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Efficacy of the mHealth application in patients with type 2 diabetes transitioning from inpatient to outpatient care: A randomized controlled clinical trial

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ABSTRACT

Introduction: No studies have assessed the efficacy of telemedicine using a platform for recording and adjusting insulin doses in patients with diabetes mellitus type 2 (DM2) transitioning from inpatient to outpatient care. This study aimed to assess, in a population of patients with DM2, discharged from a tertiary referral hospital, whether treatment based on the use of an mHealth application was associated with better glycemic control at the 3-month follow-up, than standard care.

Methods: This open, randomized, controlled clinical trial included adult DM2 patients who were transitioning from inpatient to outpatient care. The efficacy and safety of patient management with and without mHealth was compared at the 3-month follow-up. The primary outcome was the change in the Glycosylated hemoglobin (HbA1c) levels. The secondary outcomes were the rates of hypoglycemic and hyperglycemic events and treatment satisfaction measured using the Insulin Treatment Satisfaction Questionnaire (ITSQ).

Results: In total, 86 patients (41 using mHealth) were included in the clinical trial. HbA1c levels showed a significant decrease in both groups. The mean HbA1c level was significantly lower in the mHealth group. Patients using mHealth showed decreased incidence rate ratios of hypoglycemia 3.0 mmol/L [<54 mg/dl], hypoglycemia ranging from 3.0 to 3.8 mmol/L [54 to 70 mg/dl] and severe hypoglycemia. The level of satisfaction assessed using the ITSQ was higher in the mHealth group.

Conclusion: Using mHealth in patients with DM2 transitioning from inpatient to outpatient care improves metabolic control and may reduce the hypoglycemia rates.

1. Introduction

Despite advances in the pharmacological management of type 2 diabetes mellitus (DM2), only 30% of the patients in developing countries reach the goal of glycosylated hemoglobin (HbA1c) levels lower than 7%, a number that decreases to 20% among insulin users [1].

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Among the factors associated with poor disease control, limited access to healthcare professionals trained in diabetes management, suboptimal education about the disease, and lack of adherence to treatment and capillary glucose monitoring stand out [2].

In telemedicine, the use of applications on mobile devices (mHealth) has been proposed as a solution to this problem in the ambulatory setting. Many mHealth applications incorporate data collected through the self-monitoring of blood glucose (SMBG) using a platform, which can be accessed by the patient and the healthcare professional, allowing closer feedback and follow-up. The use of these applications has been reported to reduce the HbA1c levels by between 0.45% and 0.59% [3–6] compared to the reductions obtained during usual outpatient care. In addition to the improvement in the control of risk factors, such as the decrease from 1.1 to 2.6 kg of the basal weight [7–9].

Hospitalization is a common complication in patients with diabetes. Hospitalized patients have a prevalence of diabetes of 38% and 12% of them are diagnosed during hospitalization [10] and the transition from the acute care setting presents risks for all these patients [11]. According to the American Diabetes Association, an outpatient follow-up visit with the diabetes team within one month of discharge is recommended for all patients who experience hyperglycemia in the hospital. Also, these guidelines suggest early evaluation and frequent contact in patients with a change in treatment or who do not achieve adequate metabolic control to avoid hyperglycemia and hypoglycemia [11]. However, these follow-up goals after discharge are not achieved in most patients. Although telemedicine and telemonitoring are emerging as a way to strengthen self-management support outside healthcare settings, there are currently no data on the efficacy of this modality of care in patients transitioning from hospital to outpatient.

To date and to the best of our knowledge, no studies have assessed the efficacy and safety of the mHealth applications for DM2 control when transitioning patients from inpatient to outpatient care. This study aimed to assess, in a population of patients with DM2, discharged from a tertiary referral hospital, whether treatment based on the use of an mHealth application was associated with better glycemic control at the 3-month follow-up, than standard care.

2. Methodology

This was a non-blinded randomized controlled clinical trial, which included diabetic patients discharged from the Hospital Universitario San Ignacio in Bogotá, Colombia, from October 2020 to May 2021. Adult patients with DM2, under basal-plus or basal-bolus insulin therapy or taking two or more doses of insulin per day, and with HbA1c $\geq$ 6.5% were included in the clinical trial. Patients admitted for acute diabetes decompensation or acute coronary syndrome, under glucocorticoid treatment in the last three months before enrollment, using real-time or intermittent continuous glucose monitoring, with visual impairment, pregnant, or with psychiatric illness or cognitive impairment limiting the likelihood of device use, were excluded from the clinical trial. To avoid selection bias, we verified that all the patients had access to technology that allowed them to use the application, including mobile phone and data, before randomization. Therefore, it was expected that the patients in the control group vs. the m-health group would be equally digitally "fit". The patients signed an informed consent form to participate in the study. The study was approved by the Clinical Ethics Committee of the Hospital Universitario San Ignacio and the Pontificia Universidad Javeriana. (Approval number FM-CIE-0689-19).

After applying the inclusion and exclusion criteria, the included participants were invited to an initial evaluation, where they were asked to fast and monitor their pre-prandial blood glucose levels. Patients with more than 80% compliance were selected for the study. Hypoglycemia awareness was assessed using the Clarke survey that was administered at the initial visit [12]. All the patients were instructed on the use of insulin, titration, and the identification and treatment of hypoglycemic symptoms within the standard operating procedures of the institution. The selected patients were randomized for the use of the platform (ClouDi) that recorded and adjusted insulin doses, and the random assignment was not able to be changed by the attending physicians.

In the first visit, the patients assigned to mHealth were instructed about the use of the application ClouDi. ClouDi is a telemedicine platform that was developed for the remote monitoring of patients with diabetes in Colombia. It incorporated the recommendations that were published in a usability pilot study that was conducted previously with an open-source cloud platform [13]. The platform consists of a web version, a version for mobile devices and a desktop application, which is installed on the patient's personal computer, thereby allowing glucose measurements taken through the Optium Neo glucometer (Abbott Diabetes Care, Alameda, CA, USA) to be uploaded automatically to the cloud. In this trial, the glucose measurements that were uploaded to the ClouDi website, were reviewed weekly by the members of the research group who were responsible for adjusting the therapy to the insulin titration scheme prescribed for the patient [13]. The patients were informed about these adjustments by text messages sent from the web version of ClouDi to the patient's mobile phone via pop-up notifications. Additionally, both the patients in the mHealth group and the patients in the control group were assessed by the nutrition service during the course of this study, given that eating behavior is the factor most commonly associated with better behavior and metabolic control. The group of patients under the standard care of the institution was evaluated by an endocrinologist at the start of the study and at the 3-month follow-up. Additionally, they received education in the management of diabetes medications and diet by nutrition and nursing before discharge from the hospital.

In addition, in order to assess quality of life and satisfaction with the insulin regimen, patients in both treatment groups were asked to fill out the Insulin Treatment Satisfaction Questionnaire (ITSQ) [14] during the 3-month follow-up visit. The ITSQ includes 22 questions, each of which with answers on a 7-point scale, divided into five subscales, which can be analyzed separately or in combination. The results are converted into scores ranging from 0 to 100, and a score of 100 indicates complete satisfaction [14].

The HbA1c levels were measured at the start of the study and at the 3-month follow-up visit using a method certified by the National Glycohemoglobin Standardization Program (NGSP), in addition to the collection of data on weight, lipid profiles, nitrogen, hypoglycemic events <3.8 mmol/L [<70 mg/dl] (level 1) and <3.0 mmol/L [<54 mg/dl] (level 2). Also, severe hypoglycemia (level 3) events were recorded defined according to the American Diabetes Association (ADA) 2022 [15], as well as hyperglycemic events (>10 mmol/L [>180 mg/dl]) and hospitalizations.

The sample size required to detect a 0.6% decrease in the HbA1c levels, with 80% power and a 0.05 alpha error was calculated based on the study by Cho et al. [16]. The calculated sample size was 42 patients for each arm. Descriptive statistics were used for the continuous variables, reporting the means and standard deviation or the median and interquartile range, depending on whether or not the normal distribution assumption was fulfilled. The Shapiro-Wilk test was used to test this assumption. The categorical variables were described using absolute numbers and percentages. All the tests were conducted according to the intention-to-treat principle. A *t*-test was used to compare differences in the reduction of the HbA1c levels between the groups. The results of hypoglycemic and hyperglycemic events were expressed as risk or incidence rate ratios, with their 95% confidence intervals. No interim analysis was performed. All the statistical tests were performed by a researcher blinded to the treatment group assignment using the statistical package STATA 16 (StataCorp, College Station, Texas).

3. Results

150 patients were assessed for eligibility (n = 150). After meeting the exclusion criteria, 63 patients were withdrawn from the study. In total,

87 patients were randomized. 42 to mHealth group and 45 to standard care. 1 patient allocated to mHealth died before treatment, therefore only 41 (47.7%) of patients began the treatment in this group (Fig. 1). The mean age was 60 years, with a mean diabetes duration of 7.8 years. Most of the patients were men (55%). The baseline characteristics of the patients were similar in both of the treatment groups, except for the proportion of patients with obesity, which was higher in the mHealth group than in the standard care group (46% vs 29%). The most frequently used insulin regimen was the basal bolus, while metformin and the glucagon-like peptide-1 receptor agonists (GLP1a) were the most commonly used antihyperglycemic agents. The clinical characteristics of the patients are outlined in Table 1.

Five patients died during the follow-up (three in the standard care group and two in the mHealth group); therefore, only 82 patients were included in the analysis at three months. The mean HbA1c level at baseline was similar in the two groups (12.6% for mHealth vs 12.2% $P = 0.89$). At the 3-month follow-up, the decrease in the HbA1c levels showed a clinical and statistical significance in both of the groups. The mean difference in the HbA1c levels was 3.38% (95% CI: 2.45, 4.32; $P < 0.001$) in the standard care group and 5.42% (95% CI: 4.40, 6.43; $P < 0.001$) in the mHealth group. When comparing the decrease in the mean HbA1c levels between the two groups, the reduction was greater in the mHealth group (-2.03% mean difference in HbA1c, 95% CI: −3.39, −0.68; $P = 0.004$). The data on HbA1c level changes is shown in Fig. 2.

When assessing the number of hypoglycemic events at the 3-month follow-up, a similar proportion of patients had experienced at least one episode of hypoglycemia levels one, two and three in the mHealth group vs the standard care group. A similar proportion of patients with at least one episode of hyperglycemia was found in both groups (Table 2). However, when the incidence rates (IR) of hypoglycemic events per person month was assessed, a significantly lower number was observed in the mHealth group, including events of hypoglycaemia

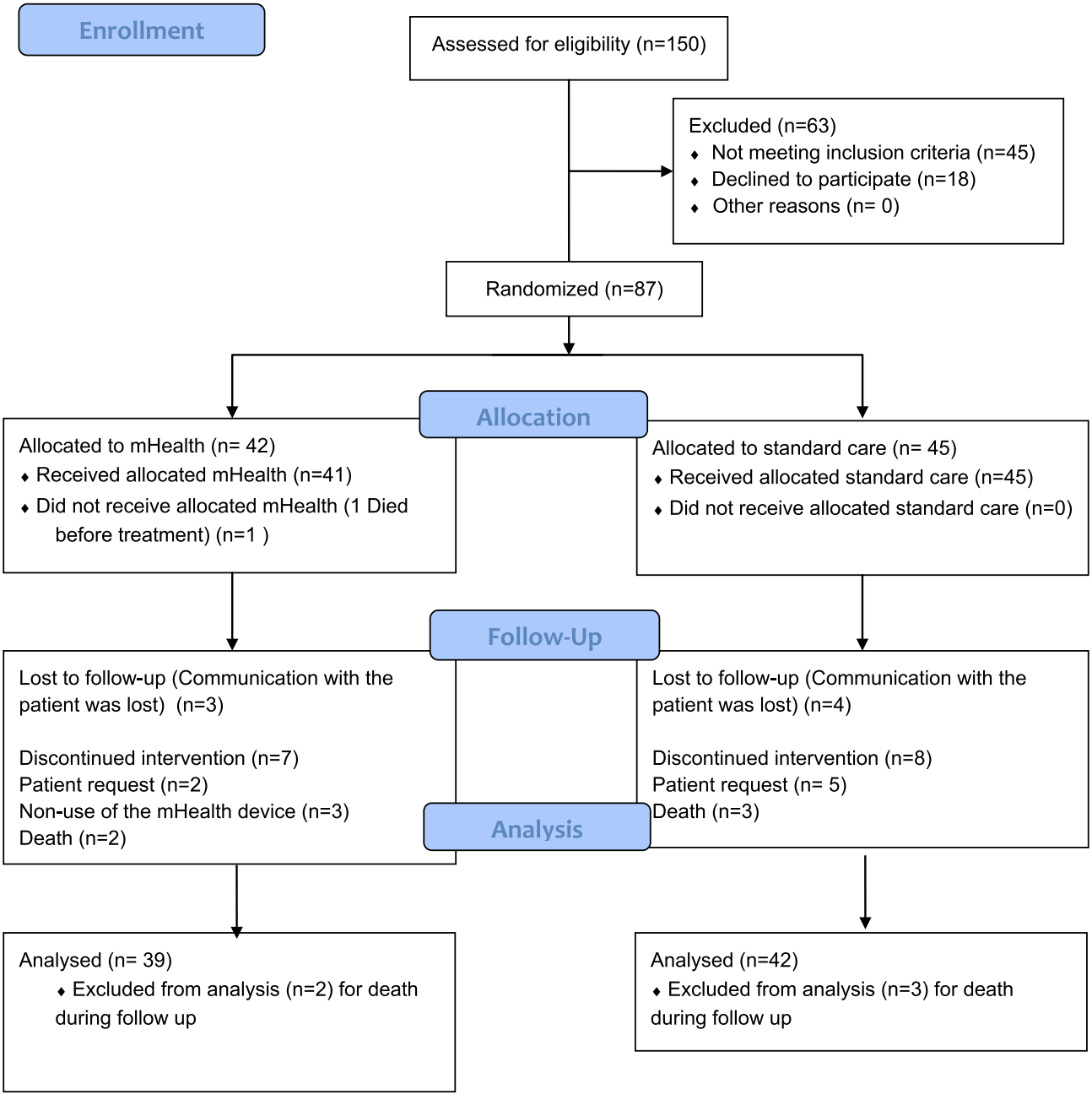

Fig. 1. CONSORT Flow Diagram.

Table 1
Baseline characteristics of the patients under mHealth or standard care.

Variable	mHealth (n = 41)	Standard care (n = 45)	P Value
Age in year, mean (SD)	58.6 (10.6)	60.5 (12.8)	0.45
Men, n (%)	23 (55.0)	26 (54.2)	0.94
Duration of diabetes in years, median (RIQ)	7.7 (6.6–8.8)	7.8 (5.9–9.7)	0.78
Glycosylated hemoglobin, %, mean (SD)	12.6 (3.0)	12.2 (2.9)	0.89
BMI, n (%)			
Normal weight	10 (24.4)	14 (31.1)	0.25
Overweight	12 (29.3)	18 (40.0)	
Obesity	19 (46.3)	13 (28.9)	
Creatinine μmol/L, mean (SD)	74.27 (52.17)	76.93 (25.64)	0.76
Creatinine mg/dL, mean (SD)	0.84 (0.59)	0.87 (0.29)	
Established cardiovascular disease, n (%)	8 (19.5)	9 (20.0)	0.95
Microvascular complication, n (%)	12 (29.3)	15 (33.3)	0.69
Retinopathy	6 (14.6)	8 (17.8)	0.68
Nephropathy	3 (7.3)	4 (8,9)	0.79
Neuropathy	3 (7.3)	3 (6.7)	0.91
Anti-hyperglycemic, n (%)			
Metformin	15 (36.6)	17 (37.8)	0.91
Sulfonylurea	0 (0)	0 (0)	–
DPP-4i	6 (14.6)	7 (15.6)	0.90
GLP1a	16 (39.0)	18 (40.0)	0.92
SGLT2i	14 (34.1)	16 (35.6)	0.88
Insulin, n (%)			
Basal insulin only	13 (31.7)	13 (28.9)	0.77
Basal-bolus insulin	28 (68.3)	32 (71.1)	
Lipid profile, mean (SD)			
Total cholesterol mmol/L	5.11 (1.53)	4.75 (1.08)	0.21
Total cholesterol mg/dL	197.9 (59.4)	183.8 (42.3)	
LDL cholesterol mmol/L	2.72 (0.85)	2.64 (0.72)	0.64
LDL cholesterol mg/dL	105.2 (33.1)	102.4 (28.2)	
Triglycerides mmol/L	3.40 (2.70)	2.88 (1.37)	0.26
Triglycerides,	301.1 (239.2)	254.9 (121.4)	
Inadvertent hypoglycemia, n (%) *	12 (29.3)	14 (30.4)	0.91

* Unawareness hypoglycemia was evaluated by administering the Clarke survey: 4 R or higher was considered inadvertent hypoglycemia. Abbreviations BMI, Body Mass Index, SD, standard deviation, DPP-4i, Dipeptidyl peptidase-4 inhibitor, GLP1a, Glucagon-like peptide-1 receptor agonist SGLT2i, sodium-glucose transporter 2 inhibitor.

<3.0 mmol/L [<54 mg/dl] (0.45 events/ person-month IR in mHealth vs 0.84 in the standard care, 0.53 IRR: 95% CI: 0.37, 0.74; $P < 0.001$), hypoglycemia ranging from 3.0 to 3.8 mmol/L [54 to 70 mg/dl] (1.74 events/person-month IR in mHealth vs 2.40 IR in standard care, 0.72 IRR, 95% CI: 0.66, 0.87; $P < 0.001$) and hypoglycemia requiring help from a third party (0.06 events/person-month IR in mHealth vs 0.18 IR in standard care, 0.39 IRR, 95% CI: 0.15, 0.91; $P = 0.02$). The number of hyperglycemic events was lower in the mHealth group when assessing episodes of hyperglycemia higher than 13.8 mmol/L [250 mg/dl] (3.03 events/person-month IR in mHealth vs 3.96 IR in standard care, 0.76 IRR, 95% CI: 0.66, 0.87; $P < 0.001$) (Table 3).

No significant reduction in weight was found in the standard care group (1.64 Kg mean difference, 95% CI: −0.28, 3.56; $P = 0.09$), whereas a significant decrease was observed in the mHealth group (3.63 Kg mean difference, 95% CI: 1.28, 5.97; $P = 0.003$). Similarly, no significant change in the BMI was observed in the standard care group (0.53 mean difference, 95% CI: −0.26, 1.32; $P = 0.18$), unlike the mHealth group, where the decrease in the BMI was significant (1.20 mean difference, 95% CI: 0.41, 1.98; $P = 0.004$).

Satisfaction, measured using the ITSQ questionnaire, that was

Table 2
Percentage of patients experiencing hyperglycemic and hypoglycemic episodes in the mHealth and standard care groups at the 3-month follow-up.

Outcome	mHealth	Standard care	RR (95% CI)	p value
Hypoglycemia (1 or more episodes)				
Level 1 (<3.0 mmol/L [<70 mg/dL]), n (%)	52.5	52.3	1.01 (0.67–1.51)	0.98
Level 2 (<3.8 mmol/L [<54 mg/dL]), n (%)	75.0	72.3	1.03 (0.80–1.33)	0.81
Level 3 or Severe hypoglycemia*, n (%)	15.0	25.6	0.59 (0.24–1.44)	0.23
Hyperglycemia (1 or more episodes)				
10–13.8 mmol/L [180–250 mg/dl], n (%)	95.0	90.7	1.05 (0.93–1.18)	0.45
>13.8 mmol/L [>250 mg/dl], n (%)	87.5	83.7	1.04 (0.88–1.25)	0.62
Hospitalization for diabetes decompensation, n (%)	2.5	15.2	0.16 (0.02–1.28)	0.06

* Any level of hypoglycemia that required help from a third party. RR: relative risk.

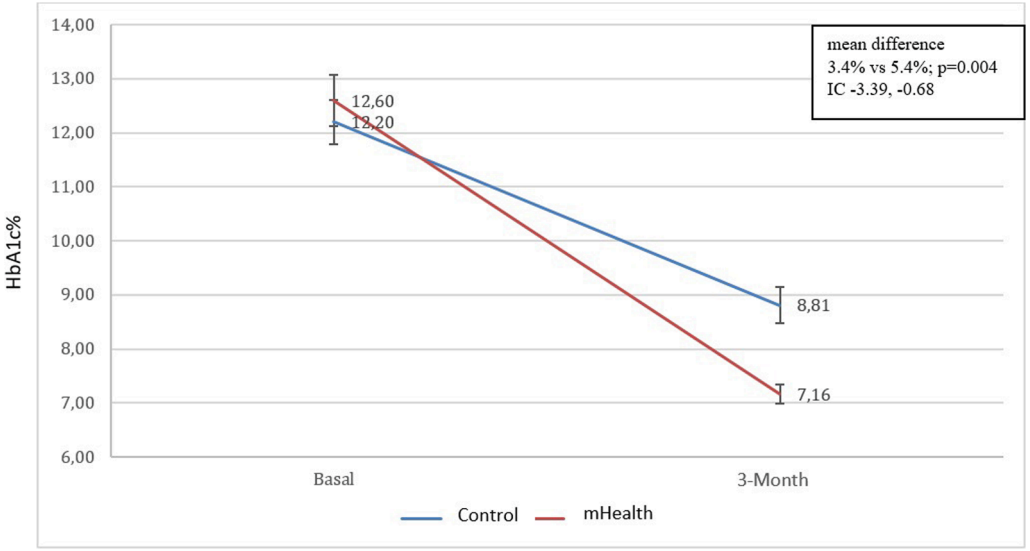

Fig. 2. HbA1c change in the mHealth group vs control group at the 3-month follow.

Table 3
Incidence and incidence rate ratios of hypo and hyperglycemia events in the mHealth and standard care groups at the 3-month follow-up.

Clinical outcome	mHealth (IR)	Standard care (IR)	IRR (95% CI)	p value
Hypoglycemia				
Level 1 (<3.0 mmol/L [< 54 mg/dL])	0.45	0.84	0.53 (0.37–0.74)	<0.001
Level 2 (3.0–3.8 mmol/L [54–70 mg/dL])	1.74	2.40	0.72 (0.61–0.87)	<0.001
Level 3 or Severe hypoglycemia	0.06	0.18	0.39 (0.15–0.91)	0.02
Hyperglycemia				
10–13.8 mmol/L [180–250 mg/dl)	6.60	7.17	0.92 (0.84–1.01)	0.09
13.8 mmol/L [>250 mg/dl)	3.03	3.96	0.76 (0.66–0.87)	<0.001
Hospitalization for diabetes decompensation	0.02	0.05	0.33 (0.33–1.73)	0.16

IR, incidence rate (cases of events per person-year); IRR, Incidence rate ratio.
Note: The incidence rate is expressed as events per person-month.

reported three months after randomization, was higher in the mHealth group (73.8 ± 11.1) than in the standard care group (42.8 ± 16.7) (30.5% mean difference, 95% CI: 24.5, 36.7; $P < 0.001$). Lastly, no significant differences in the number of hospitalizations for diabetes decompensation were found in both groups (Table 3).

4. Discussion

This study found that the treatment of patients with DM2 transitioning from inpatient to outpatient care according to the use of mHealth was associated with a greater decrease in the HbA1c levels than the treatment of patients receiving standard care, with a decrease in the rate of hypoglycemic events levels one, two and three at the 3-month follow-up. Additionally, the use of mHealth was related to a lower incidence rate of hyperglycemic events (higher than 13.8 mmol/L [250 mg/dl]) than the standard care, without a significant weight loss.

The significant difference in HbA1c observed in this study may be explained by the more frequent feedback on insulin adjustments. Cho et al. [17], Yoo et al. [18] and Rodríguez et al. [19] reported a decrease in the mean HbA1c level of between 0.4 and 0.7%. However, our results were better than those reported by Cui et al. [20] (0.40% mean difference in the HbA1c level) and Hou et al. [3] (0.57% mean difference in HbA1c). The discrepancy in results may be explained by the heterogeneity of the studies, where the application feedback ranged from every 2.5 months [20] to every 2 weeks [21]. Additionally, studies such as Shojania et al. [22] and Faruque et al. [23] showed that the use of applications that allow feedback generate better results in lowering HbA1c levels than those that do not provide this option. The intervention group of these studies provided feedback weekly, reinforcing the findings of different *meta*-analyses that showed a direct relationship between the decrease in HbA1c levels and the frequency of feedback [24,25]. Furthermore, the marked impact on the decrease in HbA1c levels found in this study may be related to the initial HbA1c levels (>12%). Studies such as Lim et al. [25] demonstrated that the patients with worse glycemic control had better results in reducing the number of events when using telemedicine. Published meta-analyses have described a greater impact on lowering HbA1c in patients with HbA1c > 9.0% [26,27].

Studies have described the deterioration of glycemic control during the pandemic in the DM2 population in the absence of telemonitoring [28]. This study was developed under mobility and interaction restrictions during the COVID-19 pandemic, favoring the difference in HbA1c between the two groups. However, restricted access to health personnel is one of the main barriers that favor poor metabolic control and it was identified prior to the pandemic [29]. Therefore, the quarterly controls reflect the frequency of standard care intervention for our population. Our findings show the relevance of telemonitoring as a follow-up strategy for diabetes clinics in patients transitioning from hospital to outpatient setting and its usefulness even after COVID-19 restrictions are lifted.

In contrast to the findings of other studies [30,31], which reported the same hypoglycemia rates when using mHealth, our study showed that the incidence rates of hypoglycemia were different in the two groups despite the fact that the number of patients who experienced hypoglycemia was the same in both groups, which suggests that the use of mHealth prevented repetitions of hypoglycemia. This finding can be explained by the greater control on the part of the patients when using the mobile application, allowing close monitoring, early adjustments of the insulin dose and instructing the patients to avoid new episodes of hypoglycemia. Our results were similar to those reported by Rossi et al. [32], who found a 86% decrease in the risk of hypoglycemia 3.0 mmol/L [<54 mg/dl] in comparison in the control group, as well as the systematic review of Hu et al.[33] who reported a reduction in hypoglycemia with an odds ratio of 0.42.

ClouDi incorporates technical characteristics that promote fluid communication between doctors and patients. For example, in the web version used by attending physicians, the patient list is organized in a manner that enables the easily identify of unread text messages from patients and the prioritization of answering questions about their treatment. In addition, the patients were notified of the text messages sent by the doctors in real time to the patient through the pop-up messages via the mobile version of ClouDi. While overall, the patients welcomed the use of this platform, some recommendations were made to improve its usability and convenience, such as not depending on a personal computer to upload the data from the glucometers to the cloud.

The reduction in the weight and Body Mass Index (BMI) in the mHealth group was not significantly different from that in the standard care group. These findings are similar to those of Clare et al. [34] who studied a similar sample of patients (n = 59) for 6-months. However, in this study, no specific intervention for weight reduction was implemented in either arm. Studies evaluating a larger sample and follow-up periods of up to 12 months, as those conducted by Park et al. [35], Gemma et al. [36] and Iskandar et al. [37] have reported a significance weight loss in comparison with standard care (mean weight change of up to 6.14 kg at 12 months; $P < 0.001$). The levels of satisfaction with the use of insulin evaluated by ITSQ were higher in the intervention group, which may have been due to the ClouDi enabling more frequent follow-ups and the provision of the medical group's insulin adjustment guidelines.

Among the strengths of this study, this was the first controlled clinical trial assessing the use of mHealth in a population transitioning from inpatient to outpatient care with limited evidence of mHealth implementation. A limitation of this study was its short-term follow-up, limiting its findings to outcomes such as the number of hospitalizations and the changes in the patients' weight. However, the highly significant primary outcome of change in HbA1c provided a favorable conclusion with regard to the improvement of glycemic control with the use of the application. New studies with a follow-up period of longer than three months will be required to strengthen these findings. Similarly, future studies should perform economic evaluations considering the direct and indirect costs of using mHealth.

5. Conclusion

This study demonstrated that the use of an mHealth application in patients with DM2 transitioning from inpatient to outpatient care improved metabolic control and reduced the hypoglycemia rates. Therefore, the implementation of this type of application prior to hospital discharge and the availability of a diabetes team that provides feedback, will benefit DM2 management.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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