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# The effect of free diabetes care on metabolic control and on health-related quality of life among youths with type 1 diabetes in Cameroon

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#### ABSTRACT

**Objective** To assess the effect of free diabetes care on metabolic control and on health-related quality of life (HRQoL) of youths living with type 1 diabetes in Cameroon. **Research design and methods** We conducted a clinical audit of a multicenter prospective cohort, performed in three of the nine clinics of the 'Changing Diabetes in Children' (CDiC) project in Cameroon. We collected data on demography, glycemic control, diabetes acute complications, and patients' HRQoL at baseline and after 1 year of follow-up.

**Results** One hundred and four patients (51 female) were included. The mean age was  $16\pm 2$  years (min–max: 9–18), the mean duration of diabetes was  $5\pm 3$  years, and the mean HbA1C level was  $11.4\%\pm 2.7\%$ . A significant reduction in HbA1c ( $11.4\%\pm 2.7\%$  vs  $8.7\pm 2.4\%$ ), episodes of severe hypoglycemia (27/104 vs 15/104), and episodes of ketoacidosis (31/104 vs 7/104) were observed after 1 year (p<0.05). We did not observe any significant difference in the total HRQoL score (p=0.66). However, we observed a significant decrease in diabetes-associated symptoms (p<0.05). Age, level of education, duration of diabetes, glycemic control, and the presence or absence of diabetes complications did not significantly affect the total HRQoL score.

**Conclusions** One year after free diabetes care offered through the CDiC project, a significant improvement was observed in glycemic control and acute complications of diabetes, but not in the total score of HRQoL of youths living with type 1 diabetes enrolled in the project.

#### **INTRODUCTION**

Type 1 diabetes (T1D) is the most common metabolic disorder and one of the most common childhood and adolescent chronic diseases.<sup>1</sup> Its impact is of such magnitude that it affects patients not only physically, but also emotionally, socially, and psychologically.<sup>2 3</sup> Recent advances in the treatment of diabetes have focused on quality-of-life outcomes as much as on complications of diabetes outcome variables, such as retinopathy, nephropathy, and neuropathy.<sup>4</sup> This is

# Significance of this study

What is already known about this subject?

- Many cases of type 1 diabetes (T1D) in Africa remain undiagnosed.
- Access to healthcare is essential for patients with T1D, yet remains a challenge in many parts of this region.

#### What are the new findings?

- One year following the implementation of free diabetes care through the 'Changing Diabetes in Children' project in Cameroon, glycemic control improved significantly and acute diabetes complications also reduced significantly. However, total health-related quality of life (HRQoL) did not show any improvement.
- Parameters such as age, level of education, duration of diabetes, glycemic control, and the presence or absence of acute diabetes complications do not significantly affect the total score of the HRQoL in this study population.

# How might these results change the focus of research or clinical practice?

These findings highlight the benefits of improving access to diabetes care for young people living with T1D. There is a need to develop and test new interventions which, together with the provision of diabetes treatment, could lead to an overall improvement in patients' QoL.

why it has become as important as treatment efficacy and safety in medical prescriptions. Several studies have demonstrated that relative to the general population, diabetes has a strong negative impact on health-related quality of life (HRQoL) in those with the condition, especially in the presence of complications.<sup>5–8</sup> It has also been shown that poor HRQoL in patients with diabetes is associated with adverse outcomes such as increased mortality.<sup>9</sup> It is well established that

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## Epidemiology/Health services research

enhancing OoL and well-being in people with diabetes is as important as metabolic control and prevention of secondary morbidity.<sup>2</sup> In analyzing the health impact of chronic diseases, HRQoL has been commonly used as an outcome indicator because patient cooperation forms the core of health plans for incurable diseases. In Cameroon, similar to many other countries in sub-Saharan Africa, there are limited data concerning diabetes in children.<sup>10</sup> In 2010, the total number of prevalent cases of T1D diabetes in children was about 37500 in the African region, which includes Cameroon and country-specific figures vary from country to country.<sup>11</sup> The condition is therefore not rare in African children,<sup>12 13</sup> and probably an important number of undiagnosed cases exist.<sup>13</sup> Prevalence rates of <1/1000 have been reported in different countries on the continent while an incidence of 1.5/100000 has been documented for Tanzania. In Ethiopia, it is said to account for 9.8% of patients attending diabetes clinic in Addis Abeba.<sup>12</sup>

Several factors may contribute to the high morbidity and mortality in children and adolescents with T1D. This includes lack of insulin and other diabetes supplies, lack of equipment for monitoring treatment, poor understanding of the specificity of diabetes in children among healthcare workers, lack of appropriate protocols, and lack of patient and parent education.

To improve this situation, the 'Changing Diabetes in Children' (CDiC) project was initiated in Cameroon in October 2010. It is an international program that aims to improve diabetes outcomes in people living with T1D through better access to diagnosis, treatment, and monitoring. This program has structured the management system of diabetes in children and adolescents in Cameroon. Nine specialized clinics have been created across the country, and the project has organized diabetes treatment and care training sessions for 664 health personnel. Since the beginning of the project, 570 children and adolescents aged up to 18 years living with T1D in Cameroon have been enrolled in the project. The purpose of the present study was to assess the effect of 1-year exposure to the CDiC project on metabolic control and on the HRQoL of people living with T1D in Cameroon.

## **RESEARCH DESIGN AND METHODS**

#### Study design and participants

This is a clinical audit of a multicenter prospective cohort, performed in three of the nine clinics of the CDiC project in Cameroon, including the Yaoundé Central Hospital, Bamenda Regional Hospital, and Bafoussam Regional Hospital. Those included in the study were children and adolescents ≤18 years (male and female) who were diagnosed to have T1D according to American Diabetes Association criteria<sup>14</sup> and who were involved in the CDiC project for at least 1-year register in the three clinics selected for this study. These clinics were the first to be opened, and therefore had the higher numbers of

eligible participants compared with other centers. Those who were not included in this project were people aged >18 years or children and adolescents without a parent consent. The study participants included a total of 104 children and adolescents (51 female). The age range of the participants was 9–18 years.

### **CDIC PROJECT**

Details of diabetes care provided to patients included in the CDiC project have previously been described.<sup>15</sup> In summary, the CDiC project offers logistics and free diabetes care to children and adolescents living with T1D in Cameroon. This includes free medical consultations, insulin, syringes, a glucose meter (Accu Check Active, Roche Diagnostics, Mannheim, Germany), glucose strips, 3-monthly HbA1c monitoring, 3-monthly group education sessions as well as a yearly screening for diabetes complications. All children enrolled in the project have a systematic medical visit every 3 months. During these visits, they undergo clinical and biological examinations and also have their treatment adjusted by the clinic personnel where necessary. At each visit, the children also receive therapeutic education delivered by a dedicated specialist nurse. All information obtained is recorded in the patient's medical record. Many of the children also visit the clinic outside of scheduled visits to collect treatment supplies or in the event of an emergency, whether related to diabetes or not. HbA1c at the time of this study was assessed using the in2it point-of-care system (Bio-Rad Laboratories, Deeside, UK). As part of the CDiC project, every child is required to complete a quality-of-life questionnaire prior to enrollment into the project and yearly thereafter.

#### **DATA COLLECTION**

Data were collected at two time points: at baseline (at enrollment) and after 1 year of follow-up on the CDiC project. This included data on sociodemographic characteristics, glycemic control, and diabetes acute complications (history of severe hypoglycemia and ketoacidosis during the 3-month period prior to the two data collection points).

Using the Pediatric Quality of Life Inventory 3.0 Type 1 Diabetes Module (PedsQL 3.0 DM) questionnaire, <sup>16</sup> we collected data related to the patients' HRQoL at baseline and a year after they entered the CDiC project.

#### **HRQoL** assessment

The PedsQL 3.0 DM is the only multidimensional diabetes-specific instrument used to assess QoL in subjects aged 2–18. It encompasses five scales: (1) diabetes symptoms (11 items), (2) treatment barriers (4 items), (3) treatment adherence (7 items), (4) worry (3 items), and (5) communication (3 items). The instrument elicits the degree to which each item had been a problem during the previous month. A five-point Likert response scale is used (0=never a problem, 4=almost always a problem). Items are reverse-scored and linearly transformed into a 0–100 scale, so that higher scores indicate better HRQoL. The total score of a scale is calculated as the average of the individual item responses. The PedsQL 3.0 DM showed good internal consistency, reliability, and construct validity.<sup>16</sup>

#### **STATISTICAL ANALYSIS**

Data were analyzed using the Statistical Package for Social Sciences V.18. Results were presented as counts with percentages and means±SD. We compared proportions using the McNemar's test for paired data, means by repeated-measure analysis of variance, paired t-test or independent t-test where appropriate. Factors associated with HRQoL were determined using baseline data. This was done using Pearson's correlation coefficient (r). Cronbach's  $\alpha$  was used to determine the internal consistency reliability of total scores and subscale scores of the PedsQL 3.0 DM questionnaire in our study population. A two-sided p<0.05 was considered statistically significant.

#### Ethics, consent and permissions

Children and adolescents received questionnaires from a diabetes care team member and completed them confidentially, independent of their parents, in a quiet room. Prior to enrollment in the CDiC project, a written informed consent form was signed by parents or guardians authorizing the CDiC project in Cameroon to use the data obtained for research. The CDiC project has also received approval from the National Ethics Committee of Cameroon (authorization no. 271/CNE/ SE/2011) to carry out research using data obtained through the project. This study also received approval from the CDiC project steering committee. Lastly, we obtained a user agreement for the use of the PedQL 3.0 questionnaire.

#### RESULTS

# Baseline general demographic and clinical characteristics of the study population

The baseline general demographic and clinical characteristics of the assessed population are shown in table 1.

In total, 104 patients with T1D, 52 from Yaoundé Central Hospital, 26 from Bamenda Regional Hospital, and 26 from Bafoussam Regional Hospital were included. Forty-nine per cent were female. The mean age was  $16\pm 2$  years (min–max: 9–18), 11 were aged 9–13 years, and 93 were aged 14–18 years. The mean body mass index (BMI) was  $21.3\pm 3.9$  kg/m<sup>2</sup>. The mean duration of diabetes was  $5\pm 3$  years, and the mean HbA1c was  $101.1\pm 22.1$  mmol/mol ( $11.4\%\pm 2.7\%$ ). Of the 104 patients, 27 had at least one severe hypoglycemia and 31 had had at least one episode of ketoacidosis in the 3-month period preceding their inclusion in the CDiC project (table 1).

Table 1Baseline general demographic and clinical data ofpeople with type 1 diabetes in the study population

Demographic characteristics	ТО
Participants, n	104
CDiC Yaoundé, n (%)	52 (50)
CDiC Bamenda, n (%)	26 (25)
CDiC Bafoussam, n (%)	26 (25)
Women, n (%)	51 (49)
Age, years, n (%)	16±2
9–13	11 (10.6)
14–18	93 (89.4)
Level of education	
Elementary	18
High school	48
Post high school	38
Clinical characteristics	
BMI, kg/m <sup>2</sup>	21.3±3.9
Duration of diabetes, years	5±3
HbA1c, mmol/mol (%)	101.1±22.1 (11.4±2.7)
HbA1c by sex, mmol/mol (%)	
Male	101.1±21.3 (11.4±2.6)
Female	101.1±22.1 (11.4±2.7)
HbA1c by study site, mmol/mol (%)	
CDiC Yaoundé	95.6±20.5 (10.9±2.5)
CDiC Bamenda	106.6±22.1 (11.9±2.7)
CDiC Bafoussam	104.4±25.4 (11.7±3.1)
Diabetes acute complications	
History of severe hypoglycemia during the three last months, n/N	27/104
History of ketoacidosis during the three last months, n/N	31/104

Data are mean ± SD, frequency (percentage).

BMI, body mass index; CDiC, Changing Diabetes in Children; T0, at the inception of the CDiC project.

## Glycemic control and diabetes complications before and after 1 year of follow-up on the CDiC project

Overall, we observed a significant improvement in glycemic control of patients a year after enrollment  $(101.1\pm22.1 \text{ mmol/mol} (11.4\%\pm2.7\%)$  at baseline vs  $71.6\pm19.7 \text{ mmol/mol} (8.7\%\pm2.4\%)$  after 1 year, p=0.000). Specifically, this improvement in glycemic control was observed for patients living in Yaoundé ( $95.6\pm20.5 \text{ mmol/mol} (10.9\%\pm2.5\%)$  at baseline vs  $70.5\pm18.9 \text{ mmol/mol} (8.6\%\pm2.3\%)$  after 1 year, p=0.000) and Bafoussam ( $108.7\pm22.1 \text{ mmol/mol} (12.1\%\pm2.7\%)$  at baseline vs  $73.8\pm22.1 \text{ mmol/mol} (8.9\%\pm2.7\%)$  after 1 year, p=0.004), but not for those living in Bamenda ( $101.1\pm23.8 \text{ mmol/mol} (9.3\%\pm2.2\%)$  after 1 year, p=0.21). Regardless of sex and level of education, we observed a significant reduction in

Table 2Glycemic control and diabetes complications of<br/>children and adolescents in the study population before<br/>and after 1 year in the Changing Diabetes in Children (CDiC)<br/>project

Variables	то	T1 year	p Value
HbA1c mmol/mol (%)	101.1±22.1 (11.4±2.7)	71.6±19.7 (8.7±2.4)	0.000
HbA1c by sex, mmol/mol	(%)		
Male	98.9±20.5 (11.2±2.5)	69.4±18.9 (8.5±2.3)	0.000
Female	98.9±21.3 (11.2±2.6)	76.0±19.7 (9.1±2.4)	0.001
HbA1c by study site, mm	ol/mol (%)		
CDiC Yaoundé, n	95.6±20.5 (10.9±2.5)	70.5±18.9 (8.6±2.3)	0.000
CDiC Bamenda, n	101.1±23.8 (11.4±2.9)	78.1±18.0 (9.3±2.2)	0.21
CDiC Bafoussam, n	108.7±22.1 (12.1±2.7)	73.8±22.1 (8.9±2.7)	0.004
HbA1c by level of educati	on, mmol/mo	ol (%)	
Elementary	103.3±23.8 (11.6±2.9)	71.6±18.0 (8.7±2.2)	0.015
High school	11.5±20.5 (11.5±2.5)	71.6±18.9 (8.7±2.3)	0.000
Post high school	94.5±23.8 (10.8±2.9)	72.7±23.0 (8.8±2.8)	0.001
Diabetes acute complicat	ions		
History of severe hypoglycemia during the three last months, n/N	27/104	15/104	0.01
History of ketoacidosis during the three last months, n/N	31/104	7/104	<0.0001

Data are mean ± SD.

T0, at the inception of the CDiC project; T1 year, 1 year after involvement in the CDiC project.

patients' glycated hemoglobin (HbA1c) levels 1 year after entry into the project (table 2).

With regards to the number of episodes of hypoglycemia and ketoacidosis in the 3-month period prior to the two data collection points, we observed a significant reduction after 1 year for both measurements ((27/104)at baseline vs (15/104) after 1 year for hypoglycemia, p=0.01) and ((31/104) at baseline vs (7/104) after 1 year for ketoacidosis, p<0.0001) (table 2).

# Patients' HRQoL scores at enrollment and after 1 year of follow-up

The description of the PedsQL 3.0 DM results from the sample of children and adolescents before and after enrollment into the project is presented in table 3.

The internal consistency coefficient ( $\alpha$ ) was 0.75, reflecting the reliability of the PedsQL 3.0DM questionnaire in the study population (table 3).

Table 3 Cronbach's α coefficients and item scores of the Pediatric Quality of Life Inventory 3.0 Type 1 Diabetes Module (PedsQL 3.0 DM) questionnaire of children and adolescents in our study population before and after 1 year in the Changing Diabetes in Children (CDiC) project	coefficie v populat	nts and item ion before ar	scores of the F	Pediatric Q in the Char	uality of Life Iging Diabet	Inventory 3. tes in Childre	0 Type 1 I n (CDiC) p	Diabetes Mo project	odule (PedsC	2L 3.0 DM	) questionna	uire of childre	ו and
	All st	All study population (n=104)	ion (n=104)		CDIC Yaou	CDiC Yaoundé (n=52)		<b>CDIC Bafc</b>	CDiC Bafoussam (n=26)	<b>(9</b> )	CDIC Bam	CDiC Bamenda (n=26)	
PedsQL 3.0DM	α	ΤO	T1 year	p Value T0		T1 year	p Value T0	TO	T1 year p Value T0	p Value	TO	T1 year	p Value
Diabetes symptoms	0.71	0.71 62.2±14.5 59.1±15.5	59.1±15.5	0.02	62.3±16.3	62.3±16.3 57.7±16.1 0.02	0.02	<b>63.4</b> ±11.8	63.4±11.8 55.3±15.9 0.08	0.08	60.9±13.6	60.9±13.6 65.3±11.8 0.09	0.09
Treatment barriers	0.57	0.57 60.2±23.2 64.2±22.2	64.2±22.2	0.05	56.9±23.5	56.9±23.5 60.2±21.8 0.30	0.30	53.6±21.8	53.6±21.8 61.5±19.9 0.61	0.61	73.3±19.2	73.3±19.2 75.0±22.6 0.64	0.64
Treatment adherence	0.65	0.65 70.3±19.5 68.2±19.8	68.2±19.8	0.25	69.1±19.9	69.1±19.9 65.4±20.9 0.18	0.18	64.9±21.7	64.9±21.7 64.9±19.4 0.98	0.98	78.2±13.7	78.2±13.7 77.0±15.3 0.77	0.77
Worries	0.41	45.5±23.3	45.5±23.3 45.1±23.3	0.85	46.2±24.2	46.2±24.2 46.6±21.8 0.87	0.87	40.7±21.8	40.7±21.8 42.9±25.0 0.55	0.55	49.1±23.3	49.1±23.3 44.2±25.1	0.35
Communication	0.54	0.54 71.6±24.8 70.8±28.4	70.8±28.4	0.77	71.2±23.9	71.2±23.9 71.2±28.2 0.98	0.98	67.9±28.3	67.9±28.3 67.6±26.6 0.95	0.95	76.3±22.8	76.3±22.8 73.0±31.4 0.58	0.58
Total diabetes score	0.75	0.75 61.9±15.5 61.5±15.4	61.5±15.4	0.66	61.1±14.3	61.1±14.3 60.2±16.8 0.60	0.60	58.1±12.3	58.1±12.3 58.5±14.0 0.85	0.85	67.6±11.4	67.6±11.4 66.9±12.7 0.81	0.81
Data are mean ± SD.													

We did not observe any significant difference in the items score and total score of the patients' HRQoL before and after spending 1 year on the project (total score of HRQoL before:  $61.9\pm15.5$  vs  $61.5\pm15.41$  year later, p=0.66). However, we observed a significant decrease in the score of diabetes-associated symptoms ( $62.2\pm14.5$  at baseline vs  $59.1\pm15.51$  year after, p=0.02) (table 3).

Subjects from the Bafoussam and Bamenda clinics did not report any significant improvement in their HRQoL (item and total score) 1 year after follow-up compared with baseline (all p>0.05).

However, the group of children and adolescents from the Yaoundé clinic reported a significant decrease in the items corresponding to their diabetes-related symptoms ( $62.3\pm16.3$  at enrollment vs 57.7±16.1 after 1year, p=0.02), but not for the total HRQoL score (table 3).

#### Factors associated with HRQoL

We evaluated the variables that could influence the HRQoL of people with T1D. No significant association was observed between the total HRQoL score and parameters such as age (r=0.004, p=0.05), duration of diabetes (r=0.038, p=0.06), glycemic control (r=0.03, p=0.6), level of education (p=0.92), and the presence or absence of severe hypoglycemia (p=0.09) and ketoacidosis (p=0.16).

#### **CONCLUSIONS**

The purpose of the present study was to assess the effect of free diabetes care on the clinical characteristics as well as on the HRQoL of children and adolescents living with T1D in Cameroon. This study showed that 1 year following the implementation of free diabetes care through the CDiC project, glycemic control improved significantly and acute diabetes complications also reduced significantly. However, total HRQoL did not show any improvement.

Many factors could potentially explain the improvement in glycemic control observed in this study. First, it is likely that the free diabetes care and self-monitoring of blood glucose played a significant role. This is supported by the findings of Dehayem *et al*,<sup>17</sup> who showed that providing free insulin and introducing blood glucose self-monitoring led to a significant reduction in HbA1c levels in children and adolescents included in the CDiC project in Cameroon. Second, the education of patients during the diabetes camps may have had a positive impact on glycemic control as well. Several studies have shown that diabetes camps have a beneficial effect on knowledge and self-management of the disease<sup>18 19</sup>

Under the CDiC project in Cameroon, patients with T1D participate in diabetes camps twice a year. In a previous study, we found that camp attendance by young patients living with T1D in Cameroon had a positive and lasting metabolic impact on their glycemic control after 12 months.<sup>15</sup> Patients' knowledge and self-management of diabetes may improve after camp. Several others studies have also shown an improvement in glycemic control including a significant reduction in HbA1c after

camp participation.<sup>20 21</sup> The improvement in glycemic control was observed for patients living in Yaoundé and Bafoussam, but not for those living in Bamenda. This difference could be explained by the limited sample size as well as possible variations in the quality of diabetes care in the different sites.

We observed a decrease in severe hypoglycemia in patients with T1D after 1 year of participation in the CDiC project. This is consistent with the improvement noted in similar studies elsewhere.<sup>15 22 23</sup> Even though we focused on acute complications, these results seem to corroborate findings from the Diabetes Control and Complications Trial (DCCT), which showed that improving metabolic control in adolescents is associated with fewer long-term complications of diabetes.

Participants' total HRQoL score did not change significantly after 1 year of follow-up on the CDiC project. In fact, for people with T1D, some studies, including those conducted as part of the DCCT, indicate that treatment intensification has no effect on QoL.<sup>24</sup> Other findings suggest that intensification may enhance QoL by reducing the immediate and chronic effects of hyperglycemia. Still other studies suggest that the relationship between treatment intensity and QoL may be curvilinear for people who have T1D since very intensive regimens may reduce QoL through highly demanding self-care regimens and increased incidence of hypoglycemia.<sup>25 26</sup>

There is no evidence that a longer follow-up period of our participants could have affected their HRQoL score differently. For instance, a prospective study that aimed to assess the impact on the QoL over 5 years in a cohort of 117 diabetic patients showed that despite the damage on metabolic control, the QoL did not change over time.<sup>27</sup> The reasons for the improvement of HbA1c and absence of HRQoL remain open for discussion. Organization of care, stricter guidelines, more education, length of follow-up, a more active role of children and adolescents themselves, and the socioeconomic level of their parents may be involved. No definite conclusions can be drawn at this time to explain this finding.

In the sample considered in this study, HRQoL showed no significant association with age, level of education, duration of diabetes, glycemic control, and the presence of diabetic complications. This finding is in accordance with results from other groups as reported by Wagner *et* al,<sup>2</sup> Laffel *et al*,<sup>28</sup> and Emmanouilidou *et al*.<sup>29</sup> It is however in contrast with those found by Graue *et al*<sup>30</sup> and by Faulkner.<sup>31</sup> According to Grey *et al*, despite achieving desired HbA1c levels and glycemic control, the presence of diabetes-related depression could significantly prevent an improvement in QoL especially in teenage girls.<sup>32</sup>

This study has two main limitations. First, there are no qualitative data to explain why improved metabolic control as observed in this sample was not associated with better HRQoL. It is however possible that this could be explained by the small sample size alone. Also, the PedsQL questionnaire has not previously been validated in Cameroon. However, it has been validated in a Nigerian pediatric

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population,<sup>33</sup> which is comparable to the population considered in this study. Besides, Cronbach's  $\alpha$  was used to determine the internal consistency reliability of total scores and subscale scores of the instruments. The internal consistency coefficient ( $\alpha$ ) was 0.75, reflecting the reliability of the PedsQL 3.0DM questionnaire in the study population. The current study is one of the first investigations in which a cohort of children and adolescents from sub-Saharan Africa was followed up and assessed for their QoL. It provided the opportunity to describe clinical and psychosocial outcomes of a group of adolescents who were successfully managed and monitored on the CDiC project.

This study showed that, 1 year after free diabetes care was initiated in youths with T1D in Cameroon through the CDiC project, a significant improvement was observed in glycemic control and acute complications of diabetes, but not in the total score of HRQoL. Parameters such as age, level of education, duration of diabetes, glycemic control, and the presence or absence of diabetes acute complications do not significantly affect the total score of the HRQoL in this study population. These findings highlight the benefits of improving access to diabetes care for young people living with T1D. There is a need to develop and test new interventions, which, together with the provision of diabetes treatment, could lead to an overall improvement in patients' QoL.

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**Contributors** ELY, CMT and MYD: study conception and design; data collection, drafting, analysis and interpretation; reviewing and editing. RT: data collection, analysis and interpretation. MJE and JS: drafting, reviewing and editing. ES: study conception and design; reviewing and editing. JCM: study conception and design; reviewing and editing. All authors approved the final version for publication. ELY, CMT, MYD, ES and JCM are the guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Competing interests None declared.

Patient consent Parental/guardian consent obtained.

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