further hamper economic growth and social development.[10] Among the 1.6 million people who yearly die from CVDs in Latin America and the Caribbean, half a million are below 70 years old.[12] Nevertheless, limited research in this field has been performed in LMICs.[13]

A multi-country cross-sectional study conducted between 2003 and 2009, including 14 LMICs,[14] found a prevalence of hypertension of 27.7% in adults, with only 46.5% and 32.5% of hypertension awareness and control, respectively, among the affected. A 2019 review focusing on LMICs[15] pooled individual-level hypertension data on people aged 15 years and older from 44 countries and found a 17.5% hypertension prevalence. Of the hypertensive individuals, 39.2% were aware of their condition, 29.9% received pharmacological treatment and barely 10% attained controlled blood pressure (BP). These reports provide information on hypertension control internationally and on variations among populations. Most studies assessing patient and healthcare provider barriers to hypertension care have been conducted at the health facility level and in high-income countries.[13] Research at the population level to document in-depth and to tackle the main gaps and barriers hampering equitable and effective hypertension care and control in LMICs is needed.

The Chronic Care Model[16] and its expanded version[5] aim to guide interventions for improving chronic disease management. It is the basis of the Standardised Hypertension Treatment and Prevention (SHTP) Project,[17] developed by the Pan American Health Organization and the Centres for Disease Control and Prevention. The SHTP Project identified six key elements to strengthen health systems at the primary care level and to improve hypertension control, using evidence-based components: guideline-based standardised treatment protocols; effective drug procurement mechanisms using a core set of medications; registries for cohort monitoring and evaluation; patient empowerment; team-based care system and community engagement.[17] This approach was reinforced by the WHO Global Hearts Initiative, primarily through the Technical Package for Cardiovascular Disease Management in Primary Health Care.[18] Operational research to assess the impact of this and other similar strategies is urgently advocated.

The objective of the present study is to evaluate the effectiveness of a multi-component intervention to reduce the gaps in hypertension care and control in low-income communes of Medellin, Colombia. In addition, we aim to assess the process and fidelity of the intervention's implementation.

Rationale

In 2016, we conducted a cross-sectional survey in a low-income commune of Medellin[19] to estimate the prevalence of hypertension in the adult population and the magnitude and determinants of the main gaps in hypertension care and control. The definitions of those gaps are shown in table 1. In summary, we found a hypertension prevalence of 43.5%, and 28.2% aware and 15.3% unaware hypertensive individuals. Moreover, among the

Table 1 Main gaps in hypertension care and control—definitions

Gap	Numerator	Denominator
Diagnosis gap	Number of unaware hypertensive individuals*	Number of unaware hypertensive individuals plus Number of aware hypertensive individuals†
Follow-up gap	Number of aware hypertensive individuals who did not attend a follow-up consultation during the last year	Number of aware hypertensive individuals
Pharmacological treatment gap	Number of aware hypertensive individuals who received a prescription but either: ► Do not take the drugs. ► Or are non-adherent.	Number of aware hypertensive individuals who received a prescription for antihypertensive medication
Control gap	Number of aware hypertensive individuals who did not manifest controlled hypertension‡	Number of aware hypertensive individuals

*Unaware hypertensive individual: participant not reporting a previous diagnosis of hypertension but presenting an average blood pressure measurement higher than 140/90 mm Hg in the survey.
†Aware hypertensive individual: participant reporting a previous diagnosis of hypertension.
‡Controlled hypertension: see text for precise definition.

Table 2 Potential determinants at the health provider, population and health system level of the main gaps in hypertension care and control

Gap	Level		
	Health provider	**Population**	**Health system**
Diagnosis gap	No measurement of blood pressure during healthcare contacts High blood pressure is detected, but confirmation of diagnosis fails due to a lack of continuity of care	Low-risk perception of hypertension Mild or no symptoms determine delayed healthcare-seeking	Passive and fragmented health services Limited opening hours of services for hypertension screening
Quality of care (treatment and follow-up gaps)	No pharmacological advice/ consultation Limited communication skills of health staff and the poor doctor–patient relationship Interrupted delivery of essential antihypertensive drugs	Low awareness of the importance of non-pharmacological treatment Low educational level hampers communication and treatment compliance	Scarcity of essential antihypertensive drugs Administrative barriers imposed on patients and health providers

Santa Cruz Commune. Medellin, Colombia, 2016.

aware persons, 14.4% presented a follow-up gap, 93.4% were prescribed antihypertensive drugs, 38.9% were not compliant and 39.0% were uncontrolled. The survey results, the—hypothesised—possible determinants of the identified gaps (table 2), and potential solutions were discussed with communities, service providers and institutional stakeholders in a series of workshops. Based on the workshops' conclusions, in consultation with the main stakeholders and inspired by the SHTP Project and the WHO Global Hearts Initiative,[17 18] we designed a multi-component intervention to improve hypertension care and control in Medellin.

METHODS AND ANALYSIS

Overview of study design

The effectiveness of a multi-component intervention in reducing gaps in hypertension care and control will be

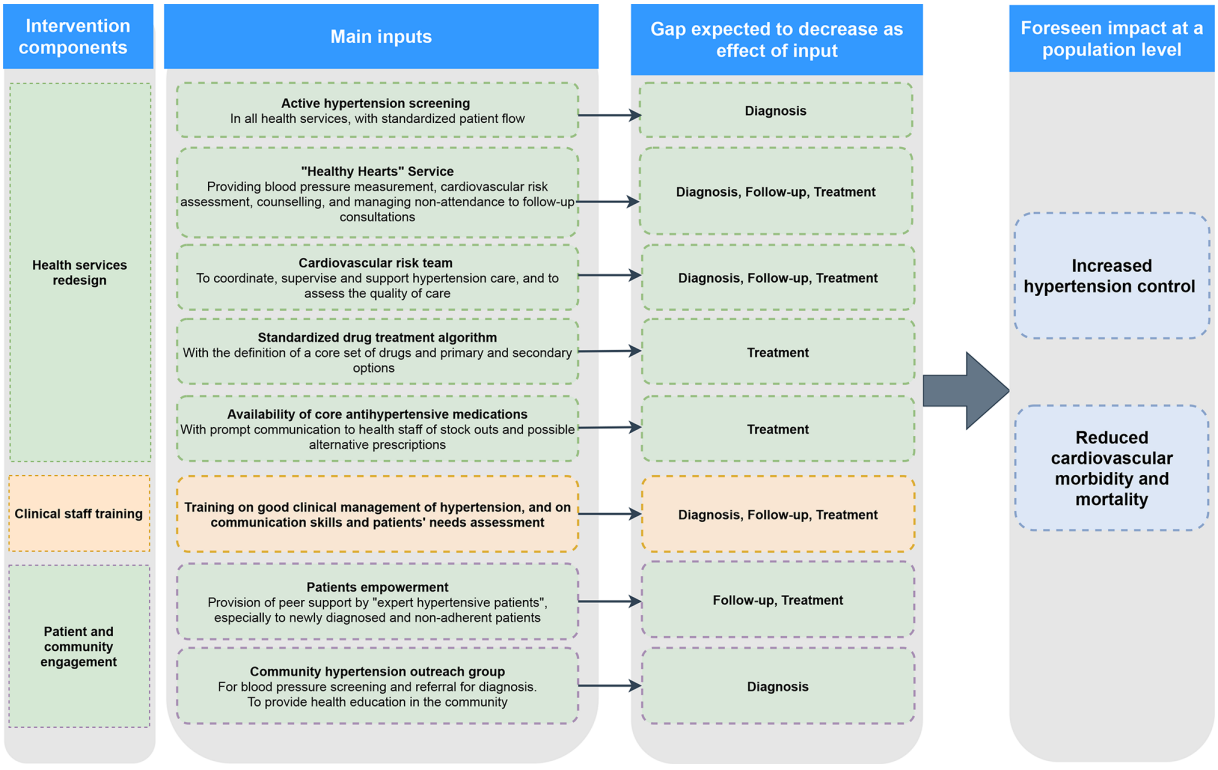

Figure 1 Model conceptualising the theory of action of a multi-component intervention to improve hypertension care and control in low-income Medellin, Colombia.

evaluated in a controlled before-after quasi-experimental study. A graphical summary of the underlying theory of action is depicted in figure 1. Besides outcomes, the process and implementation fidelity will be studied to assess to which degree the intervention components were implemented as intended. The study will use mixed methods, comprising a baseline and an endline population survey, medical records and healthcare registers analysis, self-registration forms of intervention activities, non-participant observations and interviews with key informants such as healthcare staff, managers and patients and their caregivers. The intervention will start in the first quarter of 2023 and be evaluated after 24 months.

We checked the completeness and accuracy of our research protocol using the Standards for Quality Improvement Reporting Excellence reporting guidelines (online supplemental file 1).

Patient and public involvement

From the onset of the planning phase of the intervention onwards, the main community and institutional stakeholders—the local patient's association, the community representatives to the city council, managers and clinical staff of the city's public health provider (Metrosalud) and public health practitioners from the University of Antioquia—were invited for and participated in a series of workshops to discuss the results of the previous formative research. Hence, patients, community and institutional stakeholders actively proposed pathways to improve hypertension care and control within the community and at the health facility level. We will continuously further involve all local stakeholders in monitoring, analysing and learning from the forthcoming intervention.

Study setting and population

Colombia is a middle-income country with a 2019 per-capita gross domestic product of US$6429 (current US$).[20] The mortality from CVDs in 2017 was 150.3 per 100.000 population, and 30.5% of all deaths and 16.7% of years of life lost can be attributed to CVDs.[21] The Colombian health system has two different health insurance schemes run by health insurance companies. People able to contribute and their beneficiaries are compulsorily affiliated to the contributory scheme, which covers the formally employed workers, pensioners and part of the self-employed. The state finances the subsidised scheme, which protects people who cannot afford contributions.

Medellin is the second-largest industrialised city in Colombia. It has 16 communes, and its total 2016 population was around 2.5 million.[22] The intervention will be implemented in Commune 2, northeast of Medellin. Commune 6, located northwest of Medellin, was selected as the control area to deliver routine care. Both communes are among the most deprived areas of the city[23] and share similar characteristics: urban setting, low-income population, typical functioning of the national health system and commitment of Metrosalud—the city's public healthcare provider—to develop improvement programmes based on research results.

Intervention

A multi-component intervention to improve hypertension care and control will integrate activities related to (1) health services redesign, (2) clinical staff training and (3) patient and community engagement. Each intervention component will be standardised, and its related activities described in detail in a field manual. The intervention will be implemented by health services staff with technical assistance from the investigators. The three components of the intervention are detailed in the following sections.

Health services redesign

'Healthy Hearts' service

A nursing station will be established to provide BP measurement, cardiovascular risk assessment and preventive counselling during extended opening hours. It will secure hypertensive patients' effective follow-up, especially for presumptive hypertensive individuals and those newly diagnosed. The service will facilitate serial, automated, self-measured BP testing to confirm diagnosis within the health facility premises in order to exclude white coat hypertension. It also will administer periodical anonymous exit questionnaires to patients that attended hypertension-related consultations to assess the quality of care. Results will be communicated to the cardiovascular risk team for analysis.

Hypertension screening

The healthcare flow for patients with a high BP measurement will be standardised using a written procedure. All adults attending health services who did not have their BP measured by a healthcare provider in the previous year will be referred to the Healthy Hearts service for screening. Furthermore, doctors and nurses fortuitously encountering presumptive hypertensive individuals will refer them to the Healthy Hearts service to confirm the diagnosis.

Clinical management

Creation of the cardiovascular risk team

A group of doctors supervising clinical hypertension management and coordinating action plans for improvement. It will conduct audits, periodically selecting a representative sample of clinical records of hypertensive patients and use a structured questionnaire to evaluate the fulfilment of the requirements of a complete cardiovascular risk assessment interview and physical examination, doctors' adherence to guidelines and the quality of the provided care. It also will supervise the Healthy Hearts service. This operational body will hold weekly meetings and provide regular feedback and support to health professionals involved in hypertension care.

Guideline-based standardised diagnostic and treatment protocols

A simplified diagnostic and treatment algorithm based on the national clinical guidelines and in line with the

Global Hearts Initiative will be agreed on with the general direction of Metrosalud, the direction of the health area and the clinical staff. It will identify a core set of primary and secondary options within each of the major classes of antihypertensive medication.

Availability of antihypertensive medications

It will be assured through procurement mechanisms agreed with the central drug store of Metrosalud. To timely inform on the possible need for alternative prescriptions, the availability of antihypertensive medications will be communicated to clinicians at the beginning of each week and ad hoc in case of stock-out.

Clinical staff training

Training on good clinical management of hypertension

It will be focused on correct BP measurement, use of evidence-based guidelines, cardiovascular risk assessment, a standardised diagnostic and treatment algorithm, correct prescription of pharmacological and non-pharmacological treatment, patient counselling and prevention of clinical inertia.

Training on communication skills and patients' needs assessment

This training will be designed under the 'patient-centred medicine' framework,[24] aiming to equip all health workers involved in hypertension care with tools for understanding patients' feelings and experiences of illness and improving their capacity to address social, psychological and behavioural dimensions of hypertension care.

Patient and community engagement

Patients' empowerment

'Expert hypertensive patients', under the supervision of a social worker, will provide support and transmit their know-how to other patients in need, particularly those newly diagnosed or non-adherent to treatment or presenting uncontrolled hypertension.

Community engagement

A Community Hypertension Outreach Group will be set up, composed of existing voluntary community health workers, who will be trained and certified. This group will conduct BP measurements in selected public areas of the commune, referring those with positive screening to the nearest health facility for diagnosis confirmation. It will also provide health information with an emphasis on healthy lifestyles. Additionally, local communication channels such as the community radio and the local newspaper will be engaged.

Effectiveness assessment

The primary outcome will be the control gap in the total hypertensive population (aware and unaware hypertensive individuals). The secondary outcomes will be the diagnostic, treatment, follow-up and control gaps defined in table 1.

Inclusion and exclusion criteria for the baseline and endline surveys

Eligible persons will be all 35 years or older permanent inhabitants of the selected communes, willing and able to provide written informed consent. Potential participants with a mental disability or unable to answer the questionnaire will be excluded.

Sample size and sampling procedures for the surveys

Expecting at baseline 60% non-control in the 35 years or older hypertensive population and at endline 10% difference in difference (baseline minus endline) between the intervention and control arms, a sample of 385 hypertensive individuals per arm is required for 80% power and a 95% confidence level. Given a 45% prevalence of hypertension in individuals aged 35 years or older, screening 856 individuals will allow finding the needed number of hypertensive individuals. We will increase the number screened to 1190 individuals, assuming 10% non-response and, based on previous observations, a design effect of 1.25 for our sampling scheme.

A cluster sample will be drawn from a sampling frame consisting of the addresses of all premises provided by the municipality and using maps of Medellin detailing house blocks. Given an average of 1.5 individuals ≥35 years old per household, 795 households will be sampled per study arm by selecting 53 clusters of 15 households from the different neighbourhoods of the communes, with an allocation of the number of clusters proportional to neighbourhood size. A group of trained interviewers will make up to two repeat door-to-door visits to every selected household to include all identified eligible household members aged 35 years or older in the surveys.

Data collection

Using a structured questionnaire, participants will be interviewed on sociodemographic characteristics, health-seeking behaviour, cardiovascular risk factors and previous hypertension diagnosis. In addition, participants aware of being hypertensive will be questioned on their follow-up, antihypertensive pharmacological and non-pharmacological treatment, and treatment compliance. BP will be measured using a digital manometer, following international recommendations for standardised BP measurement in population surveys.[25 26]

Operational definitions for the surveys

Hypertensive individual

Self-report of previously diagnosed hypertension or without a previous diagnosis but presenting an average repeat BP measurement equal to or higher than 140/90 mm Hg.[14 27]

Controlled hypertensive individual

Self-report of previously diagnosed hypertension and an average repeat BP measurement of less than 140/90 mm Hg for patients between 35 and 59 years old or diabetic patients and below 150/90 mm Hg for patients aged 60 years or older.[28]

Table 3 Performance indicators at the health facility level

Indicator	Operational definition
Number of hypertensive patients enrolled in the Cardiovascular Risk Programme (CVRP)	Number of hypertensive patients enrolled in the CVRP
Prevalence of diagnosed hypertension in the catchment area	Number of hypertensive patients enrolled in the CVRP/Total catchment population
Ratio of the prevalence of diagnosed hypertension to the expected prevalence of hypertension in Metrosalud's catchment area	Prevalence of diagnosed hypertension in Metrosalud's catchment area/Expected prevalence of hypertension in the population for whom Metrosalud is responsible in the catchment area
New hypertensive patients enrolled in the CVRP	Total number of new hypertensive patients enrolled in the CVRP per month
Cardiovascular risk assessment	Hypertensive patients with a recorded cardiovascular assessment in the last year/Number of hypertensive patients enrolled in the CVRP
Prevalence of high (calculated) cardiovascular risk	Hypertensive patients with calculated cardiovascular disease risk ≥20% in 10 years and systolic blood pressure (BP)≥140/90 mm Hg at the last BP measurement during the previous year/Number of hypertensive patients enrolled in the CVRP
Prevalence of controlled hypertension	Hypertensive patients with documented systolic BP<140 mm Hg and diastolic BP<90 mm Hg in the most recent BP measurement during the last year/Number of hypertensive patients enrolled in the CVRP
Prevalence of controlled hypertension 6 months after enrolment in the CVRP	Hypertensive patients who started treatment 6 months before and had systolic BP<140 mm Hg and diastolic BP<90 mm Hg at follow-up visit/Number of hypertensive patients enrolled in the CVRP during the last 6 months
Uncontrolled hypertension in patients with cardiovascular disease, renal disease or diabetes	Hypertensive patients diagnosed ≥6 months before the start of the reporting period and cardiovascular disease, renal disease, or diabetes mellitus, who had systolic BP≥140 mm Hg or diastolic BP≥90 mm Hg at the most recent BP measurement during the last year/Number of hypertensive patients enrolled in the CVRP≥6 months before the start of the reporting period
Uncontrolled hypertension	Hypertensive patients diagnosed ≥6 months before the start of the reporting period who had systolic BP≥160 mm Hg or diastolic BP≥100 mm Hg at the most recent BP measurement during the last year/Number of hypertensive patients enrolled in the CVRP≥6 months before the start of the reporting period
Resistant hypertension	Hypertensive patients diagnosed ≥6 months before the start of the reporting period and who are treated with three or more antihypertensive drugs, who had systolic BP≥160 mm Hg or diastolic BP≥100 mm Hg at the most recent BP measurement during the last year/Number of hypertensive patients enrolled in the CVRP≥6 months before the start of the reporting period
Six-monthly control of blood pressure among people who started pharmacological treatment for hypertension	Number of patients who began pharmacological treatment for hypertension during the quarter that ended 6 months before, with controlled blood pressure (SBP<140 and DBP<90) at the last clinical visit in the most recent quarter (just before the reporting quarter)/Number of patients started on the pharmacological treatment of hypertension during the quarter that ended 6 months before.

BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.

Data analysis

The difference-in-difference measures[29 30] will be calculated (endline-baseline changes in the intervention minus endline-baseline changes in the control commune) for the primary and secondary outcomes. Where relevant, we will stratify on affiliation to subsidised or contributory insurance schemes. Generalised estimation equation models will be fitted, considering the clustered nature of the data, and adjusting for potential confounding variables. Unadjusted and adjusted ORs and their 95% CI will be calculated. The Statistical Package for Social Sciences V.24 (SPSS Inc) will be used for data analysis.

Assessment of the implementation process and fidelity

The indicators to measure results at the health service level are shown in table 3. They were elaborated considering the performance indicators proposed by the SHTP Project, the Global Hearts Initiative and other propositions to improve the global prevention and control of CVDs.[17 18 31 32] The indicators we constructed for monitoring implementation are listed in table 4. The needed data will be collected in the intervention and control areas, at baseline, during implementation and at the endline. Electronic clinical and billing records of Metrosalud, registers of the 'Healthy Hearts' service, exit interviews and clinical audits will be the data sources.

For assessing implementation fidelity,[33 34] we will use self-registration forms for specific intervention activities, alongside non-participant observations and semi-structured key informant interviews. Self-registration forms will be collected monthly to determine whether actual implementation is done as intended. We will also select a heterogeneous sample of activities to be observed purposively and actors to be interviewed. Observations will provide real-time information on implementation,

Table 4 Quantitative indicators for monitoring implementation

Indicator	Operational definition
Indicators related to BP screening and hypertension diagnosis	
Adequate availability of the Healthy Hearts service	Number of effective opening hours of the Healthy Hearts service in a week/Number of programmed opening hours of the Healthy Hearts service per week
Effective referral to the Healthy Hearts service and BP screening	Number of people without BP measurement in the last year and referred for BP measurement that reaches and receive BP screening at the Healthy Hearts service/Total number of people without BP measurement in the previous year referred for BP measurement to the Healthy Hearts service
Referral for serial BP measurement to the Healthy Hearts service	Number of patients not previously enrolled in the CVRP with high BP detected at the doctor or nurse consultation who are referred for serial BP measurement to the Healthy Hearts service during the reporting month/Total number of patients not previously enrolled in the CVRP with high BP detected at the doctors or nurses consultation during the reporting month
Implementation of serial BP measurements at Healthy Hearts service	Number of individuals with high BP detected by BP screening at the Healthy Hearts service who receive serial (≥3) BP measurements/Total number of individuals with high BP detected by BP screening at the Healthy Hearts service
Result of serial BP measurement	Number of patients with average systolic BP≥140 mm Hg or diastolic BP≥90 mm Hg at serial (≥3) BP measurement/Number of individuals receiving serial BP measurements
Implementation of serial self-measured BP monitoring	Number of patients with serial self-measured BP monitoring/Number of patients with indication of serial self-measured BP monitoring
Result of serial self-measured BP monitoring	Number of patients with average systolic BP≥140 mm Hg or diastolic BP≥90 mm Hg as a result of a serial self-measured BP monitoring/Number of patients with serial self-measured BP monitoring
Indicators related to the hypertension management programme	
Implementation of BP measurements by medical and nursing staff	Number of interviewed individuals referring that they had a BP measurement/Total number of exit-interviews
Missed hypertension-related appointment	Number of patients who missed their last hypertension-related appointment during the reporting week/Patients with scheduled hypertension follow-up visits during the reporting week
Correct prescription of pharmacological treatment	Number of patients who received a proper prescription of pharmacological treatment according to the clinical condition and defined algorithm/Total number of audited clinical records
Use of recommended antihypertensive drugs	Number of patients who received a prescription of antihypertensive drugs included in the standardised algorithm/Total number of hypertensive patients receiving pharmacological treatment in the audited clinical records
Pharmacological advice by the medical doctor during the consultation	Number of interviewed hypertensive patients who referred they received pharmacological advice by the medical doctor/Total number of exit interviews
Percentage of hypertensive patients who received prescription of non-pharmacological treatment	Number of interviewed who refer they received a prescription of non-pharmacological treatment by the doctor/Total number of exit interviews
Indicators related to the training of healthcare staff	
Trained healthcare professionals	Number of trained professionals
Effectiveness of training in improving clinical knowledge	Average post-test score minus average pretest score
Effectiveness of training on acquiring BP measurement skills	Number of trained professionals passing the post-training practical test/Total number of trained professionals
Indicators related to stock management and availability of the essential antihypertensive medication	
Number of weeks without availability of essential antihypertensive drugs	Number of weeks without availability of one or more essential antihypertensive drugs
Indicators related to patients and community engagement	
Attendance to peer support group	Number of hypertensive patients who participate in the meetings of the peer support group/Number of hypertensive patients enrolled in the CVRP eligible for peer support and referred
BP screening in the population by the Community Hypertension Outreach Group (CHOG)	Number of people screened and prevalence of high BP readings during the screening
Participation of community leaders in the meetings of the CHOG	Number of community leaders participating in the meetings of the CHOG/Total number of community leaders in the CHOG

BP, blood pressure; CVRP, Cardiovascular Risk Programme.

while interviews will throw light on observed practices and reasons for non-adherence. Additionally, overall experience with the intervention will be explored through in-depth interviews with stakeholders and patients. Data saturation will be considered to determine the frequency of observations and the number of interviews. A local social scientist will analyse data with NVivo V.10 (QSR International Pty LTD, Melbourne, Australia, 2010).

A senior sociologist not involved in data collection will review the coding consistency.

We will determine whether intervention components were implemented as planned or were modified, deleted or added[35] and assess adherence to the content and dose (ie, frequency, duration and coverage) of components and the influence of moderating factors such as comprehensiveness of intervention description, facilitation strategies, quality of delivery, recruitment, participant responsiveness and context. Factors influencing implementation will be classified using these pre-established categories, and aspects not matching this coding will be categorised as intervention-specific moderating factors.[36] Finally, reasons for adapting intervention components will be identified through an inductive thematic analysis of key informants' interview responses.

Finally, we will contrast outcome data with implementation data and triangulate quantitative and qualitative results obtained from different information sources to validate and complement our findings.

Data management

Databases will be electronically encrypted, and, when relating to individuals, a single study code will be assigned to each participant. The log of participant names and their assigned codes will be stored in a separate database with restricted access. For the surveys, questionnaires will be filled in employing tablets, and the information will be consolidated using an electronic platform. We will develop checks for data entry with built-in filters and logical constraints to assess the completeness and accuracy of our data. Recorded qualitative information will be transcribed *verbatim* by a local social scientist. Transcripts will be anonymised. Study-related material will be securely stored. Paper documents and tapes will be locked, and electronic databases and backup copies will be password protected. Data will be retained following local legislation.

Ethics and dissemination

The study will be conducted in accordance with the Declaration of Helsinki of research ethics. All field staff will be trained in responsible conduct of research. Informed consent will be obtained from survey participants and partakers in the qualitative research components (online supplemental file 2). A convenient place and time for interviews will be assured. Confidentiality will be guaranteed throughout. In particular, exit interviews will be anonymous and will not inquire into the identity of the health personnel the interviewee consulted with. Patients who are hypertensive in the survey and without follow-up or treatment will be referred for care to a provider of their health insurance scheme.

The planned intervention is based on formative research and inspired by guidelines from international hypertension care initiatives and has been adapted to the local environment with the participation of all relevant stakeholders. It does not pose health risks to beneficiaries as it implies implementing evidence-based best practices in the standard health setting. The local patients' association, study site health staff and Metrosalud central authorities have agreed on any new patient care procedure. All activities are implemented conditional on adjustment when needed and planned to be continued beyond the study period.

The study protocol (online supplemental file 3) has been reviewed and approved by the Ethics Research Committee of Metrosalud in Colombia (reference 1400/5.2), the Medical Ethics Committee of the Antwerp University Hospital (reference 18/40/424) and the Institutional Review Board of the Antwerp Institute of Tropical Medicine (reference 1294/19).

The study findings will be shared and discussed in workshops with the local health authorities, health staff, representatives of Metrosalud and patient organisations in view of adjusting activities where needed, strengthening sustainability and preparing to scale up the intervention. Finally, results will be further disseminated through the media, presented at national and international conferences and published in peer-reviewed scientific journals.

Implications of this research

There is an urgent need, particularly in LMICs, to develop and test public health approaches that tackle the rising burden of non-communicable diseases.[37] Doing so within an integrated framework of care will benefit all patients.[5] When developing our proposal, we started with the international hypertension initiatives' guidelines[17 18 31 32] and stepped them up considering the local context. We will thus implement and evaluate a comprehensive multicomponent strategy involving stakeholders from community members to health programme administrators, who all participated in the protocol's design. We believe this ensures social relevance and will increase intervention uptake at the health service and community levels.

The quasi-experimental nature of our design will provide solid evidence regarding the outcome of the intervention, which can form the basis for further economic evaluation. Relevant lessons will also be learnt on what functioned, for whom and why within a specific national health system's complex dynamics. While findings should not be extrapolated to upper-class urban zones or underserved rural areas, over half of the Colombian population lives in low-income urban environments, to which the results may be readily generalisable.

Our research closely involves Metrosalud, the most significant public healthcare provider of Medellin. This major stakeholder in the Colombian health system intends to further explore the effectiveness of the multicomponent hypertension care and control intervention in other health areas of its network. Based on the results of the present trial, replication studies will be set up to evaluate and contrast, using routine data, the outcomes of the strategy in rural and urban settings and health areas with different socioeconomic levels. Study findings can also inform and inspire other initiatives for better chronic care in LMICs, particularly in Latin America. Finally, assessing the implementation fidelity of the intervention

and its determinants may provide valuable insights into the scalability of the WHO Global Hearts Initiative.

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