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# The impact of a telehealth intervention on the metabolic profile of diabetes mellitus patients during the COVID-19 pandemic - A randomized clinical trial

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ABSTRACT

*Objectives:* The objective of this study was to evaluate the impact of a telehealth intervention on metabolic outcomes and self-perceptions of the patients regarding their management of diabetes during the COVID-19 pandemic.
*Methods:* This is a non-blind randomized controlled clinical trial to assess a telehealth intervention. We included adults with diabetes mellitus. The outcomes assessed were the level of HbA1c, lipid profile, blood pressure levels, weight, body mass index and self-perceptions about diabetes management.
*Results:* A total of 150 individuals with diabetes participated in the study and at the end of telehealth intervention there were no changes in the patient's HbA1c levels between intervention and control groups for neither type 1 (8.1% vs. 8.6%; p = 0.11) nor type 2 diabetes (8.6% vs. 9.0%; p = 0.09), respectively. From the rest of the metabolic profile, triglyceride levels from type 1 diabetes group was the only variable that demonstrated improvement with telehealth intervention (66.5% intervention group vs. 86.5% control group; p = 0.05).
*Conclusions:* After 4 months of telehealth intervention, no statistically significant results were observed in HbA1c nor in secondary outcomes (with the exception of triglycerides for the type 1 diabetes group).

## 1. Introduction

Brazil was the epicenter of COVID-19 pandemic, with an infection-related mortality data exceeding 600 thousand individuals by July 2022 [1]. The COVID-19 pandemic was responsible for an immeasurable failure in the provision of medical services [2–6] and a radical change in people's lifestyle due to the institution of social distancing [4,6–9]. It is possible that the gap in diabetes mellitus continuous professional care will last for many years generating irreversible damages [2–6], since the frequent multidisciplinary follow-up for these individuals is well established as a component of the treatment [10,11]. Furthermore, adhesion to treatment of diabetes, which is based on many spheres of lifestyle habits [4,6–8,10,12,13], has been directly affected: the practice of physical exercises became restricted to the house [2,3,7,8,12,14]; diet became less healthier [8] because of diminished offer [6]; the acquisition of medicine and capillary blood glucose measurement supplies may have been compromised [3,7,8,12] and the restrains of medical follow-up [8], which probably impaired the renewal of medical

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prescriptions and the fine adjustment of medical dosage may have led to longer periods of hyperglycemia and increased number of episodes of hypoglycemia [7,12,14].(Figs. 1,2).

It is known that the pandemic and the social distancing have affected the psychological wellbeing worldwide [7,15] The fact that individuals with diabetes belong to a risk group and that they show worse outcomes when infected by the Sars-Cov-2, presenting higher complications and mortality rates [2,7,8,16], could have worsen their stress levels, which may affect the adherence to treatment and therefore their glycemic control [2,7,8,12,14,17-19].

In attempts to diminish the damage caused to these individuals and to align their care to the present disaster situation, telemedicine intervention was implemented. [9] Studies conducted prior [11,20,21] and during [12,18,19,22] the current pandemic to assess the use of telemedicine showed promising outcomes. Some of these studies (carried out before the COVID-19 pandemic) assess the glycated hemoglobin (HbA1c) in patients with diabetes and demonstrated that there was a reduction in the levels of HbA1c in those patients that received telehealth intervention when compared to the control groups [11,21].

To the present moment there are few studies that evaluated the impact of telehealth interventions focused on metabolic outcomes of the population with diabetes during periods of crisis. In view of that, the objective of this study was to evaluate the impact of a telehealth intervention on metabolic outcomes and self-perceptions of the patient regarding their management of diabetes during the COVID-19 pandemic.

## 2. Methods

### 2.1. Trial design

This is a non-blind randomized controlled clinical trial to assess a telehealth intervention during the COVID-19 pandemic period. At that time, Brazil had no lockdown decree. Rather, we had only a social distancing policy. The study began in March 2020 and lasted until October 2nd of the same year. This study was elaborated in accordance

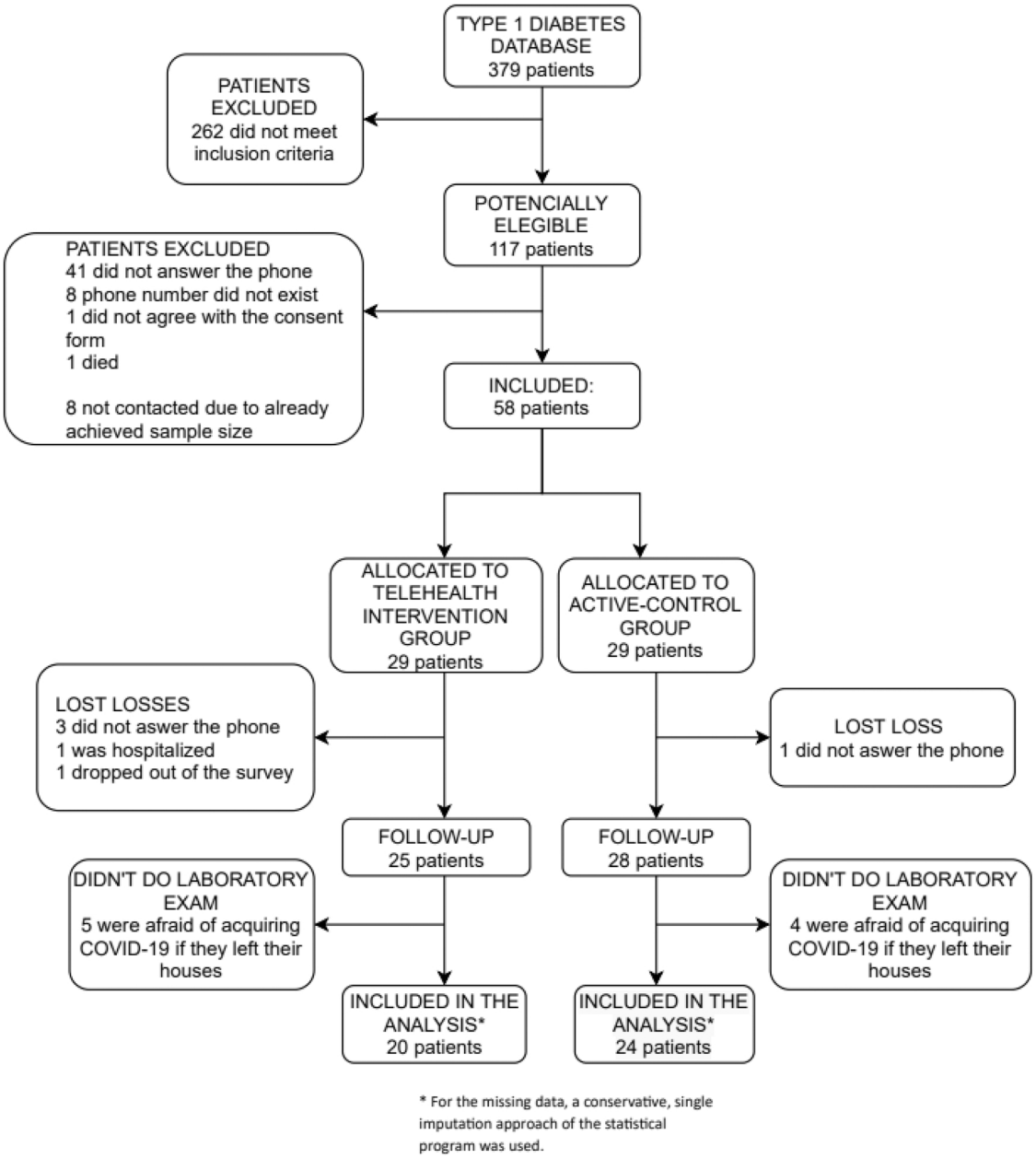


**Fig. 1.** Flowchart type 1 diabetes patients.

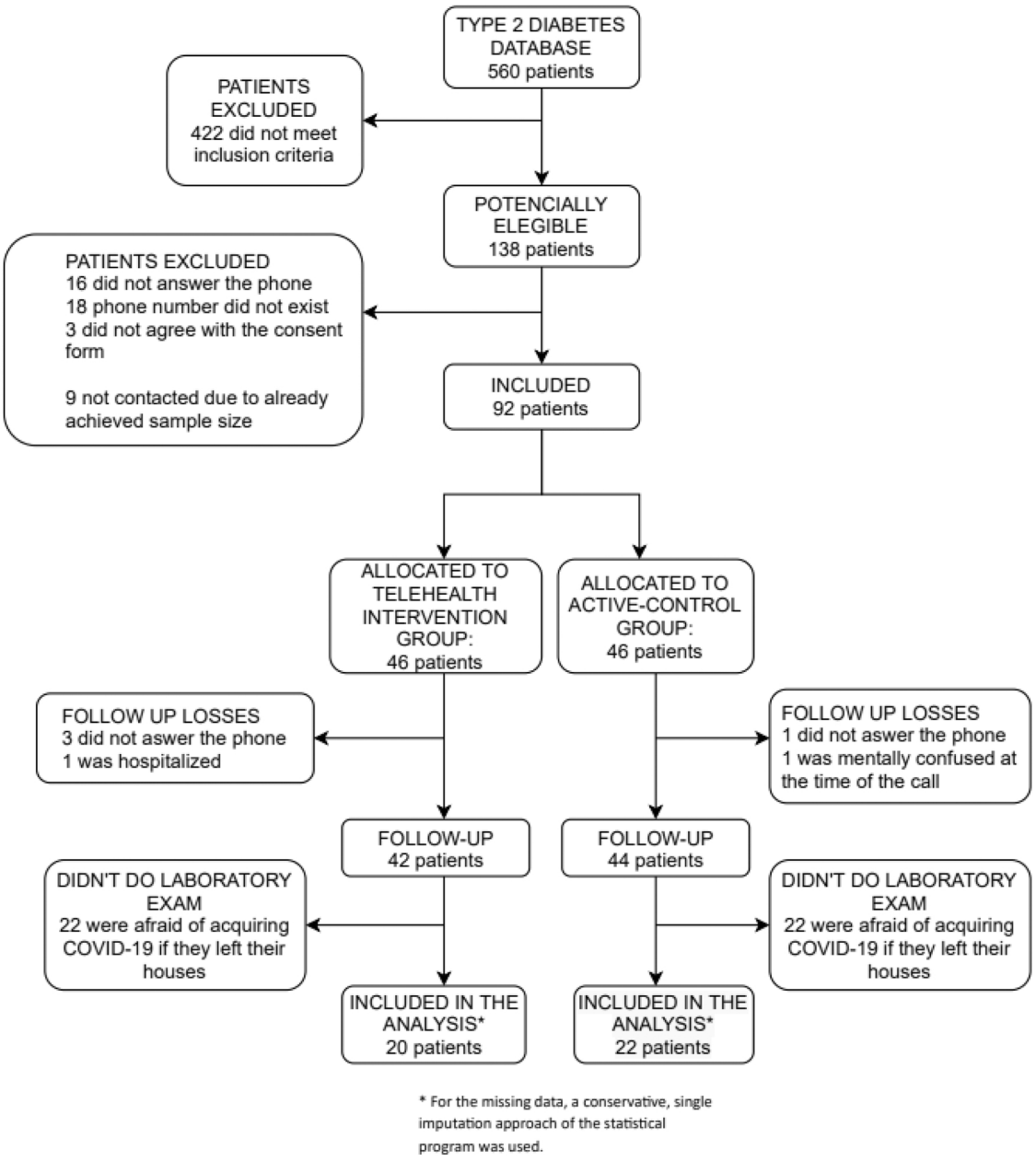


**Fig. 2.** Flowchart type 2 diabetes patients.

with the guidelines and regulatory standards for research involving human beings (approved by the National Health Council, resolution 466/12) and following CONSORT recommendations [23]. It was also registered on Clinicaltrials.gov (NCT04344210). It was approved by the ethics committee from the hospitals selected for the study and the National Ethics Committee under the register 4.029.368. There were no design nor applicability changes throughout the study.

### 2.2. Participants

In March 2020, adults (18 years old or older) with type 1 and type 2 diabetes mellitus that regularly attended their specialist physicians were invited through phone calls to participate in the study. They were recruited from two hospitals tied to the National Public Health System in Southern Brazil, which had their services reduced or suspended during the period of this study and had to have a HbA1c test performed prior to the inclusion in the study. They also had to be available to receive weekly phone calls during the period in the study. Hospitalized patients at the time of the inclusion or those who had any severe cognitive limitation, to participate in this intervention were excluded. Participants were recruited randomly from their electronic medical records in those hospitals.

### 2.3. Intervention

The intervention occurred through weekly phone calls (total of 16 weeks) and lasted between 5 and 10 min or as per demand. The objective was to prevent the patient from having to leave home during the high transmissibility period of COVID-19, therefore preserving the individuals with diabetes from unnecessary exposure and, at the same time, not allowing them to be left unattended, offering strategies that could provide medical support and maintenance of treatment and lifestyle. A multiprofessional team composed of general clinicians, cardiologists, endocrinologists, physical educators, psychologists and researchers was trained to elaborate and apply the proposed intervention. They all received 16 intervention scripts (the full protocol of the

teleintervention performed is available as supplementary material in another article) [19]. The interventions had a multidisciplinary focus, with plans and strategies for indoor physical exercises; recipes and tips to maintain a balanced diet; guidelines on hygiene and care on the Sars-Cov-2 transmissibility, as well as proposed strategies for the reduction of anxiety and depression levels and sleep care. Each participant was randomly designated to a healthcare researcher (case manager) responsible for the phone calls and intervention application. The subjects of the calls were based on themes from the American Diabetes Association's Counseling and Education Library and were of educational and interventional matters regarding healthy habits and management of diabetes in its multiple areas. All calls ended with encouragement to maintain care with the diabetes and the question: "in what way could we help you to make your diabetes's treatment easier next week?" No change was made to the dietetic program nor to the doses of prescribed medicines given by their physicians except in severe cases where the patient showed recurrent hypoglycemic episodes and after trying to contact their physician for dose adjustment.

### 2.4. Control Group Characteristics

At the study's inclusion, the control group received access to a free website address, elaborated by this research group, that had weekly posts related to diabetes (https://www.ufrgs.br/lidia-diabetes). There was no frequency control regarding patient's access to the website nor any other intervention to encourage such access.

Both groups (control and intervention) maintained their usual hospital care, however the frequency of them was drastically reduced to an average of one tele consult every 3–6 months.

### 2.5. Outcomes

In order to evaluate the effects of telehealth intervention on the primary outcome (HbA1c values), the HbA1c values analyzed by high performance liquid chromatography were gathered from electronic medical records of all patients up to 3 months prior to the start of the investigation (January, February or March 2020) to serve as baseline. A second blood sample was collected at the end of the intervention period to assess the new values of HbA1c and to be used as follow-up. For secondary outcomes (lipid profile, blood pressure levels, weight, body mass index) the initial values (baseline) were also collected from the last electronic record regarding a presential medical consultation on those cited months. Final values (follow-up) were taken by trained researchers at the end of the study. Other patient's data, such as drugs of daily use, comorbidities, race, gender and jobs were gathered from electronic medical records and confirmed with the patients at the moment of inclusion. For the purpose of evaluating their self-management of diabetes and as a feedback to the study, the patients were asked to grade their own habits - shown on Table 3 -, varying from zero to 10 (highest grade) during the study period. No differences related to data collection occurred between intervention and control groups.

### 2.6. Sample Size

To calculate the sample size, we used the *Clinicalc Sample Size Calculator* tool with a 95% significance level and a power of 80%. To achieve the desired numbers, the present study invited 134 patients (82 with type 2 diabetes and 52 with type 1 diabetes diagnosis) as properly calculated to assess the primary outcome (HbA1c), based on studies previously published [24,25]. Considering a loss up to 10% the total number of invited patients was 150, of which 92 were of type 2 diabetes and 58 were of type 1 diabetes.

### 2.7. Randomization

After initial selection, patients were electronically randomized in a 1:1 allocation between intervention group and control group, stratified for type 1 diabetes and for type 2 diabetes.

### 2.8. Blinding

Blinding was not possible due to the nature of this study. In the effort to reduce the potential bias caused by the lack of blinding, the participant's inclusion and the result's analyses were made by different researchers. None of them were involved in the randomization nor data analysis.

### 2.9. Statistic Methods

Data was revised and analyzed using a databasis created with Microsoft Excel® and transcript to Statistical Package for Social Science (SPSS®) version 22 for further analysis. Descriptive data of normal distribution was presented as mean ± standard deviation (SD). Other data was presented as either average and interquartile range (IQR) or frequency. The result's statistical analysis included Chi-square for categorical variables and T tests for continuous variables (non-paired T tests for transversal analysis between groups and paired T tests for intragroup analysis). The initial analysis was a comparison with intention-to-treat of the primary outcome between intervention and control groups during the period of the study. For the missing data, a conservative, single-imputation approach of the statistical program was used. A p value $\leq$ 0,05 was used to determine the statistical significance.

## 3. Results

The sample was composed of 150 participants. A total of 58 type 1 diabetes patients were included in the study, (29 participants for each group, control and intervention). The median number of phone calls that were received by the participants in the intervention group was 13.0 (IRQ 11.3–15.8). Four participants needed endocrinological assistance for insulin dose adjustments. At the end of the study, 9 participants did not attend the laboratory tests consults. A total of 92 type 2 diabetes patients were included in the study (46 participants for each group, control and intervention). The median number of phone calls received by the participants in the intervention group was 15 (IRQ 14.0 – 16.0). Two patients needed insulin dose adjustments during the study. At the end of the study, 24 patients did not attend the laboratory tests consults. For both type 1 and type 2 diabetes groups, many were the reasons for the *n* loss of sae's collection: hospitalization of patients, mobility difficulties and, mainly, fear of exposure to the new coronavirus (see flowchart).

### 3.1. Participant characteristics

Table 1 describes the demographic and clinical characteristics of patient's samples. In the type 1 diabetes group, composed of 58 patients, there was a predominance of women and white skin color; the mean age for this group was 43.8 ± 13.5; the mean age of type 1 diabetes diagnosis was 18.5 ± 12.2 and the diabetes duration was, in years, 24.7 ± 11.5. The mean HbA1c levels were 8.6 ± 1.4%. Within the spectrum of diabetes complications, patients had 50.0% retinopathy, 37.9% diabetic kidney disease, 25.9% neuropathy. The group presented itself with 12.1% cardiovascular diseases. The percentage of patients in use of insulin was: 43.1% in use of NPH insulin, 58.6% in use of glargine, 22.4% in use of regular insulin, 70.7% in use of lispro. We observed that 10% of the patients did not comply to the social distancing rules. The partial compliance (that in which the patient would go out only for indispensable tasks such as buying medicine at the pharmacy or buying food at the supermarket) was 58.6%, and total compliance (in which the individual would not leave the house under any circumstance) was 31.0%.

In the type 2 diabetes group, composed of a total of 92 individuals,

**Table 1**
Baseline characteristics of study participants.

| | Total | Intervention group | Control group |
|---|---|---|---|
| Type 1 diabetes | n = 58 | n = 29 | n = 29 |
| Age (years) | 43.8 ± 13.5 | 43.7 ± 13.6 | 43.9 ± 13.7 |
| Sex (% female) | 50% | 57.1% | 43.3% |
| Race/ethnicity (% white) | 94.8% | 96.4% | 93.3% |
| Lower-middle income* (%) | 70.7% | 64.3% | 76.7% |
| Regular work (%) | 56.9% | 50.0% | 63.3% |
| Age at the time of diagnosis (years) | 18.5 ± 12.2 | 17.5 ± 12.5 | 19.4 ± 12.0 |
| Diabetes duration (years) | 24.7 ± 11.5 | 26.2 ± 11.2 | 23.4 ± 11.8 |
| HbA1c (%) | 8.6 ± 1.4 | 8.3 ± 1.4 | 8.8 ± 1.5 |
| (mmol/mol) | 70.0 ± 8.6 | 67.0 ± 8.6 | 73.0 ± 9.3 |
| Diabetes complications | 50.0% | 57.1% | 43.3% |
| Retinopathy | 37.9% | 42.9% | 33.3% |
| Nephropathy | 25.9% | 28.6% | 23.3% |
| Neuropathy | | | |
| Cardiovascular disease (%) | 12.1% | 7.1% | 16.7% |
| NPH insulin use (%) | 43.1% | 35.7% | 50% |
| Glargine use (%) | 58.6% | 60.7% | 56.7% |
| Regular insulin use (%) | 22.4% | 21.4% | 23.3% |
| Lispro use (%) | 70.7% | 67.9% | 73.3% |
| Social distancing (%) | 10.3% | 3.6% | 16.7% |
| None | 58.6% | 67.9% | 50.0% |
| Partial | 31.0% | 28.6% | 33.3% |
| Total | | | |
| Type 2 diabetes | n = 92 | n = 46 | n = 46 |
| Age (years) | 61.3 ± 9.0 | 61.6 ± 9.2 | 61.1 ± 8.9 |
| Sex (% female) | 65.2% | 63.0% | 67.4% |
| Race/ethnicity (% white) | 73.9% | 73.9% | 73.9% |
| Lower-middle income* (%) | 43.5% | 39.1% | 47.8% |
| Regular work (%) | 65.2% | 69.6% | 60.9% |
| Age at the time of diagnosis (years) | 43.9 ± 10.7 | 44.6 ± 10.1 | 43.1 ± 11.3 |
| Diabetes duration (years) | 17.4 ± 9.9 | 16.9 ± 9.9 | 18.0 ± 9.9 |
| HbA1c (%) | 8.7 ± 1.7 | 8.4 ± 1.7 | 9.0 ± 1.7 |
| (mmol/mol) | 72.0 ± 10.5 | 68.0 ± 10.5 | 75.0 ± 10.5 |
| Diabetes complications | 41.3% | 39.1% | 43.5% |
| Retinopathy | 33.7% | 34.8% | 32.6% |
| Diabetes renal disease | 42.4% | 45.7% | 39.1% |
| Neuropathy | | | |
| Cardiovascular disease (%) | 37.0% | 32.6% | 41.3% |
| Metformin use (%) | 76.1% | 71.7% | 80.4% |
| Insulin use (%) | 83.7% | 89.1% | 78.3% |
| Social distancing (%) | 3.3% | 2.2% | 4.3% |
| None | 42.4% | 50.0% | 34.8% |
| Partial | 54.3% | 47.8% | 60.9% |
| Total | | | |

Data are mean ± standard deviation or %. $\alpha \leq 0.05$ indicates significant difference. HbA1c: hemoglobin A1c. * Lower-middle income* : less than 2k reais. NPH: Neutral Protamine Hagedorn. Cardiovascular disease: Stroke, heart failure and ischemic cardiomyopathy.

the mean age was of 61.3 ± 9.0 years old. There was also the predominance of women (65.2%) and white skin color (73.9%). The mean age of type 2 diabetes diagnosis was 43.9 ± 10.7 and the diabetes duration was, in years, 17.4 ± 9.9. The mean HbA1c levels were 8.7 ± 1.7%. Regarding diabetes complications, 41.3% of patients had retinopathy, 33.7% had diabetic kidney disease and 42.4% had neuropathy; 37.0% of the sample had previous cardiovascular diseases. As for medications, the total metformin usage within the group was 76.1% and the use of insulin was 83.7%. Only 3.3% of the patients in this group did not comply with the social distancing rules; 42.2% were adherent to a partial social distancing; 54.3% adhered to total social distancing (Table 1).

### 3.2. Primary Outcome

#### 3.2.1. Glycated hemoglobin (HbA1c)

Analysis of the percentage values of HbA1c on follow-up of intervention and control groups showed no difference: 8.1% (7.1 – 9.0) vs. 8.6% (7.7 – 10.3), p = 0.11 for type 1 diabetes and 8.6%(7.5–10.2) vs. 9.0% (8.2–10.8), p = 0.09 for type 2 diabetes. The same occurred in the analysis of the HbA1c variation values for type 1 diabetes [0.0 (−0.7 to 0.4) vs. − 0.1 (−0.6 to 0.8), p = 0.75] and type 2 diabetes [0.4 (−0.4 to 1.3) vs. 0.4 (−0.3 to 1.3), p = 0.69]. (See Table 2).

### 3.3. Secondary outcomes

#### 3.3.1. Metabolic and anthropometric variables

Amongst the variables for secondary outcomes, there were differences on triglycerides levels for the type 1 diabetes group, 66.5 mg/dL (53.9 – 113.5) vs. 86.5 mg/dL (67.0 – 128.0), p = 0.05 (see Table 2). As for the type 2 diabetes group there were no differences on triglycerides levels.

No differences were found on the remaining analyzed variables for either group.

#### 3.3.2. Self-perceptions about the diabetes management and daily habits

Table 3 shows the patient's self-evaluation concerning their habits and selfcare, ranging from zero (lesser grade) to 10 (higher grade) during the study period. No differences were found between the groups for the evaluated variables.

## 4. Discussion and Conclusion

This randomized clinical trial was designed to evaluate the effect of a 16-week long telehealth intervention on the metabolic outcomes of diabetes patients during the period of the COVID-19 pandemic. Our first hypothesis was that the intervention, along with the patient's increased time at home during the social distancing measures, could generate an increased dedication towards the management of their disease and, consequently, better results on the metabolic outcomes.Albeit this study showed no difference in the analyzed short-term outcomes, evidence available so far supports that telehealth interventions have the potential of enhancing adherence [11,21] and mental health [18,19] of diabetes patients, factors that are directly related to a better glycemic control [2,7,8,12,13,14,17,18,19]. It is important to highlight that the absence of statistical significance upon the immediate results after the intervention does not mean evidence of absence in the improvement of those outcomes in the long term. It is possible that the time established for the intervention and the period in which this study took place is one of the factors for no more impactful results. Three meta-analyses performed before the pandemic showed that studies that utilized various telehealth tools for treatment of diabetes led to decreases in HbA1c values of the patients that had access to such tools [11,21,26]. A case-control study with diabetes patients performed during the COVID-19 pandemic compared a group that used a digital platform as means to monitor glycemic levels and another group that did not have access to this platform, both groups were in use of insulin. At the end of the three months of follow-up, a decrease in HbA1c levels ($p < 0.047$) was shown on the group in usage of the digital platform [22].*Ghosal,* et al. utilized a mathematical simulation model to estimate the social distancing's impact on the complications of diabetes and concluded that the worsening of glycemic control would be directly proportional to the length of the quarantine [13]. A cross-sectional study evaluated the adherence of diabetes patients one month after the social distancing rules in Brazil were in place in comparison to a group of patients prior to the COVID-19 pandemic. The study demonstrated a median worsening of 4 points in adherence scores evaluated by the Self-Care Inventory Revised in patients with type 1 diabetes during the social distancing period. [12].

Many studies have demonstrated that social distancing generated a worsening in mental health parameters of patients with diabetes during the COVID-19 pandemic [7,18,19], which in turn impacts selfcare and affects adhesion to diabetes treatment [8,14]. It may be possible to attribute the lack of improvements in metabolic outcomes during this

**Table 2**
Clinical, anthropometric and metabolic parameters of the participants before and after the follow-up period.

| | Intervention group | Control group | P value (between group) |
|---|---|---|---|
| Type 1 diabetes | | | |
| HbA1c (%) | 8.2 (7.5 – 9.1) | 8.7 (7.7 – 9.4) | 0.11 |
| Baseline | 8.1 (7.1 – 9.0) | 8.6 (7.7 – 10.3) | |
| Follow up | | | |
| Variation in HbA1c | 0.0 (−0.7 to 0.4) | -0.1 (−0.6 to 0.8) | 0.75 |
| Systolic blood pressure (mmHg) | 120.0 (118.5 – 128.7) | 120.0 (110.0 – 130.0) | 0.53 |
| Baseline | 120.0 (119.0 – 132.2) | 125.0 (120.0 – 141.5) | |
| Follow up | | | |
| Diastolic blood pressure (mmHg) | 70.0 (60.0 – 80.0) | 80.0 (68.7 – 85.7) | 0.69 |
| Baseline | 80.0 (72.0 – 86.0) | 80.0 (71.5 – 82.5) | |
| Follow up | | | |
| Weight (kg) | 70.9 (61.5 – 81.8) | 64.9 (56.9 – 77.4) | 0.18 |
| Baseline | 73.9 (62.6 – 85.9) | 65.0 (59.9 – 76.6) | |
| Follow up | | | |
| Body mass index (kg/m$^2$) | 25.4 (23.3 – 27.0) | 24.5 (21.2 – 28.1) | 0.48 |
| Baseline | 25.3 (23.8 – 27.3) | 24.5 (22.1 – 29.4) | |
| Follow up | | | |
| Total cholesterol (mg/dL) | 174.6 (135.2 – 199.5) | 183.0 (155.2 – 241.2) | 0.50 |
| Baseline | 184.5 (149.2 – 241.5) | 194.6 (169.7 – 248.8) | |
| Follow up | | | |
| High-density lipoprotein (mg/dL) | 53.5 (46.2 – 62.7) | 56.5 (50.0 – 65.5) | 0.24 |
| Baseline | 61.8 (47.7 – 77.7) | 53.8 (43.7 – 64.0) | |
| Follow up | | | |
| Low-density lipoprotein (mg/dL) | 114.4 (77.9 – 148.7) | 96.2 (81.2 – 129.4) | 0.79 |
| Baseline | 127.0 (97.0 – 153.9) | 108.8 (89.6 – 157.4) | |
| Follow up | | | |
| Triglycerides (mg/dL) | 70.0 (53.2 – 114.7) | 78.0 (62.7 – 104.5) | **0.05** |
| Baseline | 66.5 (53.9 – 113.5) | 86.5 (67.0 – 128.0) | |
| Follow up | | | |
| Type 2 diabetes | | | |
| HbA1c (%) | 8.5 (7.1 – 9.6) | 8.9 (7.8 – 10.2) | 0.09 |
| Baseline | 8.6 (7.5 – 10.2) | 9.0 (8.2 – 10.8) | |
| Follow up | | | |
| Variation in HbA1c | 0.4 (−0.4 to 1.3) | 0.4 (−0.3 to 1.3) | 0.69 |
| Systolic blood pressure (mmHg) | 130.0 (113.0 – 150.0) | 130.0 (120.0 – 140.0) | 0.39 |
| Baseline | 136.5 (120.0 – 151.0) | 132.9 (120.0 – 145.7) | |
| Follow up | | | |
| Diastolic blood pressure (mmHg) | 75.9 (70.0 – 83.7) | 80.0 (70.0 – 88.5) | 0.64 |
| Baseline | 80.0 (70.0 – 90.0) | 79.5 (72.0 – 90.0) | |
| Follow up | | | |
| Weight (Kg) | 80.0 (69.5 – 96.4) | 82.6 (69.3 – 98.0) | 0.90 |
| Baseline | 83.3 (69.8 – 94.8) | 80.1 (72.2 – 97.3) | |
| Follow up | | | |
| Body mass index (kg/m$^2$) | 30.1 (26.9 – 33.6) | 30.4 (27.4 – 36.8) | 0.82 |
| Baseline | 30.5 (27.5 – 34.6) | 29.8 (27.6 – 34.6) | |
| Follow up | | | |
| Total cholesterol (mg/dL) | 166.3 (136.7 – 190.2) | 174.9 (151.0 – 206.7) | 0.41 |
| Baseline | 170.5 (130.7 – 215.5) | 184.5 (141.0 – 211.5) | |
| Follow up | | | |
| High-density lipoprotein (mg/dL) | 39.5 (31.7 – 51.0) | 41.0 (33.0 – 53.0) | 0.08 |
| Baseline | 41.0 (31.0 – 49.4) | 46.7 (36.7 – 57.2) | |
| Follow up | | | |
| Low-density lipoprotein (mg/dL) | 90.2 (70.1 – 115.0) | 81.1 (59.0 – 97.8) | 0.17 |
| Baseline | 99.7 (65.7 – 135.4) | 93.5 (55.2 – 114.1) | |
| Follow up | | | |
| Triglycerides (mg/dL) | 202.5 (112.5 – 298.7) | 191.5 (123.0 – 293.6) | 0.40 |
| Baseline | 159.0 (117.7 – 278.4) | 167 (114.0 – 222.2) | |
| Follow up | | | |

Data are median and interquartile range. HbA1c: hemoglobin A1c.

**Table 3**
Changes in habits that occurred comparing the period before and after the follow up during the COVID-19 pandemic.

| Type 1 diabetes | Intervention group n = 29 | Control group n = 29 | P value |
|---|---|---|---|
| Dietary pattern | 7.0 (6.0–8.0) | 8.0 (7.0 – 8.0) | 0.92 |
| Before | 7.0 (5.1 – 8.0) | 7.0 (5.0 – 8.0) | |
| Follow up | | | |
| Physical activity | 7.0 (3.0 – 8.0) | 7.5 (4.0 – 9.0) | 0.76 |
| Before | 5 (2.1 – 7.7) | 5.0 (2.7 – 8.0) | |
| Follow up | | | |
| Glycemic control | 7.6 (6.0 – 9.0) | 8.0 (7.0 – 9.0) | 0.24 |
| Before | 8.0 (6.0 – 9.0) | 7.5 (5.0 – 8.2) | |
| Follow up | | | |
| Mental health | 8.2 (7.2 – 9.0) | 9.0 (8.0 – 9.2) | 0.99 |
| Before | 8.0 (5.2 – 9.0) | 7.0 (5.0 – 9.0) | |
| Follow up | | | |
| Type 2 diabetes | n = 46 | n = 46 | |
| Dietary pattern | 7.0 (6.0–8.0) | 8.0 (7.0 – 8.0) | 0.92 |
| Before | 7.0 (5.16 – 8.0) | 7.0 (5.0 – 8.0) | |
| Follow up | | | |
| Physical activity | 7.0 (3.0 – 8.0) | 7.5 (4.0 – 9.0) | 0.76 |
| Before | 5 (2.1 – 7.7) | 5.0 (2.7 – 8.0) | |
| Follow up | | | |
| Glycemic control | 7.6 (6.0 – 9.0) | 8.0 (7.0 – 9.0) | 0.24 |
| Before | 8.0 (6.0 – 9.0) | 7.5 (5.0 – 8.2) | |
| Follow up | | | |
| Mental health | 8.2 (7.2 – 9.0) | 9.0 (8.0 – 9.2) | 0.99 |
| Before | 8.0 (5.2 – 9.0) | 7.0 (5.0 – 9.0) | |
| Follow up | | | |

Data are median and interquartile range. Participants were asked to estimate a score for the quality of dietary pattern, physical activity habits, perception of glycemic control and mental health, comparing the periods before the pandemic and after 16 weeks of follow-up.

pandemic period [2,7,8,13,14,17-19] to the worsening of psychological state of the patients, but more studies are needed for such a statement. Another study carried out by our research group demonstrated that patients with type 2 diabetes which received the same telehealth intervention had an improvement of 37% on their mental health scores when compared to the control group ($p = 0.04$) [18,19]. That makes us question that without this intervention the metabolic outcomes and scores for self-care evaluation (seen on Table 3) would possible be even worse for that group of patients.

More studies are needed to evaluate the effectiveness for telehealth programs directed for the management of chronic diseases [5,9]. However, we believe that it is best to provide patients with telehealth medical assistance and guidance then to leave them completely unassisted, albeit there is still a lack of studies to prove this statement [2].

The present study has some limitations. First, there was no blinding of the patients nor the professionals involved. The many patients lost was an important limitation for this work, likely limiting the power of our results. This probably occurred due to the fear of the patients to leave their homes, especially because Brazil was going through its worse transmissibility period of the coronavirus [27] at the moment of sample collection. Another limitation is that the only telehealth tool used was the phone calls. It is possible that other apps and tools, as well as a

higher call frequency, might have helped to improve the outcomes and to contribute in a more effective way for the diabetes mellitus information and improved metabolic outcomes.

Although the proposed intervention did not result in a significant improvement in the metabolic outcomes evaluated, it should be noted that it was responsible for maintaining parameters similar to those found in patients undergoing usual care in pandemic situations.

Finally, there is no doubt that telehealth interventions have an enormous scope and potential to generate health information or to alter outcomes [5,11]. Our study showed no benefit of teleinterventions in improving short-term metabolic outcomes during the COVID-19 pandemic in diabetes. However, the benefits of telehealth strategy are well established in improving mental health parameters, which are directly related to better glycemic control, and which may impact long-term metabolic outcomes.

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## Ethical aspects

This study was elaborated in accordance with the guidelines and regulatory standards for research involving human beings (approved by the National Health Council, resolution 466/12) and following CONSORT recommendations. The study was conducted only after approval by the Research Ethics Committee and the protocol register on the Consort platform. The organizers and the research team involved in this project have compromised to maintain confidentiality about the identity of the patients and to respect the confidentiality of the information of the reviewed medical records. Data analysis of the cited data has an exclusive scientific purpose.

## Consent for publication

All authors have reviewed the final version of the manuscript and agree with the publication of the results presented.

## Registry number

Clinicaltrials.gov (NCT04344210).

## Register and protocol

The study was approved by the National Research Ethics Commission of Brazil (CONEP), number 4.029.368 and register in Clinicaltrials.gov (NCT04344210). All participants agreed to the free and informed consent form, which was saved by voice record and electronic registration.

## CRedit authorship contribution statement

**Debora Wilke Franco:** Conceptualization, Methodology, Software, Data curation, Writing – original draft preparation. **Janine Alessi:** Conceptualization, Methodology, Software, Data curation, Writing – original draft. **Gabriel Luiz Kobe:** Methodology, Investigation. **GiovanaBerger Oliveira:** Methodology, Investigation. **Carolina Padilla Knijnik:** Methodology, Investigation. **Bibiana Amaral:** Methodology, Investigation, **Alice Scalzilli Becker:** Methodology, Investigation. **GabrielaHeiden Telo:** Methodology, Investigation, Conceptualization, Data curation, Writing – originaldraft. **Beatriz D. Schaan:** Conceptualization, Validation, Supervision, Writing – review & editing. Debora Wilke Francois the guarantor of this work and, as such, had full access to all the data inthe study and takes responsibility for the integrity of the data and theaccuracy of the data analysis.

## Conflicts of interest

There is no conflict of interest to declare.

## Data Availability

The data collected for the study, including deidentified participant data and informed consent form, will be available for one year after publication of the article upon justified request to the e-mail address of the main researcher and with a signed data access agreement.

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