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This is the author's manuscript

Original Citation:

Availability:

This version is available <http://hdl.handle.net/2318/1630510> since 2021-05-20T08:27:59Z

Published version:

DOI:10.23736/S0026-4946.17.04634-5

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Minerva Pediatrica 2017 Feb 07

DOI: 10.23736/S0026-4946.17.04634-5

Article type: Original Article

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A structured therapeutic education program for children and adolescents with type 1 diabetes: an analysis of the efficacy of the “Pediatric Education for Diabetes” project

Running head : A therapeutic education program for T1DM in childhood

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ABSTRACT

BACKGROUND: Therapeutic education for Type 1 Diabetes involves the process of transmitting knowledge and developing the skills and behavior required to treat the disease. guidelines agree on stressing the importance of therapeutic educational intervention in teaching self-management skills to children and adolescents with Type 1 Diabetes (T1D). This study presents the results of the “Pediatric Education for Type 1 Diabetes (T1D)” (PED) project, specifically designed for children and adolescents aged 6 to 16, and structured on guidelines indications, as part of a broader clinical-educational intervention for Type 1 diabetes.

METHODS: 24 patients with Type 1 diabetes (mean age: 12,13 y; SD = 1.48 y; range 9-14) were studied in a 12-month PED structured project followed by a educational summer camp. All the activities were designed and organized by a multidisciplinary team (dietitian, pediatric diabetologist, nurse, psychologist and adult diabetologist). Glycated hemoglobin (HbA1C), knowledge about Type 1 Diabetes (T1D) (self-monitoring and nutrition), self-management (self-monitoring, nutrition and flexibility of medical treatment), and wellbeing were used as outcome measures.

RESULTS: data suggest that the PED had a positive impact on all the targeted levels indicated for recommended care.

CONCLUSIONS: The results of this study seem to confirm the effectiveness in altering the three levels of “knowing”, “know-how” and “wellbeing” required to optimize the quality of life of young patients with Type 1 diabetes. In addition, the proposed model, where a pediatric diabetologist always cooperates with an adult diabetologist, seems to be a permanent solution to the transitional gap widely discussed in the literature.

KEY WORDS Type1 Diabetes-Therapeutic education-Adolescent

INTRODUCTION

Therapeutic education for Type 1 Diabetes (T1D) (DSME or Diabetes Self-Management Education) involves the process of transmitting knowledge and developing the skills and behavior required to treat the disease. National and international guidelines [1-5] agree on stressing the importance of therapeutic educational intervention in teaching self-management skills to children and adolescents with Type 1 Diabetes (T1D). Quality-assured structured education should be available to all children and adolescents for effective management at the time of diagnosis and for self-monitoring in order to maximize the effect of diabetes therapy. [1] Such requirement for intervention is broadly documented and its characteristics are defined and described in the aforesaid care guidelines, which suggest that therapeutic education is the keystone for diabetes care and the answer to the successful management of diabetes. Hence, the planning of therapeutic educational intervention needs to focus on both clinical medicine and research, with the latter, in particular, providing useful data for clinical application. According to Lange et al. [6] “People who do not receive education or do not continue to have educational contacts are more likely to suffer diabetes related complications.” They stress how important and necessary it is to devise targeted intervention protocols that are carefully planned, with specific aims and learning objectives, and which are shared between healthcarers. Since Type 1 Diabetes (T1D) mellitus is a chronic disease that cannot be cured but only treated, often has its onset in childhood and lasts a lifetime, a clear need exists for educational intervention that focuses not only on the awareness of patients but also on their behavior and wellbeing.

This study presents the results of a group of 24 patients who took part in the “Pediatric Education for Diabetes” (PED) project, specifically designed for children and adolescents aged 6 to 16, which forms part of a broader clinical-educational intervention program for children and adolescents with Type 1 diabetes.

METHODS

The “Pediatric Education for Diabetes”- PED Project

This study presents the results of the “Pediatric Education for Type 1 Diabetes (T1D)” (PED) project, specifically designed for children and adolescents aged 6 to 16, and structured on guidelines indications, as part of a broader clinical-educational intervention for Type 1 diabetes. The 12-month PED project (Table 1, Phase 2) comprises four scheduled meetings throughout the year, when structured activities are organized (educational workshops), followed by a four-day educational summer camp at the end of the PED project. Groups are organized by age and each group has every three months an educational group plus a individual medical visit. Its ultimate goal is to develop self-management skills. Workshops are held for small groups of the same age (7-10 children/adolescents per group on average). The four main topics covered in the educational workshops include: developing skills for self-monitoring of blood glucose; flexible management of insulin therapy; therapy management with regard to nutrition and physical activity; coping with emotions related to the disease. The activities provided at the workshops encourage patients’ active participation through play and direct experiences (simulations, role playing, specific problem-solving activities, brainstorming etc.). These educational workshops are designed, organized and run by a multidisciplinary team that takes also part in the educational summer camp and comprises a dietitian, pediatric diabetologist, nurse, psychologist and adult diabetologist. The working group is specifically organized according to the team-building concept and formed in order to achieve goals and encourage “speaking with one voice”. Figure 1 shows the metaphorical symbol of the four-leaf clover, representing the four educational areas promoted during the education project to foster self-management. Each workshop is designed and largely run by one

operator in the multidisciplinary team, with the simultaneous assistance of other operators. Not only are group activities organized for children but also educational and support activities for parents. Such educational activities complement the standard individual medical visit with a pediatric diabetologist and/or adult diabetologist.

As mentioned above, the PED is a year-long project ending with a educational summer camp that is also well-structured and multidisciplinary. The four-day educational summer camp is an opportunity for intensive experiential education, when all the information provided throughout the year is put into practice, focusing on self-management behavior under the supervision and direct observation of the operators.

Study population

The sample for this study comprises 24 participants with Type 1 diabetes (mean age: 12,13 y; standard deviation SD = 1.48 y; range 9-14), including 14 females (58%) and 10 males (42%). For these patients, the onset of the disease ranged from 1 to 11 y (mean M = 4.42 y; SD = 3.78 y). The participants are patients diagnosed with Type 1 diabetes who attend the pediatric diabetes clinic. All the participant included were attending to the educational program and to the educational camp. All the participants that were attending to the educational program but not at the educational camp were excluded. All the participant included were in basal-bolus therapy.

Measurements

To assess the efficacy of the PED project, the factors taken into account were metabolic data (HbA1C) and indicators related to the above-mentioned 4 educational areas (Table 2), measured over a three-month period before the project (T0, June-August) and a three-month period after the educational summer camp, one year later (T1, October-December).

A) Physical data: the glycated hemoglobin (HbA1C) value was recorded. Data were collected in a three-month period before (T0) and after the educational program (T1). The study presents mean data.

B) Knowing: some questions from the GISED questionnaire were asked to assess knowledge about Type 1 Diabetes (T1D).[7] In particular, 10 items assessed knowledge about the self-monitoring of blood glucose, (e.g. What is the normal blood glucose range when measured upon awakening?). In addition, five items were used to assess knowledge about diabetes-adapted nutrition (e.g. Which of the following foods contains more sugar?). Each item entailed 3 or 4 response alternatives, of which only 1 was correct. Correct answers scored 1, incorrect answers scored 0, and the sum of correct answers was computed for each participant to obtain an overall score of knowledge about self-monitoring (ranging from 0-10), and about nutrition (ranging from 0-5).

C) Know-how: the presence of appropriate behaviors for the self-management of Type 1 Diabetes (T1D) were measured. Data concerning self-management abilities were collected by an operator who directly observed behavior at interviews/educational summer camp and then compiled observation charts. Data collection mainly focused on the 9 behaviors related to the self-management of Type 1 Diabetes (T1D), as specified in the Italian standards of 2014 [3] and in the ISPAD guidelines for 2014. [1] These include a) self-monitoring of blood glucose which entails (item 1) the ability to replace a needle after taking insulin, (item 2) rotation of injection sites, (item 3) correct use of equipment for injection procedures and timing, (item 4) hand washing before measuring blood glucose; b) nutrition management which entails (item 5) the ability to count carbohydrates in food and check the insulin-to-CHO ratio, (item 6) correcting hypoglycemia by applying the "15/15 rule" [3,8] c) behaviors related to insulin therapy management, including (item 7) the ability to adjust insulin therapy according to planned activities and nutrition; (item 8) the ability of patients to always have the right amount of carbohydrates with them in order to

deal with an episode of hypoglycemia, which we call a “hypo kit” and includes 15g of simple carbohydrates required to correct hypoglycemia; and (item 9) the number of blood glucose checks carried out. [8] Each of these 9 behaviors scored 1 if present and 0 if absent. The sum of the scores (ranging from 0-9) was computed to obtain a measure of adequate behaviors.

D) Wellbeing: we assessed subjective wellbeing by measuring the locus of control, the quality of life related to diabetes and coping abilities. In more detail, we used the Diabetes Locus of Control scale (DLC) [9] to assess self-management behavior in chronic illnesses. This scale entails 18 items designed to measure 3 dimensions each with 6 items: Internal locus of control (e.g. I am responsible for my health), external locus of control divided into two dimensions: attribution to chance or fate (e.g. Good health is a matter of good fortune) and attribution to powerful others, such as health operators (e.g. Health professionals keep me healthy). Answers are given on 6-point scales (1 = don't agree, 6 = completely agree) and the scores related to each dimension resulted from the sum of scores obtained for the six items (ranging from 6 to 36). In addition, we used the Diabetes Quality of Life scale for adolescents (DQOL-ado) [10,11] which entails 38 items, associated with 5-point scales (from 1 = never, to 5 = always), designed to measure 4 dimensions: the impact of diabetes on everyday life, e.g. How often do you feel pain associated with treatment for your diabetes? (11 items, overall score resulting from the sum of scores and ranging from 11 to 55); worries related to diabetes, e.g. How often do you worry about whether you will not get a job you want? (7 items, overall score ranging from 7 to 35); intrusive parents, e.g. How often do you find that your parents are too protective of you? (3 items, overall score ranging from 3 to 15); diabetes-related life satisfaction, e.g. How satisfied are you with the flexibility you have in your diet? (17 items, overall score ranging from 17 to 85). Finally, we used the Coping Questionnaire for Children and Adolescents (COPE-ado) [12] which entails 29 items, associated with 5-point scales (from 1 = never to 5 = always), designed to

assess the following strategies of coping with diabetes: Acceptance, e.g. I accept my illness (6 items, overall score ranging from 6 to 30); avoidance, e.g. I try to ignore my illness (4 items, overall score ranging from 4 to 20); cognitive-palliative coping, e.g. I learn as much as possible about my illness (5 items, overall score ranging from 5 to 25); distance, e.g. I don't care about my illness (4 items, overall score ranging from 4 to 20); emotional reaction, e.g. I cry (6 items, overall score ranging from 6 to 30); wishful thinking, e.g. I hope that my illness disappears (3 items, overall score ranging from 3 to 15); overall coping, e.g. Overall, how well do you think you cope with your illness? (1 item ranging from 1 = not very well at all, to 5 = very well).

RESULTS

The sample for this study comprises 24 participants with Type 1 diabetes with mean age: 12,13 y; SD = 1.48 y; range 9-14. In the sample were included 14 females and 10 males. For these patients, the onset of the disease ranged from 1 to 11 y (M = 4.42 y; SD = 3.78 y). Table 3 presents the descriptive statistics for the variables measured before and after educational intervention. At least at a descriptive level, the results suggest that educational intervention had a positive impact. In particular, the mean HbA1c decreased from T0 to T1. Moreover, participants showed increased knowledge of self-monitoring of blood glucose and nutrition, the presence of more adequate behaviors at T1 than at T0, and an improvement in their psychological wellbeing.

To assess the statistical significance of the observed differences, a GLM repeated measures analysis was computed with time as the within-subject variable. Results showed a significant effect of time, $F(5, 19) = 17.35, p < .01$. As reported in Table 3, regarding physical data, mean glycated hemoglobin was significantly lower at T1 than at T0. As for "knowing", at T1 participants reported significantly more correct answers with respect to self-management of diabetes and diabetes-adapted nutrition than at T0. In addition, a

significant improvement was found in their ability to adopt adequate behaviors for the self-management of diabetes, showing that the educational program had helped to increase their know-how. With regard to wellbeing, psychological data suggest that although the Diabetes Quality of Life did not change significantly from T0 to T1, the participants at T1 attributed their health status less to chance than at T0. Moreover, at T1 they showed a greater degree of acceptance of their illness, they relied less on wishful thinking to cope with their illness and they showed a higher overall sense of coping ability to face their illness.

DISCUSSION AND CONCLUSION

4.1 Discussion

The intervention described in this study is part of a broader clinical-educational program for children and adolescents that can be put into operation at the onset of the disease and ends at the age of 25 (Table 1). [13] As mentioned in the introduction, this project aimed to develop knowledge (knowing) and management skills (know-how) implicit in the management of insulin therapy in order to improve the self-efficacy and quality of life related to the disease (wellbeing). The outcome indicators for this study focused on an analysis of the knowledge and management skills of the children and adolescents involved. The aim was to teach them to adapt their insulin needs according to their physical activity and carbohydrate intake. [14,15] Moreover, the overall aim of the PED project was to teach them to adapt their diabetes therapy through promoting an excellent lifestyle.

Overall, results suggest that the intervention program had a positive impact on all the targeted levels indicated for recommended care: the mean HBA1C decreased, whereas the knowledge of diabetes and the number of appropriate behaviors for the self-

management of diabetes increased. With regard to wellbeing, the young participants' acceptance of their illness increased, they relied less on wishful thinking to cope with their illness and showed a higher overall sense of coping ability in facing their illness. In particular, the reduction in the HbA1C value is of great clinical interest. In fact, according to the latest international guidelines [16,17] the HbA1C value should be maintained at <7.5% (59 mmol/mol) also in children and adolescents. The American Diabetes Association [4] set higher HbA1C values for this population of patients, fearing that the risk linked to hypoglycemia could be more harmful than the long-term complications of poorly monitored hyperglycemia. More recent studies, however, have shown that maintaining an HbA1C value of <7.5% (59 mmol/mol) does not increase the risk of hypoglycemia and substantially reduces micro-vascular complications in the long term. [8,17] In our study, the HbA1C value was always higher than 8% (64 mmol/mol); nonetheless it proved to be significantly reduced after the educational project. This aspect, combined with a marked increase in self-monitoring and self-management behaviors, shows the efficacy of our intervention in altering the three levels of "knowing", "know-how" and "wellbeing" required for the quality of life of diabetic patients.

4.2 Conclusion

The results of this study are in line with the approach to chronic diseases proposed by Lacroix and Assal. [18] In particular these authors sustain that a biomedical (technical) approach is insufficient, and even inadequate, when faced with a chronic disease. In fact, medical practice not only requires mastery of both the biomedical model and the integrative-global model but also the acquisition of a new form of dialogue that encourages communication with the patient." This approach envisages therapeutic educational intervention, also defined by the World Health Organization as projects designed "to help

patients and their families understand the disease and the treatment, cooperate with health care providers, live healthily, and maintain and improve their quality of life". [19,20] Therefore, it is essential for patients, especially in the developmental age, to have access to support and guidance in order to accept the disease and acquire general and specific skills for self-management of Type 1 Diabetes (T1D). All areas of educational intervention need to be developed including: Biological-physical, Psychological-mental and Social-relational (Bio-Psycho-Social model) aspects. [1]

In this study, in an attempt to evaluate the developmental age and, more specifically, the period that ends with the educational summer camp, the number of patients analyzed was relatively low. Nevertheless, we were able to make an adequate statistical analysis that shows the efficacy of the method (teaching life skills and empowerment) also for this specific and difficult age group. In fact, educational intervention successfully activated patients' "resources", allowing them to manage the treatment of their disease in a more effective, appropriate and useful way. Furthermore, it must be mentioned that the minimum recommended levels and the best care for the management and treatment of Type 1 Diabetes (T1D) are described in the guidelines but no explanation is given of the procedures used to achieve them. Moreover, it is interesting to observe how the creation of a single team of pediatric diabetologists and adult diabetologists in conjunction with procedures for the transition from the PED project (6-16 ys) to the "Youth Education for Diabetes Project" (17-25 ys), via the "transition ceremony" that takes place at the educational summer camp, allowed the transition from pediatric to adult care to be handled in a non-traumatic, almost physiological manner . [21,22]

4.3 Practice Implications

The project described in this study represents an initial structured intervention program based on a Bio-Psycho-Social model for children and adolescents with Type 1 diabetes.

From the results emerge some important directions that can be applied to the practices of the diabetes education, such as:

1. The importance of working in a multidisciplinary and structured team,
2. The need to have a shared Educational Program that develops over time and it is measurable,
3. The effectiveness to promote educational issues that include clinical, emotional and relational aspects.

The limit of the study is the small sample and the age/sex difference. Further studies are clearly required in order to check our approach and confirm our data with a bigger sample in order to evaluate difference of age and sex dividing the sample in groups. It has to be considered the possibility to use a control group and to evaluate the cost of the intervention.

Acknowledgements

This research received no specific grant from any funding agency in the public, commercial or not-for profit sectors.

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Table 1 – General diagram showing clinical-educational intervention based on patient age and the various stages of the disease.

Phases (age)	Definition of project	Composition of diabetes team	Main activities	Activities/Specific groups
0 Onset	Hospital Protocol	<ul style="list-style-type: none"> - Diabetologist - Nurse - Dietitian - Psychologist 	<ul style="list-style-type: none"> - Hospitalization/diagnosis - Basic education - Support for adapting 	<ul style="list-style-type: none"> - Support among parents (parent support group)
1 Chronic conditions in the pre-school years (0-5 ys)	Pre-school project	<ul style="list-style-type: none"> - Pediatric Diabetologist - Nurse - Dietitian - Psychologist 	<ul style="list-style-type: none"> - Individual medical visit - Specialist consulting as required to other members of the team 	<ul style="list-style-type: none"> - Carbohydrate Counting group (for parents) - Parental support group (with a psychologist)
2 Chronic conditions school years (6-16 ys)	Pediatric Education for Diabetes project	<ul style="list-style-type: none"> - Pediatric Diabetologist - Adult Diabetologist (co-presence at the educational summer camp) - Nurse - Dietitian - Psychologist 	<ul style="list-style-type: none"> - Individual medical visit - Group education (for adolescents/parents) - Educational summer camp 	<ul style="list-style-type: none"> - Parental support group (with a psychologist)
3 Chronic conditions youth (17-25 ys)	Youth Education for Diabetes project	<ul style="list-style-type: none"> - Adult Diabetologist - Nurse - Dietitian - Psychologist 	<ul style="list-style-type: none"> - Individual medical visit - Group education (for youth) 	<ul style="list-style-type: none"> - Carbohydrate Counting group - Insulin Pump group

Table 2: Outcome indicators

OUTCOME INDICATORS	DATA COLLECTED	COLLECTOR	TOOLS
PHYSICAL DATA			
Glycated hemoglobin (HbA1C, mean value)	Blood test data	Nurse	Laboratory data
KNOWING ABOUT DIABETES			
Self-monitoring	Knowing about	Nurse	GISED (10 questions)
Nutrition	Knowing about	Dietitian	GISED (5 questions)
KNOW-HOW FOR SELF-MANAGEMENT			
Self-monitoring	1. Needle replacement	Nurse	Recorded behavior chart + direct observation
	2. Site rotation		
	3. Use of medical devices		
	4. Hand washing		
Nutrition	5. Carbohydrate counting	Dietitian	Recorded behavior chart + simulated
	6. Hypoglycemic correction using the 15/15 rule		
Insulin therapy management	7. Flexibility in managing medical treatment	Pediatric Diabetologist	Medical visit and interview + behavior analysis
	8. Hypoglycemic Kit management		Recorded behavior chart
	9. No. of blood glucose checks (mean of three months)		Recorded with a blood glucose meter
WELLBEING			
Assessment of wellbeing and the ability to cope	Diabetes Locus of Control	Psychologist	Questionnaires
	Diabetes Quality of Life - ado		
	COPE-ado		

Table 3 - Descriptive statistics for variables measured before and after educational intervention

	Measures	Range	T0		T1		F(1,23)	p
			M	SD	M	SD		
Physical data	Mean HbA1c (%)		8.85	0.98	8.54	0.85	5.67	<.05
	Mean HbA1c (mmol/mol)		73		70			
Knowing	Self-monitoring of blood glucose	0-10	7.2	1.8	9.1	1.2	47.26	<.001
	Diabetes adapted nutrition	0-5	3.2	0.8	4.3	0.8	66.86	<.001
Know-know	Presence of adequate behaviors	0-9	2.0	1.3	7.1	2.5	130.02	<.001
Wellbeing								
Diabetes Locus of Control	Internal	6-36	27.8	6.1	27.9	4.6	0.01	.925
	Chance	6-36	13.5	6.0	11.0	3.5	6.32	<.05
	Powerful others	6-36	23.4	5.0	22.3	4.2	1.52	.230
Diabetes Quality of Life								
	Impact of diabetes	11-55	19.0	4.8	18.2	4.4	0.32	.576
	Worries	7-35	10.3	3.9	10.4	4.1	0.00	.959
	Parents	3-15	6.2	2.7	7.1	2.8	4.23	.052
	Satisfaction	17-85	64.3	11.6	66.8	8.3	1.52	.231
Coping								
	Acceptance	6-30	21.6	4.6	23.0	4.4	4.38	<.05
	Avoidance	4-20	10.3	2.4	9.8	2.7	0.54	.472
	Cognitive-palliative	5-25	15.3	4.1	14.0	3.2	3.10	.092
	Distance	4-20	9.1	1.9	8.8	2.9	0.43	.518
	Emotional reaction	6-30	9.0	2.2	8.8	2.6	0.20	.659
	Wishful thinking	3-15	10.6	3.4	8.6	3.8	4.67	<.05
	Overall	1-5	3.5	0.6	3.9	0.7	6.91	<.05

Figure 1: Metaphoric representation of the areas included in the diabetes education project.

