Teleconsultation on patients with type 2 diabetes in the Brazilian public health system: a randomised, pragmatic, open-label, phase 2, non-inferiority trial (TELECONSULTA diabetes trial)

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Summary

Background This study addresses the rising burden of type 2 diabetes mellitus, and explores the potential of teleconsultation, as an alternative for diabetes management. The primary objective was to test the hypothesis that teleconsultation is non-inferior to face-to-face consultation in terms of glycaemic control measured as glycated haemoglobin (HbA1c) (non-inferiority margin for the upper confidence interval for the difference between groups of 0,5% in HbA1c) for type 2 diabetes mellitus patients referred from Primary Healthcare to Specialized Care within the SUS.

Methods TELECONSULTA, is a randomized, pragmatic, phase 2, single-centre, open-label, non-inferiority trial conducted in Joinville, Brazil. A total of 278 participants diagnosed with type 2 diabetes were randomized through mandatory teleconsulting services from primary care health units. The randomization was 1:1 to teleconsultation or face to face consultation. The study was registered at the Brazilian Clinical Trial Register—REBEC, under the code RBR-8gpgyd. Study status is "Completed".

Findings This study included 278 participants in the intention-to-treat (ITT) analysis. The median age was 61 (54–68) years, 167 (60%) were women. The between-groups comparative average reduction in HbA1c was −0.6% (90% CI −1.0; −0.1) at 3-months and −0.5% (90% CI −0.9; 0.0) at 6-months in Modified Intention-to-Treat (mITT) population with imputed data, showing the non-inferiority of teleconsultation. Results with no missing data imputation and in the per protocol population were similar. The frequency of hypoglycaemia and other adverse events was well balanced between groups.

Interpretation The results underscore the transformative potential of telemedicine in addressing the complexities of diabetes management within the framework of a universal healthcare system, contributing with valuable insights for healthcare policymakers and practitioners seeking innovative solutions to tackle the growing diabetes epidemic.

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Keywords: Diabetes mellitus; Public health; Remote consultation; Telehealth; Telemedicine

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Research in context

Evidence before this study

We searched Medline (via Pubmed) and Embase for randomized controlled (RCT) trials evaluating teleconsultation for type 2 diabetes mellitus control. We applied synonyms/entry terms and controlled vocabulary (MeSH for Medline and Emtree for Embase) related to teleconsultation/telehealth/telemedicine and type 2 diabetes mellitus. A validated and sensitive RCT filter was applied in each database. Our search was limited to studies which were published before October 3, 2024, without language limitation. Between the 1316 retrieved references, a very recent systematic review was prioritized and it considered 27 RCT as eligible. Previous studies evaluated telemedicine for diabetes and showed positive results in managing blood sugar. However, these studies were conducted in different contexts and evaluated different interventions (Telephone intervention/coaching, education, telerehabilitation, home telemedicine) compared to this proposed research. Previous studies were conducted mostly in high-income countries and some of them evaluated specific populations (obese, treatment refractory, etc.). TELECONSULTA aims to be a pragmatic randomized non-inferiority trial testing telemedicine for diabetes management.

Added value of this study

TELECONSULTA trial found that teleconsultation was non-inferior to face-to-face visits regarding blood sugar control measured by means of HbA1c. TELECONSULTA trial found that patients were satisfied with the teleconsultation system applied and experienced no decline in quality of life. A few hypoglycemia events occurred in teleconsultation group with no difference when compared to face-to-face consultation. This study highlights telemedicine as a valuable tool for managing diabetes, especially for complex cases and those requiring long-term care.

Implications of all the available evidence

This study presents evidence supporting the adoption of telemedicine, particularly in the context of type 2 diabetes, as an innovative strategy for restructuring patient care flows and processes for individuals with chronic non-communicable diseases (CNCD). The findings could serve as a foundational basis for legislative adjustments pertaining to telemedicine utilization in the expansive and economically challenged healthcare landscape of Brazil and other similar contexts. Additionally, the implementation of telemedicine holds promise for enhancing healthcare service accessibility, particularly in remote areas, and increasing the availability of specialized medical professionals. Furthermore, teleconsultation has the potential to mitigate disparities in healthcare access which affect a substantial portion of individuals worldwide.

Introduction

Telehealth encompasses the remote delivery of healthcare services,[1] including continuing medical education, consultations, diagnostics, therapeutic guidance, monitoring, and patient referrals. Additionally, the implementation of strategies such as telemedicine is recognized as a valuable tool for delivering clinical healthcare remotely, fostering patient adherence, and achieving therapeutic objectives thereby improving efficiency for patients with chronic diseases and those seeking for specialized care.[2]

As of the 2020 Global Burden of Disease updates,[3] the escalating impact of diabetes mellitus has emerged as a worldwide concern, posing a significant challenge to healthcare systems. In 2017, it was estimated that 6.28% of the global population grappled with this disease, projecting that by 2030, approximately 7000 individuals per 100,000 inhabitants would be affected by type 2 diabetes mellitus, particularly in lower-middle and upper-middle income countries.[3–5] Prioritizing early identification and treatment is imperative for public authorities to enhance glycemic control and mitigate the adverse health effects on individuals, thereby reducing costs for healthcare systems.[6]

In Brazil, healthcare is constitutionally guaranteed since 1988, with a system founded on principles of universal access at all complexity levels, decentralized responsibilities across government levels, and social participation in policy implementation.[7] As of the latest Brazilian Institute of Geography and Statistics (IBGE)[8] census in 2022 Brazil's 203.080 million inhabitants are unevenly distributed across its expansive 8.52 million square kilometers. The population, infrastructure, and medical professional distribution exhibit significant heterogeneity, with urban areas and superior healthcare infrastructure concentrated mainly in the southern and southeastern regions of the country.

Despite strategies for the dissemination of digital health in Brazil occurred in parallel with the establishment of the Digital Health Observatory in 2005[9] by the World Health Organization (WHO), it was only during the covid-19 pandemic that telemedicine was temporarily regulated by the respective professional councils.[10,11] Recently, telemedicine was integrated into healthcare delivery and education dissemination plans–through Resolution No. 2314,[12] along with the principles for conducting teleconsultations in the country. To improve access, strategies must be developed to influence primary healthcare, access regulation processes, and the organization of specialized care. Studies in this context have shown noteworthy enhancements in clinical outcomes with the use of telemedicine compared to standard treatment.[13]

Considering the positive evidence for global teleconsultation use, there is a noticeable lack of scientific studies examining its effectiveness and safety for diabetes mellitus management.[14] Given this situation, it is crucial to generate reliable scientific evidence regarding the efficacy and safety of teleconsultation. Consequently, the primary objective of this study was to evaluate the performance of teleconsultation medical monitoring for patients with diabetes mellitus, in terms of safety and efficacy, using face to face consultation as control group.

Methods

This trial was reported following Consolidated Standards of Reporting Trials (**CONSORT**) statement[15] (Supplementary Table S1).

Study design and participants

The first patient was recruited on January 6th, 2020, and the last patient was recruited on March 20th, 2023. Last follow-up visit occurred on September 4th, 2023. The COVID-19 pandemic has delayed the planned recruitment. A more detailed description of study's methods was published elsewhere[16] and is available in the supplementary material (Supplementary Methods) and in the study protocol. Briefly, TELECONSULTA was a randomized, pragmatic, phase 2, single-centre, open-label, non-inferiority trial. Participants were recruited in Joinville, a city located in the state of Santa Catarina, Brazil. The study involved seven facilities affiliated with the sole participating centre, the Joinville Health Department, encompassing a Polyclinic of Specialties and six primary healthcare units spread across the city's three main districts.

Inclusion criteria comprised adults of both sexes, aged ≥18 years, with an established diagnosis of type 2 diabetes. Participants could either meet the criteria for referral from Primary Healthcare to Specialized Care or be insulin dependent with glycated haemoglobin (HbA1c) ≥8%. All participants were referred from Primary Healthcare to Specialized Care within the Brazilian Unified Health System (SUS).

The study recruited type 2 diabetes patients from all primary care health units around the city using a mandatory teleconsulting service. Cases were discussed between primary care physicians and specialists to regulate access to endocrinology specialty. Four endocrinologists acted as teleconsultants, evaluating eligibility criteria for potential participants. After confirming eligibility, patients were referred to the research and contacted by phone. An informed consent form was obtained from all participants who agreed to participate prior to the commencement of the study.

Additionally, a comparative study was also carried out on the cost of the two types of consultation, and it was published elsewhere.[17]

This trial was registered and approved by the Institutional Review Board (IRB) of the Hospital Alemão Oswaldo Cruz (coordinating centre) with the number 03434218.1.1001.0070 and by the IRB of the Municipal Council of Joinville (participant centre) with the number 03434218.1.2003.0070. Trial Registration: Brazilian Clinical Trial Register—REBEC–RBR-8gpgyd; https://ensaiosclinicos.gov.br/rg/RBR-8gpgyd. Study status was updated to "Completed", and it is awaiting review and update by REBEC.

Randomisation and masking

Research participants were randomized into two groups: teleconsultation (intervention) and face-to-face consultation (control). The randomization list was generated electronically using the RedCap software. Randomization was performed in blocks size of 4, in a 1:1 ratio. The confidentiality of the randomizations list was ensured by a web-based randomization system, available 24 h a day.

Given the nature of the intervention, investigators and participants were aware of treatment groups. Outcome assessor was aware of groups' allocation.

Procedures

Participants randomized to the teleconsultation arm were directed to designated primary healthcare units for consultations based on local proximity. A dedicated nurse professional at each primary care unit collected anthropometric data, the Diabetes Quality of Life Questionnaire (DQOL) and the satisfaction assessment questionnaire post-teleconsultation. All the procedures related to the teleconsultation and other data collection were remotely applied, via Webex®, 2022, version 43.6.0.26407. In contrast, participants receiving face to face consultation were directed to a Polyclinic, where a professional handled data collection and applied the DQOL questionnaire.[18]

Each participant underwent three visits (baseline and three months and six months follow-up) and two sets of blood tests between visits. Parameters included fasting blood glucose, HbA1c, urea, creatinine, cholesterol levels (including total, high density lipoprotein (HDL) and low-density lipoprotein (LDL)), triglycerides, and complete blood count.

Specialists documented participant information, medical history, anthropometric data, diabetes duration, medications, diet (self-report), physical activity (self-report), and potential adverse events. Subsequent exam requests and prescriptions were provided. Specialists adjusted or maintained individualized therapeutic management based on the clinical protocol. Participants needing ongoing specialized follow-up were referred accordingly, following local regulations. If necessary, guidance and medical reports were given for follow-up at the reference primary healthcare unit per local flow.

Outcomes
The primary outcome of this study was the mean change in glycated hemoglobin after six months, expressed as percentage. Exploratory outcomes measures included fasting blood glucose and complete blood count measurements, serum urea and creatinine measurements, lipid profile measurements, systolic and diastolic blood pressure measurements, body weight and Body Mass Index (BMI) measurements, incidence of any adverse events, proportion of endocrinologists and patients' satisfaction with the teleconsultation service and patient quality of life measurements using the DQOL questionnaire. Quality of life (QOL) scores are better the lower the value of DQOL. Telehealth Usability Questionnaire (TUQ) was administered to assess the usability of telehealth services.

All adverse events were assessed and classified according to their intensity, categorized as mild, moderate, or severe. For the latter, a scale was followed to determine the severity of adverse events. In defining these constructs, we used the Americas Document and the Common Terminology Criteria for Adverse Events (CTCAE) v5.0 as theoretical frameworks.[19,20]

Hypoglycaemia was evaluated through the administration of a standardized hypoglycaemia questionnaire.[21] If a participant reported a hypoglycaemic event during the consultation, the sub-investigators were required to complete this questionnaire, which includes nine different symptoms. For each symptom, they had to classify the alternatives as never, once, or more than once.

Statistical analysis
Summary statistics as frequencies, median values and interquartile range, means and standard deviations were used to describe patients. The primary efficacy outcome was the between-group mean change in the glycated hemoglobin (HbA1c%) levels at 6-months after the baseline consultation. The mean change was compared between intervention groups using Student's t-distribution. The noninferiority margin was set at 0.5%. Assuming an standard deviation of 1.3% for both groups, true difference between the means of zero, and a type I error level of 5% (one-sided), it was estimated that 117 individuals per group would be necessary to achieve 90% power.[22,23] In order to accommodate for a maximum dropout rate of 5%, the sample size was increased to 124 individuals per group.[24] The assessment of noninferiority of teleconsultation in relation to face-to-face was conducted according to the CONSORT guidelines.[15] Non-inferiority was determined when the upper bound of the two-sided 90% Confidence Interval did not lie in the non-inferiority margin. The primary endpoint was analyzed for the modified intention-to-treat (mITT) and per-protocol populations. mITT analyses included all patients randomly allocated with, at least, the baseline consultation and blood sample collection. Imputation of missing data was performed using the Last Observation Carried Forward (LOCF) method. A mITT analysis with no imputation method was carried out as a sensitivity analysis. The per-protocol (PP) analysis included patients who performed all stablished consultations within full protocol compliance. Subgroup analyses were carried out to examine the consistency of treatment effects in subgroups defined by sex, dietary regimens, physical activity, previous stroke, and baseline neutral protamine hagedorn (NPH) insulin use. Generalized estimating equation (GEE) models, assuming an unstructured covariance matrix, were applied for subgroup hypothesis testing purposes. The models included the following variables: baseline glycated hemoglobin levels, treatment group, subgroup of interest, and an interaction term between treatment and subgroup of interest. We chose to run GEE, using an unstructured covariance matrix, because GEE models do not require strict assumptions regarding data distribution. The flexibility of GEE allows for marginal mean estimates even when the true covariance structure is unknown or very complex. The p-values for the interaction term were reported.[25] Non paired t-test was applied to compare the change of quality of life scores (Baseline-6 months) between groups. The Protocol specified the use of Student's t-test and analysis of covariance (ANCOVA) with baseline levels as a covariate to compare efficacy outcomes. Results for both unpaired T-test and ANCOVA are presented. Safety analyzes were carried out using the observed data set (Safety Population), for those randomized participants who received at least baseline consultation. An interim analysis to assess safety and non-inferiority was conducted when sample size reached 125 participants. This interim analysis showed satisfactory safety results and acceptable margins. Additionally, interim analysis was primarily for safety monitoring, and the decision to proceed without adjusting for Type-1 error was based on ensuring adequate statistical power and predefined safety thresholds. Except for the primary outcome which was evaluated under a non-inferiority hypothesis, all other outcomes were analysed under the conventional two-sided hypothesis of superiority, with a significance level of 0.05.

All analyses were performed with Rstudio 1.3.959 statistical software.[26]

Role of the funding source
The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results
A total of 283 participants were randomized and 278 participants were included in the mITT analysis (138

teleconsultation group and 140 in-person group) (Fig. 1). The participants' baseline characteristics were well-balanced between the groups (Table 1). The median (interquartile range—IQR) age was 61 (54–68) years, 167 (60%) were women, and 233 (84%) were white. The time since diabetes mellitus diagnosis and the HbA1c% level at baseline were similar for both groups. Prevalence of target organ damage was high and almost a third of patients had two or more target organ damage at enrollment. The use of regular anti-diabetic medications was frequent, including injectable insulin and oral hypoglycemic agents. Complete information regarding clinical and demographic data, medicine usage, comorbidities, and behavioural characteristics are described in Table 1.

The most used anti-diabetic medications were NPH insulin 214 (77%), metformin 234 (84%), and regular insulin 132 (47%). In terms of other medicines, 199 (72%) of the participants were on statins, 146 (53%) on diuretics, and 120 (43%) on angiotensin antagonists. Self-reported conditions included dietary regimens 83 (30%), physical activity 57 (20%), tobacco use 21 (8%), and alcohol consumption 11 (4%). The most common comorbidities were hypertension 237 (85%), dyslipidemia 232 (83%), and obesity 169 (61%).

The median systolic blood pressure was 144 mmHg (IQR: 130–160), diastolic blood pressure was 80 mmHg (IQR: 70–90), capillary blood glucose was 228 mg/dL (IQR: 166–308), and BMI was 31 kg/m^2 (IQR: 27–35). The median heart rate was 84 bpm (IQR: 75–92), and urea was 36 mg/dL (IQR: 28–46). The median total cholesterol was 178 mg/dL (IQR: 159–222), LDL was 102 mg/dL (IQR: 83–131), HDL was 41 mg/dL (IQR: 34–50), and triglycerides were 187 mg/dL (IQR: 126–296). There was missing data for some variables, including educational level, blood pressure, capillary blood glucose, heart rate, urea, total cholesterol, LDL, HDL, and triglycerides.

The HbA1c reduction levels of teleconsultation group was consistently greater than the HbA1c reduction of control group for all analyses sets. The between-groups comparative average reduction was −0.6% (90% CI −1.0; −0.1) at 3-months consultation and −0.5% (90% CI −0.9; 0.0) at 6-months in mITT population with imputed data (LOCF). Results in the mITT with no imputation and PP populations were consistent with those from mITT with LOCF. These results supported the non-inferiority claim for this clinical trial results (Fig. 2). Subgroups analysis was consistent with the main results with no differences for sex, physical activity status, presence of previous stroke, dietary regimen, and baseline NPH insulin use (Fig. 3).

The occurrence of adverse events was assessed using a hypoglycaemia scale. The hypoglycaemia rate was very low for both groups, independently of the assessment approach. Generally, the events' rate was well balanced between groups. There was one severe adverse event related to hypoglycaemia reported for both

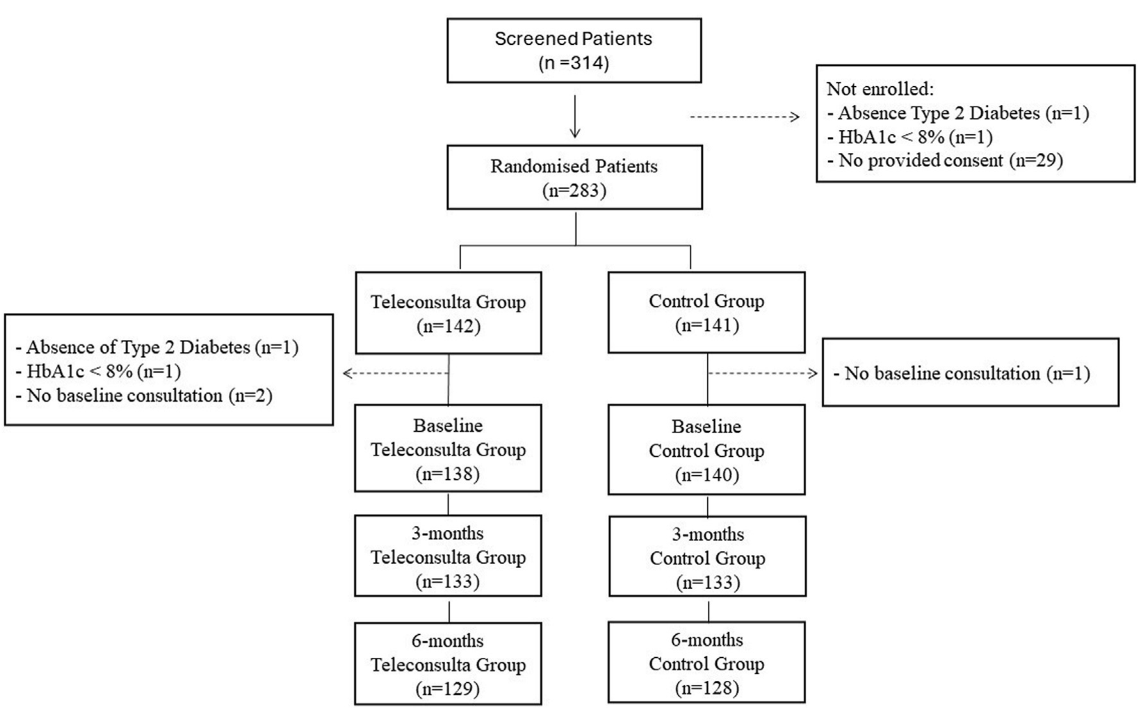

Fig. 1: CONSORT flowchart for TELECONSULTA trial.

	Teleconsultation		Control		Total	
	(n = 138)		(n = 140)		(n = 278)	
Age, median (IQR)	61	(54–68)	62	(54–67)	61	(54–68)
Female, n (%)	81	(59)	86	(61)	167	(60)
Race, n (%)						
White	115	(83)	118	(84)	233	(84)
Black	10	(7)	14	(10)	24	(9)
Mixed	13	(9)	8	(6)	21	(8)
Educational level, n (%)						
Elementary	65	(48)	67	(49)	132	(48)
High school	69	(51)	62	(45)	131	(48)
University	2	(1)	8	(6)	10	(4)
Time since diagnosis (y), median (IQR)	13	(7–20)	15	(10–21)	15	(9–20)
HbA1c (%), median (IQR)	10.3	(9.1–11.9)	9.9	(9.0–11.4)	10.1	(9.0–11.7)
HbA1c (%), mean (SD)	10.6	(2.1)	10.4	(1.9)	10.5	(2.0)
Target organ damage, n (%)						
Retinopathy	41	(30)	43	(31)	84	(30)
Neuropathy	33	(24)	30	(21)	63	(23)
Coronary disease	26	(19)	19	(14)	45	(16)
Stroke	23	(17)	10	(7)	33	(12)
Peripheral artery disease	17	(12)	12	(9)	29	(10)
Nephropathy	13	(9)	14	(10)	27	(10)
Number of target organ damage >1	42	(30)	32	(23)	74	(27)
Anti-diabetic medications, n (%)						
NPH insulin	100	(72)	114	(81)	214	(77)
Regular insulin	62	(45)	70	(50)	132	(47)
Metformin	118	(86)	116	(83)	234	(84)
Gliclazide	45	(33)	43	(31)	88	(32)
Glibenclamide	3	(2)	2	(1)	5	(2)
Glimepiride	1	(1)	0	(–)	1	(<1)
Other medicines, N (%)						
ACEi	45	(33)	42	(30)	87	(31)
Diuretics	71	(51)	75	(54)	146	(53)
Statins	95	(69)	104	(74)	199	(72)
Angiotensin Antagonists	56	(41)	64	(45.7)	120	(43)
Calcium Channel Blockers	37	(27)	44	(31)	81	(29)
Acetylsalicylic acid	60	(43)	48	(34)	108	(39)
ARB	52	(38)	55	(39)	107	(38)
Clopidogrel	6	(4)	5	(4)	11	(4)
Self-related conditions, n (%)						
Dietary regimens (patient report)	49	(36)	34	(24)	83	(30)
Physical activity (patient report)	35	(25)	22	(16)	57	(21)
Tobacco use	8	(6)	13	(9)	21	(8)
Alcohol consumption	2	(1)	9	(6)	11	(4)
Comorbidities, n (%)						
Hypertension	115	(83)	122	(87)	237	(85)
Dyslipidemia	114	(83)	118	(84)	232	(83)
Obesity	84	(61)	85	(61)	169	(61)
Mood disorders	50	(36)	47	(34)	97	(35)
Biochemical tests, median (IQR)						
SBP (mmHg)	140	(130–160)	148	(130–168)	144	(130–160)
DBP (mmHg)	80	(73–90)	80	(70–89)	80	(70–90)
Capillary blood glucose (mg/dL)	228	(163–309)	228	(167–307)	228	(166–308)
Body Mass Index (Kg/m^2)	31	(27–35)	31	(28–35)	31	(27–35)

(Table 1 continues on next page)

teleconsultation and face to face consultation. These events were well controlled with medical intervention and self-limited (Table 2).

DQOL domains evaluated were Total Score, Satisfaction, Impact, Social worries, and Diabetes worries (Table 3). Both groups showed reduction of DQOL scores after a 6-month follow-up denoting improvement of quality of life. The DQOL total score reduction was significantly greater in Teleconsultation group than Control group. Satisfaction and diabetes worries domains scores also improved prominently in the teleconsultation group, but with marginal statistical significance considering control group. Covariance analysis did not show different values and p values for the unpaired T-test are slightly conservative.

After all teleconsultation sessions, the Telehealth Usability Questionnaire (TUQ) was administered to assess the usability of telehealth services, particularly within the context of modern computer-based systems. The comprehensive data can be found in the Supplementary Tables S2 and S3. Both patients and physicians report high levels of satisfaction and usability with the telehealth system. The system was found to be particularly effective in improving access to healthcare services and saving time. While there are some concerns regarding the equivalence of telehealth visits to in-person visits, overall confidence in the system remains high. This positive feedback indicates a strong potential for the continued use and integration of telehealth services in healthcare delivery.

The exploratory outcomes analyses show various measurements at baseline and at 6 months, including systolic and diastolic blood pressure, capillary blood glucose, body mass index, urea, creatinine, total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides. There were no significant differences between the teleconsultation and control groups for these measures, for both mITT and mITT with LOCF imputation populations. Detailed data on between-group differences and associated p-values are shown in Supplementary Tables S4 and S5.

Discussion

In our study, we attested the non-inferiority of teleconsultation when compared with face-to-face consultation. The adverse events rate was well balanced between both groups, with only two self-limited severe cases. Furthermore, both consultation modalities presented favorable QoL scores, and patients in teleconsultation arm were generally well satisfied with that approach. This underscores the effectiveness, feasibility, and safety of this technology as a support strategy in glycemic control for individuals with diabetes.

HbA1c is recognized as a valuable indicator of treatment effectiveness in patients with diabetes,[27] as it reflects average glycemia over several months and is strongly correlated with diabetes complications. One systematic review[28] indicates that in diabetes patients, telemedicine strategies concomitant with usual care were associated with a mean HbA1c decline of −0.44% (−4.8 mg/dL) compared to usual care alone. In India, a study conducted during the COVID-19 pandemic found that the use of telemedicine was associated with a reduction in glycated hemoglobin of −0.44% compared to usual care.[29] In another systematic review, the author demonstrated a significant reduction in HbA1c levels (−0.5%) and improvement in diabetic foot control in patients attended via telemedicine.[30] Despite these findings, a recent systematic review, which included only 3 articles, failed to identify benefits of teleconsultation in glycemic control for elderly patients.[14]

A randomized non-inferiority clinical trial with diabetic patients conducted in Australia[31] showed that the "Beacon" integrated care model utilized in the study was non-inferior to the gold standard care provided by a specialized diabetes clinic. Like our scenario, the study highlighted the complexity of managing type 2 diabetic patients with multiple comorbidities, which exceeded the capacity of family health physicians, justifying referrals to specialized diabetes services. Additionally, the study demonstrated that diabetes management in the population can yield clinical outcomes, benefits, improvements in quality of life, satisfaction, and cost-effectiveness comparable to those achieved in specialized diabetes clinics, as also observed in our study results. Like our trial, participants receiving the intervention reported satisfaction levels with little difference compared to usual care. Lastly, this clinical trial concluded that the sustainability of benefits remains unknown, although from a clinical perspective, the greatest improvement in HbA1c was achieved at 6 months and maintained thereafter, without harm to patients but with increased satisfaction.

Teleconsultation system was perceived as user-friendly, with participants quickly learning and feeling confident in its use based on TUQ questionnaire. The teleconsultation system's interface received positive feedback, along with the quality of interaction with healthcare providers. Participants expressed a high level of confidence in the reliability of teleconsultations, considering them comparable to in-person consultations, and appreciated the system's error resolution capabilities. Overall, participants conveyed satisfaction and expressed a willingness to use teleconsultation again in the future.

When considering the extrapolation of this study to other regions, it is important to highlight findings from the 2022 research on the use of Information and Communication Technologies (ICT) in Brazilian health establishments.[32] This study revealed that Primary Health Care Units (PCU) have gradually improved access to computers and the internet over the past years, with 97% now utilizing both. However, the northern region of Brazil showed the lowest proportion of health establishments using the internet (92%). Cable or fiber optic connections were present in 95% of health establishments, while mobile connections were available in 39% of them. Only 17% of public establishments had connections above 100 Mbps, and just one-third had an

	Teleconsultation		Control		Total	
	(n = 138)		(n = 140)		(n = 278)	
(Continued from previous page)						
Heart rate (bpm)	83	(73–90)	84	(76–94)	84	(75–92)
Urea (mg/dL)	33	(27–46)	37	(30–46)	36	(28–46)
Total cholesterol (mg/dL)	174	(158–226)	180	(160–216)	178	(159–222)
LDL cholesterol (mg/dL)	93	(77–129)	105	(91–131)	102	(83–131)
HDL cholesterol (mg/dL)	42	(35–50)	40	(34–50)	41	(34–50)
Triglycerides (mg/dL)	180	(118–277)	196	(146–296)	187	(126–296)

IQR: Interquartile range, SD: Standard deviation, SBP: Systolic blood pressure, DBP: Diastolic blood Pressure. Missing data: Educational level (n = 5); SBP (n = 1); DBP (n = 1); Capillary blood glucose (n = 3); Heart Rate (n = 4); Urea (n = 172); Total cholesterol (n = 46); LDL cholesterol (n = 160); HDL cholesterol (n = 43); Triglycerides (n = 42).

Table 1: **Patient baseline characteristics.**

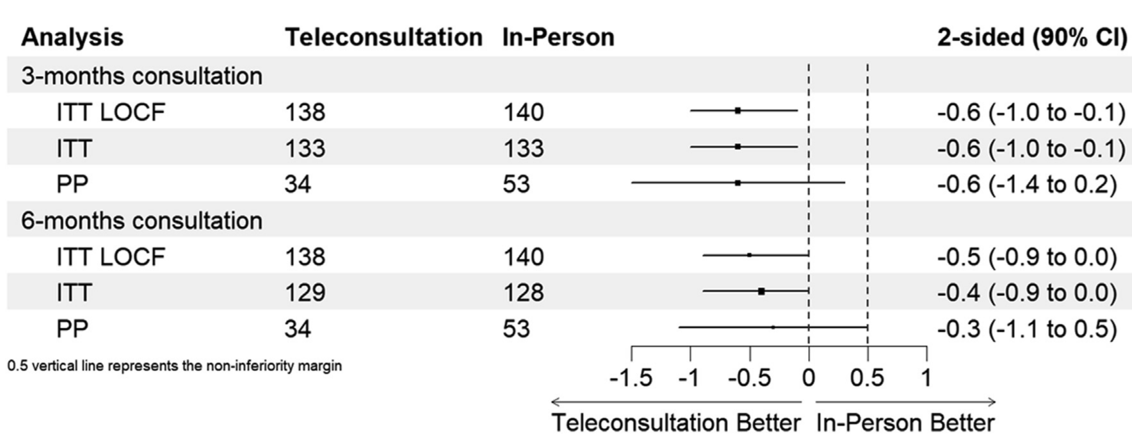

Fig. 2: Main outcome analyses. Mean difference in HbA1c variation (%) during the study between intervention groups.

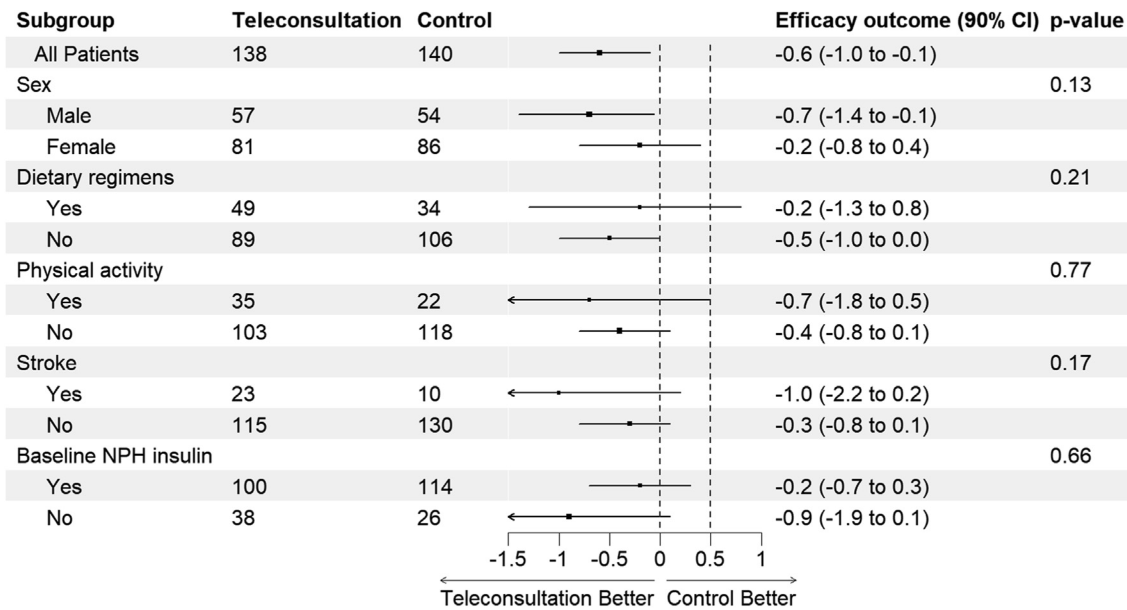

Fig. 3: Subgroup analysis of teleconsultation efficacy outcomes at 6 months.

Information Technology department. The availability of telehealth services in the country has also remained low in recent years. Remote patient monitoring, which had advanced during the pandemic, regressed by seven percentage points (13%), while teleconsultation (25%), telediagnostics (19%), and telemedicine (19%) remained stable compared to 2021.

This research has some limitations. The demographic composition of our study cohort, particularly in terms of race, deviates from the broader Brazilian population. There is a high proportion of Caucasian individuals in Joinville/SC, due to the extensive immigration of Germans, Poles, and Italians to Brazil's south region during XIX and XX centuries. Furthermore, the study's geographical focus may restrict the applicability of the findings to other regions in Brazil characterized by distinct healthcare infrastructure, population distribution, and socioeconomic features.

As the research took place during the pandemic period, adjustments were necessary due to the closure of healthcare units, resulting in delays in the interval between some teleconsultations and face-to-face appointments. This occurrence also impacted the timing and loss of some laboratory tests. The relatively brief follow-up period of 6 months poses a constraint on the study's ability to comprehensively assess the long-term impact of teleconsultation on diabetes management. Additionally, teleconsultation, like face-to-face consultation, was provided at a healthcare physical facility, which might have underestimated the effect of the intervention (mainly in QoL scores), considering that teleconsultation ideally should be applied remotely. This happened due to limited internet access and difficulty in operating technological devices, especially among the elderly and people with low income or less education. These limitations should be considered when interpreting and applying the study's findings, emphasizing the need for caution in extrapolating results to broader populations or different healthcare contexts.

Our study also has some strengths. There are very few studies evaluating teleconsultation by means of a randomized trial. Therefore, TELECONSULTA trial collaborates to increase precision in the estimates for

	Teleconsultation		Control	
	(n = 138)		(n = 140)	
Hypoglycemia event rate, n (%)	9	(7)	11	(8)
Severe Hypoglycemia event rate, n (%)	1	(<1)	1	(<1)
Hyperglycemia event rate, n (%)	2	(1)	0	(–)
Number of hypoglycemia symptoms events[a]				
Tremor	5		8	
Palpitation	3		6	
Hunger	7		6	
Difficulty concentrating, thinking, speaking, listening, or moving	8		6	
Convulsion	0		1	
Weakness/Dizziness	7		9	
Syncope	1		3	
Disturbed sleep	3		4	
Morning headache	3		3	
Documented hypoglycemia	10		13	

[a]Participants may present more than one event or present the same event more than once.

Table 2: **Frequency of related adverse events during the study.**

Domains scores	Teleconsultation (n = 136)			Control (n = 134)			Differences between changes in the two groups	
	Baseline	6 months	Baseline-6 months change	Baseline	6 months	Baseline-6 months change	Non paired t-test p-value	Analysis of covariance p-value
Total	2.5 (0.5)	2.2 (0.6)	0.3 (0.5)	2.6 (0.6)	2.4 (0.7)	0.1 (0.5)	0.015	0.012
Satisfaction	2.8 (0.6)	2.3 (0.7)	0.5 (0.6)	2.9 (0.8)	2.6 (0.9)	0.3 (0.8)	0.06	0.046
Impact	2.6 (0.7)	2.4 (0.8)	0.2 (0.6)	2.6 (0.8)	2.6 (0.9)	<0.1 (0.6)	0.10	0.08
Social worries	1.5 (0.7)	1.4 (0.6)	<0.1 (0.6)	1.4 (0.7)	1.4 (0.7)	<0.1 (0.7)	0.47	0.41
Diabetes worries	2.6 (1.0)	2.3 (1.0)	0.2 (1.0)	2.7 (1.0)	2.6 (1.0)	<0.1 (0.9)	0.09	0.05

Notes: Values are expressed as Unadjusted Mean (Standard Deviation). Higher scores denote poorer quality of life (range:1–5 points). Last observation carried forward (LOCF) imputation was performed for 8 participants of Teleconsultation group and 18 participants of Control group. Non paired t-test was applied for groups comparison.

***Table 3:* Quality of life scores during the study.**

teleconsultation effect on glycemic and preferences outcomes. Additionally, this is the first trial evaluating teleconsultation in Brazil, and it started when there was too much resistance of Brazilian Medical Association and Federal Medicine Council regarding the use of telemedicine. Thus, our results might help spread the implementation of teleconsultation across Brazil and worldwide. It is noteworthy the very narrow non-inferiority margin adopted in this study, which confirms the precision in the estimates. Moreover, subgroup analysis depicted that there is no interaction of primary outcomes and other clinical and sociodemographic variables.

Our findings underscore the potential transformative impact of telemedicine, specifically teleconsultation, on managing type 2 diabetes mellitus. The integration of telemedicine into healthcare delivery and education plans offers a promising solution to enhance access to specialized care, especially in regions with geographical barriers and uneven distribution of healthcare resources. The observed reduction in HbA1c levels through teleconsultation suggests that this approach can be non-inferior to face-to-face consultation, thus offering an effective alternative for diabetes management. This has significant implications for improving patient outcomes, reducing healthcare costs, and addressing the increasing burden of diabetes on global health systems. The study reinforces the importance of incorporating telemedicine strategies into public health policies to enhance the overall quality of diabetes care and promote more accessible healthcare services, particularly in developing countries like Brazil.

Contributors

Conceptualization: DLGR, GSB, AA, HAOJ; Methodology: AV, GBP, TBD, MSSO, FVQP, RSA, MAM; Formal Analysis: LBOA, HAOJ, GSB, DLGR; Data curation: LBOA; Investigation: DLGR, AA, HAOJ, GSB, RSA; Project administration: HAOJ, LFS, APNMP, RAA; Supervision: AA; MAM; Writing—Original Draft: DLGR, GSB, HAOJ, LBOA; Writing–review and editing: AA, MAM, APNMP, LFS, RAA, AV, GBP, TBD, MSSO, FVQP, RSA; Funding Acquisition: APNMP; HAOJ. HAOJ has final responsibility for the decision to submit the study for publication.

Data sharing statement

Anonymized participant data can be made available upon requests directed to the corresponding author. Proposals will be reviewed based on scientific merit. After approval of a proposal, data can be shared through a secure online platform after signing a data access agreement.

Editorial disclaimer

The translation of the Summary was submitted by the authors, and we reproduce it as supplied. It has not been peer reviewed. Our editorial processes have only been applied to the original version in English, which should serve as a reference for this manuscript.

Declaration of interests

The authors have none to declare.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lana.2024.100923.

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