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Research article

Community-based model for management and follow-up by non-physician healthcare workers to improve awareness, treatment, and control of hypertension: The COTRACO study protocol

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A B S T R A C T

Introduction: Cardiovascular diseases are the leading cause of death and morbidity worldwide, with a significantly higher burden in low- and middle-income countries. Hypertension, a major risk factor for cardiovascular morbidity and mortality, remains under-diagnosed and poorly controlled, especially in regions such as Latin America. The HOPE-4 study demonstrated that the involvement of non-physician health workers (NPHWs), the use of standardized treatment algorithms, the provision of free antihypertensive drugs and home follow-up can significantly improve hypertension control and reduce cardiovascular risk, as demonstrated in Colombia and Malaysia. On this basis, the COTRACO study aims to address the barriers to hypertension treatment in low- and middle-income countries by implementing a similar standardized treatment approach delivered by non-specialist health workers.

Methodology: The COTRACO study is a quasi-experimental, parallel-group, non-randomized, before-and-after study. A community-based model will be implemented in 600 patients in Colombia and the Dominican Republic, involving NPHWs to: 1) apply standardized treatment algorithms, 2) promote adherence to healthy lifestyles, and 3) provide standardized pharmacological treatment. Propensity Score Matching will be used to select 300 patients in Chile and 1200 in Spain for comparison with standard care in these populations.

Expected outcomes: The primary outcome at 12 months of follow-up is the percentage of patients achieving controlled hypertension (defined as systolic BP < 140 mmHg and diastolic BP < 90 mmHg, or < 130 mmHg, and diastolic BP < 80 mmHg for diabetic patients), ensuring it is not

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inferior to that achieved in the control countries. Secondary outcomes include changes in BP levels, cholesterol levels, BMI, handgrip strength, waist-to-hip ratio, smoking status, Interheart risk score, diet, and physical activity at 6 and 12 months.

Recommendations: If this model demonstrates superior outcomes compared to usual care, it is recommended that health authorities in low- and middle-income regions adopt and implement this approach. Using non-medical health professionals, standardized treatment algorithms and free access to antihypertensive medications, these regions can significantly improve awareness, diagnosis and management of hypertension. This strategy has the potential to reduce cardiovascular morbidity and mortality, thereby improving overall public health outcomes.

Detailed key messages:

- Previous evidence has shown that models of care implemented by NPHW based on: 1) simplified managements algorithms and counseling supervised by physician, 2) evidenced-based pharmacological treatment, and 3) treatment support; significantly reduce the cardiovascular risk and improve the hypertension control.
- The COTRACO study aims to implement a community-based model in Colombia and Dominican Republic, using NPHW to: 1) apply standardized treatment algorithms, 2) stimulate adherence to healthy lifestyles, and 3) provide standardized pharmacological treatment; to improve HT control and cardiovascular risk, as observed in the Spanish and Chilean (HIC) populations.

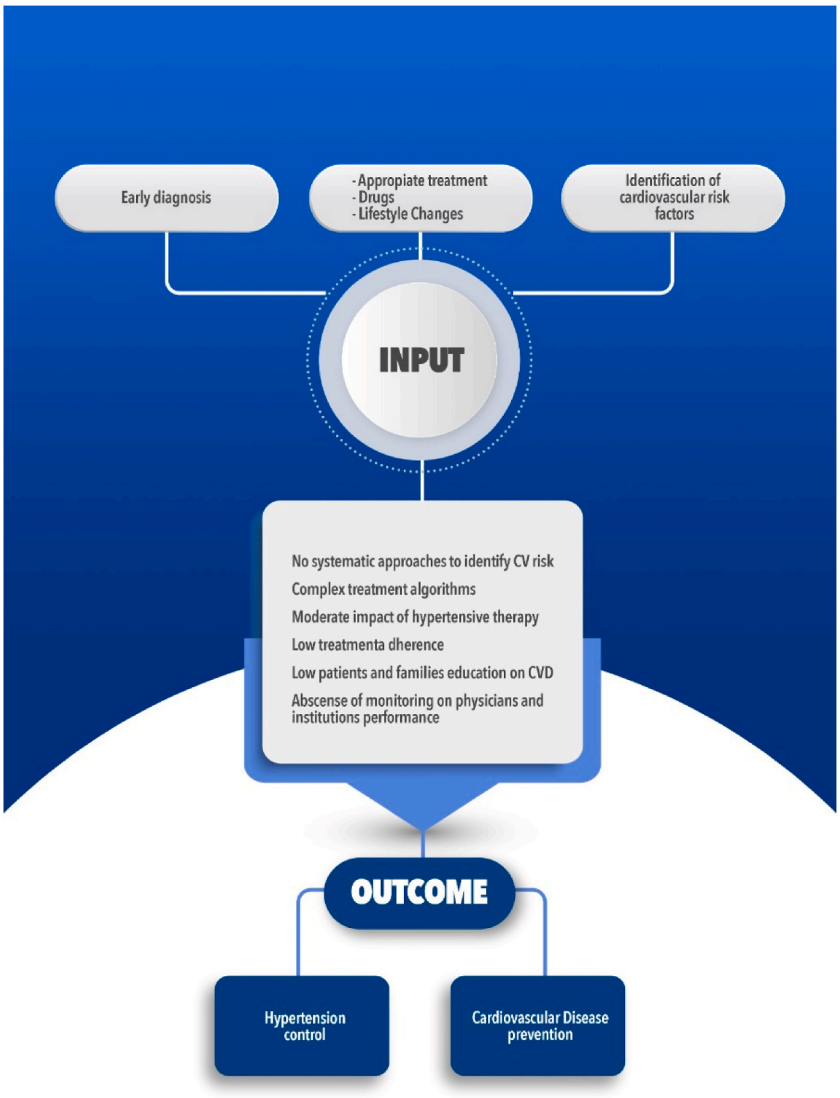

Fig. 1. Middle and low-income countries limitations regarding health care, diagnostic strategies, treatment, and control of risk factors for HT control and CVD prevention.

- If this model proves superior to usual care, health authorities can apply and enforce it in low-middle-income countries to improve HT awareness, diagnosis, and control.

1. Introduction

Cardiovascular disease (CVD) is the leading cause of mortality and morbidity globally. In 2019, it caused approximately 18 million deaths, corresponding to 32.2 % of deaths from all causes in both sexes, affecting 50 % of men and 40 % of women over their lifetimes [1]. CVD prevalence and mortality are decreasing in high-income countries, but it is increasing in middle- and low-income countries [2]. Moreover, in countries with lower incomes, CVD appears prematurely, causing an increase of three times in disability-adjusted life years than in high-income countries [3,4].

Hypertension (HT) is the leading preventable risk factor for developing CVD, affecting around 1.3 billion persons globally and is strongly related to the burden of CVD and premature death, increasing the years of life lost due to disability and associated health costs [5].

HT is a multifactorial disease influenced by and several factors, including blood pressure (BP) control, patient and disease conditions, health care providers, and health system [6]. Lifestyle changes and evidence-based therapy (with safe and low-cost medications) are practical approaches to improve HT control and decrease cardiovascular mortality and morbidity [7]. The Prospective Urban and Rural Epidemiology study (PURE) found that globally, the HT population attributable factor (PAF) for CVD and CV deaths are 22.3 % and 18 % respectively [8]. However, most persons with hypertension do not receive adequate diagnosis and treatment, with approximately 50 % of hypertensive patients undiagnosed. The PURE study also showed that in the participating South American countries (Argentina, Brazil, Colombia, and Chile), only 18.8–21.1 % of hypertensive participants had controlled BP levels (<140/90 mmHg) [3,8–11].

Different barriers interfere with HT diagnosis, treatment, and control, such as the cost of transportation from homes to health centers, copayments for antihypertensive therapy, and long waits for medical care appointments and consultations [12,13]. In addition, low income and education are also related to BP pressure control, factors that likely reflect differences in knowledge, health awareness, affordability, and access to care and medications [14,15].

Middle and low-income countries face limitations regarding health care, diagnostic strategies, treatment, and control of risk factors [6]: a) There are no systematic approaches to identify patients at risk or with HT and CVD. Primary care physicians have limited consultation time to document and analyze all potential risk factors of individuals; b) Initial treatment algorithms are complex and impractical; c) The use of antihypertensive drugs has had a moderate impact on hypertension control, possibly related to patterns of use and low adherence; d) Concomitant risk factors for HT and CV disease remain unattended; e) Lack of systematic effort to improve HT treatment adherence and to educate patients and families about influencing risk factors; f) Absence of monitoring tools to evaluate the performance of health professionals and institutions in HT control (Fig. 1). Improving this situation requires a systems-based approach that incorporates a of integrated actions, implementing an efficient HT awareness, treatment, and control program using a simplified, proven, safe, widely available, and cost-effective model [6].

To address these barriers, we previously developed the HOPE 4 study, involving 1299 patients with poorly controlled or newly diagnosed hypertension in Colombia and Malaysia. This study demonstrated that a care model involving NPHWs and addressing CVD risk factors using: 1) tablet computer-based simplified management algorithms and counseling programs supervised by physicians; 2) free antihypertensive and statin medication; and 3) support from a family member or friend (treatment supporter); significantly reduced the Framingham Risk Score (FRS) for 10-year CVD, blood pressure and LDL cholesterol It also achieved an HT control of 69 % in the intervention group compared to 30 % in the control group [16]. However, HOPE 4 did not compare the performance of the intervention with that in a high-income country (HIC), where HT control and CVD programs are better developed and achieve higher rates of CV risk control [11].

In this context, we describe an implementation project aimed at improving awareness, treatment, and control of HT through a multicenter study in Chile, Colombia, Dominican Republic, and Spain (COTRACO study). This project will use standardized treatment algorithms, promote adherence to healthy lifestyles and provide standardized pharmacological treatment during in-home visits by NPHWs, to improve HT control and CV risk, like the outcomes observed in the Spanish and Chilean (HIC) populations. These countries will serve as controls and references due to their well-developed adequate infrastructure of the primary health care systems and better current percentages of HT awareness, treatment, and control [17,18].

2. Methods

2.1. Study design

The COTRACO study includes two independent phases: phase one was conducted from a phenomenological perspective and contributed to the implementation of the next phase; phase two is a quasi-experimental parallel-group, non-randomized, before and after type study. Due to COVID-19 pandemic, the control groups in Spain and Chile will be use real-world data for information collection [19].

2.2. Objective

The goal of the COTRACO study is to evaluate a community-based health care model designed to improve awareness, treatment, and control of HT, as well as to assess changes in CV risk scores. The intervention package includes:

- Simplified algorithms implemented by NPHW and supported by e-health technologies (tablets programmed with support software for advice and decision-making).
- Standardized, evidence-based pharmacological treatment.
- Support from treatment promoters to optimize adherence to lifestyle changes and long-term medication.

2.3. Study population

Four communities have been selected to participate in Chile, Colombia, Dominican Republic, and Spain (Fig. 2). A total of 300 patients will be included in each country, except in Spain where 1200 computerized medical records of patients treated in primary care will be accessed. The communities in the Dominican Republic and Colombia will follow the intensive HT management and support program followed by NPWH for 12 months. Data will be collected via tablets and transferred directly to the international coordinating center in Colombia. The communities are selected based on feasibility for follow up, with sited chosen for their stable population. The communities in Chile and Spain will serve as the usual care group.

2.4. Sample size

The sample size calculation for this study was based on the expected improvement in hypertension control rates in the intervention group. The aim is to increase the control rate by 12 percentage points, from a baseline control rate of 69 % (P_1), as reported in the HOPE-4 study [16], with the goal of achieving a control rate of 80 % (P_2) [11]. Given the before-and-after design, where measurements are taken from the same patients at baseline and after the intervention, we used paired statistical methods for sample size estimation.

We assumed a significance level of 5 % ($Z_{\alpha/2} = 1.96$) and a power of 90 % ($Z_{\beta} = 1.28$), with an estimated type II error of 10 %. In addition, a 15 % loss to follow-up was considered in the calculation. The standard deviation of the difference in hypertension control rates was assumed to be 15 %, based on variability observed in similar studies [20]. Using the formula:

$$n = \left(\frac{\left(Z_{\alpha/2} \bullet \sqrt{2 \bullet p(1-p)}\right) + \left(Z_{\beta} \bullet \sqrt{p_1(1-p_1) + p_2(1-p_2)}\right)}{\Delta} \right)^2$$

where Δ is the minimum clinically significant difference (0.12), the required sample size was estimated to be 300 patients per intervention country to achieve sufficient statistical power.

For comparative purposes, control groups of 300 patients in Chile and 1200 patients in Spain were included. The choice of these sample sizes was based on the need to reflect population variability and resource availability, as well as to ensure statistical robustness. The larger sample size in Spain provides a more robust benchmark for assessing the effectiveness of the intervention, considering

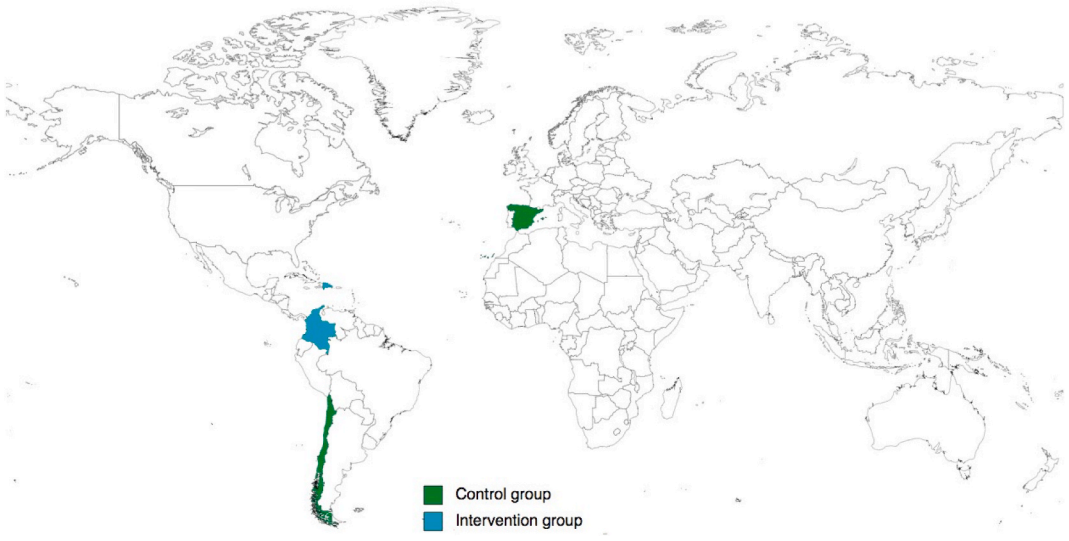

Fig. 2. Countries involved in the COTRACO study. The Dominican Republic and Colombia will follow the community-based health care model, Spain and Chile will receive the usual care.

differences in health resources and adherence rates between countries [21].

The importance of the control groups lies in their ability to provide a robust benchmark for assessing the effectiveness of the intervention. By including control groups with a 1:4 ratio between the number of individuals in the intervention and control groups, we can ensure a comprehensive comparison. This ratio helps to maximize the statistical power and reliability of the study results. The larger size of the control group allows for a more accurate estimation of the impact of the intervention by reducing the margin of error and increasing confidence in the results.

The distribution of loss to follow-up was estimated based on adherence rates observed in previous studies, with Chile showing a treatment adherence rate of approximately 37.3 % [22] and Spain with higher adherence due to better health resources [23]. This distribution was considered to ensure realistic and robust sample size calculations. These groups will serve to assess the relative impact of the intervention on hypertension control rates, providing a comprehensive assessment of the effectiveness of the intervention in different settings.

2.5. Participant selection

In primary health care institutions in Colombia and the Dominican Republic, participants will be eligible if they are between 50 and 79 years of age and have newly diagnosed or uncontrolled HT, as defined by at least one of the following criteria:

- Systolic BP $>$ 140–159 mmHg recorded at a visit, and the participant reports a medical diagnosis of HT or takes anti-HT medication.
- Systolic BP $\geq$ 130 mmHg recorded at a visit, and the participant reports a medical diagnosis of diabetes or takes medication for diabetes control
- Participants who do not meet the above criteria but whose systolic BP is 140–159 mmHg recorded on two separate visits at least 24 h apart.
- Newly diagnosis HT is defined as a participant with a medical diagnosis of HT in the 3 months before the visit.

Fig. 3. Flowchart of risk of confusion variables reduction using Propensity Score Matching.

In Spain, primary care electronic health records (EHRs) of the Community of Madrid will be used, and the control group will be selected using the same criteria. According to the National Institute of Health of Spain [24], and the HT prevalence and control rates presented in the PREDIMERC study [25] around 320,000 patients over 50 years old with unknown or uncontrolled HT at the start of the study will be eligible to form the control group.

Based on the data of the PREMIDERC study [25], around 1,570,000 people aged ≥50 years have HT (controlled or uncontrolled) in the Madrid community. With an estimated prevalence of 60.7 % and a control rate of 56.9 % and 32.9 % in patients of 30–59 and 60–74 years respectively, approximately 956,000 people are ≥50 years have recently diagnosed or uncontrolled HT.

To ensure the feasibility of comparing the evolution with the intervention group, a participant will be eligible only if they have a BP measure recorded on the primary healthcare-Madrid database at baseline and possess the necessary information to calculate the CV risk (such as sex, age, smoking status, cholesterol, diabetes and SBP). Estimating that only $^{1}/_{3}$ of this population will have complete information complete, around 320,000 patients will be eligible to form the control group.

With 320,000 subjects in the initial population eligible to form the control group, an intervention group of 600 patients and the implementation of matching techniques to analyze potential confounding variables, a Spain control group of 1200 patients will be selected with similar characteristics in terms of age, sex, dyslipidemia, diabetes, obesity, and smoking status. This will ensure comparability of the two groups and minimize the risk of selection bias. The propensity score matching technique will be used for selection through statistical software.

The program will pair each intervention patient with up to 2 patients of the control group using the matching algorithm with the previously mentioned variables. In the Province of Cautin - Chile, there are 90,000 EHRs available for selection, using the same selection criteria, 300 patients of the city of Temuco will be selected to form the control group, achieving a final control group of 1500 patients. After the pairing process, standard mean difference (SMD) will be used to ensure that the possible confounding variables are as balanced as possible between the two groups (Fig. 3).

Participants will be considered ineligible for the COTRACO study if they: a) Refuse to consent; b) Have treatment-resistant HT (blood pressure that remains above target despite the use form three anti-HT agents of different classes at their maximum tolerated doses and adequate frequency of administration). These individuals fall outside the purview of primary healthcare and will consequently referred for specialist evaluation; c) Are currently participating in any other study or health program that would compromise the COTRACO study protocol, d) Have a comorbid condition with a life expectancy of less than one year, or e) Have severe other conditions or factors likely to interfere with study participation or their ability to complete their involvement in the COTRACO study.

2.6. Informed consent

All participants aged 50 years or older will be asked to review and provide their written consent by signing an informed consent form. Following this, an initial evaluation will be performed about medical history and health status will be assessed to determine patient eligibility. Patients selected in Colombia and The Dominican Republic will be assigned to active program, while those from Chile and Spain will be assigned to usual follow-up. Informed consent will be obtained for the qualitative component of the study (focal groups, semi-structured interviews, and free listing), including authorization to record and transcribe these activities.

2.7. Qualitative component

The qualitative study was conducted beforehand, involving purposive sampling of HT patients from the databases of the participating healthcare institutions. The primary aim of this approach was to uncover patients' perceptions and experiences regarding HT control and treatment. Additionally, it aimed to identify barriers, facilitators, and strengths in the implementation of the community-based model. The insights gathered from this phase were then utilized to design and adapt the intervention for the subsequent phase.

Data collection techniques include semi-structured interviews and focus groups. In each of the intervention countries, a total of eight semi-structured interviews and three focus groups were conducted. Patient inclusion continued until theoretical saturation was reached, at which point the research team decided to discontinue inclusion because new data would not contribute additional knowledge within the established analytical categories [26].

2.8. Quantitative component

Initially, the participants from the selected communities in the Dominican Republic and Colombia (intervention countries) will enter a pilot trial. NPHWs will recruit the patients to implement the intervention and evaluate the electronic data collection form. The central committee of investigators will review and analyze the data, making any necessary corrections for the subsequent implementation and development of the trial.

2.9. Study visits and data collection

After the analysis of the pilot trial, NPHWs will conduct home visits to the potential participants. Patients will be pre-selected from primary care facilities in all countries to participate in the COTRACO model. Eligible participants will be assessed for their BP, medical history, CV risk factors, and cholesterol levels. Participants from Colombia and Dominican Republic will be assigned to the intervention arm of the COTRACO study, and those from Chile and Spain will remain in their usual follow-up on their local HT control program.

Participants will be followed for one year, and the follow-up period will differ in the groups: the intervention group will be followed by the NPHW by telephone or -home visit every two months during the first six months and every three months for the subsequent six months until the end of the program. The control group will be followed every six months (Fig. 4). In all countries, a fixed window of ten days before or after the visit will be designated.

2.10. Intervention component

The COTRACO study involves a complex intervention consisting of three core elements provided as a package (Fig. 5): a) Simplified algorithms implemented by NPHW supported by e-health technologies (tablets programmed with support software for advice and decision-making), b) Implementation of a standardized, evidence-based pharmacological treatment supported by primary care physicians, and c) Involvement of participant-nominated treatment supporters to optimize adherence to lifestyle changes and long-term medication.

Participants in Colombia and the Dominican Republic will select a support network to accompany them throughout the program implementation. This network will assist in promoting treatment adherence and lifestyle improvements. During the first visit, the NPHW will perform an initial assessment, which includes clinical and pharmacological history, lifestyle habits, and medication adherence. The NPHW will then measure vital signs (BP and heart rate), take anthropometric measurements (waist and hip circumference, height, and weight), and assess grip strength, all following standardized measurement protocols. Based on this information, treatment decisions will be made by the NPHW, in consultation with the primary care physician, following the treatment algorithm. Personalized e-health strategies will be employed, including fixed-dose combination therapy as appropriate, alongside lifestyle and healthy habits recommendations, aligned with the HEARTS strategy guidelines.

During the follow-up visits, NPHW will assess adherence to both pharmacological and non-pharmacological recommendations, reinforcing education for both patients and their support networks. BP will also be measured to inform any necessary adjustments to the treatment algorithm. Any changes to the pharmacological treatment will be evaluated, approved and prescribed by the primary care physician who will support the decision of treatment titration and perform the adequate formulation. In Colombia the social security system supplies the medication, while in the Dominican Republic, the PHARMATECH laboratory will provide the medication free of to ensure program success.

2.11. Control groups

Participants in the control group will receive the usual care attention from their health center. In Spain and Chile, the usual care model is primarily based on physician-led care, with routine follow-up visits scheduled at regular intervals as determined by the primary care physicians. During these visits, the health personnel will make regular recommendations about CVD's, lifestyle recommendations, and healthy habits without altering the usual management unless deemed necessary.

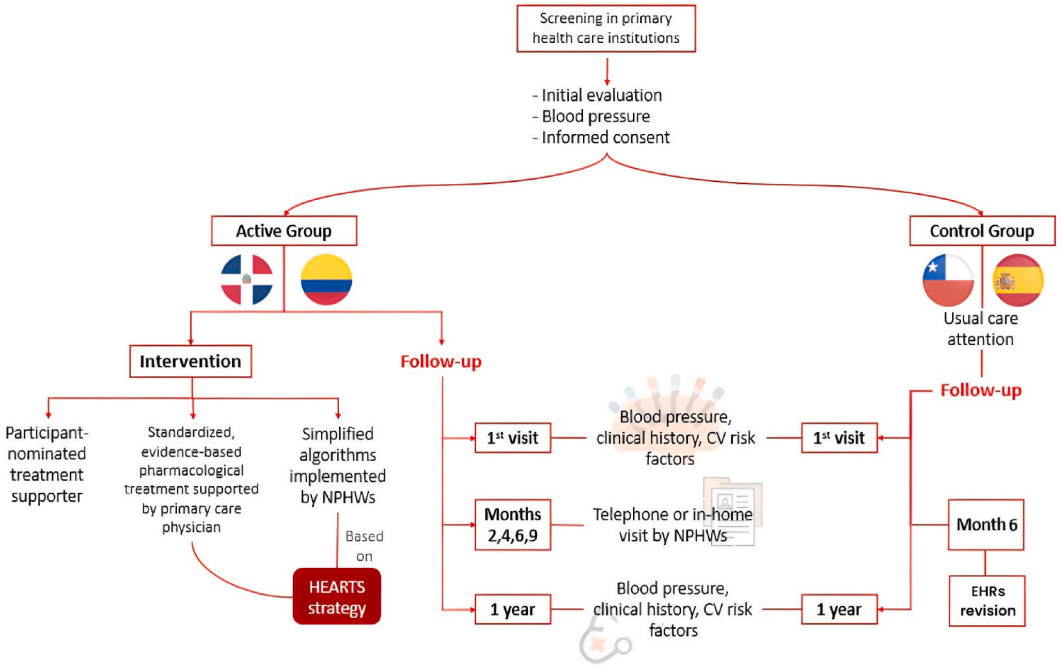

Fig. 4. Patients' selection and follow-up in the COTRACO study.

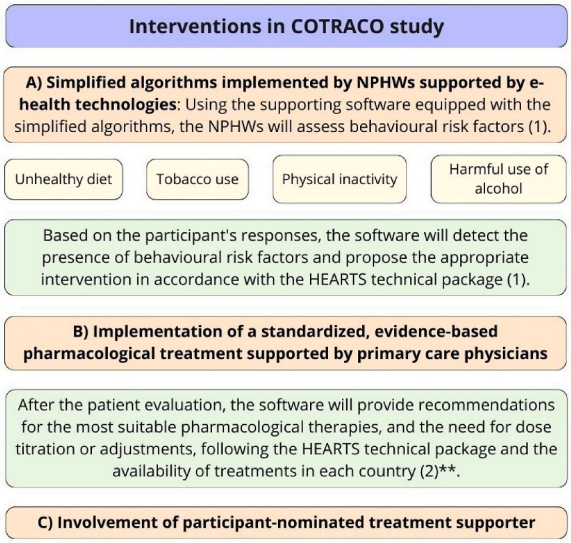

Fig. 5. Core intervention's in the COTRACO study.
** The Spanish versions of the HEARTS hypertension clinical pathway, including some antihypertensive combinations, are attached in the supplementary appendix.
1) HEARTS Technical package for cardiovascular disease management in primary health care: healthy-lifestyle counseling; Geneva: World Health Organization; 2018 (WHO/NMH/NVI/18.1). Licence: CC BY-NC-SA 3.0 IGO.
2) HEARTS Technical package for cardiovascular disease management in primary health care: evidence-based treatment protocols. Geneva: World Health Organization; 2018 (WHO/NMH/NVI/18.2). Licence: CC BY-NC-SA 3.0 IGO.

2.12. Task-shifting

The international coordination center in Colombia developed a curriculum for training of NPHWs according to the HEARTS and WHO protocols PEN 1 and 2. This 45-h curriculum covers topics ranging from common CV health knowledge and communication skills to cardiovascular risk assessment, prevention, and HT treatment according to the guidelines. The final module includes specific training for implementing the COTRACO study, with the algorithms for patient selection and follow-up of patients. NPHWs were also trained to counsel both the study participant and their nominated treatment supporter on the benefits of medication adherence and adopting healthy lifestyles (e.g., healthy diet, physical activity, and smoking cessation). Local primary health care physicians will review decisions made by the NPHW regarding HT awareness, treatment, and control. Tablets with COTRACO algorithms and questionnaires were developed and provided to all NPHWs to promote task-shifting responsibilities.

2.13. Outcomes

All the actions established in the active group are aimed to impact CVD risk by improving BP, cholesterol levels and promoting lifestyle recommendations and healthy habits. Therefore, our primary outcome is the proportion of patients achieving controlled HT (Systolic BP < 140 mmHg and Diastolic BP < 90 mmHg, or < 130 mmHg and Diastolic BP < 80 mmHg in diabetics patients) from baseline to 12 months after implementing the strategy.

Secondary outcomes are changes in: a) BP levels between the intervention and control participants, b) cholesterol levels, c) BMI, handgrip, and waist/hip ratio variables and d) smoking status, at 6 and 12 months.

The tertiary outcomes are the change in a) Interheart risk score, and b) lifestyle modifications (exercise and diet). Diet and exercise will be assessed through surveys administered to participants at 6 and 12 months. A participant will be considered to have met the objectives if, during the survey, they achieve all the evaluation goals outlined in the HEARTS technical package, and this is confirmed by the treatment support person.

Finally, we will evaluate the success rate of the program through proper use and adherence to pharmacological (percentage of medications not taken during the visit) and non-pharmacological treatment (compliance to commitments for controlling behavioral risk factors) (Fig. 6).

2.14. Data analysis

2.14.1. Qualitative component

The organization, codification, and analysis of the collected information through semi-structured interviews and focal groups were conducted using the qualitative analysis software NVivo Version Release 1.6.1.

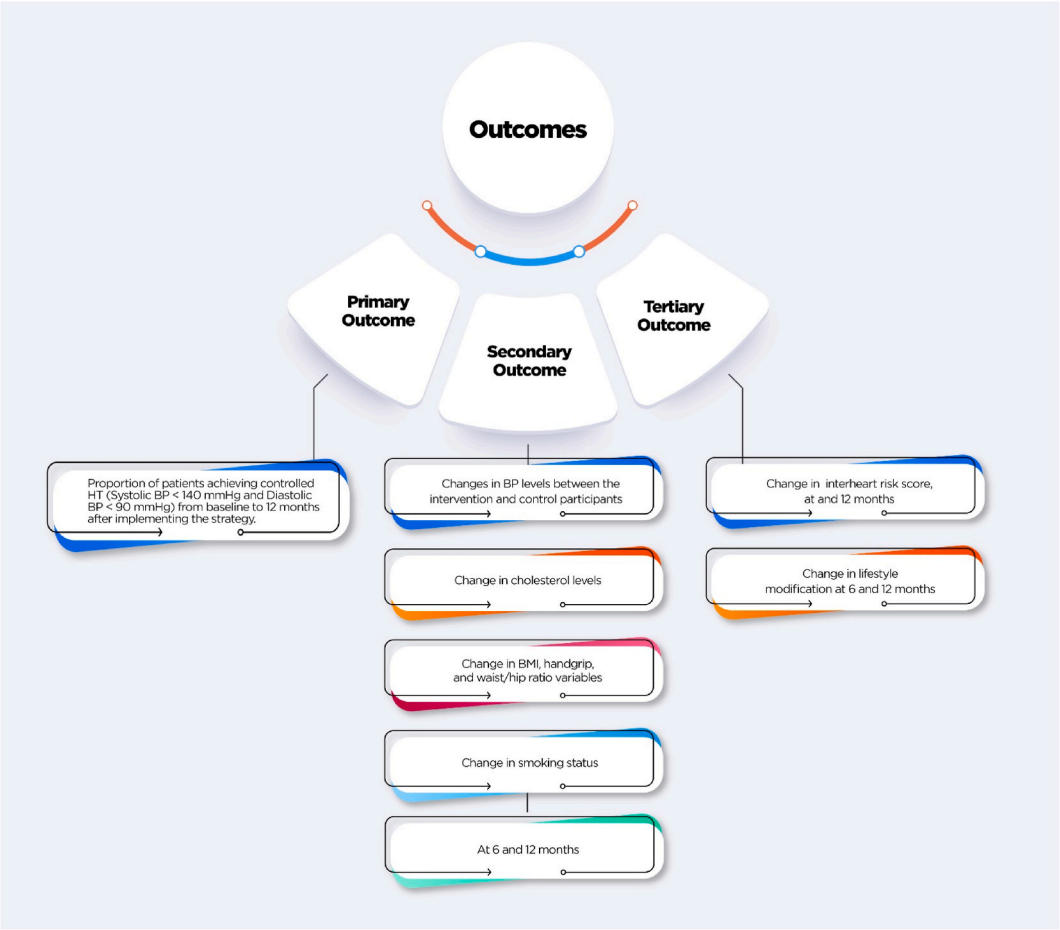

Fig. 6. Outcomes of the COTRACO study.

The compiled material (audios, transcripts of the same, and images) was organized using Google Drive folders shared with the investigators of the four participating countries. The codification process followed an axial coding methodology, allowing for the identification of relationship between categories and subcategories, to find answers to phenomena [27]. Categories were established based on a review of previous studies exploring barriers and facilitators for the management of CV risk management or the perception of people with hypertension. The information emerging from the analysis, including the categories derived from participants' experiences, was carefully considered.

2.14.2. Quantitative component

The descriptive variables will be reported in based on frequency distribution. Categorical variables will be presented as number and percentage, while continuous variables will be reported as means and standard deviations. Normality and homogeneity of variance for quantitative variables will be assessed graphically, and statistically with the Shapiro-Wilk and Levene test. We will evaluate potential differences between intervention and control groups.

The percentage of change in uncontrolled to controlled HT will be determined for known hypertensive individuals and the maintenance of controlled blood pressure will be assessed across countries. After individual adjustment, the delta of change in systolic and diastolic BP for countries and between intervention and control groups will be calculated.

The study will assess whether there is a change in blood pressure, Framingham Risk Score, body mass index (BMI), grip strength, and waist-hip ratio after the 12 months of program implementation, both within country and between the intervention and control group.

The success rate of the program will be estimated on the use and adherence to pharmacological and nonpharmacological treatments and HT control. Baseline and 12 months data will be compared using paired *t*-test for continuous and categorical measures.

Multivariate analysis will be performed to establish the potential modifying effect of the measures and identify baseline factors that may influence the finals results. This will involve binomial regression against the primary outcome, considering the Greenland criteria for parsimonious and forward model. The significance level of the study will be set at 0.05. Data analysis will be conducted using SE 17.0 software.

3. Discussion

HT is the leading risk factor for CVD, which is the leading cause of death and disability globally, with a higher burden of disease in low and middle-income countries [3]. While lifestyle changes and evidence-based pharmacologic treatment are effective, diagnosis, treatment, and control remain inadequate [8–10]. The COTRACO study aims to address barriers and limitations in HT diagnosis, treatment, management, and healthcare in low- and middle-income countries by implementing a model based on a standardized treatment algorithm administered by NPHWs. If this model is superior to usual care, health authorities can apply and enforce it in low- and middle-income countries to improve HT awareness, diagnosis, and control [28].

To the date, the baseline patients of the study has enrolled 360 patients in each intervention country (Colombia and The Dominican Republic), and pairing using the propensity score matching (PSM) in the control communities has been completed. The follow-up period is expected to be completed by the end of 2024.

CRediT authorship contribution statement

A.J. Lora Mantilla: Writing – review & editing, Writing – original draft, Visualization, Methodology, Conceptualization. **L.A. Parra Gomez:** Writing – original draft, Visualization, Methodology, Conceptualization. **P.A. Camacho-López:** Writing – review & editing, Visualization, Supervision, Resources, Project administration, Methodology, Conceptualization. **J. Otero-Wandurraga:** Writing – review & editing, Visualization, Methodology, Conceptualization. **B. Novella:** Writing – review & editing, Visualization, Project administration, Methodology. **A. González-Medina:** Writing – review & editing, Visualization, Project administration, Methodology. **O. Valdez-Tiburcio:** Writing – review & editing, Visualization, Project administration, Methodology. **F. Lanas:** Writing – review & editing, Methodology. **M.C. Rocha-Lezama:** Writing – review & editing, Methodology, Conceptualization. **J. Alonzo-Arias:** Writing – review & editing, Visualization, Methodology. **C. Rivilla-Piñango:** Writing – original draft, Visualization. **C. Cáceres-Ramírez:** Writing – original draft, Visualization. **S.J. Villabona-Flórez:** Writing – original draft, Visualization, Conceptualization. **Y. M. Giraldo-Castrillón:** Writing – review & editing, Visualization. **P. López-Jaramillo:** Writing – review & editing, Visualization, Supervision, Resources, Project administration, Methodology, Funding acquisition, Conceptualization.

4. Ethical considerations

The study will adhere to current international and national regulations of Good Clinical Practices, including the Good Clinical Practices of the International Conference of Harmonization (ICH). Written informed consent will be obtained from all study participants before any procedures are performed. Participants must authorize and sign the informed consent form according to local and national regulations. Data protection measures will meet regional and national requirements before participant enrollment.

This study may result in reports or publications of results for health authorities. Participants' identities will remain confidential, and all the precautions will be taken to maintain the confidentiality of medical history and personal information.

The protocol will be submitted to the ethics committee of each institution by the principal investigator at each site. Additionally, the researcher should review and approve the protocol annually according to current Good Clinical Practices guidelines.

Funding

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Patricio Lopez Jaramillo reports financial support, article publishing charges, and equipment, drugs, or supplies were provided by Foscal Clinic Santander Ophthalmological Foundation. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2025.e41726.

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