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ORIGINAL ARTICLE

Implementation of the Cardioprotective Diet Manual in Primary Health Care: Study Protocol

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Highlights

1. Provide a protocol to implement cardioprotective nutrition guidance
2. Potential global improvement in food consumption of patients in primary healthcare
3. Multifaceted implementation strategy for professionals in primary healthcare

ABSTRACT

The Cardioprotective Nutrition Manual for Primary Care Professionals (MAC) aims to translate dietary recommendations from guidelines on the treatment and prevention of cardiovascular risk factors into a single, playful, and comprehensive strategy. However, the best method for implementing it in Primary Health Care (PHC) remains unknown. The objective of this article is to present the implementation study protocol for the MAC in the PHC of two municipalities in southeastern Brazil. This is a type II hybrid implementation study with a cluster randomized clinical trial design. All PHC services in the municipalities (n=59) will be randomized (1:1) to the group that will receive a multifaceted strategy for MAC implementation, which includes not only the distribution of the material but also training and Audit and Feedback (intervention) or to the group that includes only the distribution of the material, mimicking the current scenario (control). The primary implementation outcome will be evaluated based on the rate of guidance on Cardioprotective Nutrition, and the primary effectiveness outcome will be evaluated by users vegetable consumption over six months of follow-up. Secondary outcomes are: comprehension of the guidance by users and professionals, rate of complementary guidance to the MAC, the perception of the incorporation of the guidance into the professionals' clinical practice, identification of barriers and facilitators for MAC implementation, and users' weight. If positive, the expansion of training to other Brazilian municipalities will be discussed.

Keywords: nutrition; heart disease risk factors; primary health care; patient care team; implementation science.

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INTRODUCTION

Cardiovascular diseases (CVD) are the leading causes of morbidity and mortality, accounting for 32% of deaths worldwide in 2019[1]. These diseases generate high costs, representing a significant impact on Brazilian public health[2]. In 2018, it is estimated that obesity, diabetes, and hypertension together generated R$3.45 billion in costs, with obesity responsible for 41% of the total costs[3].

The management of risk factors for CVD follows specific guidelines, in which care and prevention are mostly divided into pharmacological and non-pharmacological treatments. However, there is a gap regarding the implementation of the interventions proposed in the guidelines into healthcare practices.[1,3].

Understanding the multimorbidity scenario of CVD and its risk factors, the Cardioprotective Nutrition approach is introduced, translating the nutritional recommendations from protocols and clinical guidelines for people with modifiable cardiovascular risk factors into a single playful strategy[4].

The Brazilian Cardioprotective Nutrition Program guidance strategy has previously been investigated in controlled environments, and positive impacts on population health have been observed, such as improved dietary quality and weight reduction.[5,6]. Additionally, the nutritional approach aligns with the recommendations of the Dietary Guidelines for the Brazilian population from the Ministry of Health[7], being consistent with the guidelines of the National Food and Nutrition Policy[8].

Such evidence, combined with the playful strategy of dietary guidance and the encouragement of Brazilian food culture, fostered the development of the "Cardioprotective Nutrition: Manual of Guidelines for Primary Care Professionals" (MAC) [4] and the booklet "Cardioprotective Nutrition" for the patients [9]. Both printed materials were distributed to State Health Departments across the country, and their online version is available in the library of the Primary Health Care Department of the Ministry of Health. However, we question whether simply making the materials available and distributing them to health professionals is sufficient for their implementation into practice.

Understanding that there are numerous barriers to implementing new practices in the primary heath care and the need for innovation and identification of strategies to implement changes[10,11], our study proposes a multifaceted strategy for the implementation of the MAC. This strategy includes the provision of printed materials, the training of health professionals, and the execution of audit and feedback on the implementation process.

Therefore, this article aims to present the study protocol that evaluates and discusses ways to implement the MAC in Primary Health Care (PHC) services in two Brazilian municipalities.

METHODS

The study will evaluate an implementation strategy for the MAC in PHC services of the public health system in two Brazilian municipalities: Foz do Iguaçu (Paraná) and Santos (São Paulo). This is a hybrid type II implementation study with a cluster randomized clinical trial design.

As a hybrid type II implementation study, the aim is to evaluate both the implementation strategy of an intervention and the effectiveness of the intervention itself. This multifaceted implementation strategy involves components of professional training, audit and feedback, and delivery of materials. By applying this strategy, it is expected that health professionals will start guiding patients towards cardioprotective nutrition, and that them will show improvements in dietary intake, reflecting the effectiveness of cardioprotective nutrition.

The primary objective of the study is to compare the rate of cardioprotective nutrition guidance by professionals (implementation component) between the intervention and control clusters after six

months of follow-up. Additionally, it aims to compare the patients diet quality from the intervention and control clusters after six months of follow-up (effectiveness component).

The secondary objective is to understand the barriers and facilitators involved in the MAC implementation process from the perspective of health professionals and managers; to evaluate professionals adherence to other additional cardioprotective nutrition guidelines; to assess professionals form intervention group participation in training; to evaluate professionals understanding of MAC guidelines; to assess professionals perception of incorporating MAC guidelines into practice; to evaluate the effect of MAC implementation on patients body weight; to assess patients diet quality; and to evaluate users understanding of MAC guidelines.

Ethical approval and consent to participate

All procedures described in this protocol comply with the ethical standards of the institutional and/or national research committee, have been approved by the Research Ethics Committee (CEP) of the coordinating center, Hcor (CAEE nº 14604819.3.1001.0060), and will be submitted to the CEPs of the Health Departments of the municipalities of Santos and Foz do Iguaçu. Registration NCT05310526 in Clinical Trials.

Health professionals from the health services, as well as users served by these services, will be invited to participate in the study, as described below. Individuals will only be included upon signing the study's Informed Consent Form (ICF). Users, who will be contacted by phone through trained professionals, will provide their ICF remotely. After clarifying any questions regarding the study and obtaining consent, an audio recording of the user consenting to participate in the study will be requested, which will be stored in the research data capture system (REDCap).

Participants

Healthcare services

All PHC health services in Santos-SP and Foz do Iguaçu-PR that follow the traditional model or the Family Health Strategy (ESF) model will be invited. Health services that already encourage the use of MAC will be excluded; Street Consultancy Services; and/or health services that refuse to participate.

Healthcare professionals

All healthcare professionals working in health services or on multidisciplinary teams, such as community health agents, support agents, social workers, nursing assistants, pharmacy assistants, oral health assistants, dentists, dental surgeons, nurses, resident nurses, nursing interns, pharmacy interns, public health interns, pharmacists, physiotherapists, resident physiotherapists, speech therapists, managers, doctors (Family Health Strategy, gynecologists, residents, pediatricians), nutritionists, resident nutritionists, psychologists, resident psychologists, and nursing technicians will be invited. Professionals in the security, cleaning, and administrative areas will not participate in the study.

Patients

Individuals aged 20 years or older with a previous medical diagnosis of at least one of the following conditions will be invited: type 2 diabetes mellitus; systemic arterial hypertension; isolated hypercholesterolemia; isolated hypertriglyceridemia; overweight.

Users with any of the following conditions will be excluded: previous cardiovascular event; psychiatric or neurocognitive condition that prevents understanding of instructions; life expectancy of less than six months; pregnancy/lactation; liver failure with a history of encephalopathy or anasarca; chronic renal failure; organ transplant; gastroplasty less than a year ago; inability to eat orally; no access to a landline or mobile phone.

RANDOMIZATION

Healthcare services (cluster units) will be randomized (central randomization stratified by municipality with concealed allocation) to either receive or not receive the multifaceted implementation strategy (intervention group or control group). The randomization lists will be generated with equal probability of allocation to one of the groups by the statistics department of the coordinating center and will be accessible to the data manager and the principal investigator of the study.

The cities of Santos-SP and Foz do Iguaçu-PR have 30 and 29 healthcare services respectively. Thus, 30 health services will receive the study intervention, and 29 will not. At least 15 users will be consecutively included over a period of five days per week or until the health service completes the minimum sample size, totaling 885 users.

All professionals within the same health service will receive the same intervention. All professionals on multidisciplinary teams will be allocated to the intervention group and will receive the multifaceted strategy. Figure 1 presents the study flowchart.

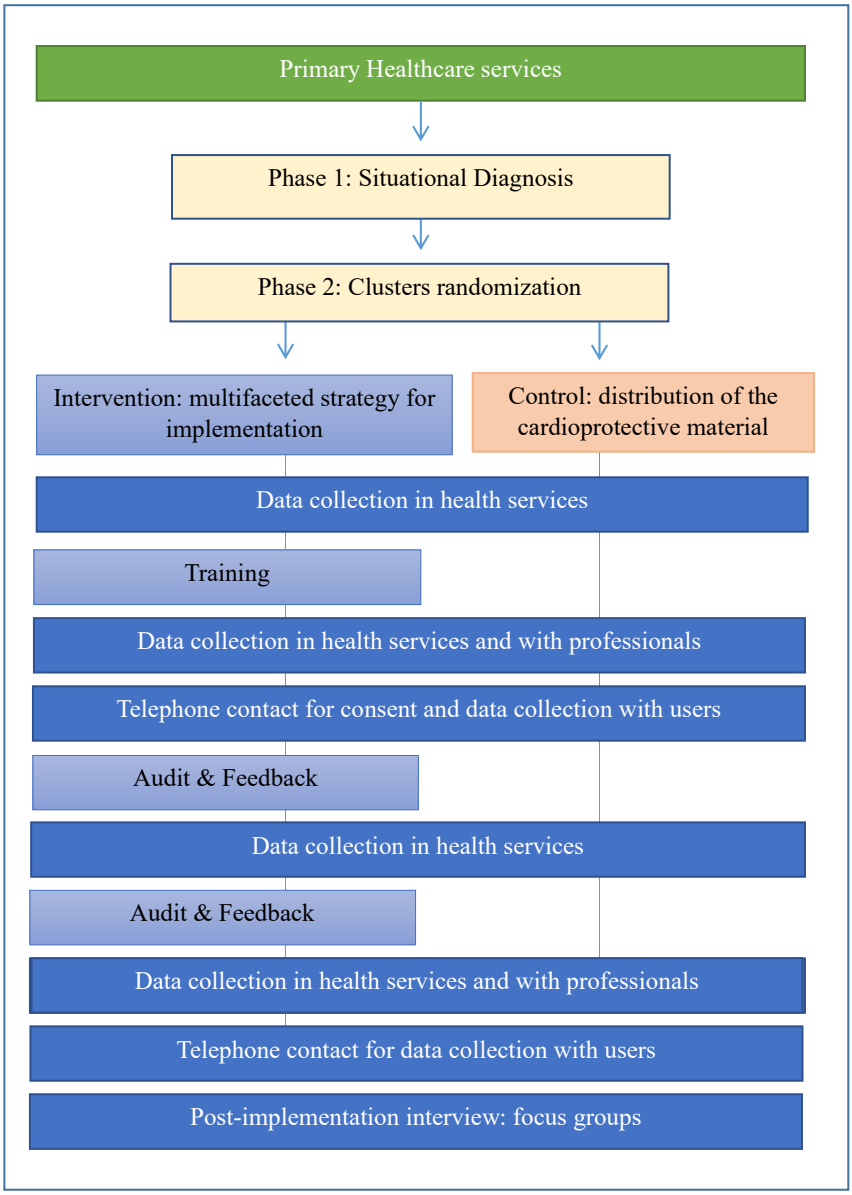

Figure 1 – Flowchart with all stages of conducting the study.

BLINDING

Given the nature of the intervention, both healthcare professionals and users will not be blinded. However, data collectors, outcome assessors, and statisticians will be ensured to be blinded.

STUDY PROCEDURES

Intervention group

The health services randomized to the intervention group will receive three simultaneous implementation strategies (training, audit & feedback, and material delivery), characterizing a multifaceted strategy.

The goal of the training is to facilitate the understanding of the Brazilian Cardioprotective Food Guide strategy, as well as to promote the implementation of the MAC through active teaching and learning methodologies for use by healthcare professionals in their daily work routine.

The training has a bimodal character, with face-to-face activities and activities in a Virtual Learning Environment (VLE), totaling 25 hours, with 20 hours face-to-face and 5 hours in the VLE. The program content is distributed across five modules (Table 1) and concludes with the collective construction of the Cardioprotective Food Guide implementation plan in the health service (Supplementary Material 1) among professionals' working in the same service. We estimate a period of 15 days for professionals to organize themselves both to discuss and to implement the knowledge acquired during the training. The training intervention will last a total of up to eight weeks, with the delivery of the face-to-face modules within six weeks, followed by two weeks for the completion of the implementation plan. Throughout the eight weeks, the VLE will be available to professionals, with the release of the online modules offered in parallel with the face-to-face modules.

Understanding the high demand on professionals in primary healthcare services, various strategies will be adopted to ensure greater adherence by professionals and minimal impact on user care. Thus, the training schedule and division of groups will be agreed upon with the municipal health management and service managers. Additionally, each module will be offered in two or three morning periods and two or three afternoon periods on different days of the week, allowing for greater flexibility in aligning professionals' schedules according to demand and working hours. Finally, the VLE will be structured with a summary of the content covered in the face-to-face modules, ensuring professionals have access to the content even if they miss the face-to-face modules.

Table 1 – Programmatic content of the training to guide Cardioprotective Nutrition, of a bimodal nature, aimed at the intervention group of the study

Module		CL distribution
	Module 1 – Qualitative concepts of Cardioprotective Nutrition	4 hours in person + 1 hour in VLE
	Module 2 – Concepts of dividing foods into cardioprotective food groups	4 hours in person + 1 hour in VLE
	Module 3 – Assessment of the individuals eating habits	4 hours in person + 1 hour in VLE
	Module 4 – Techniques for individual and group dietary guidance	4 hours in person + 1 hour in VLE
	Module 5 – MAC implementation	4 hours in person + 1 hour in VLE
Total CL: 25 hours		

CL: Course load, MAC: Cardioprotective Nutrition Manual, VLE: Virtual Learning Environment.

As part of the active teaching and learning methodologies, the face-to-face meetings will include activities such as bingo, crossword puzzles, simulation of care, interactive games, among others. Additionally, the VLE features exercises to reinforce the content.

The rate of adherence to the Cardioprotective Food Guide will be monitored and reported to the health service managers as part of the audit & feedback (A&F) process. This can be defined as a summary of the performance of professionals and/or health services (audit) over a specific period of time, and the provision of this summary (feedback) to the health teams or organizations[12].

Control group

The health services allocated to the control group will receive copies of the MAC and brochures on Cardioprotective Food aimed at users. The materials will be delivered during a brief visit to the services by the study coordinating team. The visit includes a concise explanation of the ongoing study and the materials, without any encouragement or training for the use of the MAC in these health services.

DATA COLLECTION

Situational diagnosis

The characterization of health services will be based on the count of services in each municipality, type of service, number of healthcare professionals, as well as the geographical location of health services. The situational diagnosis will be done through a questionnaire sent to the managers of the Municipal Health Departments (Supplementary Material 2). Additionally, a questionnaire is provided to the health service managers to understand the volume of care provided in each service (appointments per week) and the proportion of care for users with type 2 diabetes, systemic arterial hypertension, dyslipidemia, or overweight or obesity (Supplementary Material 3).

Outcomes

Table 2 presents the list of outcomes, tools, and data collection period.

Table 2 – Description of tools and data collection period by outcome

IMPLEMENTATION COMPONENT				
Outcome	**Data collection tool**	**Assessment level**	**Collection method**	**Collection moments**
Orientation rate (primary outcome of implementation)	Medical records of users of health units	Healthcare services	Active search for records of cardioprotective nutrition guidelines in the electronic medical records of eligible users.	Up to 15 days before training; Up to 15 days after training; Three months after training; Six months after training.
Knowledge of professionals	Study-specific and original questionnaire (supplementary material 4)	Healthcare professionals	Questionnaire sent to professionals' email or collected in person	Up to 15 days after training; Six months after training.
Extra recommendations	Study-specific and original questionnaire (supplementary material 5)	Healthcare professionals	Questionnaire sent to professionals' email or collected in person	Up to 15 days after training; Six months after training.
Perception of incorporation	Study-specific and original questionnaire (supplementary material 6)	Healthcare professionals	Questionnaire sent to professionals' email or collected in person	Up to 15 days after training; Six months after training.
Presence in training *(intervention group only)*	Presence lists	Healthcare professionals	Identification of presence from attendance lists throughout the face-to-face modules and via the VLE performance report	Throughout the entire training (intervention).
Implementation barriers and facilitators	Semi-structured interview guide	Healthcare professionals and service managers	Presential focus group	6 months after training.
EFFECTIVENESS COMPONENT				
Outcome	**Data collection tool**	**Assessment level**	**Collection method**	**Collection moments**
Diet quality (primary effectiveness outcome)	Questionnaire adapted from VIGITEL (supplementary material 7)	Eligible patients	Telephone call	Up to 15 days after training; Six months after training.
Anthropometry	Self-report	Eligible patients	Telephone call	Up to 15 days after training; Six months after training.
Understanding cardioprotective diet	Study-specific and original questionnaire (supplementary material 8)	Eligible patients	Telephone call	Up to 15 days after training; Six months after training.

VIGITEL: Surveillance of Risk and Protective Factors for Chronic Diseases by Telephone Survey; VLE: Virtual learning environment.

The quality of the user's diet will be assessed using a questionnaire adapted from the Surveillance of Risk Factors and Protection for Chronic Diseases by Telephone Survey Report[13], a survey for gathering epidemiological data among the Brazilian population (Supplementary Material 7). For anthropometry, we will use self-reported current weight, maximum lifetime weight, and self-reported height. With this information, Body Mass Index (BMI) will be calculated. Understanding of Cardioprotective Nutrition among healthcare service users will be evaluated using a proprietary and original questionnaire, where each question contributes to a score that forms a final score (Supplementary Material 8). The questionnaire consists of 10 questions, with a maximum score of 8 and a minimum of 0. User information will be collected via a telephone call conducted under the responsibility of the coordinating center.

The orientation rate for patients to adhere to the Brazilian cardioprotective diet by healthcare professionals will be calculated as follows: the number of consultations where nutritional guidance was provided to eligible patients, divided by the total number of consultations conducted for eligible individuals throughout one week. The coordinating center team is responsible for data collection regarding the orientation rate, without requesting or delegating data collection tasks to any healthcare service professionals for the research. In addition to suggesting cardioprotective nutrition guidelines, the MAC also promotes the establishment of community gardens, preparation of herbal salt, water consumption, among others. To assess if these additional guidelines are implemented, an original questionnaire will be emailed to healthcare professionals (Supplementary Material 5). The perception of incorporating cardioprotective nutrition guidance into clinical practice among healthcare professionals will be assessed using an original questionnaire with Likert scale-based responses (Supplementary Material 6). To evaluate healthcare professionals' knowledge of cardioprotective nutrition, an original questionnaire will be used where each question contributes to a score forming a final score (Supplementary Material 4). The questionnaire consists of five questions, with scores ranging from 0 to 10. The questionnaire will be emailed to healthcare professionals by a single link for responding in a virtual format. A 15-minute time frame has been allotted for completing the questionnaires.

In the intervention clusters, we will also assess the attendance/participation frequency of healthcare professionals from these services in training sessions. Attendance lists from the training days will be utilized, along with access data and activities in the VLE.

To identify barriers and facilitators of implementing cardioprotective nutrition guidance in Primary Health Care (PHC), focus groups will be conducted with healthcare professionals and service managers from both intervention and control groups. A script with guiding questions will be developed for the focus groups, based on theoretical models and frameworks of implementation[14,15].

Data management

Data will be entered into the REDCap® electronic system (REDCap - Research Electronic Data Capture), a securely structured digital platform for developing electronic medical records and managing online databases.

Study data will be collected by researchers from the coordinating center, who are appropriately trained and referred to as "facilitators." These facilitators will have the sole responsibility of data collection. Each facilitator will have a unique and non-transferable username and password for tracking activities within the REDCap Acadêmico® system.

Qualitative data will be derived from transcriptions of focus group recordings, subsequently transcribed using Microsoft Word© text tool and data spreadsheet via Microsoft Excel© for analysis and categorization of the data.

Data analisys

Characteristics of healthcare services and users will be described categorically by absolute and relative frequencies. Continuous variables will be described using position statistics (mean, median) and dispersion (standard deviation, interquartile ranges).

Comparisons between groups will be conducted using an extension of regression procedures for cluster studies called Generalized Estimating Equations (GEE) models. Effects will be expressed as population average odds ratios (Orpa) for qualitative variables or as mean differences for quantitative variables, with respective 95% confidence intervals. Adjusted analyses are planned for region, healthcare service type (traditional or Family Health Strategy - ESF), region size, number of healthcare professionals, presence or absence of community health agents, along with sensitivity analyses considering per-protocol analyses and excluding clusters with possible contamination (clusters with professionals working in multiple healthcare services).

Analyses will be performed using the latest version of the R software. The significance level was set at 5% for two-tailed hypothesis tests.

For qualitative data, thematic content analysis will be conducted with transcripts from focus groups. This analysis aims to describe and understand perceptions, interpretations, and beliefs from the perspective of managers and professionals regarding the implementation of MAC (Cardioprotective Nutrition). It involves identifying themes or cores of meaning that compose communication[16]. Thematic cores will be defined post hoc according to the frameworks and models of implementation used in the focus groups.

Qualitative analysis will provide insights into understanding quantitative research results, assuming that focus group techniques allow for the formation of opinions and attitudes through interaction among individuals[16].

Furthermore, data triangulation will be employed as a methodological resource using different methods, techniques, sources, and researchers to evaluate a research problem[17]. This approach underscores the relevance of developing mixed-methods studies for a comprehensive understanding of data, combining positivist elements from quantitative methodology and, conversely, interpretative elements from qualitative approaches[17].

Statistical power for quantitative analysis

For sample calculation, randomization of 58 healthcare services was estimated, each including consecutively at least 15 users over a period of five days per week or until the healthcare service completes the minimum sample, totaling 870 users.

Calculations were performed using two-proportion comparison tests in cluster studies18, with the assistance of the CRTSize[19] package in R software 4.0.5[20].

This sample will have 85% power to detect an absolute increase of 15% in the primary implementation outcome, with a two-tailed significance level of 5% and a moderate intra-cluster correlation coefficient (ICC) of 0.20. Assuming a success rate estimate of 75% in the control group[21].

Additionally, this sample will ensure 90% power to detect an absolute increase of 20% in the primary effectiveness outcome, with a two-tailed significance level of 5% and a moderate ICC of 0.15. Considering an adherence rate of 24.5% to recommendations in the control group[13].

DISCUSSION AND FINAL CONSIDERATIONS

Cardioprotective Nutrition is an initiative by the Brazilian Ministry of Health that has been studied over the past decade[5,22-24]. In secondary prevention patients, an improvement in diet quality was observed even four years after the intervention with the Brazilian Cardioprotective diet. However,

this improvement did not impact the prevention of new cardiovascular events[23]. Recognizing the importance of adherence to proper nutrition and the challenge of developing strategies to maintain patient adherence to treatment, the secondary prevention study results were encouraging[23]. Based on these results, an educational booklet for patients with cardiovascular risk factors or undergoing cardiovascular disease (CVD) treatment was developed and published in the virtual library of the Brazilian Ministry of Health. Additionally, an educational manual for healthcare professionals was created, outlining the concepts of Cardioprotective Nutrition and providing instructions on how to incorporate these guidelines into clinical practice with patients[4,9].

This material was printed and distributed to the State Health Departments across the country, and it is also available online for free. However, we acknowledge that producing and providing high-quality guidelines does not guarantee their implementation in healthcare practice. Therefore, an active implementation strategy is necessary to encourage their utilization[25].

Adherence to clinical guidelines may fall short of ideal levels regardless of a country's economic power, as demonstrated by studies from Australia[26], Sweden[27], and Norway[28]. Numerous factors can influence the acceptance and utilization of evidence, including individual-level factors (individual and clinical behavior), organizational-level factors, or political and geographical contexts[29-31]. Therefore, understanding the landscape in which integrated practice is sought is essential for establishing implementation strategies.

The implementation gap of interventions and research findings into healthcare practices has been widely discussed, particularly considering that Evidence-Based Practices (EBP) take an average of 17 years to be integrated into routine healthcare, and only half of them achieve widespread adoption[32,33]. This delay is often associated with the academic paradigm, where health researchers invest significant efforts in interventions typically conducted in academic settings with highly selected populations, aiming for high-impact publications that often lack reach, dissemination, and impact in public health[34]. Thus, there is a need to develop specific strategies to promote the use of EBP in healthcare delivery.

In the present study, the strategy to promote the use of Evidence-Based Practice (EBP), specifically the Cardioprotective Nutrition Manual, includes training, audit and feedback. A systematic review of thirty-six systematic reviews compiled evidence on barriers and facilitators to guide behavior change among users in primary care. Highlighting four barrier themes and three facilitators, the authors emphasize the importance of addressing healthcare professionals' perceptions, providing adequate training, and encouraging focus on prevention and management of health conditions[35]. The authors further emphasize that adequate training is crucial for healthcare professionals to introduce behavior changes during routine consultations.

These findings support our intervention, which is based on training professionals in the use of technology (Cardioprotective Nutrition Manual) and closely monitoring with healthcare unit managers (audit and feedback), using unit performance data. Audit and feedback play a crucial role in supporting behavior change and improving quality in healthcare, defined as summaries of clinical performance aimed at enhancing provider performance[36-38]. In a qualitative study, the audit and feedback strategy contributed to creating tension for change in the implementation of matrix support, demonstrating the acceptability, appropriateness, and adoption of this approach[39].

The present study differs from previous studies on Cardioprotective Nutrition. The hybrid type II implementation study design will provide two relevant responses: one from the user perspective and another from the perspective of healthcare professionals and managers. Over a short period of 6 months, we will assess the intervention's impact on diet quality in primary prevention of cardiovascular disease, which has not been evaluated yet, as well as its impact on the adoption of the new practice by

healthcare professionals. Conducting this study will require establishing a strong partnership between our research group, the Ministry of Health of Brazil, and the health departments of the involved municipalities, a critical component of implementation research.

The lack of blinding among study participants is a limitation. While blinding is not feasible, statisticians and data collectors will be blinded to the interventions. Potential contamination of the intervention between groups may also occur, given that multiple healthcare professionals may work across different healthcare services. However, with the situational diagnosis of municipalities, we will understand how many and which professionals are involved, enabling us to conduct subsequent analyses, including or excluding clusters affected by possible contamination.

Another potential limitation is the data collection via telephone with users, where anthropometry is self-reported and not measured by researchers. Another limitation could be potential underreporting regarding the guidance on Cardioprotective Nutrition. Varied access levels among professions, unstable internet connections, outdated computer equipment, and system errors may result in the inability to record Cardioprotective Nutrition guidance in patient records. Reminders and reinforcement of the importance of recording guidance in patient records will be conducted during the Audit & Feedback process. Additionally, despite coordination with municipal health managers to determine the best dates and locations for training sessions, not all healthcare professionals in the intervention group may be able to attend, potentially resulting in low adherence to the intervention.

If the study results show positive changes in the behavior of healthcare professionals and users, this data will provide grounds for expanding training to other Brazilian municipalities and regions, potentially leading to overall improvement in dietary habits among populations at cardiovascular risk.

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