# Study protocol

# Feasibility of a Person-centered Nursing Intervention on Adherence and Control in Patients With Arterial Hypertension and Diabetes Mellitus. CERCANO pilot trial

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## March 19, 2025

## 1. GENERAL INFORMATION

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| **Project title:** | Feasibility of a Person-centered Nursing Intervention on Adherence and Control in Patients With Arterial Hypertension and Diabetes Mellitus. CERCANO pilot trial. | | |
| **Project duration (in months):** | 18 | **Modality** | Internal Call for Proposals |

## 2. ABSTRACT

**Background**. Approximately 80% of people with type 2 diabetes mellitus (DM) or arterial hypertension (HTN) do not achieve adequate disease control. **Objective**. To evaluate the feasibility of a research study assessing the impact of an educational and nursing counseling intervention with a person-centered care (PCC) approach to improve adherence and control in patients with arterial hypertension and diabetes mellitus in Colombia. **Methods**. A pilot randomized controlled clinical trial will be conducted. Adults with DM or HTN enrolled in cardiovascular or metabolic risk programs will be included. A total of 100–200 patients is expected to be recruited. The intervention group will receive counseling and education tailored to their preferences following the PCC approach, while the control group will receive standard care according to the program they belong to. Follow-up will last 6 months, and the primary outcomes to be measured in both groups are: medication adherence, DM control (HbA1c at target levels, change in HbA1c), and HTN control (SBP and DBP at target levels, changes in SBP and DBP). **Results**. The findings of this study will provide insight into the feasibility of conducting larger-scale studies to evaluate the effectiveness of PCC-based interventions in Colombia.

## 3. PROJECT DESCRIPTION

### PROBLEM STATEMENT

Type 2 diabetes mellitus (DM) and arterial hypertension are chronic diseases with a high prevalence and burden at both the global and national levels. In 2021, DM ranked as the seventh leading cause of disability and mortality worldwide and the fifth leading combined cause of disability and mortality in Colombia (1,2). During the same year, hypertension (HTN) was considered the second leading risk factor contributing to disability and the primary risk factor associated with mortality worldwide (3), while in Colombia HTN ranked as the leading risk factor associated with disability and combined mortality, respectively (4).

The impact generated by these two conditions is related to limitations in their diagnosis, treatment, and control. It is estimated that only 60% of people living with DM are aware of their diagnosis (95% CI = 56.5%–63.5%). Of this group, 45.0% (95% CI = 41.5%–48.5%) receive treatment, and among those receiving treatment, 42.0% (95% CI = 39.5%–44.5%) achieve disease control. In other words, when considering all patients diagnosed with DM, the overall proportion achieving disease control is only 20.0% (95% CI = 18.0%–22.0%) (5).

Regarding HTN, it is estimated that only 46.5% (95% CI = 41.9%–51.1%) of people with hypertension are aware of their diagnosis. Of this group, 36.9% (95% CI = 33.8%–40.0%) receive pharmacological treatment, and 37.1% of treated individuals (95% CI = 33.6%–40.5%) achieve blood pressure control. This means that only 13.8% (95% CI = 11.4%–16.3%) of all individuals diagnosed with HTN have blood pressure values within control ranges (6). Additionally, factors such as gender, age, area of residence, and the socioeconomic income level of the country of residence have been identified as disparities affecting the diagnosis and treatment of DM and HTN. Meanwhile, DM control is influenced by the country's socioeconomic income level and area of residence (5,7,8).

Despite the existence of evidence-based clinical practice guidelines (CPGs) with effective recommendations for the management of DM and arterial hypertension, patients' lack of adherence to treatment continues to be a major issue affecting the adequate control of both conditions, consequently generating the high burden of morbidity, mortality, and

disability described above (9,10). In this regard, implementing strategies to improve these health indicators should be considered a priority objective in the management of these conditions.

The Colombian Ministry of Health and Social Protection has developed two clinical practice guidelines (CPGs) that synthesize evidence-based recommendations for the management of HTN and DM. To optimize treatment adherence and the achievement of therapeutic goals, both CPGs recommend the implementation of structured follow-up programs that include educational interventions (11,12). Consequently, it is common for healthcare institutions to have cardiovascular risk or metabolic risk programs in which patients with these two conditions (among others) are enrolled for follow-up care. Within these programs, most educational interventions use traditional methodologies, some of which are supported by information and communication technologies.

Although some studies evaluating educational interventions in these populations have shown results suggesting improved medication adherence in patients with DM, no evidence of improvement has been found in patients with arterial hypertension. Due to methodological limitations and the low quality of evidence in these studies, the effectiveness of education alone remains controversial (13). Other educational interventions using mobile applications also appear to show positive results in improving medication adherence in patients with DM; however, most studies report results that are not statistically significant and have a substantial risk of bias (14).

Person-centered care (PCC) is a care approach aimed at ensuring that healthcare delivery is humanized, individualized, and based on each person's needs, preferences, and values (15). When integrated within the concept of evidence-based practice, this approach not only improves quality of life and well-being but also enhances patient satisfaction and autonomy within healthcare services (16). Some systematic reviews evaluating the effectiveness of the PCC approach as a strategy for hypertension control compared with usual care have shown that patients receiving PCC had an increased likelihood of improving blood pressure values (RR = 1.23; 95% CI = 1.01–1.48) compared with those receiving usual care. In particular, educational strategies based on the PCC approach significantly reduced diastolic blood pressure (mean difference: 4.86 mmHg [95% CI = 0.88–8.83]), and PCC-based counseling interventions for behavioral change compared with usual care resulted in improvements of 3.2 mmHg (95% CI = 1.2–5.3) in diastolic blood pressure (DBP) and 11.1 mmHg (95% CI = 4.1–18.1) in systolic blood pressure (SBP) (17,18).

Regarding the impact of PCC on DM control, systematic reviews also suggest favorable outcomes compared with usual care, showing a significant reduction in HbA1c of −0.56 (95% CI = −0.79, −0.32) in patients with DM after receiving PCC interventions in mixed modalities (face-to-face or virtual), or a 0.3% reduction in HbA1c in mHealth interventions. These effects were greater when: 1) educational and behavioral components were combined; 2) the intervention duration was ≤ 3 months; and 3) interventions were delivered by nurses and implemented in community settings (19,20).

Despite the fact that the results of these systematic reviews suggest that implementing the PCC approach could improve the control of patients with DM or HTN, there is still uncertainty regarding the validity of its impact due to the moderate to high risk of bias present in most of the included studies. Furthermore, this approach has been scarcely evaluated in the Latin American context (only a couple of studies were identified in Brazil and Mexico), where healthcare system conditions may represent different facilitators or barriers to the implementation of PCC interventions (21), and where social determinants specific to our population may also lead to variations in PCC effectiveness.

**RATIONALE**

Due to the magnitude of HTN and DM in Colombia (as described in the previous section) and the uncertainty that persists regarding traditional educational interventions that are part of current cardiovascular and metabolic risk programs attended by these patients, it is essential for healthcare professionals to seek effective strategies to improve adherence and disease control and reduce the risk of associated complications.

The implementation of appropriate strategies could effectively reduce the proportion of complications leading to disability and mortality in these two conditions, particularly impacting patients diagnosed with HTN or DM who are enrolled in both the subsidized and contributory health insurance regimes in Colombia. The diversity of the population attending these healthcare settings will also allow us, through the proposed intervention in this study, to address disparities associated with HTN and DM control.

In this sense, this project aims to evaluate the impact of an educational and nursing counseling intervention using a person-centered care approach to improve adherence and control in patients with arterial hypertension and diabetes mellitus in Colombia. However, given that the effectiveness of this type of intervention has no precedent in our context and that the particularities of our healthcare system may represent barriers to large-scale implementation, we initially propose a pilot study to assess the feasibility, methodology, acceptability, and preliminary impact of a nursing intervention based on the person-centered care approach to improve adherence and control in patients with arterial hypertension and diabetes mellitus, which will provide the necessary data to plan a larger trial.

## BACKGROUND

Burden of arterial hypertension and type 2 diabetes mellitus

Type 2 diabetes mellitus (DM) and arterial hypertension are chronic non-communicable diseases with a significant global burden. In 2021, DM had a prevalence rate of 6,123.6 per 100,000 inhabitants (95% CI = 5,723.4–6,585.8), ranking as the seventh leading cause of disability (Years Lived with Disability [YLD] = 41.2 million [95% CI = 29.0–56.5 million]) and the tenth leading cause of mortality (19.6 deaths per 100,000 inhabitants) worldwide (1,2).

In the Latin America and Caribbean region, DM represented the third leading cause of disability and the fifth leading cause of death, with an age-standardized mortality rate of 36.3 deaths per 100,000 inhabitants (95% CI = 33.2–39.3) (1,2). In Colombia, this disease was the fifth leading cause of combined disability and mortality, after COVID-19, ischemic heart disease, interpersonal violence, and low back pain (4). Consequently, DM has had a negative impact on life expectancy between 1990 and 2021, resulting in a global loss of 0.1 years of life expectancy (1,2). Moreover, DM is projected to become the third leading cause of disability and the ninth leading cause of mortality by 2025 (22).

On the other hand, worldwide, after exposure to particulate matter pollution, elevated systolic blood pressure or arterial hypertension (HTN) is the second leading risk factor contributing to the total burden of disability-adjusted life years (DALYs) (7.8% of total DALYs; 95% CI = 6.4%–9.2%) and the leading risk factor associated with mortality (137.52 deaths per 100,000 inhabitants [95% CI = 116.87–158.85]) (23). Although in Latin America and the Caribbean elevated systolic blood pressure ranks as the seventh leading risk factor contributing to disability (DALYs = 124.20; 95% CI = 87.47–164.56), it remains the leading risk factor associated with mortality in the region (94.15 deaths per 100,000 inhabitants [95% CI = 78.52–108.80]) (23). Consistently, in Colombia elevated blood pressure is the risk factor contributing most to combined disability and mortality, with a change rate from 2011 to 2021 of 274.8 DALYs per 100,000 inhabitants (4).

Magnitude of these two conditions is related to their macrovascular and microvascular complications (e.g., ischemic heart disease, heart failure, cerebrovascular disease, chronic kidney disease, peripheral vascular disease, and retinopathy), which are usually the result of inadequate treatment and control among affected individuals (24,25). It is also known that elevated blood pressure is twice as common in people with DM compared to those without DM (26), and several studies have reported that hypertension in people with diabetes is an independent predictor of these complications (27–30).

Awareness, treatment, and control of HTN and DM

In terms of diagnosis, treatment, and control of these two conditions, it is estimated that 60% of people with DM are aware of their diagnosis (95% CI = 56.5%–63.5%), 45.0% (95% CI = 41.5%–48.5%) receive treatment, and among those treated, only 42.0% (95% CI = 39.5%–44.5%) achieve disease control. The situation is even more critical when considering all patients

with a diagnosis of DM, where the overall proportion achieving control is only 20.0% (95% CI = 18.0%–22.0%). Additionally, factors such as being female, older age, living in high-income countries, and living in urban areas increase awareness and treatment of DM, although control is influenced only by the socioeconomic income level of the country and urban residence (5).

Regarding arterial hypertension, a systematic review that included 131 studies published between 1995 and 2014 found that 46.5% (95% CI = 41.9%–51.1%) of individuals with hypertension were aware of their diagnosis, 36.9% (95% CI = 33.8%–40.0%) reported receiving pharmacological treatment, 37.1% of treated individuals (95% CI = 33.6%–40.5%) achieved blood pressure control, and only 13.8% of all individuals with hypertension achieved control (95% CI = 11.4%–16.3%). For this risk factor, gender, age, place of residence, and country income level represent disparities in diagnosis and treatment similar to those identified in the management of DM (6–8).

Person-centered care approach for treatment adherence and control of HTN and DM

Person-centered care (PCC) is a care approach aimed at ensuring that healthcare delivery is humanized, individualized, and based on each person's needs, preferences, and values (15). When integrated within the concept of evidence-based practice, this approach not only improves quality of life and well-being but also enhances satisfaction and autonomy with healthcare services (16). In this sense, PCC is based on key principles such as patient empowerment, effective communication, individualized care, the creation of healthy environments, and continuous evaluation of care quality (31).

Consequently, the clinical practice guideline with evidence-based recommendations on person- and family-centered care from the Registered Nurses' Association of Ontario promotes the use of this approach for multiple purposes: first, to improve the safety and effectiveness of care; second, to encourage shared decision-making with patients; and third, to reduce the rate of adverse events (32).

Additionally, evidence suggests that PCC increases patient and family satisfaction by respecting their values and expectations in healthcare delivery, while maintaining efficiency by optimizing care resources and reducing unnecessary hospitalizations. From the perspective of healthcare professionals, the PCC approach has also demonstrated benefits by improving organizational climate and contributing to the creation of work environments with lower stress and greater team collaboration (32).

Two systematic reviews have been identified that evaluate the effectiveness of the person-centered care (PCC) approach for hypertension control. The first review included 8 randomized clinical trials involving 5,654 patients, assessing the impact of PCC-based strategies compared with usual care on hypertension control among adults attending primary care services. It was observed that patients receiving PCC strategies had a higher probability of achieving improved blood pressure values (RR = 1.23; 95% CI = 1.01–1.48) compared with those receiving usual care. Additionally, results showed that PCC self-management activities had a greater impact on achieving control targets (RR = 1.43; 95% CI = 1.23–1.65), while patient education and reminders using the PCC approach significantly reduced diastolic blood pressure (mean difference: 4.86 mmHg; 95% CI = 0.88–8.83). Common characteristics of effective PCC interventions identified in this review included personalized communication with patients, the use of health information technologies, and multidisciplinary collaboration (17).

On the other hand, a systematic review of 15 studies (4,072 patients with hypertension) provides a synthesis of the independent and incremental effects of three PCC-based behavioral interventions (counseling, self-monitoring, and training courses) on blood pressure control. Of the fifteen studies, 10 evaluated counseling (3,459 participants), 1 self-monitoring (136 participants), 1 training courses (123 participants), and 4 combined interventions (477 participants). Results showed that in patients with hypertension, PCC-based counseling for behavioral interventions compared with usual care led to an improvement of 3.2 mmHg (95% CI = 1.2–5.3) in diastolic blood pressure (DBP) and 11.1 mmHg (95% CI = 4.1–18.1) in systolic blood pressure (SBP). In contrast, patients receiving self-monitoring interventions showed a reduction of 8.9 mmHg

(95% CI = 5.2–12.6) in DBP. Furthermore, when PCC counseling was combined with training courses, a higher proportion of patients achieved blood pressure control (95%; 95% CI = 87–99) compared with those receiving only PCC counseling (51%; 95% CI = 34–66) or training alone (64%; 95% CI = 48–77). However, these findings should be interpreted with caution due to the low-to-moderate quality of evidence and important methodological limitations in study selection and evaluation (18).

Regarding the impact of PCC on DM control, a systematic review with meta-analysis of 19 randomized clinical trials involving 1,599 patients with type 2 diabetes mellitus evaluated the effectiveness of PCC compared with usual care on diabetes self-management. It showed that PCC-based self-care interventions significantly reduced HbA1c by −0.56 (95% CI = −0.79, −0.32) compared with usual care. These effects were greater when: 1) educational and behavioral components were combined (HbA1c reduction −0.66; 95% CI = −0.97, −0.34); 2) intervention duration was ≤ 3 months (HbA1c reduction −0.85; 95% CI = −1.28, −0.43); 3) interventions were delivered by nurses (HbA1c reduction −0.80; 95% CI = −1.44, −0.16); and 4) interventions were implemented in community settings (HbA1c reduction −0.70; 95% CI = −1.14, −0.26) (19).

The person-centered care (PCC) approach has also been evaluated in remote interventions for these patients. A systematic review that included 30 studies (randomized clinical trials and cohort studies) with 27,142 patients assessed the effectiveness of mHealth interventions with a PCC approach in the control of patients with type 2 diabetes mellitus in low- and middle-income countries. In 12 studies, HbA1c was measured as a control outcome; of these, 83.3% reported that mHealth interventions with PCC favored a 0.3% reduction in HbA1c compared with interventions that did not use this approach or modality (20).

Despite the fact that the results of these systematic reviews suggest that implementing the PCC approach could improve the control of patients with DM or HTN, there is still uncertainty regarding the validity of its effect due to the moderate to high risk of bias present in most of the included studies. Furthermore, this approach has been scarcely evaluated in the Latin American context (only a couple of studies were identified in Brazil and Mexico), where healthcare system conditions may represent various facilitators or barriers to the implementation of PCC interventions (21), and where social determinants specific to our population may lead to variations in PCC effectiveness.

Evidence-based recommendations for adherence and control of HTN and DM

The Colombian Ministry of Health and Social Protection has developed two clinical practice guidelines (CPGs) that synthesize evidence-based recommendations for the management of HTN and DM. Therefore, PCC-based interventions offered to these populations in the Colombian context are expected to use these CPGs as a key reference framework.

To optimize treatment adherence and the achievement of therapeutic goals, these CPGs recommend the implementation of structured follow-up programs that include educational interventions (11,12). For example, the CPG for the management of hypertension highlights that treatment adherence improves when patients are provided with a higher number of follow-ups or contacts, education on blood pressure self-monitoring, reminders, and referral to a pharmacist, achieving an increase in adherence ranging from 8% to 32% (11). Consequently, it is common for healthcare institutions to have cardiovascular risk or metabolic risk programs in which patients with these two conditions (among others) are enrolled for follow-up care.

The CPGs promote comprehensive patient education as a key element of good clinical practice for achieving adequate disease management. This education includes six domains: (1) disease pathophysiology and therapeutic options, (2) lifestyle and nutritional changes, (3) promotion of regular physical activity, (4) pharmacological management, (5) health monitoring and follow-up, and (6) prevention, detection, and treatment of complications.

Finally, the CPG for the diagnosis, treatment, and follow-up of DM recommends personalized pharmacological management, including the use of drugs with proven efficacy and fewer adverse effects, as well as health monitoring and follow-up with emphasis on periodic assessment of parameters such as HbA1c to allow timely treatment adjustments. Meanwhile, the CPG for hypertension management advocates for an individualized therapeutic strategy that includes

initiating monotherapy in low-risk cases and using combination therapy in patients who do not achieve treatment targets. Health monitoring and follow-up are based on tools such as ambulatory blood pressure monitoring (ABPM) and home self-monitoring, which allow timely assessment of treatment response (11,12).

**GENERAL OBJECTIVE**

To evaluate the feasibility of a research study assessing the impact of an educational and nursing counseling intervention using a person-centered care approach to improve adherence and control in patients with arterial hypertension and diabetes mellitus in Colombia.

**SPECIFIC OBJECTIVES**

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| Specific Objective 1 | To determine the acceptance rate of healthcare institutions, as well as the eligibility and participation (enrollment) rates of patients to take part in the study. |
| Specific Objective 2 | To describe the sociodemographic and clinical characteristics of the patients included in the study, the preferences for individualized care plans in the intervention group, and patient adherence in each study group. |
| Specific Objective 3 | To identify potential issues in the conduct of the study that may inform adjustments to the design of the main trial. |
| Specific Objective 4 | To explore the impact of the nursing intervention using a person-centered care approach on adherence and control in patients with arterial hypertension and diabetes mellitus in Colombia. |
| Specific Objective 5 | To estimate the sample size required to conduct the main study. |

## 4. METHODS

**Design:** A pilot randomized controlled clinical trial, with outcome assessors blinded to group allocation.

**Settings:** Collaborating centers from the public and private healthcare network in Colombia, which will be included once the project is approved by the respective institutional research and ethics committees.

**Participants:** Individuals from participating institutions that have ethical committee approval and meet the following inclusion criteria:

- Adults (18 years or older).
- Diagnosis of type 2 diabetes mellitus (DM) or arterial hypertension (HTN) (or both), documented in the medical record.
- Prescription of pharmacological treatment for the condition.
- Enrollment in a cardiovascular or metabolic risk program and scheduled for a medical follow-up visit within the next 3 to 6 months.
- Written informed consent to participate in the study.

The following exclusion criteria will be applied:

- Mental disorders that impair autonomy or understanding of the interventions.
- Congestive heart failure, ischemic or valvular heart disease, end-stage renal disease requiring dialysis, chemotherapy treatment, autoimmune diseases, recent hospitalization due to disease decompensation (within the last month), or any other condition preventing the patient from receiving general health recommendations according to their primary diagnosis.
- Physical limitations such as quadriplegia, total loss of motor function, or contraindications to physical activity as indicated by medical prescription.

**Expected sample size:** For this pilot study, between 100 and 200 participants are expected to be included.

**Recruitment:**
Initially, the project nurses will approach patients in person after their medical consultation in cardiovascular/metabolic risk programs to assess eligibility and obtain informed consent. Once the patient agrees to participate in the study, they will be randomly assigned to either the intervention or control group using a centralized randomization method.

**Intervention Group:**

Patients assigned to the intervention group will receive, in addition to usual care provided within the cardiovascular/metabolic risk program, an individualized education and counseling plan based on the person-centered care (PCC) approach, which includes the following components:

1. After the routine in-person medical follow-up consultation within the cardiovascular or metabolic risk program, the initial nursing consultation related to this study will be conducted. Following informed consent and baseline outcome assessment, the purpose of the nursing consultation will be for the study nurse to engage with the patient around what matters to them and co-create a goal-oriented care plan (medication adherence, disease control, and adherence to general lifestyle recommendations).

Therefore, the nursing consultation will include the following activities based on the functional interview model by Cole and Bird, adapted by Jennings and Mold (33):
a) Identify the characteristics of the person's health situation and context.
b) Identify the patient's needs and preferences.
c) Identify barriers, challenges, and opportunities in managing their health condition.
d) Share relevant information with the patient regarding options for individualized education and counseling.
e) Negotiate an initial individualized education and counseling plan, including the preferred delivery modality.

The individualized plan with educational and counseling interventions will include up to six content domains:
1. Disease pathophysiology and treatment
2. Healthy diet and nutrition
3. Physical activity
4. Medication use
5. Health monitoring and follow-up
6. Prevention, detection, and management of complications

The educational and counseling content will be based on the general recommendations for the management of arterial hypertension and diabetes mellitus included in the clinical practice guidelines of the Colombian Ministry of Health and Social Protection, respectively.

Patients will be able to choose the domains of counseling according to their interests and preferences, as well as the modality and frequency through which they wish to receive the intervention.

The estimated duration of this initial nursing consultation, including care plan development, will be between 30 and 40 minutes.

The implementation of the intervention and follow-up will be carried out according to patient preferences through telephone calls, video calls, or WhatsApp. Over a maximum period of 6 months, patients in the intervention group will receive the intervention according to the individualized plan established in the first consultation, with a minimum of one intervention per month and a maximum of one intervention per week. The educational and counseling interventions across the six domains described above will be guided by evidence-based recommendations from the clinical practice guidelines for the management of DM and HTN issued by the Colombian Ministry of Health. Each educational or counseling session will last between 10 and 15 minutes. (See Figure 1)

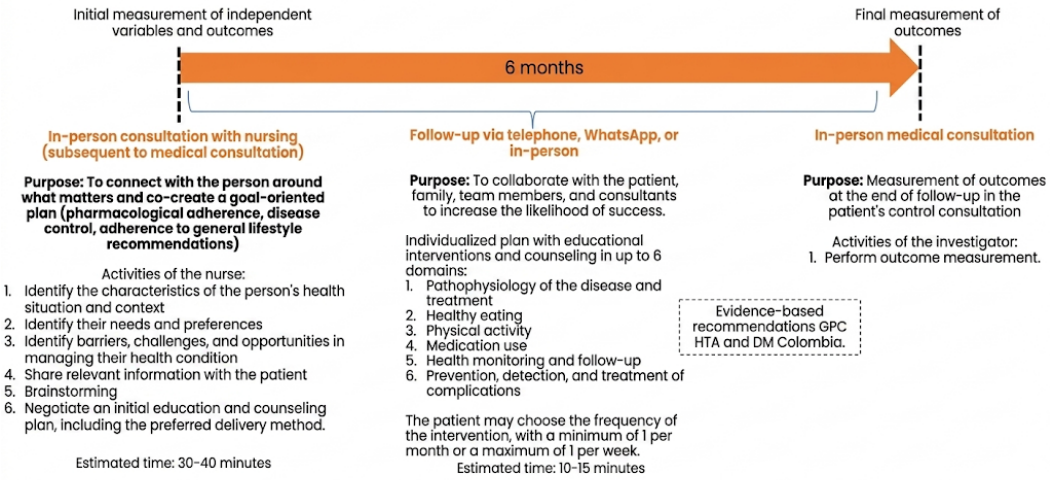


Figure 1. Activities for the intervention group

Therefore, each patient in the intervention group will receive a fully individualized educational and counseling plan that may differ from the preferences of other patients included in the same group.

**Control Group:**
Patients assigned to the control group will receive usual care interventions provided within the cardiovascular/metabolic risk programs to which they belong at each participating healthcare institution. (See Figure 2)

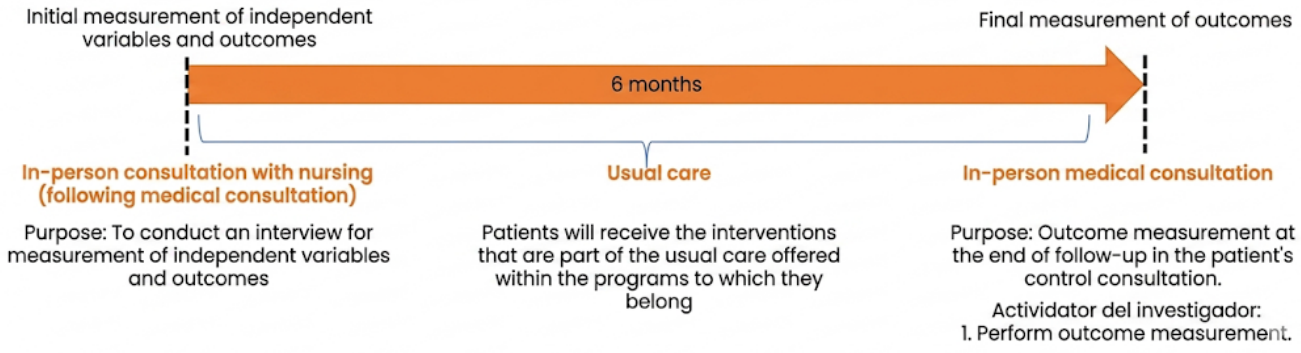


Figure 2. Activities for the control group

**Randomization method:**
A stratified block randomization method will be used, stratified by sex (female/male) and age (18–60 / >60 years). The randomization procedure will be designed to ensure allocation concealment from the nurses delivering the intervention, as well as from the researchers responsible for data analysis.

**Outcome assessment:**
Outcome assessment will be performed by a trained individual who will not be involved in the delivery of the intervention. Outcomes related to clinical control will be obtained from clinical records (blood pressure measurements taken during medical consultations and laboratory HbA1c results).

For other outcomes, validated open-access instruments (e.g., the Morisky–Green questionnaire) will be used and administered by designated study personnel. Additionally, the research team will develop a structured form to collect independent variables of interest. The study procedures flow and timeline are summarized in Figure 3 and Table 1.

**Blinding (Masking):**
Due to the nature of the intervention in this study, neither patients nor the nursing professionals delivering the intervention can be blinded. However, several strategies will be implemented to minimize potential bias arising from this limitation:

1. A centralized randomization system will be used, preventing knowledge of the allocation sequence by the professionals responsible for delivering the interventions and conducting study measurements.
2. Study personnel not involved in the intervention delivery will perform baseline and end-of-study outcome assessments. These individuals will be blinded to participant group allocation.
3. Investigators responsible for statistical analysis will remain blinded to group assignments during data analysis.

**Study variables:**
**Independent variables of interest:**
The following sociodemographic and clinical variables will be considered: sex, age, marital status, socioeconomic stratum, area of residence, occupation, household composition, medical history, surgical history, hospitalization history, family history, toxicological history, primary diagnosis, duration of diagnosis, prescribed medications, health insurance provider (EPS), type of insurance regime, and healthcare institution (IPS) where the patient is enrolled in the cardiovascular or metabolic risk program.

**Primary outcomes:**
The primary outcomes of this study are medication adherence and disease control.

- Medication adherence will be measured using the Morisky–Green questionnaire (short version, 4 items), which has been validated in previous studies in populations with chronic conditions in the Colombian context.
- Disease control will be defined as:
    - For DM: HbA1c within target range.
    - For HTN: systolic blood pressure (SBP) and diastolic blood pressure (DBP) within target ranges.

Additionally, for DM patients, change in HbA1c from baseline to end of follow-up will be assessed, and for HTN patients, changes in SBP and DBP over the same period will be evaluated.

**Secondary outcomes:**
Secondary outcomes include adherence to general lifestyle recommendations (diet and physical activity), disease-related knowledge, and patient satisfaction.

**Additional variables for intervention characterization and feasibility assessment:**
The following variables will be considered to characterize the intervention and assess feasibility: duration of the initial nursing consultation, duration of each intervention session, number of interventions per patient, patient-preferred educational domains, preferred delivery modality, and intervention resources (transportation costs and costs associated with educational material development).
Feasibility indicators will also include the acceptance/participation rate of patients and institutions.

**Statistical analysis plan:**

Participant characteristics will be summarized using absolute and relative frequencies for categorical variables, and measures of central tendency and dispersion for continuous variables according to their distribution. Baseline characteristics will be presented for both study groups (intervention and control). Differences in baseline distribution will be assessed using the chi-square test or Fisher's exact test for categorical variables, and the Mann–Whitney U test for continuous variables.

The analysis will be conducted under the intention-to-treat principle. The proportion of participants in each study arm classified as adherent and controlled at the end of follow-up will be estimated (blood pressure or HbA1c within target ranges, according to diagnosis). Changes in blood pressure values before and after the intervention will be calculated for patients with HTN, as well as changes in HbA1c levels for patients with DM. These changes will be summarized using means and standard deviations or medians and interquartile ranges, depending on their distribution.

Differences between intervention and control groups in these outcomes will be assessed using the chi-square test or Fisher's exact test for categorical outcomes, and the Student's t-test for continuous change variables. Logistic regression models will be used to compare both study groups, adjusting for independent variables that are not evenly distributed at baseline. Statistical significance will be set at $p < 0.05$. Stata software version 12.0 will be used for the analysis.

**Ethical considerations:**

In accordance with Resolution 8430 of 1993 issued by the Colombian Ministry of Health, this study is classified as minimal-risk research (34). The study will be conducted following approval by the ethics committees of the participating healthcare institutions, as well as voluntary participation through signed informed consent. All data collected in this study will be stored securely and will be accessible exclusively to the research team.

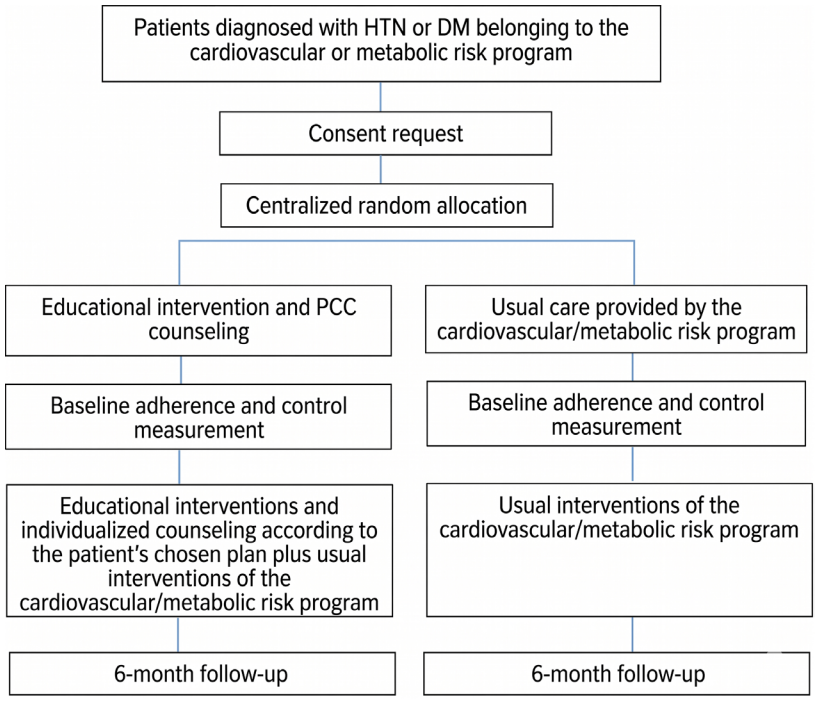


Figure 3. Flowchart of the CERCANO pilot trial

Table 1. CERCANO pilot trial schedule of procedures

| Time Period | Screening | Baseline | Post-randomization months | | | | | | Follow-up at month 6 |
|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | |
| Eligibility assessment | X | | | | | | | | |
| Informed consent request | X | | | | | | | | |
| Randomization | X | | | | | | | | |
| Measurement of sociodemographic variables, medical history, and medication prescriptions | | X | | | | | | | |
| Medication adherence questionnaire | | X | | | | | | | X |
| Lifestyle adherence questionnaire (diet and physical activity) | | X | | | | | | | X |
| Disease knowledge questionnaire | | X | | | | | | | X |
| Patient satisfaction questionnaire | | X | | | | | | | X |
| Clinical record data collection (blood pressure or HbA1c values) | | X | | | | | | | X |
| Educational and individualized counseling interventions (Intervention group) | | | X | X | X | X | X | X | |
| Usual care (Control group) | | | X | X | X | X | X | X | |

| Specific Objective | Activities | |
|---|---|---|
| 1 | 1.1 | Presentation of the project protocol and invitation to participate to partners from health institutions that have cardiovascular risk or metabolic risk programs. |
| | 1.2 | Submission of project documents for approval to the technical-scientific committees and research ethics committees of each interested institution. |
| | 1.3 | Design and development of case report forms (CRFs). |
| | 1.4 | Design and development of the database. |
| | 1.5 | Selection and testing for validation of outcome assessment instruments that require it. |
| | 1.6 | Design and development of educational materials to be used in the intervention group with CCP. |
| | 1.7 | Training of nurses who will carry out the PCC intervention to standardize procedures. |
| | 1.8 | Design and development of the randomization system for the intervention. |
| 2 | 2.1 | Recruitment of participants, follow-up, and measurement of exposure and outcomes (review of clinical records and laboratory tests). |
| | 2.2 | Data quality review and data cleaning. |
| | 2.3 | Statistical analysis of the data. |

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|---|---|---|
| 3 | 3.1 | Development of the patient recruitment flow according to institutional dynamics. |
| | 3.2 | Monitoring the conduct of the study. |
| | 3.3 | Analysis of variables related to the feasibility of study implementation. |
| | 3.4 | Identification of intervention costs and required resources. |
| 4 | 4.1 | Statistical analysis of the data. |
| | 4.2 | Preparation of tables and figures. |
| | 4.3 | Writing of the manuscript, research report, and other project outputs. |
| 5 | 5.1 | Estimation of sample size to design the larger-scale trial. |
| | 5.2 | Preparation of the methodological design document that will be part of the protocol for the larger-scale study. |

| Activity | Scheduled (Months) | | | | | | | | | | | | | | | | | | | | | | | |
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| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| 1.1 | | | | | | | | | | | | | | | | | | | | | | | | |
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| 2.1 | | | | | | | | | | | | | | | | | | | | | | | | |
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| 3.1 | | | | | | | | | | | | | | | | | | | | | | | | |
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## 5. ETHICAL CONSIDERATIONS

This study strictly adheres to the fundamental ethical principles governing research involving human subjects.

In this regard, the principles of beneficence and non-maleficence are applied, considering that the educational and counseling-based intervention in this study could have a positive impact on patients with arterial hypertension and diabetes mellitus by improving the control of their conditions, with a very low likelihood of adverse events or risks that could compromise patient safety.

Likewise, the principle of autonomy will prevail, as participation in this study will be subject to the voluntary acceptance of participants through the signing of an informed consent form. For this purpose, all participants will be clearly, concisely, and comprehensibly informed about the purpose of the study, the procedures, potential benefits and risks, the confidentiality of their data, and their right to refuse participation or withdraw from the study at any time without any penalty (see Informed Consent).

To ensure the principle of justice, participant selection will be carried out equitably, avoiding any form of coercion and considering exclusively the inclusion and exclusion criteria described in this research protocol. No one will be excluded from participation on the basis of gender, race, ethnicity, religion, socioeconomic status, or any other characteristic not directly related to the objectives of the study.

In accordance with Resolution 8430 of 1993 of the Colombian Ministry of Health, this study is classified as minimal-risk research (34). Its conduct will be subject to approval by the ethics committees of the participating health institutions, as well as to the voluntary acceptance of participants through the signing of informed consent forms.

All participant data collected in this study will be stored and accessed exclusively by the research group, in accordance with Statutory Law 1581 of 2012, Regulatory Decree 1377 of 2013, and Law 1266 of 2008 (Habeas Data Law). The information collected will be used solely for research purposes in the development of this study. All data will be securely stored at the research center of the Universidad Autónoma de Bucaramanga (UNAB). All patient-sensitive information such as name, address, and contact phone number will be removed from the

databases and replaced with an identification number. The information obtained in this study will be retained in accordance with legal provisions for up to 15 years after the completion of the study.

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