Original research

Culturally adapted mobile application for optimizing metabolic control in type 1 diabetes: a pilot study

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ABSTRACT

Objective. To evaluate whether use of a culturally adapted mobile application (app) for adolescents with type 1 diabetes is associated with improved metabolic control.

Methods. The Dominican Republic's National Institute of Diabetes, Endocrinology, and Nutrition and the Learning to Live clinic recruited 23 pediatric participants for the study. Blood tests were performed before and after use of the app for a period of 3 months. Based on the user profile, participants were encouraged to use the app's bolus insulin calculator after each meal. The app included a list of regionally and culturally specific foods, color-coded to indicate a high glycemic index (GI) as red; medium GI as yellow; and low GI as green. The color-coding was designed to assist participants in making healthier eating choices.

Results. There were statistically significant improvements in lipid profile. Mean high-density lipoprotein values rose to acceptable levels, while low-density lipoproteins and triglyceride levels fell to the recommended values. The overall quality of life increased, although glycated hemoglobin levels showed no statistically significant changes.

Conclusion. The findings of this study suggest that using this culturally tailored app can help young patients with type 1 diabetes to improve metabolic health.

Keywords Diabetes mellitus, type 1; glycemic control; insulin; mobile applications.

Type 1 diabetes mellitus (T1DM), previously known as juvenile diabetes and insulin-dependent diabetes mellitus, is a chronic endocrine condition (1) affecting approximately 9 million people worldwide (2). Current treatments focus on delaying complications, improving quality of life, and preventing disease progression. Adequate metabolic control and timely adjustment of T1DM treatment represent a pillar in preventing the complications of this condition (3). Medical nutritional therapy, such as carbohydrate (carb) counting, is a strategy that favors adequate control of postprandial glycemic values, thereby yielding optimal metabolic control (4-6). To obtain and maintain glycemic control, patients with T1DM need to have carb counting skills and mastery of insulin adjustments according to food intake; effectively managing macronutrient count can often become arduous (3).

Use of relevant technology has been shown to help with metabolic control among individuals with T1DM (7-9). However, only some integrated electronic resources make performing the calculations easy, and those that do seem to lack adequate instructions and specific decision-making guidance (10). Evidence to support the effectiveness of mobile applications (apps) remains limited (11); moreover, existing apps are not available in Spanish and lack the foods typical of Latin America and the Caribbean.

Bolus insulin, insulin sensitivity calculators, and basal-bolus schemes have long been part of the treatment plans for

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people with T1DM (12); however, as stated, apps that are in English only, are not free, and do not include typical foods of Latin America and the Caribbean are of limited utility in the region. Therefore, we designed the Diabetes Azul mobile app to address these gaps (13).

Diabetes Azul includes Latin American and Caribbean regional foods and was culturally adapted from Costa Rica, the Dominican Republic, Mexico, and Panama. By including foods commonly consumed in this region, our intention was to help people with T1DM be more involved in the decision-making process that leads to better metabolic control. A list of international foods from the US Department of Agriculture is also included. In addition, the app provides a coding of carbohydrates (for carb counting) along with each food's glycemic index—when considered, this may allow for slower absorption and more sustainable distribution of glucose during the post-absorption time (14).

This study aimed to evaluate the association of a culturally adapted mobile app with decision-making regarding food selection by people with T1DM in Latin America or the Caribbean. The app uses relevant information to calculate insulin adjustment for the individual user and the impact of intake on metabolic control.

METHODS

This was a cross-sectional, interventional pilot study including users of the pediatric diabetes service of the Dominican Republic National Institute of Diabetes, Endocrinology, and Nutrition and the Dominican Republic's Learning to Live clinic. The study sample was composed of male and female children and adolescents (10-18 years old) with T1DM.

Intervention design

Clinicians instructed participants to use the app's manual calculator for each daily insulin administration. The standardized calculator was used for prandial insulin bolus doses (15). Another instruction was that participants choose their foods and use the app's bolus insulin calculation daily for the entire 3-month study period. Participants received free technical assistance 24 hours a day via telephone, 7 days a week, plus tests, glucometers, and test strips. In addition, the research team maintained weekly communication with the researchers via telephone conversations to verify that all contingencies were covered.

The research team explained the study procedures to participants and their parents or guardians in three training sessions, including before, during, and after the study, during face-to-face sessions. The usability and preferences available for this app had been tested in a previous qualitative study, in which the needs of individuals of similar ages were adapted and subsequently included in the development of the application (16, 17). The research team documented and recorded all of the topics presented during the three training sessions, allowing participants to ask questions at any time. All participants received a training session, a glucometer with strips, and an explanation of the basic principles of nutrition required for identifying carbohydrates in food.

The study considered an intention-to-treat basis. We had a dropout rate of 43.5% (Figure 1), resulting in 10 participants for the final analysis. Dropouts occurred during holidays because participants could not pick up their strips and other materials for glucose measures. Participants received glucometers and test strips even when they opted to exit the research study before completion. The study could not afford to provide transportation for material pick up, which was likely the leading factor contributing to dropout.

Outcomes and measures

The primary outcome of this pilot study was to determine the effectiveness of app use for metabolic control, defined as changes in glycated hemoglobin (HbA_{1C}), glycemic, and lipid profile values. The secondary outcome was the association of the app with improvements in quality of life and changes in users' habits. Metabolic outcomes after using the app for metabolic control were compared with baseline measurements taken before using the app, including data on HbA_{1C}, variation coefficient, blood glucose, and ketone values. Once eligible for the study, a bioanalyst took laboratory samples for testing of HbA_{1C}, lipid profile, and prandial blood glucose levels at baseline and after 3 months of app use.

Participants completed the Spanish version of the World Health Organization Quality of Life Questionnaire (WHOQOL-BREF), which measures quality of life through four domains: physical health, psychological health, social relationships, and environmental factors. The WHOQOL-BREF section on sexual intercourse was excluded given the age range of the target sample. The WHOQOL-BREF scores for each domain are scaled in ascending order, with higher scores denoting better quality of life and 100 being the maximum score ($\alpha = 0.90$).

Statistical analysis

Tables with means and standard deviations (SDs) present the quantitative data. The primary endpoint—HbA_{1C} coefficient of variation at baseline and after 3 months of app use—was analyzed with t test to compare before and after groups. Statistical analyses were performed using SPSS Statistical (IBM), JASP (University of Amsterdam), and Excel (Microsoft).

Ethical approval

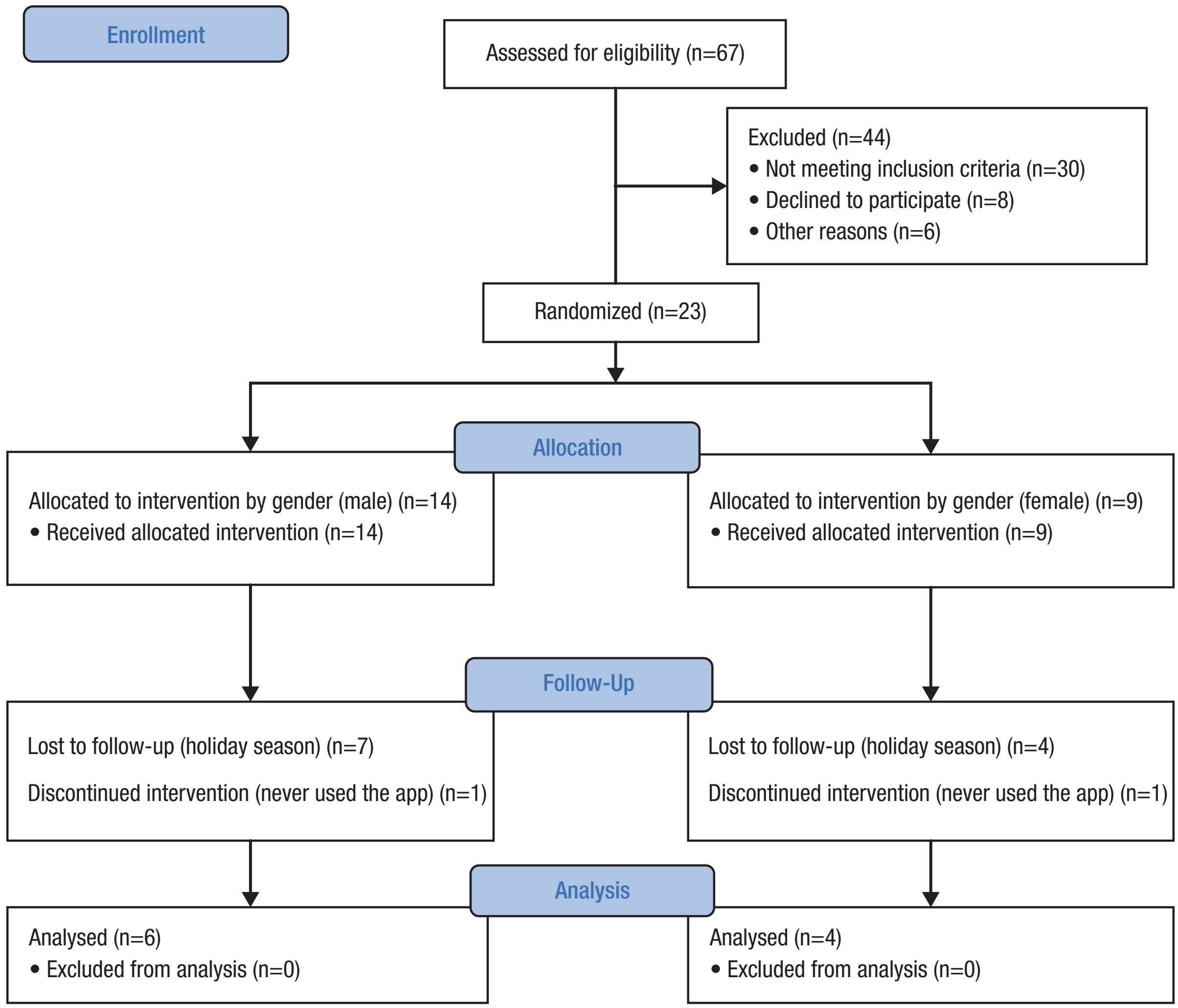
Informed consent was read and signed by parents or legal guardians and the participants in accordance with the principles of the Declaration of Helsinki (18th World Medical Assembly; June 1964). Regardless of whether the parent or guardian consented, the child's refusal to participate in the study was honored. The consent form advised participants to refuse to answer inappropriate or sensitive questions. It was also made clear that participation was optional and that participants could withdraw at any moment.

RESULTS

The study recruited 67 patients of whom 23 met the inclusion criteria, which included having access to a cellphone with an uninterrupted internet connection. The 23 participants completed the baseline measurements and data collection before using the app and after using it for 3 months, from 8 October 2021 to 10 January 2022.

The mean (SD) age of female participants was 14.3 (2.4) years, and of male participants, 15.0 (1.6) years. The minimum (SD)

FIGURE 1. Consort flow diagram of the eligibility process of the study participants



Source: Prepared by the authors from the study results.

time from T1DM diagnosis was 3.0 (3.8), with a range of 0.3 to 7.0 years. Significant differences ($P = 0.05$) were observed in lipid profiles (triglyceride, high-density lipoprotein, and low-density lipoprotein) between baseline and 3 months after app use. However, we did not observe statistically significant changes in HbA_{1C} or glycemic variability (Figure 2). However, the results of a paired student's *t* test demonstrated a significant reduction (improvement) in lipid profiles after app use (Table 1) (18).

When evaluating the quality-of-life domains and observing the means with the SDs, all related domains increased after 3 months of app use, except the physical domain. However, there were no statistically significant changes in any domain (Figure 3). Table 2 includes the before and after values of the dimensions of the WHOQOP-BREF. There were no significant changes between the before and after measurements for any of the quality-of-life dimensions.

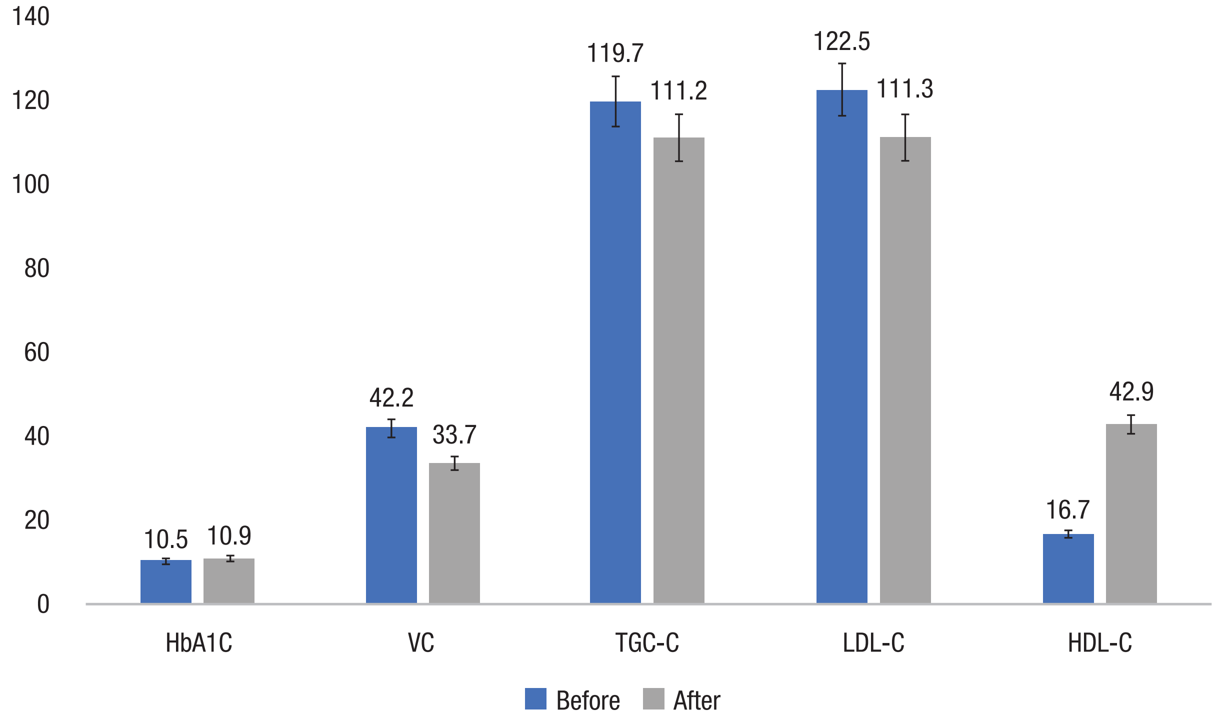
DISCUSSION

The observed changes in biological markers after participants used the culturally adapted app for 3 months did not include fasting and postprandial glucose levels, in which other studies have found significant differences (19, 20). Although carbo counting is a proven tool, our study's small sample (n=10) and relatively short follow-up period (3 months) could have influenced these nonsignificant results. Demonstrating the effectiveness of glycemic markers of this app may require further studies with a larger sample and a longer follow-up period (21).

The associated impact on the lipid profile is inferred to be related to the participants' selection of the foods, color-coded according to their glycemic content. Another possible relationship may be using the bolus insulin calculator and calculating the specific insulin sensitivity, which is calculated automatically when the participant entered the initial data and when selecting food in the app.

As observed in this study, the significant changes in atherogenic lipid profile (low-density lipoprotein and tryglyceride) led to an associated reduction of cardiovascular risk and long-term complications. This is evidenced by other studies that have found an association between selecting foods with a low glycemic index and these benefits (22-27). Another element

FIGURE 2. Metabolic profile of the participants' before and after using the mobile application



Source: Prepared by the authors from the study results.
Abbreviations: HbA1C, hemoglobin glycosylated A1C; HDL, high-density lipoproteins; LDL, low-density lipoproteins; TGC, triglycerides;VC, variability coefficient.*
LDL, low-density lipoproteins; HDL, high-density lipoproteins.

added to this app was the bolus calculator with correction factors, allowing better metabolic control for users with T1DM. This calculation allows rapid insulin to correct blood glucose levels 2 hours after food intake (23). In addition, the individualization of insulin use, glycemic sensitivity, and carbohydrate counting has demonstrated their effectiveness in the metabolic control of T1DM (12, 28). However, concurring with findings of previous studies, this study showed that the changes in glucose levels were less apparent (11, 22, 23).

In contrast, this study demonstrated statistically significant changes and improvements in serum lipid levels. Other studies using mobile health interventions (eg, mHealth) based on smartphone applications to help patients with diabetes in self-controlled situations did not show statistically significant effects concerning improvements in serum lipids (29). Other studies also have shown a modest impact on glycemic control and HbA_{1C} changes after mHealth app-based interventions (30-32). Our study, however, did not show statistically significant differences in glycemic control or HbA_{1C} (18).

The results related to quality-of-life domains are possibly due to the small sample. The effect size also depowered the statistical tests (significance still needs to be reached). This was very noticeable in the environmental component in which the effect size was d = 0 .37, almost reaching a medium effect. Nevertheless, most produced only a small effect, except in the physical component (Table 2).

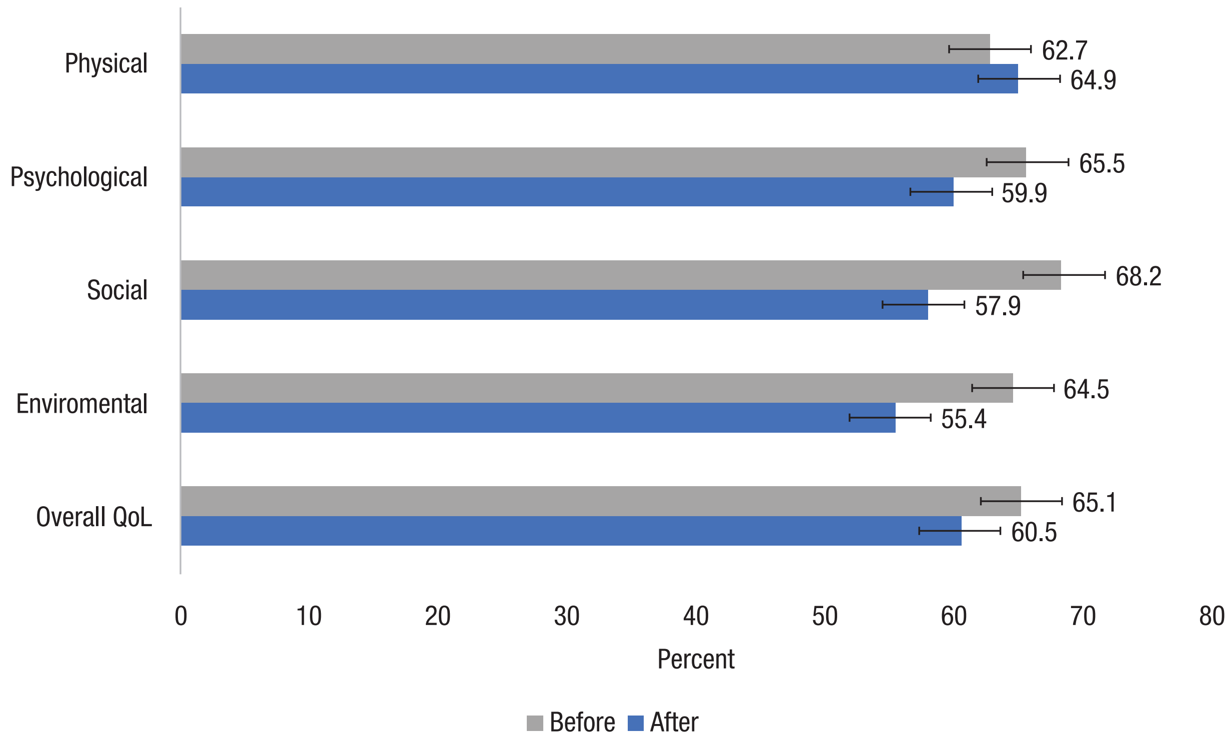
As evidenced in this pilot study, using an app to improve the overall quality of life in patients with T1DM can be effective and favorable. Addressing the metabolic health of persons with T1DM can improve quality of life, prolong life expectancy, and help prevent some of the many complications

TABLE 1. Impact on the metabolic control profile in people with T1DM

Measures	*t*	*p*	*Cohen's d*
HbA_{1C}	1.152	0.279	0.364
VC	-1.293	0.228	-0409
TGC	-2.266	0.050	-0.717
LDL	-2.417	0.039	-0.764
HDL	9.307	<0.001	2.943

Source: Prepared by the authors from the study results.
Abbreviations: HbA1C, hemoglobin glycosylated A1C; HDL, high-density lipoproteins; LDL, low-density lipoproteins; TGC, triglycerides;VC, variability coefficient.

FIGURE 3. Domains that influence quality of life in participants with T1DM using the mobile application



Source: Prepared by the authors from the study results.
Abbreviation: QoL, quality of life.

associated with uncontrolled diabetes (21, 33). In addition, as various authors have shown, the use of carbo counting and individualized insulin adjustments can improve quality of life (34).

Limitations

This study was limited by its small sample size. Effect size also depowered the statistical tests. We also acknowledge that some patients could not participate because of their lack of access to the required technology. Moreover, the quality-of-life effect was likely due to participants having glucometers and test strips, and not necessarily associated with the app. Future research should include continuous glucose monitors. It is crucial to use questionnaires specific to the age and condition of the participants. This approach can provide more accurate and meaningful data, as well as a higher follow-up rate, which would improve the validity of the findings.

Conclusions

The findings of this pilot study indicate that clinicians and patients benefit from continued investment in technological resources, especially in developing countries where access to cost-effective treatments is paramount. Mobile apps are cost-effective for patients and will decrease the burden of treating dyslipidemia complications secondary to diabetes. In addition, mobile apps can help educate patients and encourage lifestyle modifications, including the selection of more regional foods with low glucose content. Together, these changes can reduce the risk of diabetes-related complications. Future studies using larger sample sizes and longer

TABLE 2. Measures of domains of quality of life before and after use of mobile application

Measures	*t*	*P*	Mean difference	Standard error difference	*Cohen's d*
Physical	0.268	0.603	2.275	8.496	0.081
Psychological	-0.652	0.264	-5.680	8.709	-0.197
Social interaction	-0.742	0.237	-10.227	13.778	-0.224
Environmental	-1.236	0.122	-9.090	7.352	-0.373
Overall QoL	-0.630	0.271	-4.636	7.362	-0.190

Source: Prepared by the authors from the study results.

follow-up times are needed to more definitively determine whether the app can positively affect the glycemic profile of its users and whether there are additional implications for the findings.

Author contributions. JC, AM, and CRM conceived the original idea, planned the experiments; JC, DS, PSP, VW, and IM collected the data; JC, AM and CRM analyzed the data and contributed data or analysis tools and interpreted the results; and all of the authors wrote and reviewed the paper. All authors reviewed and approved the final version.

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Conflicts of interest. None declared.

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Aplicación móvil adaptada desde el punto de vista cultural para optimizar el control metabólico en la diabetes tipo 1: estudio piloto

RESUMEN

Objetivo. Evaluar si el uso de una aplicación móvil (app) para adolescentes con diabetes tipo 1, adaptada desde el punto de vista cultural, se asocia a una mejora del control metabólico.

Métodos. El Instituto Nacional de Diabetes, Endocrinología y Nutrición de República Dominicana y Learning to Live Clinic reclutaron a 23 participantes pediátricos para el estudio. Se realizaron análisis de sangre antes y después de utilizar la aplicación durante un período de 3 meses. En función del perfil de usuario, se alentó a los participantes a utilizar la calculadora del bolo de insulina de la aplicación después de cada comida. La aplicación incluía una lista de alimentos propios de la región y la cultura, codificados por colores para indicar un índice glucémico (IG) alto (rojo), medio (amarillo) o bajo (verde). El código de colores se diseñó para ayudar a los participantes a adoptar opciones de alimentación más saludables.

Resultados. Se observaron mejoras estadísticamente significativas en el perfil lipídico. Los valores medios de las lipoproteínas de alta densidad aumentaron hasta niveles aceptables, mientras que los niveles de las lipoproteínas de baja densidad y los triglicéridos descendieron hasta los valores recomendados. Se observó una mejora en la calidad de vida general, si bien no se observaron cambios estadísticamente significativos en los niveles de hemoglobina glucosilada.

Conclusiones. Los resultados de este estudio sugieren que el uso de esta aplicación adaptada desde el punto de vista cultural puede ayudar a los pacientes jóvenes con diabetes mellitus tipo 1 a mejorar su salud metabólica.

Palabras clave Diabetes mellitus tipo 1; control glucémico; insulina; aplicaciones móviles.

Aplicativo móvel culturalmente adaptado para otimizar o controle metabólico do diabetes tipo 1: estudo-piloto

RESUMO

Objetivo. Avaliar se o uso de um aplicativo móvel culturalmente adaptado para adolescentes com diabetes tipo 1 está associado a um melhor controle metabólico.

Métodos. O Instituto Nacional de Diabetes, Endocrinologia e Nutrição da República Dominicana e a clínica Learning to Live recrutaram 23 participantes pediátricos para o estudo. Foram realizados exames de sangue antes e depois do uso do aplicativo por um período de 3 meses. Com base no perfil de usuário, os participantes foram incentivados a usar a calculadora de bolus de insulina do aplicativo após cada refeição. O aplicativo incluía uma lista de alimentos específicos da região e da cultura, codificados por cores para indicar índices glicêmicos (IG) altos em vermelho; IG médios em amarelo; e IG baixos em verde. O código de cores foi criado para ajudar os participantes a fazer escolhas alimentares mais saudáveis.

Resultados. Houve melhoras estatisticamente significantes no perfil lipídico. Os valores médios de lipoproteínas de alta densidade subiram para níveis aceitáveis, e os níveis de lipoproteínas de baixa densidade e de triglicerídeos caíram para os valores recomendados. A qualidade de vida geral aumentou, embora os níveis de hemoglobina glicada não tenham apresentado alterações estatisticamente significantes.

Conclusão. Os resultados deste estudo sugerem que o uso desse aplicativo culturalmente adaptado pode ajudar pacientes jovens com diabetes tipo 1 a melhorar sua saúde metabólica.

Palavras-chave Diabetes mellitus tipo 1; controle glicêmico; insulina; aplicativos móveis.