

Effect of diabetes self-management education on health related quality of life of Tunisian children with type 1 diabetes mellitus and their parents: A randomized controlled trial

Effet de l'éducation à l'autogestion du diabète sur la qualité de vie liée à la santé des enfants Tunisiens atteints de diabète de type 1 et de leurs parents : Un essai contrôlé randomisé

Imen Ben Abdesslem^{1,2,3,5}, Raoudha Kebaili^{4,5}, Khansa Derbel^{1,5}, Hichem Ben Said⁴, Lamia Boughammoura^{3,4,5}, Sonia Rouatbi^{1,2,3,5}, Jihene Bouguila^{3,4,5}

1. Department of physiology, Farhat Hached university hospital, Sousse, Tunisia.
2. Laboratory of physiology, Faculty of medicine of Sousse, University of Sousse, Sousse, Tunisia
3. Research laboratory "Heart failure" (LR12SP09), University of Sousse, Sousse, Tunisia.
4. Department of pediatrics, Farhat Hached university hospital, Sousse, Tunisia
5. Faculty of medicine of Sousse, University of Sousse, Sousse, Tunisia

ABSTRACT

Aim: To assess the effect of diabetes self-management education (DSME) on health related quality of life (HRQoL) of Tunisian children/adolescents with type 1 diabetes mellitus and their parents.

Methods: This monocentric study used a randomized controlled trial design, during five-month intervention and five-month follow-up and including 110 patients (54 in the DSME intervention group and 56 in the Individual Education by Pediatrician (IEP) control group) and their parents. Pediatric Generic Core Quality-of-Life Inventory 4.0-Scale (PedsQL4.0) evaluated HRQoL.

Results: At baseline, both groups had similar clinical features and PedsQL4.0 scores ($p > 0.05$). In DSME, clinical outcomes were significantly improved from baseline to follow-up ($p < 0.001$), while in the IEP group, which received no intervention, these outcomes remained unchanged. During follow-up, DSME showed higher PedsQL4.0 scores in parents' proxy-report and children/adolescents self-report ($p < 0.001$). According to parents' proxy-report, PedsQL4.0 scores were significantly higher during follow-up compared to baseline in DSME ($p < 0.001$) while they remained the same in IEP ($p > 0.05$). DSME had higher percentage of change in the PedsQL4.0 scores than IEP ($p < 0.01$). The median change varied from -5.01% to 0% vs 5.41% to 36.36% in IEP and DSME, respectively.

Conclusion: Encouraging healthcare professionals to incorporate these interventions could enhance the HRQoL of diabetic children and bolster their self-esteem.

Key words: Type 1 diabetes mellitus, child, Health related quality of life, Diabetes self-management intervention.

RÉSUMÉ

Objectif: Évaluer l'effet de l'éducation à l'autogestion du diabète (DSME) sur la qualité de vie liée à la santé (HRQoL) des enfants Tunisiens atteints de diabète de type 1 et de leurs parents.

Méthodes: Cette étude monocentrique a utilisé un essai contrôlé randomisé, au cours d'une intervention et d'un suivi de cinq mois, et a inclus 110 patients (54 dans le groupe d'intervention (DSME) et 56 dans le groupe Témoin d'éducation individuelle par le pédiatre (IEP)) et leurs parents. Le Pediatric Generic Core Quality-of-Life Inventory 4.0-Scale (PedsQL4.0) a permis d'évaluer la HRQoL.

Résultats: Au départ, les deux groupes présentaient des caractéristiques cliniques et des scores PedsQL4.0 similaires ($p > 0,05$). Dans DSME, les résultats cliniques se sont améliorés de manière significative entre le début et la fin ($p < 0,001$), tandis que dans le IEP qui n'a pas reçu aucune intervention, ces résultats n'ont pas varié. Au cours du suivi, la DSME a montré des scores PedsQL4.0 plus élevés dans le rapport des parents et des enfants ($p < 0,001$). Selon le rapport des parents, les scores PedsQL4.0 étaient significativement plus élevés au cours du suivi par rapport à la base dans la DSME ($p < 0,001$), alors qu'ils sont restés les mêmes dans le PEI ($p > 0,05$). Le pourcentage de PedsQL4.0 était plus élevé dans la DSME que dans l'IEP ($p < 0,01$). Le changement médian variait de -5,01 % à 0 % contre 5,41 % à 36,36 % pour le PEI et la DSME, respectivement.

Conclusion: Encourager les soignants à intégrer ces interventions pourrait améliorer la QVLS des enfants diabétiques et à renforcer leur estime de soi.

Mots clés: Diabète sucré de type 1, Enfant, qualité de vie liée à la santé, Intervention d'autogestion du diabète

Correspondance

Imen Ben Abdesslem

Department of physiology, Farhat Hached university hospital, Sousse, Tunisia.

Email: benabdesslem12imen@gmail.com

INTRODUCTION

In recent years, type 1 diabetes mellitus (T1DM) is considered as the most severe and frequent endocrine disorder in childhood (1). It is an increasing public health problem (2) with a high risk of acute and long-term complications affecting growth and quality of life (3). An estimated 537 million people are living with diabetes worldwide in 2021, with around 18.7 million people living in low-income and middle-income countries (4, 5). The World Health Organization (WHO) reported in 2022 that the number of cases of T1DM in African children/adolescents increased fivefold (ie; from 4 to 20 cases per 1000 children/adolescents). In Tunisia, T1DM had a rate of 6.95/100000 per person in 2011 (6).

T1DM in children/adolescents is defined by insufficient insulin production in the pancreas due to the immune system's attack on the pancreas' beta cells responsible for insulin production (7). It requires strict daily management, including insulin administration, regular glycaemia monitoring, balanced meals and snacks and regular physical activity in order to lead healthy, active lives (7). On a day-to-day basis, children/adolescents with T1DM are at increased risk of depression, anxiety and eating disorders (8), which can have a negative impact on their future development and HRQoL.

The aim of diabetes education is to help patients acquire the necessary knowledge, self-care techniques and attitudes to manage their diabetes effectively. Recognizing the many challenges associated with self-management of T1DM, it is important for healthcare professionals to provide children and their parents with therapeutic education based on more structured goals that are assessed and ongoing to solve problems, self-manage, change behaviors (1) and improve HRQoL in children as well as parents as primary care givers. Since healthcare delivery systems, religious beliefs, cultural practices, and family dynamics vary significantly across societies, it is crucial to conduct a study on the HRQoL in different communities (8). To the best of the authors' knowledge, there are few international scientific studies that have investigated the impact of a therapeutic education program on the HRQoL of children/adolescent with T1DM (1, 9-16). Only one North-African study (17) evaluated the HRQoL and glycemic control of 503 adolescents with T1DM (121 in interventional group vs 122 in control group) and investigated the impact of an educational program. The research of Abolfotouh et al. shows that educational and counseling interventions aimed at improving the acquisition of diabetes self-management skills can lead to improved HRQoL for people with diabetes (17)

The objective of this study is to assess the effect of DSME on HRQoL of Tunisien children/adolescents with T1DM and their parents.

METHODS

Study design

This monocentral study used a randomized controlled trial (RCT) design. It was conducted from January 2020 to May 2023, including 5-month of intervention (June- October 2022) and a 5-month follow-up post intervention (November2022- March 2023) (figure1). The study carried out at Farhat Hached university hospital in Sousse, Tunisia.

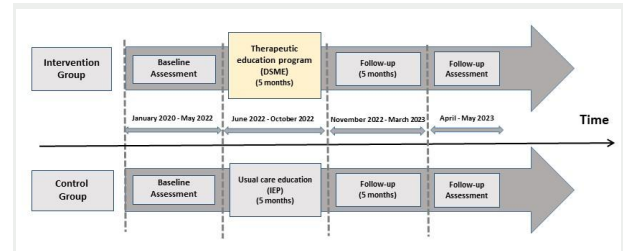


Figure 1. The schedule of the study conducted to improve the HRQoL among the children and adolescents with T1DM and their parents

The study obtained ethical approval from the Ethics Committee of the Faculty of Medicine of Sousse ((Approval number: CEFMS: 61/2021)). Consent was obtained from the parents of the children/adolescents, and adolescents over 13 years of age also provided their consent. The participants were fully informed about the study protocol, its objectives, and their right to withdraw at any time. In addition, the study adhered to recommended preventive measures against the transmission of severe acute respiratory syndrome coronavirus during this period. To ensure the confidentiality and anonymity of the data, each patient was assigned a unique code. Permission to use the PedsQL4.0 questionnaire for assessing HRQoL in children/adolescents and their parents was obtained from authors of the questionnaire (18).

Sample size

To estimate the total sample size, we employed the following formula (19):

$$N=(r+1) (Z_{\alpha/2}+Z_{1-\beta})^2 \delta^2 /rd^2$$

"N" is equal to n1 + n2 ("n1" and "n2" are the sample sizes for the two groups of experimental and control groups); " $Z_{\alpha/2}$ ": normal deviate at a level of significance (1.96 for 5% level of significance); " $Z_{1-\beta}$ ": normal deviate at 1- β % power with β % of type II error (= 1.64 at 95% statistical power); "r" (equal to n1/n2): ratio of the sample size required for the two groups (r = 1 gives the sample size distribution as 1:1 for the experimental and control groups); " δ " and "d" are the pooled standard-deviation (SD) and the difference of the HRQoL means of the two groups. Given the pioneer character of this study, these two values were obtained from a previous study aiming to determine the efficacy of two Internet-based psycho-educational programs designed to improve outcomes for youth with T1DM transitioning to adolescence(10).

In the above-named study, 128 patients in the intervention group and 122 in control group were included. The percentage mean score \pm SD of the total HRQoL of the two groups were 81.28 \pm 10.75 and 85.97 \pm 11.07, respectively. The total sample size was 140 patients (70 in each group). The assumption of 20% for the non-inclusion and

exclusion criteria gives a revised sample of 140 patients [=114/ (1.0-0.20)]. Randomization was performed in permuted blocks using the random sequence application with 14 blocks of 10.

Study Population

Figure 2 describes the study consort flowchart. Only children aged 8 to 12 years, adolescents aged 13 to 18 years, and their parents were included. In this study, we used the terms: “children” (6 to 12 years old; <http://www.ncbi.nlm.nih.gov/mesh/68002648>;) and “adolescents” (13 to 18 years old; <http://www.ncbi.nlm.nih.gov/mesh/68000293>;) . Both were accompanied by their parents. They were included in the study, children/adolescents who had a medical diagnosis of T1DM at least one year before the inclusion in the study, who received only insulin analogues for at least three months and who had a valid telephone number. Children/adolescents who had a mental retardation, a sensor neural disorder that interferes with normal communication; or another chronic disease, such as celiac disease, were not included in this study.

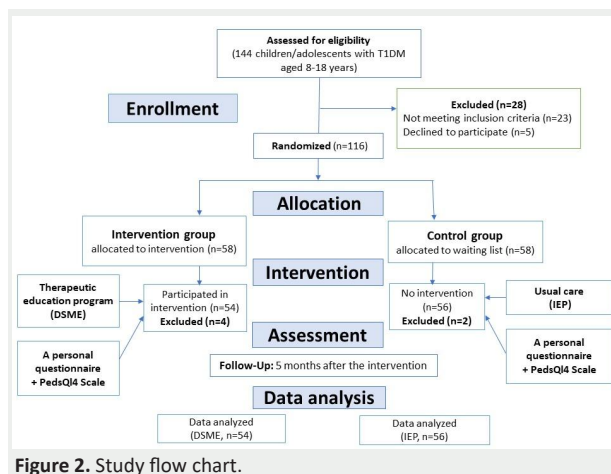


Figure 2. Study flow chart.

Study groups and intervention

After enrolment, a total of 144 eligible children and adolescents with T1DM were randomly assigned to the experimental or control group by the principal investigator using opaque sealed envelopes.

A total of 58 families in the intervention group received DSME. The control group (IEP) 58 families received no intervention. IEP is the usual care education demonstrated by a regular 5 minutes by the Paediatrician at the end of the patient’s consultation. At last, 54 families completed the study in the intervention group and 56 families in the control group (Figure 2).

The sessions’ topics included basic information about T1DM: Symptoms, the basics of therapeutic education (B1: Pen insulin therapy, B2: Daily glycaemic control, B3: Nutritional management, B4: Physical activity, B5: Medical check-ups every three months, B6: What to do in special situations (Hypoglycaemia (at rest and during exercise), Hyperglycaemia (at rest and during exercise), Self-management skills for T1DM.

The content of the diabetes self-management program

(DSMP) was written by the principal researcher and reviewed by the pediatrician. The program, designed to enhance intervention outcomes, was implemented at the Faculty of Medicine in Sousse. It consisted of five group sessions. Each group attended a 180-minute session over a 5-month period, with one session per month.

During the intervention and follow-up periods, families in the intervention group maintained telephone contact with the researcher to address any concerns they encountered. A T1DM education booklet, a care booklet and an emergency card were provided in the participants' mother tongue. Several teaching methods were used during the educational sessions, including group discussion.

Visual aids, including PowerPoint presentations, a whiteboard, a booklet, a care booklet and a diabetic card were utilized during the educational sessions. The educational sessions were led by the researcher and a multidisciplinary team (two clinical teachers, a dietician and a nurse).

Instruments

A pre-designed structured interview questionnaire written in Arabic was used for data collection, with one investigator (IBA in the list of authors) responsible for administering and collecting the questionnaire. At the beginning of the consultation day, the questionnaire was given to patients and parents independently to enhance the response rate. The questionnaire was then collected at the end of the morning of the same day and took 15 minutes to complete. It was divided into four parts:

Personal and sociodemographic characteristics

The following data were collected: sex (ie; male; female), age (ie; years, children (8 to 12 years), adolescents (13 to 18 years)); BMI (kg/m²), corpulence status (ie; normal weight; overweight or obese) (29) siblings in the family (ie; number sibling > 2), family history of diabetes mellitus (ie; yes, no)

Clinical characteristics

The following data were collected: duration of disease (ie; year), diet (ie; yes, no), number of hypoglycemic attacks within the last three months (ie; number, yes, no), average glycemia during the hypoglycemia episodes (ie; g/l), home self-monitoring (ie; yes, no), home self-monitoring frequency (ie; never, > 1), duration of HbA1C control (ie; control < 3 months, control > 6 months), lipodystrophy (ie; yes, no), . Two subgroups of patients (ie; non-active; active) were formed according to regular sports activity based on the response to the following question: do you practice any sports activities outside of school?

Record review

Data were collected glycemic control as measured by HbA1c (controlled diabetes ≤7.5 and uncontrolled diabetes >7.5) based on International Society for Pediatric and Adolescent Diabetes Guidelines (20).

Pediatric Generic core Quality of life Inventory 4.0 Scale (PedsQL4)

The HRQOL of children and parents were the primary outcomes of this study. The Arabic version of the (PedsQL4) was used to assess the HRQOL of children aged 8 to 18 years (21).

The latter was developed to assess HRQoL in children/adolescents (self-report) and their parents (proxy-report) and that of their parents (proxy-report) (18, 22). HRQoL is assessed in four domains: 1) physical functioning (8 items), 2) emotional functioning (5 items), 3) social functioning (5 items), and 4) educational function (5 items) (18, 22). The following five scores are calculated: total score, physical (8 items), emotional (5 items), social (5 items), and educational scores (5 items). The total score is obtained by summing the scores and by the total number of items completed. Patients and parents were asked to rate the 'problem in the last three months' on 5 Likert scales from 0 to 4 (0 = never a problem; 1 = almost never a problem; 2 = sometimes a problem; 3 = often a problem; 4 = almost always a problem). Each item was then scored backwards and linearly transformed on a scale from 0 to 100 (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), so that the highest score indicates better HRQoL (18, 22). The PedsQL4.0 has corresponding forms for child self-report, parent proxy-report (18) and has shown good internal consistency, reliability and consistency, reliability and validity (18). The validated Arabic version of the PedsQL4.0 has been used (21).

Statistical Analysis

The Kolmogorov Smirnov test was used to analyze quantitative data's distribution. Quantitative data with a normal distribution, were expressed as means ± standard deviation, otherwise they were expressed as median [interquartile]. Categorical data were expressed as number (frequency). Comparisons DSME vs. IEP of the sociodemographic and anthropometric characteristics, clinical features and the PedsQL4.0 scores whether first at baseline or during the follow-up were performed by the Student T test, Mann Whitney U test and Chi square test for normal, not normal and categorial data, respectively. Comparisons of the changes in the PedsQL4.0 scores (100 × [(Follow-up – Baseline)/Baseline]) between baseline and follow-up conditions for each group were performed by the Wilcoxon test. Analyses were carried out using Statistica software (Statistica Kernel version 12; StatSoft, Paris, France). Significance was set at the 0.05 level.

RESULTS

Among the initial sample of 144 Children/adolescents, only 110 were retained (54 in the DSME group and 56 in the IEP group). Both groups were matched for their anthropometric and socio-demographic data (Table 1). The two groups were anthropometrically and socio-demographically comparable. In DSME group, 55.6% were adolescents compared with 67.7% of the IEP group. Sex-ratio was 0.8 and 1.4 in DSME and IEP groups respectively (Table 1).

Table 1. Socio-demographic and anthropometric characteristics of children/adolescents with type-1 diabetes mellitus in both groups DSME and IEP (n=110).

	Category	Experimental group (DSME) (n=54)	Control group (IEP) (n=56)	P-value
Accompanying tutor ^a	Mother	45 (83.3)	39 (69.6)	0.189
Age ^b	Years	13 [11 -16]	14 [11- 17.5]	0.261
Age range ^a	Adolescents (13-18 years)	30 (55.6)	38 (67.7)	0.350
Sex ^a	Female	30 (55.6)	23 (41.1)	0.129
Body mass index ^b	kg/m ²	21.16±3.66	20.98±3.85	0.803
Corpulence status ^a	Overweight/obese	21 (38.9)	14 (25.0)	0.118
Siblings in the family ^a	≥ 2	35 (64.8)	38 (67.7)	0.736
Duration of T1DM ^b	Years	6 [3 8]	7 [3 9]	0.274
Family history of T1DM ^a	Yes	14 (25.9)	17 (30.4)	0.766

Data were ^a Number (%) and ^b Mean±standard deviation, DSME: diabetes self management education, IEP: the individual education by paediatrician, T1DM: Type1 diabetes mellitus

baseline both groups had similar clinical features (p>0.05) while, the DSME group showed better features than the IEP group, during the follow-up (p<0.001) (Table 2). In the DSME group, clinical outcomes were significantly improved from baseline to follow up mainly HbA1c levels, hypoglycemia episodes and lipodystrophy (p<0.001) (Table 2). Nevertheless, in the IEP group, these outcomes did not differ and HbA1c levels increased (Table 2).

Table 2. Comparison of primary and secondary patients' outcomes during baseline and follow-up: DSME and IEP Groups.

Outcomes	Groups	Baseline	Follow-up	P-value ^a
Diet (No) ^a	DSME (n=54)	50 (92.6)	28 (51.9)	<0.001 [§]
	IEP (n=56)	51 (91.1)	50 (89.3)	1.000
	P-value*	0.771	<0.001 [§]	
Regular physical activity (Yes) ^a	DSME (n=54)	43 (79.6)	52 (96.3)	0.012 [§]
	IEP (n=56)	38 (67.9)	33 (58.9)	0.063
	P-value*	0.161	<0.001 [§]	
Physical activity sessions (Number/week) ^b	DSME (n=54)	1 [1 2]	2 [1 3]	0.001 [§]
	IEP (n=56)	1 [0 2]	1 [0 2]	0.005 [§]
	P-value*	0.611	<0.001 [§]	
Home self-monitoring frequency (Never) ^a	DSME (n=54)	28 (51.9)	13 (24.1)	0.007 [§]
	IEP (n=56)	31 (55.4)	32 (57.1)	0.109
	P-value*	0.989	0.001 [§]	
Lipodystrophy (Yes) ^a	DSME (n=54)	33 (61.1)	12 (22.2)	<0.001 [§]
	IEP (n=56)	37 (66.1)	38 (67.9)	1.000
	P-value*	0.589	<0.001 [§]	
Hypoglycemia (Yes) ^a	DSME (n=54)	52 (96.3)	31 (57.4)	<0.001 [§]
	IEP (n=56)	56 (100)	52 (96.3)	0.125
	P-value*	0.146	<0.001 [§]	
HE (Number) ^b	DSME (n=54)	4.0[3.05.0]	1.0[0.02.0]	<0.001 [§]
	IEP (n=56)	4.5[4.05.0]	4.0[3.05.0]	0.025 [§]
	P-value*	0.253	<0.001 [§]	
Average glycaemia during HE (g/l) ^b	DSME (n=54)	0.5[0.40.6]	0.6[0.00.6]	<0.001 [§]
	IEP (n=56)	0.5[0.50.6]	0.5[0.50.6]	<0.001 [§]
	P-value*	0.827	0.691	
HbA1c (%) ^c	DSME (n=54)	10.60±1.60	9.28±1.19	<0.001 [§]
	IEP (n=56)	10.69±1.52	11.08±1.61	0.015 [§]
	P-value*	0.747	<0.001 [§]	

Data were ^a Number (percentage) ^b Median [Quartiles] ^c Mean±standard deviation
^{*}: Student T test, Mann Whitney U test or Chi square test between the two groups in the same experimental condition for parametric, non parametric and qualitative data, respectively.

[§]: Student T test, Wilcoxon test or Mc Nemar test between baseline and follow up in each group for parametric, non parametric and qualitative data, respectively.

[§]p-value < 0.05. DSME: diabetes self management education. IEP: the individual education by paediatrician. HbA1C: Glycosylated hemoglobin. HE: Hypoglycemia episodes

At baseline DSME and IEP groups had similar PedsQL4.0 subscales and total scores in parents' proxy-report and children/adolescents' self-report ($p>0.05$) (Table 3). During the follow-up, the DSME group showed higher PedsQL4.0 scores in parents' proxy-report and children/adolescents self-report ($p<0.001$) (Table 3).

Table 3. Comparison of total and subscale scores of the Pediatric Generic Core Quality of Life Inventory 4.0 Scale : Parents' proxy-report and children/adolescents' self-report during baseline and follow-up: DSME and IEP Groups.

		Baseline	Follow-up	P-value*
Parents' proxy report				
Physical health	DSME (n=54)	70.20±25.82	86.92±12.28	<0.001 [§]
	IEP (n=56)	68.14±17.14	65.46±17.10	0.182
	P-value*	0.622	<0.001 [§]	
Emotional function	DSME (n=54)	57.87±21.56	74.72±13.82	<0.001 [§]
	IEP (n=56)	55.89±19.66	53.48±16.84	0.211
	P-value*	0.616	<0.001 [§]	
Social function	DSME (n=54)	84.35±16.96	92.04±13.37	0.001 [§]
	IEP (n=56)	81.07±18.94	79.64±19.23	0.438
	P-value*	0.341	<0.001 [§]	
Academic function	DSME (n=54)	72.59±17.61	87.96±9.54	<0.001 [§]
	IEP (n=56)	67.14±23.41	68.39±18.78	0.547
	P-value*	0.170	<0.001 [§]	
Total score	DSME (n=54)	71.25±14.04	85.41±8.56	<0.001 [§]
	IEP (n=56)	68.06±13.91	66.49±14.10	0.280
	P-value*	0.234	<0.001 [§]	
Children/adolescents' self-report				
Physical health	DSME (n=54)	68.06±16.49	83.74±11.23	<0.001 [§]
	IEP (n=56)	65.40±18.27	61.70±18.57	0.117
	P-value*	0.426	<0.001 [§]	
Emotional function	DSME (n=54)	53.06±19.12	72.04±12.23	<0.001 [§]
	IEP (n=56)	52.68±20.91	46.88±18.33	0.028 [§]
	P-value*	0.922	<0.001 [§]	
Social function	DSME (n=54)	80.56±17.61	92.22±11.60	<0.001 [§]
	IEP (n=56)	81.07±18.03	74.20±21.59	0.003 [§]
	P-value*	0.880	<0.001 [§]	
Academic function	DSME (n=54)	70.93±17.49	84.35±10.14	<0.001 [§]
	IEP (n=56)	67.59±23.78	62.23±25.10	0.013 [§]
	P-value*	0.405	<0.001 [§]	
Total score	DSME (n=54)	68.15±10.87	83.04±7.53	<0.001 [§]
	IEP (n=56)	66.27±14.60	61.95±16.67	0.020 [§]
	P-value*	0.446	<0.001 [§]	

Data were Mean±standard deviation

*: Student T test, Mann Whitney U test or Chi square test between the two groups in the same experimental condition for parametric, non parametric and qualitative data, respectively.

‡: Student T test, Wilcoxon test or Mc Nemar test between baseline and follow up in each group for parametric, non parametric and qualitative data, respectively.

§: p-value < 0.05. DSME: diabetes self management education, IEP: the individual education by paediatrician

According to parents' proxy-report, PedsQL4.0 subscales and total scores were significantly higher during follow-up compared to baseline in the DSME group ($p<0.001$) while they remained practically the same in the IEP group ($p>0.05$) (Table 3). According to children/adolescents' self-report, these scores were significantly higher during follow-up in DSME group ($p<0.001$), but they further decreased in the IEP group (Table 3).

The DSME group had higher percentage of change in the PedsQL4.0 subscales and total scores than the IEP group ($p<0.01$), mainly concerning the emotional function subscale (Table 4). In fact, the median change in the IEP group varied between -5.01% and 0%, while in the DSME

group it varied between 5.41% and 36.36% (Table 4).

Table 4. Pediatric Generic Core Quality of Life Inventory 4.0 Scale changes (%): Parents' proxy-report and children/adolescents' self-report in both groups.

	DSME (n=54)	IEP (n=56)	P-value
Parents' proxy report			
Physical health	14.29 [3.64 46.62]	-0.83 [-9.77 7.69]	<0.001
Emotional function	29.02 [-5.56 88.89]	0.00 [-14.82 9.09]	<0.001
Social function	5.41 [0.00 27.08]	0.00 [-11.11 12.15]	0.007
Academic function	14.29 [5.88 35.90]	0.00 [-7.69 11.11]	<0.001
Total score	18.11 [2.10 31.37]	-0.22 [-7.46 6.71]	<0.001
Children/adolescents' self-report			
Physical health	20.87 [4.45 50.00]	-5.01 [-11.91 3.93]	<0.001
Emotional function	36.36 [18.18 68.33]	0.00 [-26.32 18.18]	<0.001
Social function	11.11 [0.00 28.57]	0.00 [-13.49 0.00]	<0.001
Academic function	12.50 [5.88 30.95]	0.00 [-18.18 0.00]	<0.001
Total score	17.27 [10.52 33.83]	-4.13 [-9.82 4.56]	<0.001

Change (%) = $100 \times [(Follow-up - Baseline)/Baseline]$.

Data were Median [interquartiles]

Mann Whitney U test was used to compare data in the two groups.

PedsQL4.0: Pediatric Generic core Quality of life Inventory 4.0 Scale

DSME: diabetes self-management education

IEP: the individual education by paediatrician

DISCUSSION

This study aimed to investigate the impact of DSME on the HRQOL of children/adolescents with T1DM and their parents in Tunisia. The results revealed improvements in HRQOL, glycaemic control (HbA1C) and clinical features. Additionally, acute diabetes complications were significantly reduced compared to IEP

In this study, we have used DSME which is a long-term program based on self-management of the illness, empowerment of the family and strengthening of the child-parent-nurse relationship. It is comparable to other intervention studies (table 1S) (11, 13, 15). Two trials proposed a behavioural intervention (10, 23), nine proposed a psychological intervention (9, 11, 12, 14), and three proposed a combination of psychological and behavioural interventions (1, 17).

In the present study, one of the parents was involved in the DSME program and in the follow-up of children/adolescents with T1DM, which is the case in other similar studies (1, 11, 16). The current results contribute to the growing evidence that family education can lead to better results in terms of diabetes control and HRQOL for children with diabetes and their parents than individual education (10).

The study's findings indicated a significant improvement in clinical and biological attributes as well as HRQOL scores in children/adolescents with (T1DM) and their parents who underwent DSME, compared to those who participated in IEP. Moreover, this improvement was sustained even after a follow-up period of five months.

Effect of DSME on the clinical features

In this study, the interventional group (DSME) included more patients respecting their balanced diet, practicing regular physical activity and self-monitoring their disease. The DSME group also had less lipodystrophy

and hypoglycaemia episodes compared to the control group (IEP) (table2). Abdelftough et al (2011) found that the interventional group improved its total adherence to T1DM management (17).

Based on a systematic review, 10 of the 21 studies reported an improvement in adherence. The results of the present study demonstrated a significant impact of DSME on diet adherence, which is consistent with other studies (13, 17).

We observed a reduction in severe hypoglycaemia in patients with T1DM after 5 months of participation in the DSME program. This is consistent with the improvement noted in similar studies(13, 24).

Importantly, parental involvement is associated with more frequent blood glucose monitoring in children/adolescents , while neither less nor excessive parental support is associated with good diabetes outcomes(25). Which is the case in the current study (table 2).

Effect of DSME on HRQoL score (PedsQL4.0) of Tunisian children/adolescents with T1DM (self-report) and their parents (proxy-report)

T1DM affects the psychological and emotional well-being of patients and their families, which is why HRQoL, in addition to HbA1c is a primary outcome parameter for education programs (1).

The main findings of the present study of 110 diabetic children with T1DM (and their parents) were that the DSME group had significantly higher scores on the PedsQL4.0 subscales and total scores during follow-up compared with baseline ($p < 0.001$), while the IEP group had minimal changes in these scores ($p > 0.05$) (Table 3).

In a large-scale study, better metabolic control was associated with better quality of life (26). This correlates well with our study (tables 3 and 4)

In general, lower HRQoL scores were linked to factors such as advanced age, inadequate glycaemic control, an increasing number of hypoglycemic episodes, complications, low educational attainment and attainment of goals, self-reported depression, and being female(17). Furthermore, a correlation was found between poorer quality of life and older age, a greater number of hospital admissions within the last 6 months, higher levels of depression, low self-esteem, and diminished self-efficacy(17).

Effect of DSME on HBA1C

Deteriorating glycaemic control is a common issue in adolescents with T1DM (17, 27). This study demonstrated a significant improvement in HbA1c levels from baseline in the experimental group, in contrast to a significant unfavourable deterioration in the control (table2). The effect of educational programs on glycaemic control differs between studies. Some, including our study, have reported an improvement in glycemic (13, 15, 26, 28, 29) However, other studies have reported results contrary to ours (12, 14, 17). This could be explained by the fact that they used different intervention methods (psychological and behavioral approach in the studies of Abolfotouh

et al., 2011 and Mayer-Davis et al., 2018) and that the duration of the intervention was shorter in these studies (Table 1S).

Recent studies showed that good glycaemic control is correlated with better HRQOL (30, 31) and that Successful diabetes treatment is highly dependent on appropriate self-management. Children and adolescents need family support and assistance to be effective in their self-management (25).

Limitations of this study

Our study has three main limitations. First, this study lacked computerised diabetes registry: our population is not representative of the total population of diabetic children in Tunisia or North Africa. Second, long-term prospective studies often have a high drop-out rate that could be the case in the current study. Third, during the recruitment process of volunteering families, this study may have favoured families who were both willing and able to engage in a fairly intensive program.

CONCLUSION

It is important to encourage healthcare professionals (doctors, nurses, psychologists and families) to integrate these interventions to improve the quality of life and glycaemic control of children with type 1 diabetes. This easy, inexpensive, and multidisciplinary approach enables effective management of diabetic children

Encouraging healthcare professionals (including doctors, nurses and psychologists) to integrate these interventions is crucial for enhancing the quality of life.

This method is not only simple and economical but also utilizes a multidisciplinary framework to efficiently handle diabetic children.

Abbreviations' list

HbA1C: Glycosylated hemoglobin

HRQoL: Health related quality of life

PedsQL4.0: Pediatric Generic core Quality of life Inventory 4.0 Scale

SD: Standard deviation

T1DM: Type1 diabetes mellitus

DSME: Diabetes self-management education

IEP: Individual education by paediatrician

WHO: World Health Organization

REFERENCES

1. Von Sengbusch S, Müller-Godeffroy E, Häger S, Reintjes R, Hiort O, Wagner V. Mobile diabetes education and care: intervention for children and young people with Type 1 diabetes in rural areas of northern Germany. *Diabetic medicine : a journal of the British Diabetic Association.* 2006;23(2):122-7.
2. El-jamal S, Houda E, Barakat I, Sahel K, Mziwira M, Aziz F, et al. Association of socio-demographic and anthropometric characteristics with the management and glycemic control in type 1 diabetes children from the province of El Jadida (Morocco). *AIMS Medical Science.* 2021;8:87-104.
3. Madrigal MA, López M, Sánchez A, Cao MJ, Castro MJ, Jiménez JM. Type 1 Diabetes Mellitus in Pediatric Patients and Its Impact on Relationships in the Family Environment. *Diabetes Metab Syndr Obes.* 2020;13:4973-80.

4. Ogle GD, James S, Dabelea D, Pihoker C, Svensson J, Maniam J, et al. Global estimates of incidence of type 1 diabetes in children and adolescents: Results from the International Diabetes Federation Atlas, 10th edition. *Diabetes research and clinical practice*. 2022;183:109083.
5. Gomber A, Ward ZJ, Ross C, Owais M, Mita C, Yeh JM, et al. Variation in the incidence of type 1 diabetes mellitus in children and adolescents by world region and country income group: A scoping review. *PLOS Global Public Health*. 2022;2(11):e0001099.
6. Padoa CJ. The epidemiology and pathogenesis of type 1 diabetes mellitus in Africa. *Journal of Endocrinology, Metabolism and Diabetes of South Africa*. 2011;16(3):130-6.
7. Bekele BT, Demie TG, Worku F. Health-Related Quality-of-Life and Associated Factors Among Children and Adolescents with Type 1 Diabetes Mellitus: A Cross-Sectional Study. *Pediatric health, medicine and therapeutics*. 2022;13:243-56.
8. Girma D, Murugan R, Wondossen K, Yeshiwass S, Wale A, Tilahun S. Health-Related Quality of Life and Its Associated Factors in Children and Adolescents with Type1 Diabetes, Addis Ababa, Ethiopia. *Global pediatric health*. 2021;8:2333794x211030879.
9. Booger EA, Noordam C, Kremer JA, Prins JB, Verhaak CM. Teaming up: feasibility of an online treatment environment for adolescents with type 1 diabetes. *Pediatric diabetes*. 2014;15(5):394-402.
10. Grey M, Whittemore R, Jeon S, Murphy K, Faulkner MS, Delamater A. Internet psycho-education programs improve outcomes in youth with type 1 diabetes. *Diabetes care*. 2013;36(9):2475-82.
11. Murphy HR, Wadham C, Hassler-Hurst J, Rayman G, Skinner TC. Randomized trial of a diabetes self-management education and family teamwork intervention in adolescents with Type 1 diabetes. *Diabetic medicine : a journal of the British Diabetic Association*. 2012;29(8):e249-54.
12. Jaser SS, Whittemore R, Choi L, Nwosu S, Russell WE. Randomized Trial of a Positive Psychology Intervention for Adolescents With Type 1 Diabetes. *Journal of pediatric psychology*. 2019;44(5):620-9.
13. Lontchi-Yimagou E, Mapa-Tassou C, Dehayem MY, Essi MJ, Saji J, Takogue R, et al. The effect of free diabetes care on metabolic control and on health-related quality of life among youths with type 1 diabetes in Cameroon. *BMJ Open Diabetes Res Care*. 2017;5(1):e000397.
14. Mayer-Davis EJ, Maahs DM, Seid M, Crandell J, Bishop FK, Driscoll KA, et al. Efficacy of the Flexible Lifestyles Empowering Change intervention on metabolic and psychosocial outcomes in adolescents with type 1 diabetes (FLEX): a randomised controlled trial. *The Lancet Child & adolescent health*. 2018;2(9):635-46.
15. Brorsson AL, Leksell J, Andersson Franko M, Lindholm Olinder A. A person-centered education for adolescents with type 1 diabetes-A randomized controlled trial. *Pediatric diabetes*. 2019;20(7):986-96.
16. Waller H, Eiser C, Knowles J, Rogers N, Wharmby S, Heller S, et al. Pilot study of a novel educational programme for 11–16 year olds with type 1 diabetes mellitus: the KICK-OFF course. *Archives of Disease in Childhood*. 2008;93(11):927.
17. Abolfotouh MA, Kamal MM, El-Bourgy MD, Mohamed SG. Quality of life and glycemic control in adolescents with type 1 diabetes and the impact of an education intervention. *International journal of general medicine*. 2011;4:141-52.
18. Varni JW, Seid M, Kurtin PS. PedsQL 4.0: reliability and validity of the Pediatric Quality of Life Inventory version 4.0 generic core scales in healthy and patient populations. *Medical care*. 2001;39(8):800-12.
19. Maxwell SE, Kelley K, Rausch JR. Sample Size Planning for Statistical Power and Accuracy in Parameter Estimation. *Annual Review of Psychology*. 2008;59(1):537-63.
20. DiMeglio LA, Acerini CL, Codner E, Craig ME, Hofer SE, Pillay K, et al. ISPAD Clinical Practice Consensus Guidelines 2018: Glycemic control targets and glucose monitoring for children, adolescents, and young adults with diabetes. *Pediatric diabetes*. 2018;19(S27):105-14.
21. Abdul-Rasoul M, Alotaibi F, Almahdi M, Alkandari H. Reliability and validity of the Arabic version of the PedsQL TM 4.0 generic core scales and PedsQL TM 3.0 diabetes module. *Journal of Diabetes Mellitus*. 2012;02.
22. Varni JW, Burwinkle TM, Jacobs JR, Gottschalk M, Kaufman F, Jones KL. The PedsQL in type 1 and type 2 diabetes: reliability and validity of the Pediatric Quality of Life Inventory Generic Core Scales and type 1 Diabetes Module. *Diabetes care*. 2003;26(3):631-7.
23. Grey M, Boland EA, Davidson M, Li J, Tamborlane WV. Coping skills training for youth with diabetes mellitus has long-lasting effects on metabolic control and quality of life. *The Journal of pediatrics*. 2000;137(1):107-13.
24. Dehayem MY, Takogue R, Choukem SP, Donfack OT, Katte JC, Sap S, et al. Impact of a pioneer diabetes camp experience on glycemic control among children and adolescents living with type 1 diabetes in sub-Saharan Africa. *BMC Endocr Disord*. 2016;16:5.
25. Hirose M, Beverly EA, Weinger K. Quality of Life and Technology: Impact on Children and Families With Diabetes. *Current Diabetes Reports*. 2012;12(6):711-20.
26. Hoey H, Aanstoot HJ, Chiarelli F, Daneman D, Danne T, Dorchy H, et al. Good metabolic control is associated with better quality of life in 2,101 adolescents with type 1 diabetes. *Diabetes care*. 2001;24(11):1923-8.
27. Daneman D, Wolfson DH, Becker DJ, Drash AL. Factors affecting glycosylated hemoglobin values in children with insulin-dependent diabetes. *The Journal of pediatrics*. 1981;99(6):847-53.
28. Matam P, Kumaraiah V, Munichoodappa C, Kumar KM, Aravind S. Behavioural intervention in the management of compliance in young type-I diabetics. *J Assoc Physicians India*. 2000;48(10):967-71.
29. Tang TS, Gillard ML, Funnell MM, Nwankwo R, Parker E, Spurlock D, et al. Developing a new generation of ongoing: Diabetes self-management support interventions: a preliminary report. *The Diabetes educator*. 2005;31(1):91-7.
30. Viklund G, Örtqvist E. Factors predicting glycaemic control in young persons with type 1 diabetes. *European Diabetes Nursing*. 2014;11(3):75-8.
31. Hood KK, Beavers DP, Yi-Frazier J, Bell R, Dabelea D, Mckeown RE, et al. Psychosocial burden and glycemic control during the first 6 years of diabetes: results from the SEARCH for Diabetes in Youth study. *Journal of Adolescent Health*. 2014;55(4):498-504.