# Impact of pharmaceutical teleconsultation on glycemic control of people with type 2 diabetes mellitus in a public pharmacy in Brazil: A randomized clinical trial protocol (TelePharmaceutical Care Diabetes Trial) – TPCDT

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**Abstract**

Telepharmacy is a fundamental tool to ensure glycemic control in patients who don't access health services. The objective of this protocol is to report the procedures of a randomized clinical trial that will evaluate the impact and economic evaluation of a pharmaceutical teleconsultation service for patients using dapagliflozin, recently incorporated by the Brazilian public health system for the treatment of type 2 diabetes (T2D). Patients aged 65 years or older, with T2D, and who withdraw dapagliflozin in a public pharmacy located in southern Brazil will be recruited. They will be electronically randomized with allocation for intervention or control group. The intervention will be conducted out through three teleconsultations, one per month, with a pharmacist. The main outcomes will be glycemic control (hemoglobin A1c) and treatment adherence. Secondary outcomes will include lipid profile, blood pressure, and body mass index, number of hospital admissions, number of emergency room visits, number of medical consultations performed, number of problems related to pharmacotherapy identified and resolved, cost related to service and quality of life. The economic evaluation will be carried out using time-driven activity-based costing. Through this research, we will be able to identify whether pharmaceutical teleconsultation services can complement face-to-face consultations to improve health outcomes in T2D patients on dapagliflozin. The study was registered in Clinical Trials (NCT05380596).

**Keywords:** telehealth, pharmaceutical care, diabetes mellitus, pharmaceutical services, tele-interventions.

# Impacto da teleconsulta farmacêutica no controle glicêmico de pessoas com diabetes mellitus tipo 2 em uma farmácia pública no Brasil: Protocolo de ensaio clínico randomizado (TelePharmaceutical Care Diabetes Trial) – TPCDT

**Resumo**

A telefarmácia é uma ferramenta fundamental para garantir o controle glicêmico em pacientes que não acessam os serviços de saúde. O objetivo deste protocolo é relatar os procedimentos de um ensaio clínico randomizado que avaliará o impacto e a avaliação econômica de um serviço de teleconsulta farmacêutica para pacientes em uso de dapagliflozina, recentemente incorporado pelo sistema público de saúde brasileiro para o tratamento do diabetes tipo 2 (DM2). Serão recrutados pacientes com idade igual ou superior a 65 anos, portadores de DM2 e que retirem dapagliflozina em uma farmácia pública localizada no sul do Brasil. Eles serão randomizados

eletronicamente com alocação para grupo intervenção ou controle. A intervenção será realizada através de três teleconsultas, uma por mês, com um farmacêutico. Os principais desfechos serão o controle glicêmico (hemoglobina A1c) e a adesão ao tratamento. Os desfechos secundários incluirão perfil lipídico, pressão arterial e índice de massa corporal, número de internações hospitalares, número de atendimentos de emergência, número de consultas médicas realizadas, número de problemas relacionados à farmacoterapia identificados e resolvidos, custo relacionado ao serviço e qualidade de vida. A avaliação econômica será realizada usando o custeio baseado em atividades baseado no tempo. Por meio desta pesquisa, poderemos identificar se os serviços de teleconsulta farmacêutica podem complementar as consultas presenciais para melhorar os resultados de saúde em pacientes com DM2 em uso de dapagliflozina. O estudo foi registrado em Clinical Trials (NCT05380596).

**Palavras-chave:** telessaúde, cuidado farmacêutico, diabetes mellitus, assistência farmacêutica, teleintervenções.

## 1. Introduction

Diabetes Mellitus (DM) is a heterogeneous group of metabolic disorders that have in common hyperglycemia resulting from defects in insulin action, insulin secretion or both, causing long-term complications. Type 2 diabetes mellitus (T2D), that comprises 90-95% of all types of diabetes, mainly encompasses individuals with overweight or obesity, conditions that in themselves cause insulin resistance, leading to a condition of relative insulin deficiency (Sbd, 2022; Ada, 2019).

Recent epidemiological reports estimate that the world population with diabetes is around 463 million people between 20 and 79 years of age, with about 80% of these individuals living in developing countries (Saeedi et al., 2019). Still, surpassing past forecasts, estimates indicate that by 2040 the number of adults will reach almost 700 million (Lovid et al., 2020). In Brazil, the fourth country in terms of the number of individuals with T2D in the world, the prevalence of diabetes is around 12%, with a significant increase in the last three decades (Ada, 2019; Telo et al., 2016).

Managing diabetes and its complications is an expensive process and creates a substantial economic burden on the healthcare system (Ada, 2018). There is no cure; instead, optimal glycemic control is needed to minimize complications. However, less than 70% of people with diabetes are achieving target glycemic control, demonstrating that effective disease management for people with diabetes remains a challenge (Alessi et al., 2021). For some patients, particularly in rural areas, the failure to achieve desired glycemic controls is due, at least in part, to poor access to qualified health professionals (Zhang et al., 2012). In response to the growing demand for health care and a decreasing availability of health care providers, information and communication technologies have shown the potential to improve accessibility and reduce the costs of providing health services (Charles, 2000).

Telehealth and telemedicine are the terms used to describe the exchange of health information in situations in which professionals and users are physically apart, so the service is provided through communication technologies and aims to improve health outcomes (Tuckson et al., 2017). This form of service has become important for health systems and is used with the aim of reaching users who are in remote locations, where there is often a lack of health professionals, but also with the aim of facilitating access and reduce displacements (Hanjani et al., 2020; Alessi et al., 2021b).

This concept includes telepharmacy, which corresponds to the performance of pharmaceutical services and pharmaceutical care actions remotely, through communication technologies, with the objective of improving health outcomes and the safety of pharmacotherapy (Omboni et al., 2019). In Brazil, telepharmacy is regulated by Resolution nº 727 of 30/06/2022 from professional advice, being carried out in some health services in the country in the model of pharmaceutical teleconsultations, teleinterconsultations, telemonitoring and teleconsulting (Cff, 2022). The Pharmaceutical Teleconsultation service was implemented in 2020, at the State Health Secretariat of the State of Rio Grande do Sul, in Porto Alegre, Brazil, as a strategy to combat COVID-19 and guarantee care, with promising results in the control of asthma and chronic obstructive pulmonary disease (Gossenheimer et al., 2021; Gossenheimer et al., 2021b).

The incorporation of new technologies in the self-care process can contribute to improving the results obtained with classic diabetes treatment techniques and has been documented so far, bringing positive and negative results. A low-cost technology that has been used to reinforce the educational process and self-care of patients with diabetes is direct telephone contact or by sending text messages by cell phone. Web-based and remote health interventions (also called “Internet Interventions” or “eHealth”) are typically behavioral treatments, which are operationalized and transmitted via the internet or remotely (Eberle et al., 2021). Moreover, teleconsultation can

add by getting different healthcare providers together through a common objective, a well-known strategy for chronic diseases including T2D (Garcia et al., 2022).

A meta-analysis demonstrated that the use of eHealth in the diabetes preventive program has promising evidence of the effectiveness of interventions in patients' weight loss (Joiner et al., 2017). In the United Kingdom, since 2011, there has been a program called the "New Medicine Service (NMS)", which consists of a first dispensation service, that is, when the patient will start using the medication, in which the pharmacist performs the monitoring of the patient via remote, using phone calls. In this program, they evaluated adherence and cost, and the results published so far state that there was an increase in adherence to treatment when compared to usual practice, which resulted in increased health gains and a reduced overall cost (Elliot et al., 2016; Elliot et al., 2017). However, there are few studies that expand the use of this technology in health involving the role of the pharmacist and with the possibility of having the support of a multidisciplinary team to promote self-care and adherence (Sharp et al., 2021).

Dapagliflozin was recently incorporated into the Brazilian public system for the treatment of T2D (Brasil, 2020). Considering that there are no studies in Brazil so far on the use, adherence to treatment and problems related to pharmacotherapy associated with its use, and also considering that the guidance and monitoring of patients remotely have become more frequent and necessary, the purpose of this protocol is to describe a clinical trial that will evaluate the impact of a pharmaceutical telecare service on aspects related to treatment adherence, disease control and costs, offered as to people with T2D using dapagliflozin. The hypothesis that will be tested is that pharmaceutical teleconsultation can significantly contribute to the glycemic control of DM2 and to the adherence outcome, and that it will have a favorable cost-effectiveness for the sustainability of the service.

The aim of this trials to evaluate the impact of the pharmaceutical teleconsultation service on users who receive Dapagliflozin for the treatment of T2D in a public pharmacy in the state of Rio Grande do Sul, Brazil.

## 2. Materials and Methods

### *2.1 Study design*

This is an unblinded randomized clinical trial comparing the outcomes between a group that will receive a pharmaceutical intervention through telehealth (pharmaceutical teleconsultation service via telephone), and the control group that will receive only usual care. All stages of this study will follow the recommendations of the CONSORT guideline for clinical trials (Schulz et al., 2010) and the SPIRIT Checklist for clinical trial protocols (Chan et al., 2013). This protocol was registered with ClinicalTrials.gov under number NCT05380596. Figure 1 presents the clinical trial flowchart.

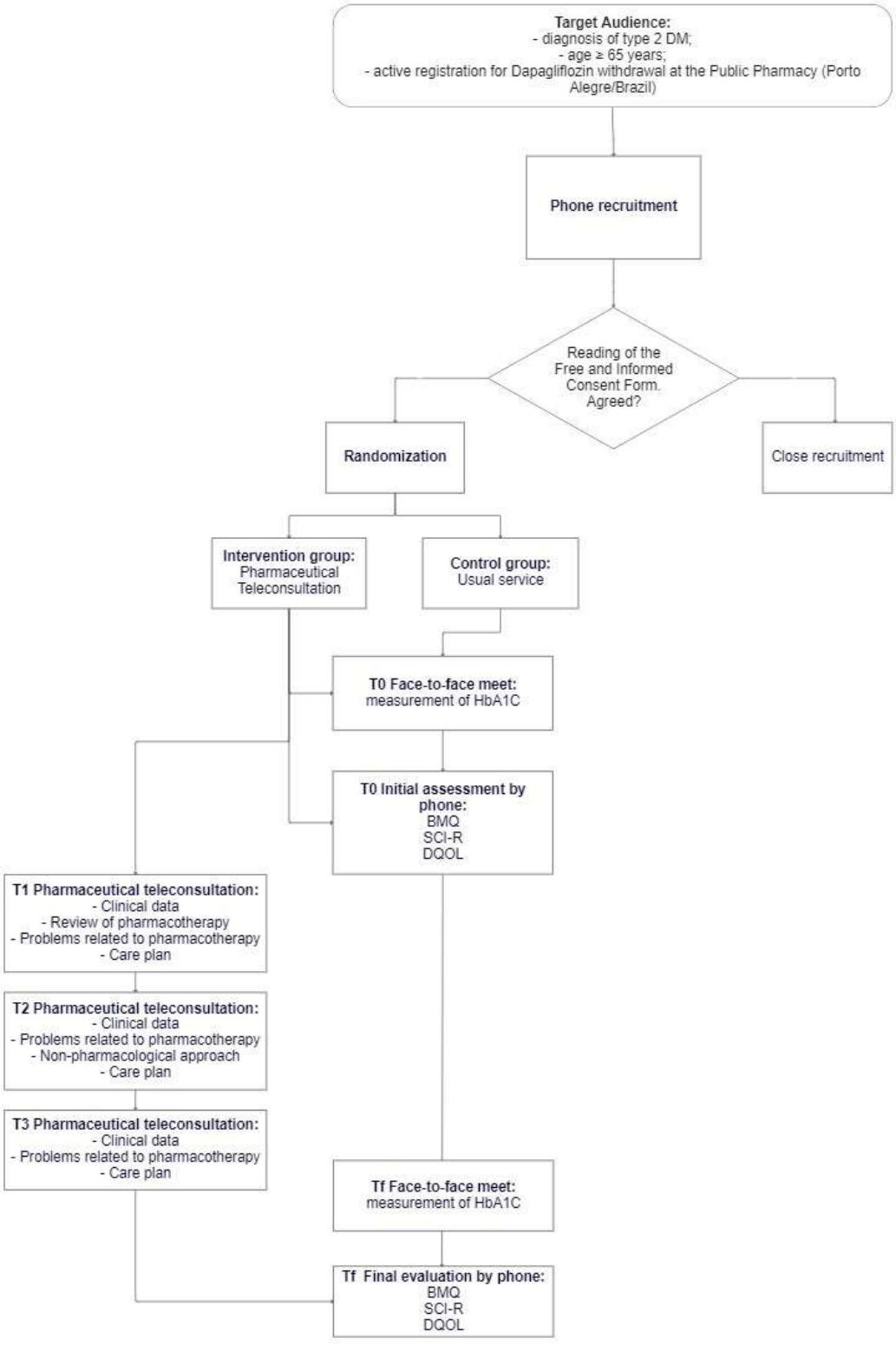


**Figure 1.** Flow chart of participant recruitment, randomization, and assessments.

*2.2 Population*

The recruitment of participants started in May 2022 and the deadline is December 2022 for all users who meet the criteria of the clinical protocol of the Ministry of Health for T2D (Brasil, 2020). The initial participants are people who withdraw the drug dapagliflozin monthly at a public pharmacy located in Porto Alegre, State Rio Grande do Sul, Brazil, and meet the established criteria. The inclusion criterion will be people aged 65 or over with type 2 DM diagnosis (ICD-10: E11) and availability to receive phone calls. The exclusion criteria are not present a telephone record registered in the electronic system; unsuccessful contact within the timeframe established in this study; be participating in another diabetes education program; pregnancy; severe cognitive problems; communication difficulties; presence of other diseases that make participation impossible; patients who are hospitalized at the time of recruitment. Table 1 presents the research inclusion and exclusion criteria.

**Table 1.** Inclusion and Exclusion Criteria for the TelePharmaceutical Care Diabetes Trial.

| Inclusion and Exclusion Criteria for the TelePharmaceutical Care Diabetes Trial | | |
|---|---|---|
| | Clinical trial criteria | Criteria of the Ministry of Health of Brazil |
| Inclusion | ≥ 65 anos<br>type 2 DM diagnosis (ICD-10: E11)<br>availability to receive phone calls | ≥ 65 anos<br>type 2 DM diagnosis (ICD-10: E11)<br>established cardiovascular disease (previous acute myocardial infarction, coronary artery bypass graft surgery, previous myocardial infarction, previous coronary angioplasty, stable or unstable angina, accident previous ischemic stroke, previous transient ischemic attack, and heart failure with ejection fraction below 40%) who have not achieved adequate control in optimized treatment with metformin and sulfonylurea |
| Exclusion | not present a telephone record registered in the electronic system;<br>unsuccessful contact within the timeframe established in this study;<br>be participating in another diabetes education program; pregnancy;<br>severe cognitive problems;<br>communication difficulties;<br>presence of other diseases that make participation impossible,<br>patients who are hospitalized at the time of recruitment. | type 1 DM diagnosis<br>< 65 anos<br>that does not meet the criteria set out above |

Note: ICD: International Classification of Diseases. Source: Authors, 2022.

*2.3 Outcomes*

Primary outcomes will be change in hemogobin A1c (HbA1c) and adherence. Secondary outcomes include quality of life and costs.

*2.4 Sample size*

The sample size calculation was based on the primary outcomes HbA1c and adherence. The sample size calculation was designed with the objective of detecting a difference in the adherence scores and in the HbA1c values (Oh et al., 2003) of moderate-high effect size between the groups, with a power of 80% and a significance level of 0.05. A total sample of 102 participants will be required to obtain the proposed results. Given the possibility of loss to follow-up (estimated at approximately 20%), the sample target for recruitment will be inflated to 124 participants (62 in the pharmaceutical teleconsultation service group and 62 in the control group).

*2.5 Team training*

Before the start of any procedure in this study, the entire team of researchers and health professionals who will be part of any stage of the study will receive appropriate training in remote meetings until the guarantee of adequate standardization of conducts. The team will have two research managers, health researchers trained for the proposed tele-guided intervention, in addition to a multidisciplinary team including professionals involved in diabetes care (endocrinologist, pharmacist, nutritionist), who will participate in the training to each stage of the intervention, as well as guided discussions if individual doubts of each patient are raised during the intervention. Two pharmacists will be assigned to perform the intervention.

*2.6 Ethics and informed consent*

The ethical aspects of this research were analyzed and approved by the Ethics Committee in Research with Human Beings of the School of Public Health to Rio Grande do Sul, under number: 44126821.2.0000.5312. The proposed intervention can benefit the patient by providing a regular and qualified listening environment, where they can share their doubts related to the treatment of diabetes, in addition to being a space for offering guidelines that complement the clinical care of the patient with diabetes in this period of measures prevention of contagion by coronavirus in which there is reduced access to health services, encouraging medication adherence and care with diet and physical exercise - both fundamental for the good control of your disease.

Recruitment will take place by telephone, based on the patient's registration data, and in person when patients are going to pick up their medications, and will take place through presentation and reading of the Free and Informed Consent Form (FICT) (Supplementary appendix 1). Due to the nature of the study, the FICT may be applied by telephone. Patients who choose to participate will compose a database that will be used in the randomization process.

*2.7 Randomization and blinding*

Patients who agree to participate in this study will be invited to complete the baseline assessment questionnaires by telephone, which correspond to the assessment of treatment adherence through the Brief Medication Questionnaire (BMQ) (Ben et al., 2012), a self-care questionnaire in diabetes - Self-Care Inventory (SCI-R) (Teló et al., 2020) and the Diabetes Quality of Life Measure (DQOL-BR) (Correr et al., 2008) quality of life assessment questionnaire, all validated for Brazilian Portuguese (Ben et al., 2012; Teló et al., 2020; Correr et al., 2008). In addition, sociodemographic data such as education and financial income; clinical data, such as the last measurements of fasting glucose tests, height, weight and, finally, complementary questions, such as hospitalizations due to diabetes, trips to the emergency room and medical consultations carried out in the last three months will be informed. The collection of HbA1c will be carried out through a rapid test in person when patients go to collect their medicines at the pharmacy or by scheduling with collection at home.

Subsequently, they will be electronically randomized, allocated between one of the groups: Remote consultation via telephone intervention group and control group. Randomization will be performed by the Randomizer software in blocks of 4 in a 1:1 ratio. The confidentiality of randomization will be ensured by the creation of a central database and the use of an electronic case report form. Access to the system will be granted through specific usernames and passwords provided to each investigator or study team. The patient will be allocated to one of the groups (pharmaceutical teleconsultation service or usual care) only after registering in the system. The recruitment and management of the research will be carried out by a team different from the team responsible for carrying out the intervention; however, given the nature of the intervention, blinding is not feasible. Data analysis will be performed by a statistician blinded to the allocated patient.

*2.8 Intervention*

The intervention will be carried out monthly through three teleconsultations with the pharmacist (times 1, 2 and 3) with a standardized attendance record. Each phone call will last a maximum of 20 to 30 minutes. At time 01, the first pharmaceutical consultation will be carried out via telephone and consists of collecting data on the patient's health and clinical history. A review of pharmacotherapy and identification of problems related to pharmacotherapy will be carried out, as well as an assessment of self-perception about diabetes. The patient will be guided in relation to the understanding of diabetes and the correct use of medications, and an evaluation of the problems related to pharmacotherapy will be performed. A care plan will be developed together with the patient.

At time 02, the second phone call, aspects dealt with in the first consultation will be resumed: care plan and medication use, in addition to updating regarding the prescription, if any. Non-pharmacological treatment will be addressed, resuming guidance provided by other professionals, such as nutritionists and doctors, if applicable. Life habits will be addressed in a very broad way in order to know the patient's routine and identify problems that can be oriented. At time 03, the third phone call, the care plan established in calls 1 and 2 will be resumed.

The final contact will be made for the application of the BMQ, SCI-R and DQOL-Brazil questionnaires, in addition to information on the number of hospitalizations, visits to the emergency room and medical consultations performed.

The intervention will only be discontinued in the following cases:

a) hospitalization of patients during the research, without the possibility of receiving telephone calls;

b) voluntary withdrawal of the patient from the research for self-interest;

c) change of treatment;

d) comorbidities affecting diagnostic cognitive ability after study initiation,

d) death.

*2.9 Control group*

Patients in the control group will be invited to respond to the initial assessment of baseline data through telephone contact and to collect HbA1c at time zero; The final contact will be made after three months, repeating the collection of the same data. They will not receive any intervention during the research period, except for the usual care, which consists of receiving the medicines at the public pharmacy without telephone contact. After completion of the project, the control group will receive educational materials related to care for people with diabetes and, if the effectiveness of the pharmaceutical teleconsultation service is proven, this possibility of care will be offered to them.

*2.10 Measurement variables and instruments*

Primary outcomes are variation in HbA1c levels and adherence to treatment. The variation in HbA1c levels will be evaluated by blood tests that reflect the blood glucose of the last three months. Collection of HbA1c will be performed in the initial evaluation by the Afinion AS100 equipment. Adherence to treatment will be measured at the beginning of the study by the SCI-R and BMQ, Brazilian versions already validated. The SCI-R is a 15-question questionnaire that uses a 5-point Likert scale to reflect how well respondents have followed diabetes treatment recommendations in the past 1-2 months (i.e., 1 = “never” to 5 = “always"). Higher scores indicate better adherence (Teló et al., 2020). The BMQ is a questionnaire divided into three domains that identify barriers to adherence regarding the regimen, beliefs and recall regarding drug treatment in patient perspective (Ben et al., 2012).

Secondary outcomes will include the following comparative assessments between the intervention and control groups after 3 months:

Metabolic variables:

a) Body mass index (BMI): Comparison between the BMI groups in the control group in the first remote consultation and in the last one, and in the intervention group after receiving it. It will be calculated through the last measurement of weight and height of the patients. Data for this variable will be self-reported by patients.

b) Number of hospitalizations in the period: Corresponds to the number of hospitalizations due to T2D during the study period between the control group and the intervention group. Data for this variable will be self-reported by patients.

c) Number of medical consultations performed: Corresponds to the number of medical consultations performed due to T2D during the study period between the control group and the intervention group. Data for this variable will be self-reported by patients.

d) Number of emergency room visits: Corresponds to the number of emergency room visits due to T2D during the study period between the control group and the intervention group. Data for this variable will be self-reported by patients.

e) Quality of life measured by DQOL-Brazil: The DQOL-Brazil is an instrument for measuring the quality of life of people with diabetes and corresponds to 46 multiple-choice questions organized into four domains: satisfaction (15 questions), impact (20 questions), social/vocational concerns (7 questions), and diabetes-related concerns (4 questions). Responses are organized on a 5-point Likert scale and satisfaction is distributed on an intensity scale (1 = very satisfied; 2 = quite satisfied; 3 = moderately satisfied; 4 = somewhat satisfied; 5 = not at all satisfied). The responses for the domains of impact and concerns are distributed on a frequency scale (1 = never; 2 = almost never; 3 = sometimes; 4 = almost always; 5 = always). In these scales, the closer the result is to 1, the better the assessment of quality of life (Correr et al., 2008).

f) Amount of identification and resolution of problems related to pharmacotherapy, as classified by the Pharmaceutical Care Network Europe (PCNE), version 9.1 in problems and causes. The basic classification has 3 primary domains for problems, 9 primary domains for causes and 5 primary domains for planned interventions, 3 primary domains for level of acceptance (of interventions) and 4 primary domains for the status of the problem (Pcne, 2020).

g) Service-related cost: Survey of cost related to the implementation of the remote consultation service, through the Time-Driven Activity Based Costing (TDABC) (Kaplan, 2014).

### *2.11 Economic analysis*

To calculate the real cost of a teleconsultation service in a way that is comparable with the cost of the face-to-face service and to generate a cost parameter for the health services that will use this type of technology, the TDABC will be used (Kaplan, 2014). In addition to the costs of the resources used, this method also considers the amount of time spent in each step of the process, making it possible to identify the phases in which the teleconsultation accelerates or decelerates the process, reducing or increasing costs in relation to face-to-face consultation and usual care.

This study will also include other indicators, such as transportation costs for patients and pharmacists in a real-world scenario, to make cost-effectiveness estimates. Finally, we intend to discuss issues related to the cost reduction that increased access to pharmaceutical care via teleconsultation can generate for the system. The data from the economic analysis (consultations with health professionals, telephone consultations, internations, home visits, displacement, among others) will be extracted from the patients' self-reported records, as well as from the service's medical records.

### *2.12 Patient and public involvement*

Patients were not involved in the development of this protocol. At the time of recruitment, patients are informed of the potential risks and benefits of the research, as well as the time required to participate in the research, and are free to choose whether to participate in the study.

The results of this clinical research will be openly disclosed in articles and scientific events in the health area. In addition, if there are positive results, they may contribute to the development of pharmaceutical teleconsultation protocols in the public health system.

### *2.13 Statistical analysis*

All patient data will be placed by two researchers in a database. Only the researchers who will analyze the data will have access to the database with the results. Data from participants who discontinued the survey will be disregarded. All analyzes will be performed according to the intention-to-treat principle, seeking to collect data from all participants. In case of missing data, data imputation techniques (multivariate imputation by chained equations) will be used.

Mean predictive correspondence and logistic regression will be used for continuous variables (eg, glycated hemoglobin) and categorical variables (eg, quality of life and adherence), respectively. For comparison, a per-protocol analysis will also be performed. All missing data will be comprehensively reported along with reasons why this data is missing, and patterns will be explored. This information will be useful to appropriately adjust protocols for future studies. No interim analysis is planned.

Descriptive statistics will be reported as means (SD) or medians (interquartile range) for continuous variables and proportions for categorical variables. All statistical analyzes will be performed with a type I error rate of 5%.

In the analysis of primary outcomes, we will compare the proportion of patients with adequate glycemic control after three months, in the control and intervention groups, using the Chi-square test.

## 3. Conclusions

The objective of this protocol is to evaluate the effectiveness of a pharmaceutical teleconsultation intervention on glycemic control and adherence to treatment in patients with diabetes mellitus. The literature suggests that the use of telecommunication technologies in health can help in the effectiveness of treatment and monitoring of clinical outcomes, in addition to being more effective than usual care, especially for type 2 diabetes and also for older patients where the duration of the intervention was greater. However, data on results from teleconsultations led by pharmacists are scarce, which further drives the need to evaluate the effectiveness of studies such as this one. If we demonstrate the positive effects that we hypothesize, we can encourage other health services to restructure programs where the pharmacist can play the role of facilitator of the care process through remote assistance.

## 4. Acknowledgments

We thank the State Department of Health for providing the data for this research.

## 5. Auhors' Contributions

*Agnes Nogueira Gossenheimer* was responsible for the conception and design of the research and supervised all stages of study construction. *Fernanda Fávero Alberti* was involved in the process of recruiting people, building the intervention and writing the protocol. *Vanessa Klimkowski Argoud, Diego da Silva Gouvea* e *Thales Preissler* participated in the protocol review and proposed intervention review process. *Roberto Eduardo Schneiders, Ana Paula Rigo* e *Beatriz D. Schaan* participated in the evaluation of the proposed intervention and review of the final writing. All authors read and approved the final manuscript.

## 6. Conflicts of Interest

No conflicts of interest.

## 7. Ethics Approval

Yes applicable. The ethical aspects of this research were analyzed and approved by the Ethics Committee in Research with Human Beings of the School of Public Health to Rio Grande do Sul, under number: 44126821.2.0000.5312.

## 8. Supplementary appendix 1 - Free and Informed Consent Form

### Free and Informed Consent Form

You are being invited to participate in the research "Impact of Pharmaceutical Telecare in people with Type 2 Diabetes Mellitus, assisted at the Special Medicines Pharmacy of the State of Rio Grande do Sul: a randomized clinical trial (TelePharmaceutical Care Diabetes Trial)" whose objective (general) is to evaluate the impact of interventions of Telehealth services on patients with diabetes, to be carried out in the State of Rio Grande do Sul, at the State Department of Health. This research seeks to verify which is the best service for people who pick up medicines at the State Pharmacy.

This research involves minimal risks and is related to discomfort in relation to the act of answering the questionnaire, possible embarrassment in relation to any question. In the event of these, the researchers undertake to accept your manifestation and deal with it with you so that any discomfort or embarrassment is communicated, in addition, we have a Telehealth service available with assistance from psychology professionals for cases with this need.

You are free to accept this invitation or not, without your refusal interfering with the usual service you receive at the State Medicines Pharmacy. You will not receive any remuneration for entering the research, as the

face-to-face part will be carried out on the days you go to the pharmacy to collect your medicines or via home and you can withdraw your consent at any time during the study, thus ceasing your participation. In this case, your information will not be used, without prejudice to you. If there is any damage resulting from the research, you will have the right to request compensation through legal channels (CNS Resolution No. 510/16, Article 17, Item IX).

This research will bring the benefit of receiving a pharmaceutical service remotely to optimize your drug treatment, guide you in relation to the correct use of medicines and improve the quality of life. The Intervention Group will receive three phone calls over the course of three months. Each call will last approximately 30 minutes. The first call will cover a review of the medications you use, in order to provide you with information to optimize your treatment. The second link will cover non-pharmacological treatment and some useful information about it. The third call will be similar to the first and care plans will resume. The control group is the usual service attendance. In addition, in the first and last month you will perform a rapid test to check your serum glycated hemoglobin levels. After consent, participants will be drawn to verify which of the two groups the person will participate in. After the draw you will not be able to change groups, not having the possibility to choose which intervention you will receive. Regardless of the group you are in, you will respond to the initial assessment and perform the rapid test of glycated hemoglobin. The interviews will be recorded in the State's dispensation system, AME system.

The results of this study will be used exclusively for academic purposes, with anonymity of your identity being guaranteed.

This research is being funded by the Health Department of the State of Rio Grande do Sul. If you have any questions or need clarification, contact the researcher in charge Agnes Nogueira Gossenheimer by phone 051 991751771 and with the assistant researcher, Ana Paula Rigo by phone 051 984053184, as well as the Research Ethics Committee in Health at the School of Public Health, by phone (51)3901-1532. The Ethics and Research Committee is a collegiate body, formed by a group of experts, whose function is to defend the interests, integrity and dignity of the participants, contributing to the following ethical standards in research with human beings.

You will receive a copy of this Free and Informed Consent Term, duly signed and initiated by the researcher.

“I believe I have been sufficiently informed about what I read or was read to me about the research: “Impact of Pharmaceutical Telecare on people with type 2 Diabetes Mellitus, treated at the Special Medicines Pharmacy in the State of Rio Grande do Sul: a trial randomized clinical trial (TelePharmaceutical Care Diabetes Trial)”. I discussed with the principal investigator or with the assistant responsible for the research, about my decision to participate in the study. The purposes of the study, the procedures, confidentiality guarantees, permanent clarifications and exemption from expenses were clear to me. I voluntarily agree to participate in this study.”

_____ (Place) of_____, 2022.

Name and signature of research participant (or legal representative)

_____

Name and signature of the researcher in charge

_____

Name and signature of the assistant/academic researcher/resident researcher

_____

This Free and Informed Consent Form follows Resolutions No. 466/12, 510/16 and 580/18 of the National Health Council/Ministry of Health.

Ethics Committee in Health Research of the School of Public Health (ESP/RS) Av. Ipiranga, 6311, room 26 - Bairro Partenon, Porto Alegre, RS - CEP 90.610-001 Phone: (51) 3901-1532 – E-mail: ceps-esp@saude.rs.gov.br

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