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Investigation of the therapeutic education effect on glycemic control and quality of life of children and adolescents with type-1 diabetes mellitus: A non-randomized controlled study

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Abstract:

BACKGROUND: Type-1 diabetes mellitus (T1DM) is one of the most dreaded chronic diseases, especially in children or youth. To help patients and their families effectively manage their disease, structured therapeutic patient education (TPE) is essential.

MATERIALS AND METHOD: The purpose of this non-randomized before and after controlled study was to assess TPE program effects. In total, 200 T1DM children and adolescents, aged 8–18 years, selected from two pediatric departments, were equally assigned to the intervention and control groups. The primary endpoints were differences between groups at 3 months follow-up in measured HbA1c and health-related quality of life (QoL) assessed by a validated questionnaire.

RESULTS: At 3 months follow-up of a TPE intervention for T1DM children and adolescents, although there was no significant change in HbA1c for both groups, a significant improvement was observed in the maximum pre- and postprandial blood glucose levels (r: ~0.3; variation rates: -10,47% and -3,85%, respectively) in the intervention group, whereas there was a significant increase in the maximum and minimum of preprandial blood glucose levels in the control group (r: ~0.3, variation rates: 14.29% and 25%, respectively). Global and dimensional QoL mean scores variation rates showed a significant difference between groups, with an improvement in the intervention group ($r \geq 0.7$, Cohen's > 0.8) and a decrease in the control group ($r \geq 0.7$).

CONCLUSION: These results support the hypotheses of difference between the study groups in favor of better glycemic control and QoL for the intervention group.

Keywords:

Children and adolescents, glycemic markers, quality of life, therapeutic patient education, type 1 diabetes mellitus

Introduction

Type-1 diabetes mellitus (T1DM) is one of the most dreaded chronic diseases in terms of morbidity (over 1.2 million children and adolescents aged 0–19 years worldwide and approximately 43.3 thousand in Morocco in 2021) and mortality (a significant excess in the first years after diagnosis).[1-3] Mainly observed in children or young adults, T1DM is often a complex disease and is challenging and time-consuming, which

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burdens both patients and their families as it requires daily involvement and self-management; otherwise, it leads to serious metabolic complications of diabetes in the short and long term, such as ketoacidosis and hypoglycemia.[1,2,4-6]

Indeed, T1DM, a disease so far incurable, presents itself as a complex and continuous struggle, as well as a great challenge both for children who face the disease and for their parents. The complex management of treatments (e.g., frequent and daily control of blood glucose, control and regulation of carbohydrate intake, administration of insulin, adaptation of insulin doses to dietary habits and physical activity, urine tests if necessary,…)) often leads to physical and psychological complications in family members.[7] These issues resulting from the management of the disease are often linked to a poor quality of life (QoL) for people with T1DM.[8] As such, health professionals have a crucial role in therapeutic education to allow optimal diabetes self-management by the pediatric patient and his environment.[9]

Good management of T1DM requires, since diagnosis, therapeutic patient education (TPE) of the child and his family by a team of specialists as an essential part of the care process.[5] TPE, for a long time confused with simple information and instructions formulated during hospitalization or medical consultations, is an educational approach whose beneficial effects on salient outcome measures (e.g., glycemic control; less behavioral, emotional, and social problems; fewer hospital admissions for related complications; and better QoL and wellbeing) have been reported in many studies.[10-19] Indeed, TPE is a structured and targeted approach, focused on skills related to diabetes self-care and to psychological patient components as well.[13,20]

Similarly, several diabetes education programs for children and adolescents with T1DM, where educational interventions were compared to usual management for several chronic diseases including T1DM, have reported improved glycemic control and better QoL.[21-26]

To achieve the expected results and develop the necessary skills, educational interventions must be based on clear theoretical psycho-educational principles and be designed as a continuous process of supporting patients and their families in the individualized management of their disease.[17,27]

One of the relevant models used in TPE in chronic diseases is a 4-phase model: 1) diagnosis of patient educational needs, 2) definition and prioritization of disease management skills to plan an individual program, 3) educational program implementation in an appropriate way with the right educational methods, and 4) program's process and outcomes assessment.[28-31]

However, in the Moroccan context, educational interventions remain most often defined only by their thematic content, limited to patient information and not following a structured educational approach. Thus, this study aimed to design and implement a structured TPE program for children and adolescents with T1DM to assess its effects on glycemic markers and health-related QoL (HRQoL) in comparison with T1DM children and adolescents who did not benefit from any educational intervention.

Materials and Methods

Study design and setting

It is a non-randomized before and after controlled study, conducted from January to December 2022, to assess the effect of a structured education intervention for children and adolescents with T1DM on their glycemic markers and QOL as compared with a control group not receiving a structured TPE program [Figure 1]. Measurements were obtained before intervention (baseline T0) and at 3 months follow-up after (follow-up T1) for both intervention and control groups. The primary endpoints were the differences in glycated hemoglobin (HbA1c) and HRQoL scores between the groups at 3 months.

Study participants and sampling

During their consultation at the pediatric departments of the Prefectural Hospital Centers, the recruitment of children and adolescents with T1DM was made based on eligibility criteria, from January to September 2022. The inclusion criteria were as follows: all patients with T1DM for more than 6 months, aged 8–18 years, providing written informed consent, and able to understand and speak Arabic language. The exclusion criteria were as follows: type-2 diabetics, aged less than 8 years, with comorbidity and significant inability verbal communication. As there was not any exhaustive primary list of T1DM children and adolescents in the pediatric departments, 200 patients were included, without randomization, by using a convenience sampling non-probabilistic method. They accepted to participate in the study and were equally assigned, at baseline, to intervention (N1 = 100) and control groups (N2 = 100). The intervention and control groups were selected separately in the pediatric departments of two hospitals.

Using the GPower tool, the minimal sample size was calculated as 95 in each group, based on data from a pilot study (HbAc1 group 1 = 10.12% ± 1.55 and group 2 = 9.39% ± 1.19), with effect size d = 0.5283, alpha error <0.05, and statistical power = 95%.[32] At the endline, 3 months after the TPE program, one patient withdrew

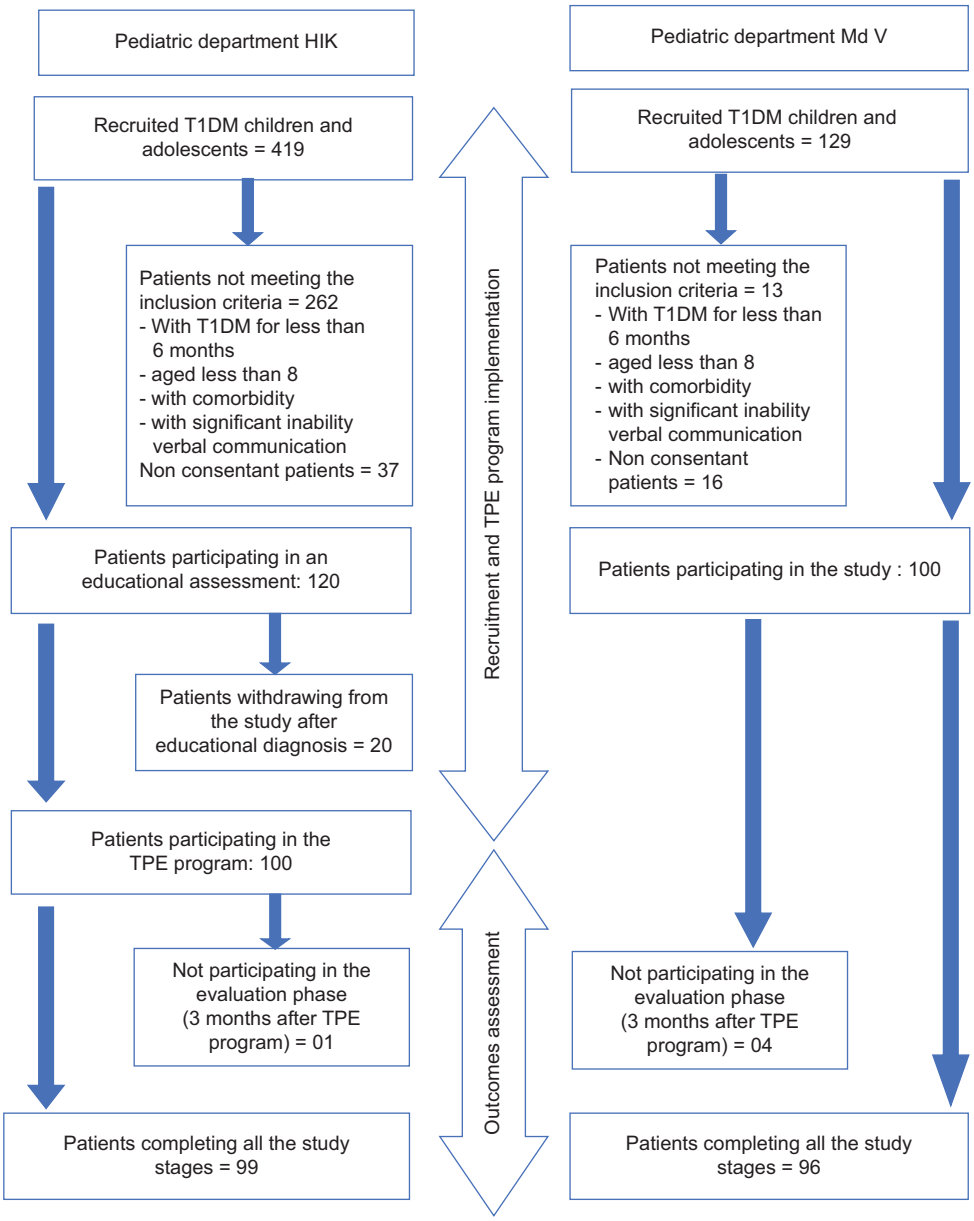

Figure 1: Study protocol diagram

from the intervention group and four patients from the control group.

Intervention

An original and structured TPE program was developed for 100 patients included in the intervention group, in accordance with the 4-step model of D'Ivernois and Gagnayre (2008), as there is no structured one for T1DM children and adolescents in Morocco.

In the first and second stages of this model, an educational assessment of patients' needs and expectations was used to plan a personalized educational program.[29,33] This program defines the needed skills that best meet these participants' needs and concerns and which revolve around two main categories namely self-care and adaptation.[33,34] To develop these skills, pedagogical and specific objectives were formulated, as well as the education methods needed to achieve them, which made it possible to define a reference framework of skills.[33,35]

100 T1DM children and adolescents, as well as their parents and carers, were invited to participate in the intervention. The TPE program consisted of three weekly group sessions of 90 minutes each, with the participation of 2–11 patients per group. In collaboration with a pediatric dietician nurse and a nurse educator trained in TPE, one of the authors of this article mainly conducted the three group sessions at a nursing center located in the same hospital. Active and adapted education methods were used to promote learning among these young participants.

In the first session, the focus was on the pathophysiology of T1DM and on how to perform self-monitoring measures and insulin therapy. The educational methods used for this purpose are mainly brainstorming, PowerPoint presentations with drawings and pictures, and simulation. Session 2 objective was to teach participants, by the same teaching methods and using role-plays, how to detect and treat short-term complications (hypoglycemia and diabetic ketoacidosis) and to prevent or identify earlier the long-term ones. In the third and last session, in addition to the abovementioned education methods, group discussions were used to develop skills related to diet and positive attitude toward T1DM and associated emotional troubles and concerns.

In this study, the educational intervention was inspired by a theory often used in pediatric diabetes: Bandura's social cognitive theory. This theory is based on the concept of the self-efficacy feeling, whose sources are active experience, vicarious experience based on the observation of various models such as peers, verbal persuasion and positive behaviors, and emotional states leading to the successful execution of the desired behavior. With this self-efficacy feeling, individuals believe in their own abilities to adopt the right behaviors and achieve particular performances.[36,37]

Data collection tool and technique

Sociodemographic data were collected at baseline for patients from both intervention (N = 100) and control groups (N = 100). Assessment of the primary outcomes, glycemic markers and HRQoL, was performed at baseline and 3 months following the TPE intervention. Measurements of HbA1c were taken, and minimum and maximum pre- and postprandial blood glucose values were noted from the patients' logbooks for the last 2 weeks before the measurement.

To assess participants' HRQoL, the Pediatric Quality of Life Inventory PedsQL 3.0 was used (User License Agreement was obtained from Mapi Research Trust "MRT"). It is a validated specific HRQoL module questionnaire developed for T1DM, with good internal consistency, reliability, and validity (Cronbach's alpha of the child self-report and parent proxy report was greater than 0.70).[38] It is a 5-scale questionnaire with 28 items: 1) diabetes symptoms (11 items), 2) treatment I barriers (4 items), 3) treatment II adherence (7 items), 4) worry (3 items), and 5) communication (3 items). Each participant was asked how much of a problem each item had been during the past 1 month. A 5-point Likert response scale was used (0 = never a problem, 4 = almost always a problem). Then, items were reverse-scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, and 4 = 0), which were then combined to produce a total diabetes score. Scale scores were computed as the sum of the items divided by the number of items answered; higher scores indicate better HRQoL.[38]

Data related to participants' sociodemographic characteristics, glycemic markers, and QoL were processed and analyzed using the Statistical Package for Social Sciences IBM SPSS Statistics version 25.

Kolmogorov–Smirnov test (n > 50) was performed to assess the variables distribution normality of both groups. Parametric data are expressed as means ± standard deviation (95% confidence interval (CI)), whereas non-parametric variables are expressed as median and interquartile range (25^{th}–75^{th}).

To assess changes in variables within the same group from baseline to 3 months after TPE intervention, paired-samples Student's *t*-test was applied for the normally distributed variables, and the related-samples Wilcoxon signed-ranks test was applied for those not normally distributed. Differences in glycemic and HRQOL outcomes between groups at baseline t0 and at 3 months follow-up after t1 were estimated using U Mann–Whitney test and variation rate test. Statistical significance level was set at a two-tailed $P < 0.05$ for all tests.

Ethical consideration

In accordance with ethical requirements, a study agreement was obtained from the Hospital-University Ethics Committee of the University Sidi Mohamed Ben Abdellah Fez, based on a study protocol (Protocol code: 14/22, approval date: January 2022). Participant recruitment was carried out after receiving oral and written information about the study. In addition, formal written consent was obtained from participants' parents and carers as they are minors. Researchers ensured that internationally accepted ethical principles for research involving human subjects were adhered to throughout this research, and all methods were applied in accordance with relevant guidelines and regulations.

Results

To assess the effect of a structured TPE program on glycemic markers and QoL, 200 T1DM children and adolescents participated in a non-randomized before and after controlled study from January to December 2022. Patients were equally assigned, at baseline, to intervention (N1 = 100) and control (N2 = 100) groups. All participants follow an insulin therapy regimen with two daily injections.

At baseline, the two groups' sociodemographic characteristics [Table 1] showed homogeneity between

the groups in terms of age and gender. On the contrary, there was a slight difference between the two groups in terms of T1DM duration, study level, and the area they live. Physical activity was more regular in the control group than in the intervention group.

The response rates for intervention and control groups at 3 months follow-up were 99% (*N1* = 99) and 96% (*N2* = 96), respectively. Measurements (glycemic markers and HRQoL) were taken for both groups at baseline (T0) and 3 months later (T1).

Glycemic markers

Within the intervention group [Table 2], the HbA1c mean value slightly improved (0.34 point less) from baseline to 3 months after TPE intervention, though with a small effect and not significantly ($P = 0.160$). In contrast, the maximum values of preprandial and postprandial blood glucose levels significantly decreased 3 months after the intervention: 0.26 (r = −0.33; $P < 0.001$) and 0.45 (r = −0.11; $P < 0.001$) points less than that at baseline, respectively. However, there was no significant change in their minimum.

In the control group [Table 2], at the endline (3 months after TPE intervention), there was no statistically significant change in the HbA1c median value ($P = 0.323$), with a small effect. It was the same for the maximum and minimum median values of postprandial blood glucose levels. Moreover, the maximum and minimum median values of preprandial blood glucose levels significantly increased between T0 and T1 (2.5 (2.0–3.0) vs. 3.0 (2.5–3.85); $P < 0.0001$ and 0.8 (0.6–1.15) vs. 0.95 (0.6–2.0); $P < 0.0001$, respectively).

Before the intervention [Table 2], using the Mann–Whitney U test, there was a significant difference between intervention and control groups in terms of values related to HbA1c, maximum and minimum postprandial blood glucose levels, and minimum preprandial blood glucose level. However, the difference in maximum preprandial blood glucose levels between the groups was not significant.

At the endline [Table 2], using the same non-parametric statistical test (Mann–Whitney U test), although there was no statistically significant difference between intervention and control groups in minimum preprandial blood glucose level ($P = 0.729$), there was a difference between groups in HbA1c, maximum and minimum postprandial blood glucose levels, and maximum preprandial blood glucose level, and it was significant.

Furthermore, for deeper analysis, glycemic markers variation rates were compared between the intervention and control groups 3 months after the intervention [Table 2]. These variation rates showed a significant difference ($P < 0.0001$) between the intervention group and the control group in terms of maximum and minimum preprandial blood glucose levels, which were clearly reduced in the intervention group (r: ~0.3, variation rates -10,47%; -3,85% respectively) in the intervention group, whereas they increased significantly in the control group (r: ~0.3, variation rates: 14.29% and 25%, respectively).

Nevertheless, these variation rates showed that HbA1c recorded no change in the two groups and that there was no significant difference between the intervention and control groups ($P = 0.650$). Regarding the variation rate of postprandial blood glucose level, although its maximum values decreased in the intervention group, this was without significant difference with the control group ($P = 0.092$).

Table 1: Participants' baseline sociodemographic characteristics (*n*=200)

	Intervention (*n*1=100)		Control (*n*2=100)	
	Percentage	Mean (±SD)	Percentage	Mean (±SD)
Age (years)		11.90 (±2.4)		11.72 (±2.41)
Years with T1DM		4.16 (±3.12)		5.42 (±3.39)
Sex				
Male	50.0		51.0	
Female	50.0		49.0	
Urban/Rural area				
Urban area	92.0		88.0	
Rural area	8.0		12.0	
Study level				
Primary school	62.0		61.0	
Secondary school	37.0		39.0	
Not educated	1.0		0	
Physical activity				
Yes	44.0		85	
No	56.0		15	

Categorical variables are expressed in percent (%) and continuous variables in mean (standard deviation)

Table 2: Participants' glycemic markers (*n*=200) compared within and between the intervention group (*n*1=100) and the control group (*n*2=100) at baseline T0 and 3 months following the TPE intervention T1

Glycemic markers	Intervention group (*n*=100)				Control group (*n*=100)				Difference between groups	
	T0	T1	Effect size	Variation rate*	T0	T1	Effect size	Variation rate*	P T0	P T1
HbA1c	10.6239±2.56	10.2840±2.47	0.14[a]	0.00 (−13.93; 9.01)	9.0 (8.4–10.65)	9.0 (8.5–10.0)	−0.10[b]	0.00 (−10.68; 8.74)	0.002[c]	0.016[c]
Preprandial maximum blood glucose	2.37 (1.81–3.21)	2.11 (1.51–2.58)	−0.33[b]	−10.47 (−33.00; 12.29)	2.5 (2.0–3.0)	3.0 (2.5–3.85)	−0.38[b]	14.29 (−9.42; 43.75)	0.356[c]	0.000[c]
Preprandial minimum blood glucose	1.01 (0.78–1.31)	0.93 (0.75–1.31)	−0.11[b]	−3.85 (−31.20; 29.05)	0.8 (0.6–1.15)	0.95 (0.6–2.0)	−0.46[b]	25.00 (−11.01; 73.90)	0.002[c]	0.729[c]
Postprandial maximum blood glucose	2.95 (2.07–3.99)	2.50 (1.90–3.27)	−0.32[b]	−7.39 (−31.72; 10.49)	4.0 (3.57–5.0)	4.0 (3.12–4.5)	−0.20[b]	0.00 (−19.29; 9.20)	0.000[c]	0.000[c]
Postprandial minimum blood glucose	1.13 (0.85–1.54)	1.19 (0.90–1.54)	−0.04[b]	5.88 (−23.15; 37.56)	2.0 (2.0–3.0)	2.0 (1.7–3.0)	−0.11[b]	0.00 (−19.29; 17.40)	0.000[c]	0.000[c]

Data are expressed as means±standard deviation for the normally distributed variables or as median and interquartile range (25^{th}–75^{th}) for the non-normally distributed. [a]Effect size Cohen's d. [b]Effect size Wilcoxon signed rank "*r*". [c]The Mann–Whitney *U* test for independent groups. *Variation rate (%)=((VT1–VT0)/VT0) × 100. A negative variation rate indicates a decrease in the parameter value and a positive variation rate indicates an increase in the parameter value

Health-related QOL

The PedsQL 3.0 questionnaire was used to measure HRQOL.

In the intervention group [Table 3], at 3 months of TPE intervention (T1), both global and dimensional QoL mean scores showed a significant improvement as compared to baseline measurements T0 ($r \geq 0.7$, Cohen's > 0.8; $P = 0.000$). Indeed, participants seemed to have fewer disease-related problems as they had a better overall mean QoL score (63.41 (±7.79) vs. 52.96 (±8.78)). Same for the mean diabetes QoL score, which improved from 50.00 (45.45–54.54) to (56.82 (52.27–61.36), showing less pronounced symptoms. Similarly, there was a significant improvement in mean treatment I and II QoL scores (62.50 (62.50–68.75) vs. 56.25 (43.75–62.50) and 50.00 (46.43–53.57) vs. 42.86 (35.71–50.00), respectively), indicating fewer treatment barriers or adherence issues for participants at T1. Similarly, fewer illness-related worries and communication problems were observed for participants as the mean scores of their worry QoL and communication QoL dimensions increased respectively from 41.67 (33.33–50.00) to 50.00 (50.00–58.33) and from 33.33 (25.00–50.00) to 50.00 (50.00–58.33) from baseline to 3 months after TPE intervention.

Within the control group [Table 3], both global and dimensional QoL mean scores significantly decreased ($r \geq 0.7$; $P < 0.0001$) at T1 3 months after the intervention. Thus, these results show more pronounced symptoms, more treatment barriers or adherence issues, and more illness-related worries and communication problems for participants at T1 as compared to baseline T0.

To compare differences between the two independent groups (intervention and control groups) regarding HRQoL at baseline T0 and 3 months after the intervention T1, the Mann–Whitney U test was performed [Table 3]. At baseline, before the intervention, all values related to both global and dimensional QoL showed a significant difference between the intervention and control groups ($P < 0.0001$). The same results were observed at the endline in terms of overall mean QoL score and mean scores of diabetes QoL, treatment I QoL, and worry QoL (a significant difference between groups, $P < 0.0001$). Nevertheless, there was no statistically significant difference between the groups regarding treatment II QoL and communication QoL dimensions, indicating the same treatment adherence issues and communication problems for participants in both groups after intervention ($P = 0.266$ and $P = 0.493$, respectively).

In addition, for more in-depth comparative analysis between groups, the mean overall and dimensional QoL scores variation rates were compared between the

Table 3: Participants' HRQoL (*n*=200) compared within and between the intervention group (*n*1=100) and the control group (*n*2=100) at baseline T0 and 3 months following the TPE intervention T1

HRQOL	Intervention group (*n*1=100)			
	T0	T1	Effect size	Variation rate *
QOL global mean score	52.96 (±8.78)	63.41 (±7.79)	−1.65[a]	18.75 (11.33; 26.60)
QOL Diabetes symptoms mean score	50.00 (45.45–54.54)	56.82 (52.27–61.36)	−0.77[b]	9.52 (3.89; 23.20)
QOL treatment I barriers mean score	56.25 (43.75–62.50)	62.50 (62.50–68.75)	−0.72[b]	11.11 (0.00; 28.57)
QOL treatment II adherence mean score	42.86 (35.71–50.00)	50.00 (46.43–53.57)	−0.81[b]	18.18 (7.69; 30.58)
QOL worry mean score	41.67 (33.33–50.00)	50.00 (50.00–58.33)	−0.73[b]	20.00 (0.00; 50.00)
QOL communication mean score	33.33 (25.00–50.00)	50.00 (50.00–58.33)	−0.75[b]	20.00 (0.00; 75.00)

HRQOL	Control group (*n*2=100)				Difference between groups	
	T0	T1	Effect size	Variation rate*	*P* T0	*P* T1
QOL global mean score	65.18 (58.26–72.99)	50.0 (47.32–55.36)	−0.76[b]	−18.44 (−29.34; −6.13)	0.000[c]	0.000[c]
QOL Diabetes symptoms mean score	43.18 (56.56–52.27)	61.36 (56.82–65.91)	−0.78[b]	38.61 (14.28; 71.35)	0.000[c]	0.000[c]
QOL treatment I barriers mean score	87.5 (75.0–100)	37.5 (31.25–43.75)	−0.84[b]	−56.25 (−64.28; −41.96)	0.000[c]	0.000[c]
QOL treatment II adherence mean score	83.93 (68.75–89.29)	50.00 (46.43–53.57)	−0.86[b]	−36.36 (−45.63; −21.05)	0.000[c]	0.266[c]
QOL worry mean score	58.33 (41.67–75.0)	37.5 (25.0–50.0)	−0.48[b]	−33.33 (−58.75; 0.50)	0.000[c]	0.000[c]
QOL communication mean score	100 (87.5–100)	50.00 (25.0–75.0)	−0.82[b]	−50.00 (−65.63; −20.00)	0.000[c]	0.493[c]

Data are expressed as median and interquartile range (25^{th}–75^{th}) for the non-normally distributed. Data are expressed as means±standard deviation for the normally distributed variables or as median and interquartile range (25^{th}–75^{th}) for the non-normally distributed. [a]Effect size Cohen's d. [b]Effect size Wilcoxon signed rank "*r*". [c]The Mann–Whitney *U* test for independent groups. *Variation rate (%) = ((VT1 – VT0)/VT0) × 100. A negative variation rate indicates a decrease in the parameter value and a positive variation rate indicates an increase in the parameter value

intervention and control groups 3 months after the TPE intervention [Table 3]. The variation rates showed a statistically significant difference ($P < 0.0001$) between the intervention group and the control group in terms of both overall and dimensional QoL mean scores. These scores increased for the intervention group, while they decreased for the control group. This indicates that the intervention group, compared to the control group, experienced better QoL 3 months after the TPE intervention, manifested by less pronounced T1DM symptoms, fewer barriers to treatment or compliance issues, fewer illness-related worries, and fewer illness-related communication problems.

Discussion

The objective of this non-randomized before and after controlled study was to assess the effects of a structured education intervention for children and adolescents with T1DM on their glycemic markers and QoL, as compared with a control group, which did not participate in any structured TPE program.

In both intervention and control groups, at 3 months after the TPE intervention, the results indicated that there was no statistically significant improvement in HbA1c participants' levels. These results are consistent with those of other studies, where structured education programs have not been shown to have a beneficial effect on glycemic control measured by HbA1c levels.[13,21-24,39] However, at the endline, there was a significant difference between groups in HbA1c ($P = 0.016$). Similarly, the difference between groups regarded other glycemic markers in this study (maximum and minimum postprandial blood glucose levels and maximum preprandial blood glucose level) was significant ($P < 0.000$), which suggests that patients who benefited from the educational program had better glycemic control than those who did not have this opportunity. Same was observed in an integrative review looking at the quality and outcomes of diabetes education programs for children and adolescents with T1DM, where improved glycemic control was reported in 40% (n = 12 of 30) of studies measuring HbA1C as an endpoint for education programs.[25] Similarly, data from meta-analyses and reviews of Anglo–Saxon literature reporting the results of randomized controlled studies wherein educational interventions were compared with usual management for several chronic diseases, including T1DM, confirm this observation.[26]

In addition, the variation rate analysis of glycemic markers in children and adolescents with T1DM in our study showed that HbA1c recorded no change in the two groups and no statistically significant difference between them. Moreover, the variation rate of maximum postprandial blood glucose values decreased in the intervention group and did not change in the control group, though this difference was not significant. In this regard, the contribution of postprandial blood glucose level to the elevation of HbA1c has long been debated. Indeed, it has been concluded that its contribution to total hyperglycemia decreases with the severity of the glycemic imbalance.[40] In other words, higher HbA1c levels are associated with a lower postprandial contribution to hyperglycemia and greater glycemic

variability.[41] Thus, studies have suggested that postprandial glycemic excursions constitute a third component of the glycemic triad and may have a role in overall glycemic load and may also reflect glycemic control.[42] Indeed, for a patient with fairly good control of diabetes (HbA1c < 7.3%), postprandial glycemia makes a predominant contribution (70%) in the fluctuations of HbA1c; however, for a patient with poorly controlled diabetes, it is the fasting or preprandial glycemia that is the main contributor to the change in HbA1c.[42]

On the contrary, in contrast to the results related to glycemic markers, the TPE intervention showed an improvement in the QoL, as assessed by PedQL 3.0, of those who participated. Thus, the global QoL mean scores, as well as those of the QoL dimensions, improved significantly 3 months after the TPE intervention, something which was not observed for the control group, where not only the QoL scores did not increase, but they decreased significantly. In contrast to the unobserved effect of TPE intervention on HbA1c, QoL assessed by PedQL 3.0 as well as the dimension QoL improved significantly 3 months after the TPE intervention. Furthermore, 3 months after the TPE intervention, although there was no statistically significant difference between the groups regarding treatment II and communication QoL dimensions (the same treatment adherence issues and communication problems in both groups), values related to overall mean QoL score and mean scores of diabetes QoL, treatment I QoL, and worry QoL were significantly different between intervention and control groups ($P < 0.0001$).

Furthermore, 3 months after the intervention, the variation rates showed a statistically significant difference between the intervention group and the control group, in terms of both overall and dimensional QoL mean scores, which increased markedly for the intervention group and markedly decreased for the control group.

These results confirm those of other studies that reported a positive impact of structured education programs on participants' QoL.[21-24] This then leads to the conclusion that TPE programs help children and adolescents with T1DM who have participated in it to better adhere to treatments and face their barriers, to better deal with their concerns, to reduce the disease's symptoms, and to overcome communication barriers with caregivers about the disease.

Ultimately, even if the TPE program did not have the expected effect on glycemic control, this can in no way reflect the effect of the intervention alone as outcomes may be affected by the nature of the program and the individual receiving it. Thus, this study's results can also be attributed to the assessment duration, which should be extended to the long term, to the biopsychosocial effects of puberty, to the intervention timing, as well as readiness to change for some T1DM children and young people.[22,23]

Furthermore, improved QoL scores and encouraging glycemic marker results can be achieved if therapeutic programs focused on interventions that have been shown to reduce diabetes-specific family conflict proved to affect diabetes and to be detrimental to the overall QoL of children and young people with T1DM, over and beyond intensifying glycemic control.[43]

Limitation and recommendation

In our Moroccan context, our study should be congratulated for being the first to integrate a TPE intervention with T1DM children and adolescents according to a structured approach that meets standards. However, it has limitations such as the short-term assessment, which is not sufficient to confirm this study's results.

Conclusion

The results of this study support the hypotheses of difference between the study groups in favor of better glycemic control and QoL for the intervention group despite the non-significant change in HbA1c levels. This suggests that structured TPE has the potential to help T1DM children and adolescents acquire skills, allowing them to better manage and live with their disease. Nonetheless, for better achievements and to sustain these gains, TPE interventions must be incorporated into routine care in a regular and coordinated way.

Author contributions

Conceptualization, H.A.L., M.A.R. and K.H.; methodology, H.A.L., M.A.R. and K.H.; formal analysis, B.Z., H.A.L. and H.A; investigation, H.A.L., A.B and Y.Z; resources, H.A.L.; data curation, H.A.L.; writing-original draft preparation, H.A.L. and M.A.R.; writing—review and editing, H.A.L., M.A.R., H.A., B.Z. and K.H.; supervision, H.A.L.; project administration, H.A.L., M.A.R. and K.H. All authors have read and agreed to the published version of the manuscript.

Institutional review board statement

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by University Hospital Ethics Committee of Sidi Mohamed Ben Abdellah Fez University (Protocol code: 14/22, date of approval: January 2022).

Informed consent statement

Informed consent was obtained from all subjects

involved in the study. All the participants' parents and carers signed written consents, as the participants are minors.

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Conflicts of interest

There are no conflicts of interest.

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