

Phone call for diabetic people: protocol for a pragmatic, type 1 effectiveness-implementation hybrid clinical trial



Chamada telefônica para pessoas diabéticas: protocolo de um ensaio clínico randomizado pragmático híbrido tipo 1 de efetividade-implementação
Llamada telefónica para individuos diabéticos: protocolo para un ensayo clínico aleatorio pragmático de tipo 1 híbrido de efectividad e implementación

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How to cite this article:

Sala DCP, Costa PCP, Baumann AA, Cardoso MMA, Horta ALM, Okuno MFP. Phone call for diabetic people: protocol for a pragmatic, type 1 effectiveness-implementation hybrid clinical trial. Rev Gaúcha Enferm. 2024;45(spe1):e20240045. <https://doi.org/10.1590/1983-1447.2024.20240045.en>

ABSTRACT

Objective: To describe an implementation study protocol for an intervention based on educational guidelines focused on seven self-care behaviors, through phone calls to individuals with type 2 diabetes.

Method: We will conduct a hybrid type 1 effectiveness-implementation pragmatic randomized clinical trial, with 198 individuals with type 2 diabetes on insulin therapy, from the Glycemic Self-Monitoring Program of two Primary Health Care in the city of São Paulo and three in Campinas, located in the state of São Paulo. Patients will be allocated in a 1:1 ratio to either the intervention or control group. Both groups will receive standard care, with the intervention group also receiving a phone call. During the call, nurses will provide guidance based on seven self-care behaviors, known as The ADCE57 Self-Care Behaviors™. Evaluations will happen at the baseline, and after 3- and 6-months post initiation of the trial. Glycemic levels and adherence to self-care behaviors will be compared before and after the intervention using multiple linear regression models. Through interviews with participants from the intervention group, implementation determinants based on the Capability, Opportunity, Motivation-Behavior (COM-B) model, and implementation outcomes feasibility, acceptability, and appropriateness will be evaluated.

Expected outcomes: We will evaluate the effectiveness of an intervention while exploring contextual conditions for its implementation in clinical practice of Primary Health Care. This study will provide preliminary evidence on the effectiveness of educational guidance through nurse-led telephone calls, as well as implementation determinants and outcomes in the clinical practice of Primary Health Care. Its results are important for expanding this assistance in locations where nursing consultation for people with diabetes is absent, hindered, or restricted. Study is registered on the ReBEC platform.

Descriptors: Diabetes Mellitus, Type 2. Health Education. Telephone. Nursing. Implementation Science.

RESUMO

Objetivo: Descrever um protocolo de estudo de implementação de uma intervenção baseada em orientações educativas focadas em sete comportamentos para o autocuidado, por meio de chamadas telefônicas para pessoas com diabetes tipo 2.

Método: Será conduzido um ensaio clínico randomizado pragmático híbrido tipo 1 de efetividade-implementação, com 198 pessoas com diabetes mellitus tipo 2, em insulino terapia, do Programa de Automonitoramento Glicêmico de duas Unidades Básicas de Saúde da cidade de São Paulo e três de Campinas, situadas no estado de São Paulo. Os pacientes serão alocados na proporção 1:1 para o grupo intervenção ou controle. Ambos os grupos receberão cuidados habituais, sendo que o grupo intervenção também receberá uma chamada telefônica. Durante a chamada, os(as) enfermeiros(as) fornecerão orientações baseadas em sete comportamentos para o autocuidado, conhecidos como The ADCE57 Self-Care Behaviors™. As avaliações ocorrerão no início e após 3 e 6 meses do início do ensaio. Níveis glicêmicos e adesão aos comportamentos de autocuidado serão comparados antes e depois da intervenção por modelos de regressão linear múltiplos. Por meio de entrevistas com os participantes do grupo intervenção, serão avaliados determinantes da implementação baseados no modelo Capacidade, Oportunidade, Motivação para mudança do Comportamento (COM-B), e os desfechos de implementação viabilidade, aceitabilidade e adequação.

Resultados esperados: Este estudo fornecerá evidências preliminares sobre a efetividade da orientação educativa por chamada telefônica feita pelo(a) enfermeiro(a), bem como de determinantes e desfechos de implementação na prática clínica da Atenção Primária à Saúde. Seus resultados são importantes para expandir essa assistência em locais onde a consulta de enfermagem para pessoas com diabetes é ausente, dificultada ou restrita. Estudo registrado na plataforma ReBEC.

Descritores: Diabetes Mellitus tipo 2. Educação em saúde. Telefone. Enfermagem. Ciência da Implementação.

RESUMEN

Objetivo: Describir un protocolo de un estudio de implementación de una intervención basada en orientaciones educativas centradas en siete comportamientos de autocuidado, a través de llamadas telefónicas a personas con diabetes tipo 2.

Método: Se llevará a cabo un ensayo clínico aleatorio pragmático híbrido tipo 1 de efectividad-implementación, que involucrará 198 personas con diabetes mellitus tipo 2 en terapia con insulina, del Programa de Automonitorización Glucémica de dos Unidades Básicas de Salud de la ciudad de São Paulo y tres de Campinas, ubicadas en el estado de São Paulo. Los pacientes se asignarán en una proporción de 1:1 al grupo de intervención o control. Ambos grupos recibirán atención habitual, y el grupo de intervención también recibirá una llamada telefónica. Durante la llamada, los(as) enfermeiros(as) proporcionarán orientación basada en siete comportamientos de autocuidado conocidos como The ADCE57 Self-Care Behaviors™. Las evaluaciones se realizarán al inicio y después de 3 y 6 meses desde el inicio del ensayo. Los niveles de glucemia y la adherencia a los comportamientos de autocuidado se compararán antes y después de la intervención mediante modelos de regresión lineal múltiple. A través de entrevistas con los participantes del grupo de intervención, se evaluarán los determinantes de implementación basados en el modelo de Capacidad, Oportunidad, Motivación-Cambio de Comportamiento (COM-B), y los resultados de implementación viabilidad, aceptabilidad y adecuación.

Resultados esperados: Este estudio proporcionará evidencia preliminar sobre la efectividad de la orientación educativa a través de llamadas telefónicas lideradas por enfermeiros(as), así como los determinantes y resultados de implementación en la práctica clínica de la Atención Primaria de Salud. Sus resultados son importantes para expandir esta asistencia en lugares donde la consulta de enfermería para personas con diabetes está ausente, dificultada, o restringida. Estudio registrado en la plataforma ReBEC.

Descriptores: Diabetes Mellitus Tipo 2. Educación en Salud. Teléfono. Enfermería. Ciencia de la Implementación.

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INTRODUCTION

Brazil has a high number of people with diabetes mellitus — the sixth highest in the world and the highest in Latin America^(1,2). Estimates indicate 15.7 million new cases, 96% of which are type 2, with nearly one third of cases remaining undiagnosed^(1–3). This is a chronic condition that requires behavioral changes, care, and continuous monitoring. An inadequate management of care can increase the chances of complications and death. In Brazil, diabetes is the fifth most common cause of death⁽⁴⁾ and loss of years of life due to disability⁽⁵⁾. Furthermore, one third of people with diabetes reported having at least one other complication, while one in every ten has two or more⁽⁶⁾, especially among users who are not in insulin therapy^(7,8).

People with diabetes type 2 (DM2) who adopt healthy habits are 52% less likely to die from cardiovascular diseases than those who do not adopt these habits⁽⁹⁾. However, studies have found that changing the behavior of people with DM2 is challenging, due to several obstacles. In addition to social determinants of health, such as low educational level and income^(10,11), multi-level contextual characteristics make it harder to achieve behavioral change. This includes difficulties having access to health services and professionals, little social support, lack of knowledge about the disease and its care, demotivation, discrimination, and even violence in health care environments^(12–19).

This study proposes an intervention targeted at two of these obstacles: the knowledge about the disease and the access to nursing professionals in primary health care services. Difficulties or the outright impossibility of people with DM2 to access professional consultations has been well documented in literature as a barrier for the adoption of healthy habits^(14–16,18–19). Regarding knowledge, certain difficulties stand out, such as the understanding and clinical management of the disease; the use of information with no scientific basis; lack of guidance for individual needs (e.g. exercises that are not adapted to physical limitations and diets which do not take cultural and social contexts into consideration)^(13–15,17–19).

Therefore, one of our goals is to provide educational guidance to promote knowledge for self-care, based on a program of seven behaviors developed by the American Diabetes and Care Education Specialists, the *ADCES 7 Self-Care Behaviors*^{™(20)}. The 7 Self-Care Behaviors program for people with diabetes is a set of principles and orientations created to help, guide, and evaluate the adequate management of the disease, and the establishment of healthy life habits, which include confronting and eating healthily; being active; taking medication; monitoring oneself; solving problems;

and reducing risks⁽²⁰⁾. Educational guidance based on these behaviors have helped people with diabetes to improve their glycemic control, their quality of life, prevent complications, and reduce health costs^(21–26). In Brazil, researchers have also been using this program⁽²⁷⁾.

We also seek to use phone calls as a strategy to increase access to educational orientations from nurses for people with DM2 who are undergoing insulin therapy, and, therefore, are more likely to develop complications⁽²⁸⁾. Information and communication technologies (ICT) have been increasingly used in distance health. In the case of diabetes, they can help achieve a mean reduction of 0.41% glycated hemoglobin (HbA1c%) when compared to other treatment methods⁽²⁹⁾. Specifically regarding phone calls, several studies have been showing promising results in reducing glycemia and promoting self-care in DM2, including cases of insulin therapy⁽³⁰⁾, especially when conducted by nurses^(31–37), showing a mean decrease of 0.53% in HbA1c⁽³⁸⁾.

In general, phone calls are a strategy applied weekly or monthly as a complement to other strategies, such as text messages via Short Message Service (SMS) or email, video calls, and monitoring via app^(31,38). For this study, we chose to evaluate the effectiveness of educational guidance with a single call, due to pragmatic considerations regarding the implementation of this strategy in the reality of nurses from Primary Health Care Units (UBS). Furthermore, phone calls are a consolidated strategy in UBS for the active search for patients. It has been expanded and intensified during the COVID-19 pandemic, especially in order to monitor groups with moderate-to-high risk chronic conditions^(39,40).

UBSs are, according to the National Policy for Primary Care, a public service that conducts actions and provides services to individuals, families, and collectives. Their activities involve promotion, prevention, protection, diagnosis, treatment, rehabilitation, damage reduction, and palliative care⁽⁴¹⁾. The care provided by the UBS is based on principles such as universal, integral, and egalitarian health, developed through integrated practices of care and qualified management. These are carried out by multiprofessional teams and directed to the population of a certain territory, over which the teams take sanitary responsibility⁽⁴¹⁾. The UBS is an essential base of Primary Health Care in Brazil, providing broad and continuous care to the local community⁽⁴¹⁾. Currently, more than 70% of the Brazilian population has access to UBS for vaccines, wound dressings, multiprofessional consultations for childcare, prenatal care, diagnosis and treatment of chronic conditions, as well as health promotion activities and others⁽⁴²⁾.

Nurses are a part of the health team, and among the activities they perform, such as nursing consultations, health

surveillance, and group, family and home activities, the coordination of care management in these practices stands out^(43,44). Therefore, the results of this evaluation can provide subsidies for the implementation of this strategy in place where UBS nurse consultations are still nonexistent, difficult, or restricted⁽⁴⁵⁾, in order to complement well-structured consultations⁽⁴⁶⁾ and even give support to the gaps in the guidance for self-care in the Program of Glycemic Self-Monitoring (PAMG)⁽⁴⁷⁾. The PAMG is an activity carried out in the UBS to ensure the availability of medication (such as regular and human insulin), supplies (such as glucometers and dipsticks), and follow-up for people with diabetes undergoing insulin therapy⁽⁴⁷⁾.

Thus, our goal is to describe the protocol of a study to implement an intervention based on educational guidance, focused on seven self-care behaviors, using phone calls to people with diabetes type 2. The study aims to answer the following question: How effective is the implementation of an intervention based on educational orientations focused on seven behaviors for self-care using phone calls conducted by nurses to reduce the levels of glucose and improve self-care in people with DM2, especially those under insulin therapy, when compared to the usual practices at UBSs, and what are the factors that influence this?

We will carry out a pragmatic, type 1, effectiveness-implementation hybrid clinical trial⁽⁴⁸⁾. This type of study is based in the science of implementation. Its goals are (1) identifying obstacles and facilitators (i.e., determinants) in order to implement a health intervention, (2) develop and apply strategies to overcome the barriers found, and optimize the facilitators, in order to promote the adoption and integration of the intervention in specific contexts⁽⁴⁹⁾. This type of study has been increasingly used in Portuguese-speaking countries⁽⁵⁰⁾.

■ METHOD

Type of study

This is a pragmatic, type 1 effectiveness-implementation hybrid clinical trial to test the effectiveness of phone calls and, simultaneously, explore the contextual conditions to implement them in the clinical practice of primary health care⁽⁴⁸⁾. Traditional methodological approaches used in research to evaluate the effectiveness and efficacy of health interventions have been criticized for not investigating important factors that hinder or prevent their implementation, such as their feasibility and knowledge about the settings where the intervention will take place⁽⁴⁹⁾. With this in mind,

we will use the type 1 hybrid in this study, as its main goal is to evaluate effectiveness, while the secondary one is to implement an intervention in a specific context, mapping determinants and implementation outcomes⁽⁴⁸⁾.

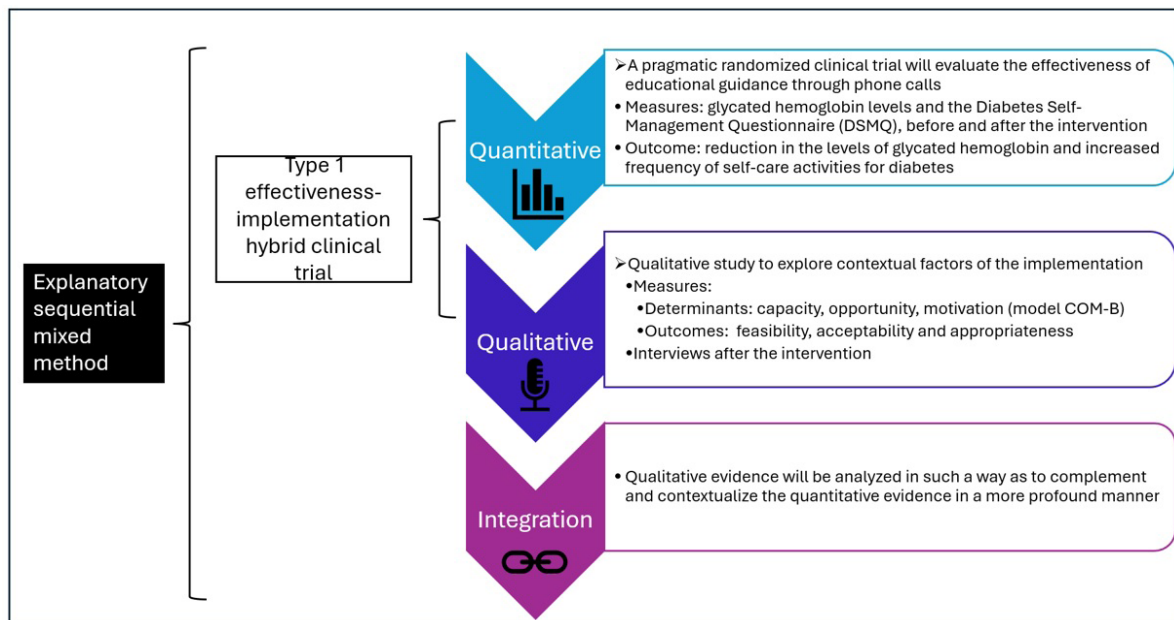
It should be noted that the English word “design”, in the case of “hybrid designs”, refers to a set of procedures related to this focus on effectiveness and implementation, depending on the stage of the implementation of the intervention. However, the fact that the design is hybrid is not a definition of research methods in itself^(48,49). Therefore, we will incorporate the principles of the type 1 hybrid to the methods to collect and analyze established data, ensuring methodological rigor and coherence. Thus, to evaluate whether the intervention is effective or not, we will carry out a pragmatic randomized clinical trial⁽⁵¹⁾, and, to explore contextual factors related to its implementation, we will carry out a qualitative research⁽⁵²⁻⁵⁴⁾.

For this investigation setting, the application of mixed methods of data collection and analysis is an efficient alternative, as it combines quantitative evidence (effectiveness) with qualitative evidence (people’s experience), including broader decision-making aspects such as feasibility, priority, acceptability, impact on equality, and values and preferences of patients^(53,54). In the context of this study, the data will be collected in a sequential and exploratory manner, that is, quantitative data will be collected to test a hypothesis with a larger population (i.e.: is this intervention effective?), and then, qualitative data will be collected, with a smaller population, for exploratory and implementation purposes (i.e., what are the contextual factors that influenced the implementation?)⁽⁵⁴⁾. The notion that qualitative and quantitative evidence are complementary is based on the assumption that they address different aspects or dimensions of a phenomenon of interest. Therefore, one cannot confirm nor refute the other.^(53,54) Figure 1 shows a general view of the study. The questions that will guide the stage of data interpretation are:

When compared to regular care, do phone calls with guidance based on the seven behaviors for health care, made by Primary Health Care nurses:

1. Show preliminary evidence regarding the reduction of the glycemic levels of participants?
2. Show preliminary evidence of improvement in the self-care of participants?
3. Are they viable, acceptable, and adequate from the perspective of participants?
4. Offer elements to improve the capacity, opportunity, and motivation for a change in behavior, from the perspective of the participants?

Figure 1 – Overview of the study design. São Paulo, São Paulo, Brazil. 2023



Theoretical frameworks of implementation science

Regarding the determinants of the implementation of behavioral change, we will use the COM-B model⁽⁵⁵⁾. Determinants are factors that work as intervening variables which mediate or moderate the implementation of health interventions. They can be obstacles or facilitators to the implementation. Identifying and measuring these factors help identify what is bringing success, limitations, or preventing an intervention from reaching its expected results⁽⁴⁹⁾. The model *Capability, Opportunity Motivation-Behaviour* (COM-B) is a theoretical model originated from implementation science. It is widely used in behavioral psychology and in the area of public health, in order to understand and analyze complex behavior, including people with DM2⁽⁵⁶⁻⁵⁸⁾. It states that behavior comes from an interaction between capacity, opportunity, and motivation, and was developed as part of a framework called Behaviour Change Wheel (BCW)⁽⁵⁵⁾.

Using the COM-B, one can understand three determinants that influence the promotion of behavioral change: (1) capability, related to knowledge, abilities, and physical and mental resources needed to adopt the desired behavior; (2) opportunity, which is related to external factors such as physical, social, and cultural environments that can influence behavior; and (3) motivation, related to psychological processes that excite and direct behavior⁽⁵⁵⁾. This includes intrinsic motivation, such as beliefs, values, and desires, and

extrinsic motivation, such as external incentives, in addition to self-motivation⁽⁵⁵⁾.

In summation, this model suggests that effective behavioral change takes place when interventions are directed at these components. Therefore, to encourage healthy behavior, it is possible to improve one's skills by providing educational activities to develop necessary skills; create opportunities by changing one's physical or social environment in order to facilitate their promotion; and increase motivation using strategies to encourage or enhance self-motivation⁽⁵⁵⁾. In this regard, this model will be used to analyze whether educational guidance through phone calls will provide elements that influence behavior regarding the ability to adopt the seven behaviors of self care, and whether it provides adequate opportunities to the needs of users, working as a motivation for change.

Regarding the outcomes of the implementation, we will attempt to ascertain whether phone calls are viable, acceptable, and adequate for people with DM2 who attend UBSs. Implementation outcomes are the effects of intentional actions projected to implement interventions^(49,59). Considering concepts that have been analyzed in depth by scholars in the field⁽⁵⁹⁻⁶¹⁾, it can be stated that:

- Feasibility refers to how possible it is to implement or conduct an intervention in a certain environment. It also involves evaluating whether it is viable, possible to put it in practice, and whether it can be carried

out considering the specific conditions in which it is being implemented. This includes perceptions regarding resources, logistics, costs, capabilities, and how easy or difficult it is to execute. Considering feasibility is essential to determine the real possibility of implementing an intervention.

- Acceptability refers to one's receptivity and willingness to accept the intervention. Therefore, it involves evaluating the attitudes, opinions, values, and expectations of those involved regarding the intervention at hand. Evaluating the acceptability is important to understand whether the intervention is culturally appropriate and ethical, since this can have a significant influence on the adherence to the intervention.
- Appropriateness, in turn, is related to how appropriate or adequate the intervention is considered to be in regard to the specific context where it is being implemented. Here, checks are made as to whether the intervention must be adjusted to ensure that it is relevant and efficient within a specific environment, considering factors such as culture, politics, resources, and expectations of those involved. That does not mean, necessarily, changing the essence of the intervention, but rather to adjust it to better fit the context.

This report followed recommendations from SPIRIT, whose checklist is filled in and attached⁽⁶²⁾.

Participants and place of study

The population will be formed by people with DM2. Inclusion criteria comprise: being 30 or older, having a confirmed DM2 diagnosis, being under insulin therapy, and being registered in the PAMG of the UBS. Exclusion criteria were: being pregnant; having dementia, according to medical records; and having one's registry removed from the UBS after the start of the study.

The study will be carried out in a UBS from the state of São Paulo (SP), addressing two units in the southeast of the city of São Paulo, and three in the north of the city of Campinas. These UBS were chosen after an analysis of the PAMG data and due to the uniformity of care. The first criteria was the number of people registered in the PAMG. It was, at least, 100, aiming to reach the target population. Then, we considered the social and assistance-related context of the UBS care. The three UBSs attend highly socioeconomic vulnerable people, who live in irregular homes, with no basic infrastructure (e.g. basic sanitation), in densely populated regions. They offer

medical consultations and health promotion groups to patients with diabetes, but do not offer nursing consultations to people with DM2. Finally, we considered the collaboration of the institution as a way to enable, logistically, the execution of the research, not to mention that the results would be interesting to improve the care provided.

Quantitative approach

In regard to its quantitative elements, this study aims to evaluate the effectiveness of the intervention. To do so, we aim to carry out a pragmatic randomized clinical trial, a type which is less rigid in the way it can be conducted and closer to the practice, in order to establish an adequate scientific base for decision making⁽⁶³⁾. It is defined by four key points: (1) recruitment of a population in real-world clinical practice settings; (2) the trial is carried out in a real-world environment, instead of places that are exclusive for the research; (3) the trial should have an active control branch for comparison, as opposed to a placebo; (4) the trial should capture relevant results in addition to the data found from records⁽⁵¹⁾.

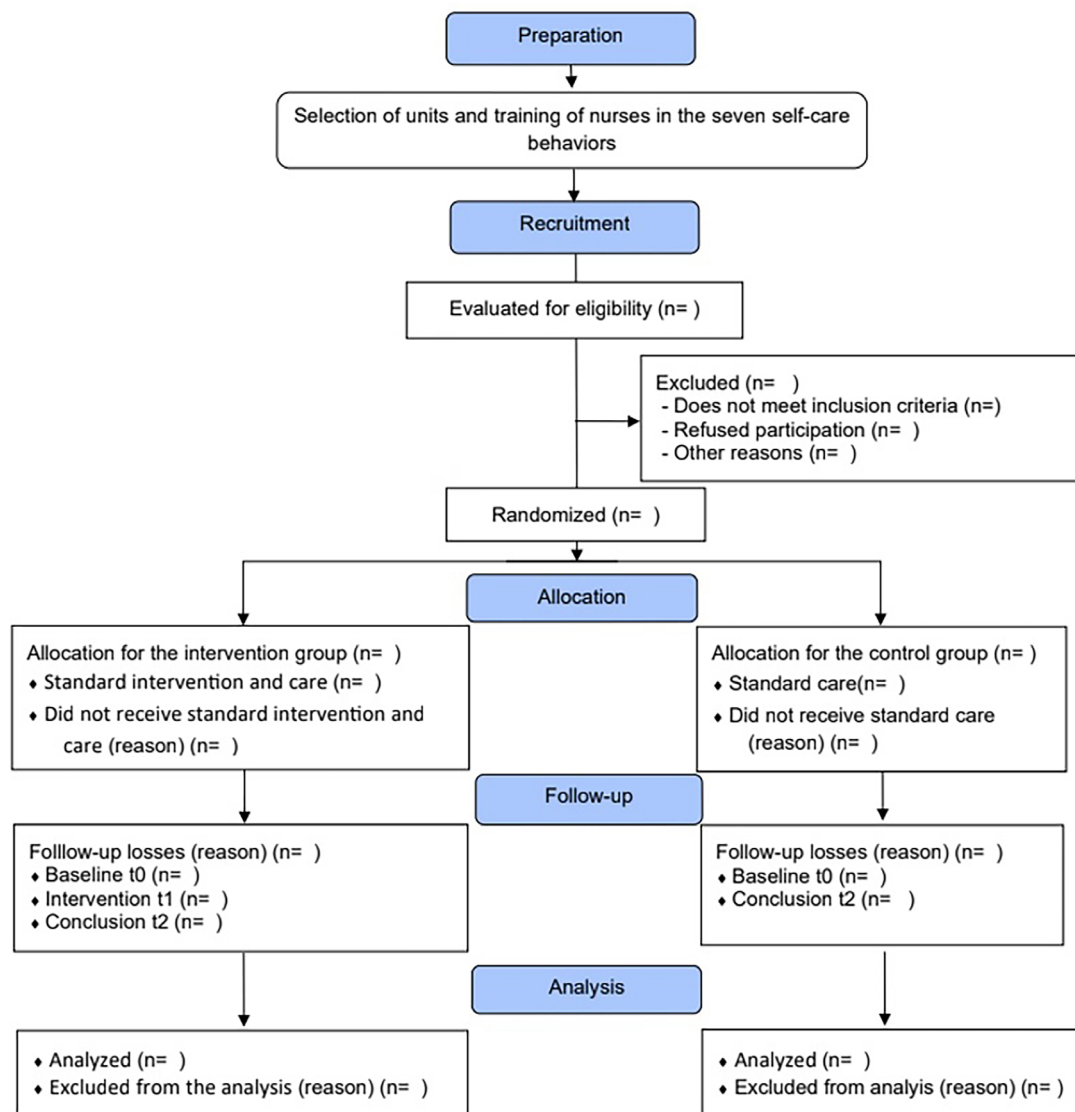
The sample size for the pragmatic clinical trial was calculated considering the goal of comparing two parallel groups (intervention and control) in two periods. For this calculation, we adopted a significance level of 5%, a testing power of 95%, and an effect size of 0.25, which can be considered of a medium level⁽⁶⁴⁾. The calculation considered a rate of 20% in possible losses, leading to a sample of 198 participants who will be divided in 99 per group. For the sample calculation, we used the software G*Power 3.1.9.2.

The evaluation of the study will be conducted in three stages. In the first stage (t0), all participants will be evaluated and the result will be used as a baseline. The second stage (t1), will take place three months after t0, and the intervention will be applied to the participants of the IG via phone call. In the third stage (t2), conducted six months after t0, all participants will be reevaluated and the study will be concluded. Stages t0 and t2 will take place in person, at the UBS. Figure 2 shows the diagram of the study.

Recruitment

Medical records will be consulted to identify potential participants. Those who are in accordance with inclusion criteria will be selected at random, using a phone invitation to participate in the study. Those who agree will be approached in the UBS after their regular consultations and requested to sign an informed consent that will include acceptance of an audio recording.

Figure 2 – Diagram of the stages of the pragmatic randomized clinical trial. São Paulo, São Paulo, Brazil. 2023
Source: Diagram adapted from the CONSORT⁽⁶⁵⁾.



Allocation

Participants will be randomly distributed, in a 1:1 proportion, in an electronic database, generated by the website randomizer.org. The numerical order will be stored in opaque, sealed envelopes. This will be done by a person who is not part of the research group. Due to the characteristics of the intervention, blinding will not be possible. Therefore, to minimize potential biases, the allocation will only be known

after the first evaluation is conducted (t0). Only then will the envelopes be distributed to the researchers. To analyze the outcomes, the researcher responsible will be blinded. She will not be involved in the inclusion of patients in the study, their randomization, data collection, nor on the application of the intervention itself. The patient whose connection to the PAMG is removed during the study (because they stopped using insulin), who do not undergo collections for biochemical exams (HbA1c), as well as those who are not present at the closing of the study, will be considered as losses.

Characteristics of the intervention

The control group (CG) will receive the usual care at the UBS (medical consultations and health promotion groups), while the intervention group (IG) will have available to them, in addition to the usual care, educational guidance based on the seven self-care behaviors, through a phone call carried out by the nurse. All researchers were nurses and will be previously trained to carry out the intervention. They will use a script with standardized principles and guidance, according with the seven behaviors to promote self-care: living well with diabetes, eating healthily, being active, taking medicine, monitoring, reducing risks, and solving problems (The ADCE57 Self-Care Behaviors™)⁽²⁰⁾. Although these guidelines are standardized, their use will revolve around the needs of individuals (e.g., food preferences, physical activity limitations, questions). The intervention is estimated to last for 30 minutes. During the intervention, many pieces of data will be recorded, such as the nurse who carried out the call, the name of the UBS, difficulties to contact the patient via phone, duration of the calls, and number of attempts until reaching the patient. It will also be ascertained whether the patient has been hospitalized or died.

Outcome measures, data collection and analysis procedures

Sociodemographic, clinical and behavioral data will be collected, based on clinical standards determined by specialists⁽⁶⁶⁾ and by the Brazilian Institute of Geography and Statistics. These include:

- Age: in complete years;
- Sex: female; male
- Self-reported ethnicity or skin color: Asian, white, brown, black, indigenous;
- Educational level: No education or less than 1 year of study, incomplete or complete elementary school, incomplete or complete high school, incomplete or complete higher education.
- Religion: Buddhism, Candomblé, Catholic, Evangelical, Spiritist, Spiritualist, Umbanda, none;
- Marital status: single, married, divorced, widowed;
- Occupational situation: employed, unemployed, searching for work, on leave from work, retired or pensioner, student or working as an apprentice;
- Family income: total income of the family who lives with the participant, according to the number of minimum-wages, considering 2023 values.
- Regarding clinical evaluation, the dependent variable (primary outcome) will be glycated hemoglobin (HbA1c):
- We will consider HbA1c > 7% as an altered value. Percentage values will be compared before and after the intervention.
- Other variables include:
- Time since DM2 diagnosis: less than 10 years or greater than or equal to 10 years;
- Associated comorbidities, self-reported or reported in medical records: systemic arterial hypertension, dyslipidemia, depression, coronary diseases, cerebrovascular diseases, etc;
- Acute and chronic complications, self-reported or reported in medical records: moderate (69 – 54 mg/dL) or severe hypoglycemia (lower 54 mg/dL), hyperosmolar hyperglycemic state, diabetic ketoacidosis, retinopathy, nephropathy, neuropathies, diabetic foot, heart disease, cerebrovascular disease, etc.
- Drugs registered in medical prescriptions;
- Anthropometric data:
 - Weight in kg;
 - Height: in centimeters;
 - Body Mass Index: regular weight (18.5 – 24.9 kg/m²), overweight (25.0 – 29.9 kg/m²), and obese (greater than or equal to 30.0 kg/m²);
 - Waist circumference: normal if less than or equal to 94cm for men and less than or equal to 80cm for women;
- Arterial pressure: high if over 130x85 mmHg;
- Alcohol use: men will be considered alcoholic if they drink more than one 650ml bottle of beer or two 50ml shots of spirits twice a week or more; women, if they drink more than half a 650ml bottle of beer or one 50ml shot of spirits more twice a week or more.
- Participation in health promotion groups in the UBS, according with medical records: yes or no.
- Presence in medical consultations in UBS, according to medical records: yes or no.

An evaluation of the habits of self-care will be the secondary outcome, carried out according with the Diabetes Self-Management Questionnaire (DSMQ), translated and validated into Portuguese, with reliability indexes of the items in the test and retest of ($\alpha = 0.15$ to $\alpha = 1.0$) and inter evaluator reliability of ($\alpha = 0.29$ to $\alpha = 1.0$)⁽⁶⁷⁾. The DSMQ has six dimensions and 15 items to evaluate diabetes self-care:

general diet (with two items); specific diet (three items); physical activity (two items); glycemic monitoring (two items); foot care (three items); and medication use (three items, used according with the medication schedule). There are also three other items to evaluate smoking. Patients report how often they did the indicated actions or behaviors in the seven previous days. Responses vary from 0 to 7, where a 0 indicates the least desirable performance in self-care management, and 7, the most desirable.

The estimated time for data collection is 60 minutes. Tools used will include: blood pressure monitor, tape measure, and a scale of the UBS. Biochemical exams will be carried out in the UBS itself, as is standard protocol. One collection will be carried out every six months. We will consider the most recent exam collected by the patient in the UBS before the first and after the last evaluation. For data collection, we will use a standardized electronic form (Google Forms) to minimize input errors in the quantitative research. The team responsible for data collection will be trained, ensuring that the procedures will be uniform and preventing biases.

To analyze the quantitative variables, mean, standard deviation, median, quartiles, minimum and maximum will be used. For the categorical variables, frequency and percentage will be calculated. To compare the quantitative variables of the groups in the initial and final periods of collection, multiple linear regression models will be applied, using generalized Estimating Equations (GEE) as their modeling. Regarding dichotomous categorical variables, modified multiple Poisson regression models with robust variance will be applied, also using GEE modeling. The models will also include potentially confounding variables such as age and time of diagnosis. The significance level considered for all analyses will be 5% (p-value 0.05%). The softwares SAS 9.4 and SPSS 23 will be used. For the statistical analysis, data will be prepared adequately, including identifying and treating absent values and outliers. After the study is complete, data will be published, allowing the validation and reproduction of results by other researchers.

Qualitative approach

This study will use a qualitative approach to analyze the determinants of behavioral change and the implementation outcomes of these interventions, from the perspective of people with diabetes⁽⁵⁴⁾. All participants who received the intervention will be considered eligible to participate. Exclusion criteria will be: users who could not communicate (ex.: hospitalization) and did not answer the phone in 15 days after the intervention. Two researchers, experienced in qualitative research, will be responsible for establishing

phone contact, to invite the participants for this stage of the study. Participants will be asked about whether they prefer in-person interviews at the UBS or at their home, or via phone, as well as their preferred date and time. The interviews are estimated to last from 20 to 30 minutes. The privacy and confidentiality of the individual will be ensured. Theoretical saturation will be used as a criteria for the end of recruitment. Participants will be requested to express their opinions and reflect on their experience with the phone call. The guide for the interview, with the semistructured script, can be found in Appendix 1. The interview will be recorded and the audio transcribed in full.

Data analysis

We will carry out a thematic content analysis, which is a systematic approach involving the identification, description, and interpretation of topics or patterns of meaning that underlie the textual data collected⁽⁵²⁾. Considering the research goals and the theoretical references of implementation science (COM-B model, feasibility, acceptability, and appropriateness), categories or topics of analysis will be defined in a deductive and inductive manner. The deductive analysis will allow categorizing the data starting with pre-existing theoretical concepts. The inductive analysis will enable latent topics to emerge as the data is analyzed, without attempts to make it fit preconceived frameworks. Thus, the methodological rigor is higher, and the analysis can be conducted in a more profound way. Data will be analyzed, coded, categorized, and interpreted by two researchers, one of which studies in the field. Data will be discussed until consensus is reached. Quantitative and qualitative data will be integrated during the interpretation stage, with no strategy of data transformation. This means that evidence will be kept in its original form, supporting, separately, a single line of argumentation⁽⁵⁴⁾.

Ethical aspects and research funding

This study was submitted to the Plataforma Brasil under CAAE 59832822.7.1001.5505 and approved by the Research Ethics Committees and institutions involved, under opinion No. 5.610.643. The confidentiality of the data will be ensured, and if it becomes necessary to change the protocol, all parties involved will be made aware. Security measures to protect the data collected against unauthorized access, continuous evaluation processes to identify and correct mistakes or inconsistencies, and actions for regular backups, to avoid data loss, will be guaranteed during the study. Any change in the records will be recorded and justified. Privacy and ethical

measures, such as consent and confidentiality forms, will be respected. This study has been registered in the platform Brazilian Records of Clinical Trials (ReBEC) on July 20, 2023.

■ EXPECTED RESULTS

The description of a protocol for a pragmatic, type 1 effectiveness-implementation hybrid clinical trial, with mixed data collection and analysis, shows how important this approach is as a first step to accelerate the adoption and integration of evidence-based interventions. Considering this perspective, our design aimed to test the effectiveness of an intervention, while it explores contextual conditions for its implementation, in the clinical practice of Primary Health Care. The results will be important to understand implementation mechanisms and what moderates them, as these are fundamental to implement and expand educational guidance aimed at changing the self-care behavior of people with diabetes using phone calls conducted by nurses in these settings in a more effective manner.

■ CONCLUSION

The results of this study have the potential to give support to the work process of nurses in UBSs, regarding people with DM2 under insulin therapy, especially in the PAMG, in countless regions where nursing consultations are not available yet, are difficult to obtain, or restricted. Phone calls with guidance based on seven behaviors for self-care can be an alternative in these settings. In places where this practice is already adopted, results of this study can also contribute as a complementary alternative to nursing care and used for monitoring. They can also be used to deal with extraordinary circumstances, such as those experienced during the COVID-19 pandemic, in climate catastrophes, and in difficult to access regions, cases in which in-person consultations are carried out as emergency measures. Thus, we expect to provide recommendations for professionals, managers, and other interested parties, regarding the limitations and potential of this intervention, considering its effectiveness, which is determinant for behavioral change, as well as its feasibility, acceptability, and appropriateness for the context observed. Furthermore, this research protocol can help other researchers design future studies in the field of implementation science.

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■ Acknowledgements

The authors would like to thank the financial support from the National Council for Scientific and Technological Development – CNPq, the Ministry of Science, Technology and Innovations (MCTI), and the National Fund for Scientific and Technological Development (FNDCT) through Universal Call No. 18/2021. We would also like to thank the Coordination for the Improvement of Higher Education Personnel (CAPES) for its support through the capes PrInt program, notice No. 41/2017. This work would not have been possible without the support of these institutions.

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Received: 02.28.2024

Approved: 05.23.2024

Associate editor:

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