Improved Health-related Quality of Life in Children and Adolescents with Type 1 Diabetes: A Two-year Prospective Family Intervention RCT Study

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Abstract: The aim of this two-year prospective RCT-study was to evaluate children's HRQOL after a family intervention providing support with four sessions for six months following diagnosis of type 1 diabetes (T1DM), with follow-up sessions at 12, 18, and 24 months. Ninety-eight children aged 3-15 years, recently diagnosed with T1DM, participated with their parents. At six and 24 months after diagnosis, the child, mother, and father independently completed the PedsQL 4.0 Generic Scale and PedsQL 3.0 Diabetes Module Scale, and the child's glycemic control (HbA1c value) was measured. After six months, children in the intervention group had better generic HRQOL than the control group ($P < 0.03$). At 24 months, these children and their fathers rated the child's diabetes-specific HRQOL as significantly better ($P < 0.01$, $P < 0.04$) and the child's worry as lower ($P < 0.02$, $P < 0.03$) compared to the control group. Communication skills improved significantly over time in the intervention group ($P < 0.01$). There were no significant differences between control and intervention group regarding glycemic control, measured as HbA1c, either at 6 or 24 months. This study highlights the importance of psychological support after the onset of T1DM, especially facilitating communication skills within the family in the immediate and ongoing care.

Key words: HRQOL, family intervention, RCT, HbA1c, type 1 diabetes, children—adolescents, glycemic control.

1. Introduction

Attention has been paid to psychosocial factors and psychosocial support since the diagnosis of type 1 diabetes mellitus (T1DM) in a child affects the whole family [1]. Previous studies have shown that the parental support of young adolescents after the onset of T1DM has its peak within the first year after diagnosis. After this period it is common that parental involvement decreases [2]. Parental over-involvement is often a starting point for future conflicts, and it is essential to establish a balance in the interaction between parents and the child with T1DM as soon as the diagnosis is established [3]. Children

who get more responsibility for diabetes self-care than is appropriate for their social and cognitive maturity are more likely to have a worse glycemic control [4]. Thus, the importance of discussing and defining responsibility for diabetes management has been highlighted [5]. Parental support and a warm and understanding attitude towards the child have a positive effect on the child's diabetes self-care. Reducing stress among the parents has had encouraging results in improving the interaction between parents and child [6]. Some support has been found for parenting skills training, especially among children with T1DM and behavioral problems [7]. Furthermore, a high parental education level has been shown to have an overall protective effect on the child's glycemic control.

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In summary, the association between family dynamics and glycemic control has been studied nationally and internationally for more than two decades [8, 9]. Methodological questions have been raised, pointing out the need for larger samples in randomized controlled studies in combination with long-term follow-ups [10-12]. The effectiveness of family interventions have been discussed in systematic reviews and some positive effects on family climate, diabetes-related knowledge and glycemic control have been shown [12-14].

Glycemic control has been the primary outcome measurement in a large number of intervention studies. Other outcomes, such as improved health-related quality of life (HRQOL) focusing on diabetes-specific aspects, could be seen as a meaningful goal. Assessment of HRQOL in a clinical setting has been recommended for children with T1DM [15]. Measuring HRQOL is important, since it might help the diabetes team to understand how children and adolescents perceive having diabetes. HRQOL might also indicate the presence of diabetes-related conflict within the family, lower psychological well-being or the occurrence of depression. HRQOL measurement might also contribute to the understanding of poor glycemic control and the design of therapeutic interventions [15-19].

The aim of this study, which is part of a two-year prospective randomized controlled trial (RCT) family intervention study, was to evaluate the effect of this psychological intervention, measured as both generic and diabetes-specific HRQOL at six months after the diagnosis of the T1DM to 24 months after diagnosis. The child, mother, and father independently completed the PedsQL 4.0 Generic Scale and PedsQL 3.0 Diabetes Module Scale. It was hypothesized that the children assigned to the intervention group would report a higher degree of general and diabetes-specific HRQOL than the children in the control group. It was hypothesized that facilitating communication skills training would have a positive effect on glycemic control.

2. Methods

2.1 Study Design

The family intervention study was a randomized, controlled longitudinal study designed to facilitate communication and coping strategies, starting at diabetes onset and continuing for two years. The treatment-as-usual regimen included support from the whole diabetes team except for the specific support of a family psychologist-psychotherapist with special training in diabetes. Families in the intervention group were also provided with therapy sessions focusing on including both parents in the diabetes care of the child and supporting parental communication skills and age-appropriate expectations for the child, to share the responsibility of the treatment and to prevent future conflicts around diabetes treatment (Figure 1).

This family intervention has its theoretical base in developmental psychology, which takes into account that parents need to support their child in different ways according to the age and maturity of the child [20].

2.2 Participants

The participants were recruited at the pediatric diabetes center at the Queen Silvia Children's Hospital, Sahlgrenska University Hospital, Gothenburg, Sweden during the time period October 2008 through December 2011. The total population consisted of 214 children, recently diagnosed with T1DM, and their primary caregivers.

The eligibility criteria were age range 3-15 years, recent onset of T1DM, and fluency in the Swedish language. Children with developmental disability or intellectual disability were excluded, as were children with any significant medical disease in addition to T1DM. Children with well-controlled celiac disease and thyroid disorders were accepted for inclusion. Children receiving their primary medical follow-up at another medical center were excluded. Participation in any other research study was also an exclusion criterion. Parents having a child-custody case were excluded as
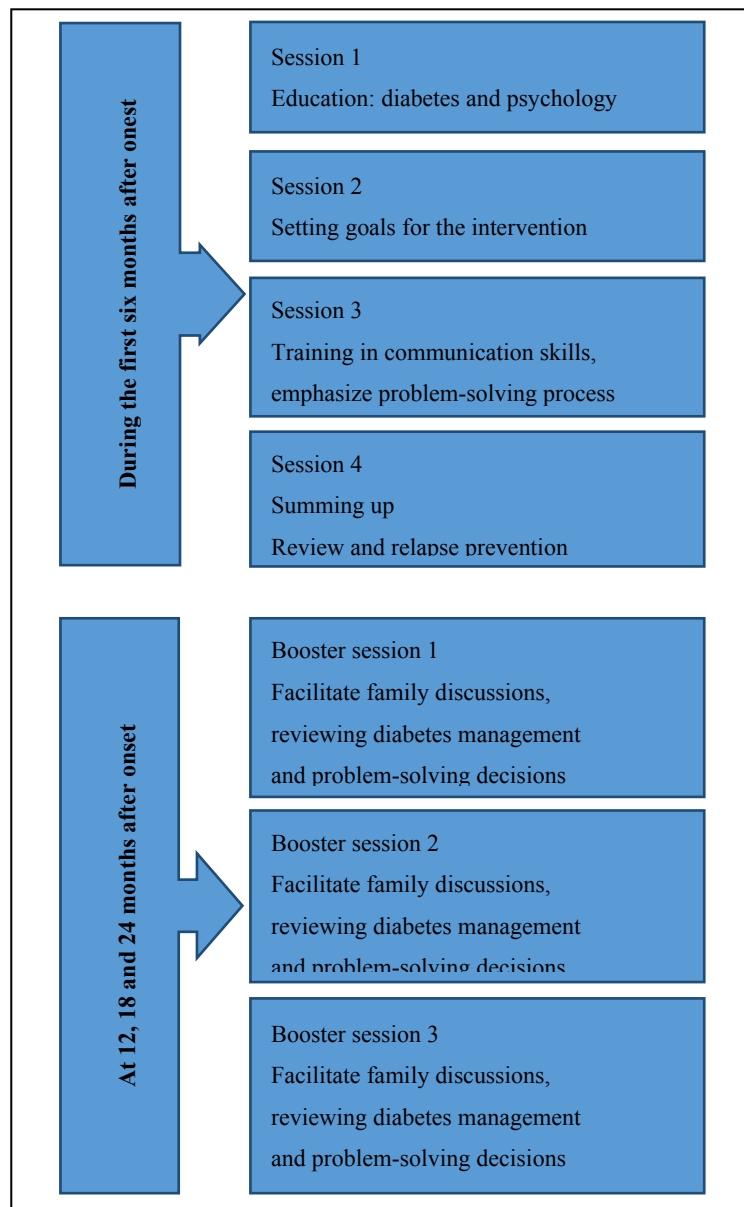
During the first six months after onset

Session 1

Education: diabetes and psychology

Session 2

Setting goals for the intervention

Session 3

Training in communication skills,
emphasize problem-solving process

Session 4

Summing up

Review and relapse prevention

At 12, 18 and 24 months after onset

Booster session 1

Facilitate family discussions,
reviewing diabetes management
and problem-solving decisions

Booster session 2

Facilitate family discussions,
reviewing diabetes management
and problem-solving decisions

Booster session 3

Facilitate family discussions,
reviewing diabetes management
and problem-solving decisions

Fig. 1   Intervention plan.

well. Of the 121 families who met the eligibility criteria, 104 (86%) agreed to participate in the study. At the end of year two, six of the families had chosen to drop out of the study, leaving 98 participants for follow-up (Figure 2). Two of the families were single parent households. In total there were 11 children aged three to four years who did not fill in self-report questionnaires.

2.3 Procedure

The participants were recruited three to five days after the diabetes onset, while still receiving in patient care. The inpatient care was about 7-12 days long. One assigned diabetes nurse or pediatrician informed the families about the study, both verbally and by written letter. The parents and children (8 years old) who agreed to participate in the study were asked to fill out separate informed consent forms. The families were then randomized either to the control group, given treatment as usual, or to the intervention group. The age-groups were stratified into 3-7.99 and 8-15 years in order to control for age in intervention and control group. The families in the intervention group received
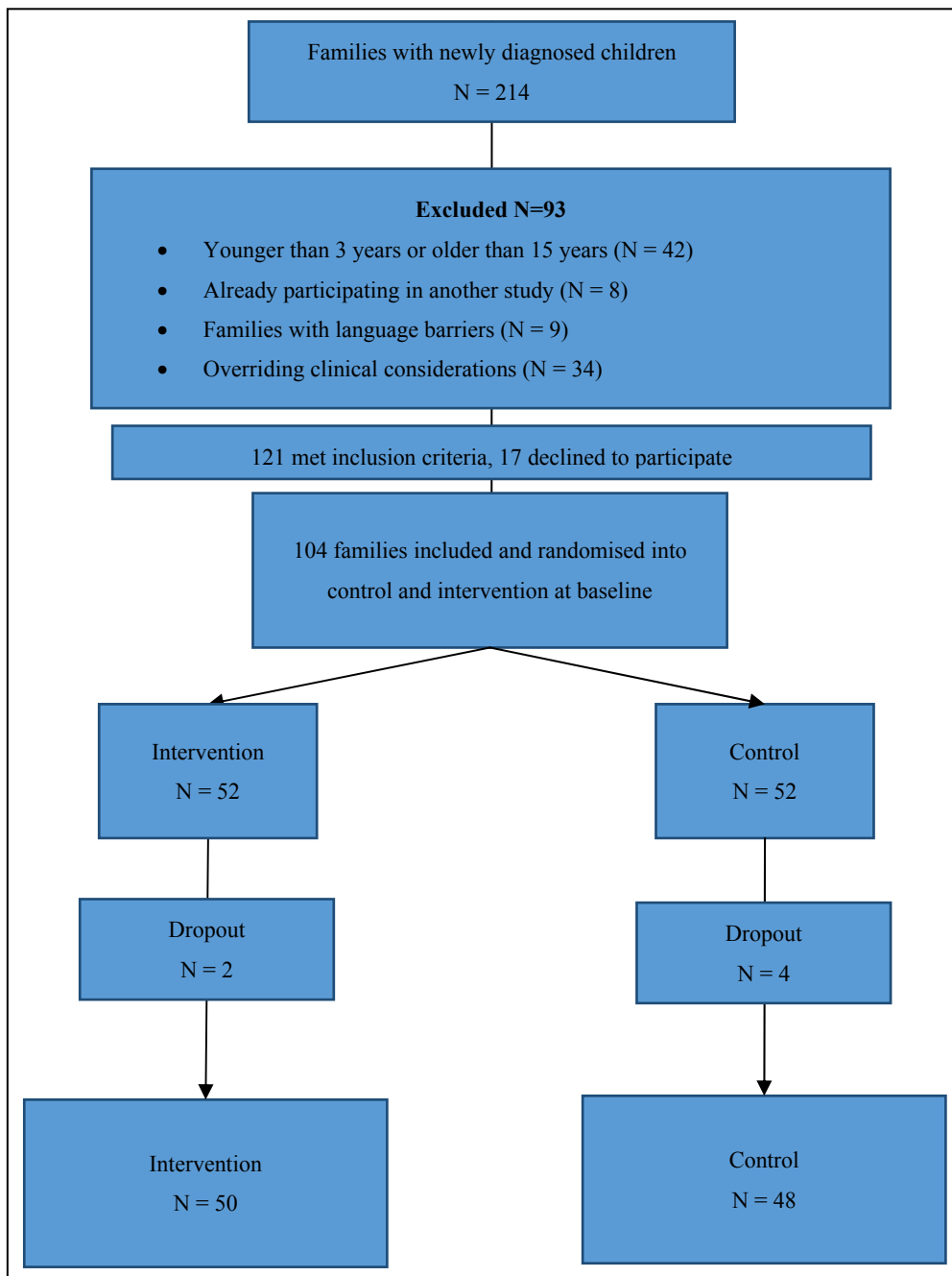
Fig. 2   Selection of participants.

four scheduled sessions with a pediatric psychologist during the first six months, with three follow-up sessions between year one and two. For preschool children the intervention was adapted in the form of parental training. For children above the age of six, the intervention was family-based, parents and siblings were invited to participate.

The current study examines data from the six-month and 24-month data sets in the family intervention study. Study measurements were collected at the pediatric diabetes center during the children's scheduled medical outpatient visits. An assigned research assistant collected the study data and assisted the children and caregivers in completing the questionnaires when needed. Children, mothers, and fathers were asked to answer the questionnaires separately. The study was

performed in accordance with the Declaration of Helsinki and was reviewed and approved by the Regional Ethical Review Board of Western Sweden.

2.4 Measures

2.41 Health-related Quality of Life

Each item in the PedsQL 3.0 and PedsQL 4.0 is measured by a five-point Likert scale where 0 = never a problem and 4 = always a problem, except for the three-point Likert scale (where 0 = not at all, 2 = sometimes, 4 = a lot) used in the child report for the five- to seven-year-olds.

The PedsQL 3.0 Diabetes Module Scales consists of 28 items and five scales: 1. diabetes symptoms (11 items), 2. treatment barriers (four items), 3. treatment adherence (seven items), 4. worry (three items), and 5. communication (three items).

The PedsQL 4.0 Generic Core Scales consists of 23 items and covers four scales: 1. physical functioning (eight items), 2. emotional functioning (five items), 3. social functioning (five items), and 4. school functioning (five items; in the age group two to four years, three items). The psychometric properties of the Swedish versions of the PedsQL 3.0 and the PedsQL 4.0 have shown acceptable psychometric properties [21-23].

2.4.2 Parent Educational Level

Parent educational level was measured in the demographic questionnaire as a two-point categorical variable where parents were asked to report their educational level as 12 years or less (primary school, college), or more than 12 years of education (Table 1).

2.4.3 Glycemic Control

HbA1c was measured with DCA Vantage (Siemens Healthcare Diagnostics Inc., Tarrytown NY, USA) with a normal value of 27-42 mmol/mol (4.6-6.0% NGSP). The quality was assured in accordance with Equalis (External quality assurance in laboratory medicine in Sweden, www.equalis.se). There was no deviation from the set targets during the study period. All patients were initially treated with intravenous insulin for one to three days, there after with multiple daily injections (MDI) or insulin pump.

2.5 Statistical Analysis

Statistical analyses were performed with IBM SPSS for Windows, version 20. Descriptive statistics were calculated for the background variables. Internal consistency of the PedsQL 3.0 and PedsQL 4.0 Total Scale Scores was assessed with Cronbach's alpha for child, mother, and father reports [24]. Correlations between gender and HRQOL and between age and HRQOL were made using the Pearson product-moment correlation coefficient. Fisher's permutation test was used to test the differences between control group and intervention group regarding HbA1c [25, 26]. The level of significance was set to $P = 0.05$.

2.6 Power Analysis

Whereas the level of HbA1c varies as the most during puberty, the calculation was based on the distribution of the variation in measurements taken in 2004, on 2,883 patients in the age group 10-15 years. The estimated standard deviation of the individual HbA1c measurements of an individual was set to about 0.7% (Mono S). This means that the difference between two individual measurements should be one standard deviation. If the average change in the two groups, (fifty families in the intervention group and fifty families in the control group) is differentiated with 0.7 points as in the family intervention the power is 0.89, i.e. 89% probability in order to identify such difference at a level 5% of significance.

3. Results

3.1 Descriptive Statistics

The mean age for the children in the sample was 8.9 years and 54% were boys (Table 1). In the control group, HbA1c values at six months ranged from 38 to 78 mmol/mol with a mean value of 52.8 mmol/mol (mean value 7.0% NGSP, range 5.6-9.3% NGSP). In the intervention group, HbA1c values ranged from 33

to 104 mmol/mol with a mean value of 53.8 (mean value 7.1% NGSP, range 5.2-11.7% NGSP) mmol/mol.

At 24 months, HbA1c values in the control group ranged from 42 to 91 mmol/mol with a mean value of 59.1 mmol/mol (mean value 7.6% NGSP, range 6.0-10.5% NGSP). In the intervention group, HbA1c values ranged from 33 to 96 mmol/mol with a mean value of 57.2 (mean value 7.4% NGSP, range 5.2-10.9% NGSP) mmol/mol (Table 4).

There were no significant correlations between any of the background variables (age, gender, HRQOL, and HbA1c) at either six or 24 months.

The level of education among the parent groups was generally high, especially among mothers: 64% of the mothers and 46% of the fathers had more than 12 years of education (Table 1).

3.2 Internal Consistency

The PedsQL 3.0 Diabetes Module Total Scale Score reached high Cronbach's alpha coefficients for child, mother, and father reports ($\alpha = 0.88$, $\alpha = 0.89$, and $\alpha = 0.87$, respectively). The total PedsQL 4.0 Generic Core Total Scale Score also reached high Cronbach's alpha coefficients for child, mother, and father reports ($\alpha = 0.88$, $\alpha = 0.89$, and $\alpha = 0.89$, respectively).

3.3 Outcomes of HRQOL at Six Months

At six months after onset of T1DM, children in the intervention group estimated their generic HRQOL higher than the control group did ($P = 0.03$), (Table 2),

(Cohen's $d = 0.50$).

Mothers in the control group gave higher estimates of their child's communication skills than mothers in the intervention group did ($P = 0.04$) (Table 2), (Cohen's $d = 0.40$).

Fathers, as well as the children, in the intervention group estimated their child's worry significantly lower than fathers in the control group did ($P = 0.03$, $P < 0.01$), (Table 2), (Cohen's $d = 0.56$) and (Cohen's $d = 0.61$).

3.4 Outcomes of HRQOL at 24 Months

After 24 months, the children in the intervention group reported significantly better diabetes-related HRQOL ($P < 0.01$), less worry ($P = 0.01$) and better communication skills ($P < 0.00$) than the control group (Table 3), (Cohen's $d = 0.71$, (Cohen's $d = 0.61$) (Cohen's $d = 1.05$).

There were no significant differences between the intervention group and the control group in how mothers estimated their child's HRQOL at 24 months (Table 3).

Fathers in the intervention group similarly gave higher ratings of their child's diabetes-related HRQOL ($P = 0.04$) and emotional functioning ($P < 0.01$), lower levels of worry ($P < 0.03$) and fewer problems with diabetes symptoms ($P = 0.04$) than fathers in the control group did at 24 months after the onset of the child's T1DM (Table 3), (Cohen's $d = 0.40$), (Cohen's $d = 0.53$), (Cohen's $d = 0.57$) and (Cohen's $d = 0.48$) .

Table 1   Background characteristics.

	Intervention	Control		
Boys (N)	22	31		
Girls (N)	28	17		
Children in total (N)	50	48		
Age (Mean and range)	8.8 (3-15)	9.0 (3-15)		
Parents	Mothers	Fathers		
194 (N)	97	97		
HbA1c (mmol/mol) at 3 months (Mean and range)	50 (36-88)			
	Mothers (Intervention)	Mothers (Control)	Fathers (Intervention)	Fathers (Control)
Education 12 years or less %	35	37	51	57
Education more than 12 years %	65	63	49	43

Table 2 Comparison between mothers, fathers and children in the control and intervention groups at six months after onset of type 1 diabetes, the lower mean the better.

	Intervention		Control		P-value
	Mean	SD	Mean	SD	
PedsQL 3.0 Mothers Total Scale	1.01	0.46	0.88	0.49	0.1993
Diabetes Symptoms	1.23	0.58	1.10	0.56	0.2427
Treatment Barriers	0.89	0.58	0.96	0.62	0.5650
Treatment Adherence	0.89	0.62	0.73	0.59	0.2070
Worry	0.77	0.81	0.72	0.90	0.7760
Communication	0.87	0.95	0.51	0.77	0.0425* -
PedsQL 3.0 Fathers Total Scale	0.79	0.39	0.84	0.41	0.3946
Diabetes Symptoms	1.06	0.45	1.06	0.47	0.8204
Treatment Barriers	0.75	0.53	0.85	0.65	0.4081
Treatment Adherence	0.60	0.49	0.60	0.50	0.6548
Worry	0.47	0.53	0.82	0.70	0.0309* +
Communication	0.58	0.81	0.56	0.69	0.6974
PedsQL 3.0 Children Total Scale	0.82	0.42	0.93	0.45	0.2529
Diabetes Symptoms	1.23	0.56	1.37	0.54	0.1616
Treatment Barriers	0.73	0.65	0.82	0.67	0.7938
Treatment Adherence	0.51	0.57	0.49	0.46	0.6715
Worry	0.49	0.76	0.65	0.69	0.2870
Communication	0.54	0.68	0.72	0.78	0.4611
PedsQL 4.0 Mothers Total Scale	0.59	0.31	0.61	0.49	0.9735
Physical Functioning	0.30	0.37	0.37	0.45	0.9398
Emotional Functioning	0.88	0.65	1.01	0.75	0.5794
Social Functioning	0.45	0.48	0.39	0.53	0.8735
School Functioning	0.90	0.58	0.79	0.69	0.6851
PedsQL 4.0 Fathers Total Scale	0.47	0.31	0.56	0.44	0.8222
Physical Functioning	0.26	0.31	0.35	0.48	0.5613
Emotional Functioning	0.72	0.53	1.02	0.71	0.2486
Social Functioning	0.38	0.40	0.42	0.50	0.7559
School Functioning	0.66	0.63	0.58	0.60	0.4534
PedsQL 4.0 Children Total Scale	0.53	0.33	0.77	0.60	0.0332* +
Physical Functioning	0.40	0.31	0.60	0.69	0.0978
Emotional Functioning	0.55	0.51	0.92	0.69	0.0080** +
Social Functioning	0.45	0.55	0.73	0.83	0.1174
School Functioning	0.79	0.51	0.95	0.63	0.3538

Test of correlation by use of Fisher's permutation test, the sign + or - in the column P-value indicate whether the correlation is positive or negative.

Table 3 Comparison between mothers, fathers and children in the control and intervention groups at 24 months after onset of type 1 diabetes, the lower mean the better.

	Intervention		Control		P-value
	Mean	SD	Mean	SD	
PedsQL 3.0 Mothers Total Scale	1.12	0.58	1.04	0.51	0.4887
Diabetes Symptoms	1.26	0.64	1.26	0.58	0.9565
Treatment Barriers	1.03	0.74	0.97	0.67	0.6827
Treatment Adherence	1.11	0.80	0.93	0.61	0.2760
Worry	0.85	0.75	0.85	0.70	0.9684
Communication	0.87	0.86	0.76	0.84	0.4841
PedsQL 3.0 Fathers Total Scale	0.79	0.39	0.98	0.50	0.0401* +

Table 3 continued

	Intervention		Control		P-value
	Mean	SD	Mean	SD	
Diabetes Symptoms	0.97	0.41	1.22	0.61	0.0342* +
Treatment Barriers	0.84	0.65	0.92	0.59	0.6451
Treatment Adherence	0.67	0.55	0.83	0.59	0.2494
Worry	0.49	0.52	0.87	0.78	0.0287* +
Communication	0.64	0.88	0.66	0.79	0.6744
PedsQL 3.0 Children Total Scale	0.72	0.40	1.07	0.57	0.0095** +
Diabetes Symptoms	1.21	0.64	1.43	0.69	0.0822
Treatment Barriers	0.6	0.48	0.99	0.80	0.1032
Treatment Adherence	0.28	0.39	0.65	0.54	0.0597
Worry	0.34	0.45	0.78	0.81	0.0136* +
Communication	0.42	0.63	1.19	0.83	0.0001*** +
PedsQL 4.0 Mothers Total Scale	0.72	0.44	0.61	0.48	0.1963
Physical Functioning	0.50	0.48	0.38	0.45	0.3198
Emotional Functioning	1.03	0.66	0.81	0.66	0.1959
Social Functioning	0.48	0.56	0.49	0.60	0.6598
School Functioning	1.01	0.66	0.89	0.61	0.1592
PedsQL 4.0 Fathers Total Scale	0.51	0.35	0.60	0.38	0.0664
Physical Functioning	0.35	0.40	0.33	0.32	0.8571
Emotional Functioning	0.65	0.48	0.97	0.7	0.0054** +
Social Functioning	0.37	0.39	0.52	0.50	0.0938
School Functioning	0.79	0.6	0.77	0.48	0.2257
PedsQL 4.0 Children Total Scale	0.62	0.43	0.76	0.60	0.0926
Physical Functioning	0.46	0.39	0.54	0.57	0.1502
Emotional Functioning	0.81	0.66	1.05	0.86	0.2789
Social Functioning	0.53	0.66	0.56	0.77	0.5614
School Functioning	0.79	0.51	1.03	0.6	0.1847

Test of correlation by use of Fisher's permutation test, the sign + or - in the column *P*-value indicate whether the correlation is positive or negative.

Table 4   Insulin regimen.

MDI/CSII	(%)
At 6 months	80/20
At 24 months	60/40
HbA1c (mmol/mol)	
6 months / 24 months after onset	Mean (SD)
Whole group	53.3 (11.4) / 58.1 (11.9)
Control	52.8 (8.8) / 59.1 (11.4)
Intervention	53.8 (13.5) / 57.2 (12.3)

3.5 Glycemic Control

There were no significant differences between control and intervention group regarding glycemic control, measured as HbA1c, either at 6 or 24 months.

4. Discussion

This study evaluated a structured psychological intervention starting immediately after T1DM onset, with follow-up communication skills training sessions that included the family members of the child with diabetes. We hypothesized that this family intervention could improve the children's HRQOL two years later.

Overall, children and adolescents in the intervention group had a significantly better generic HRQOL by six

months after the onset of diabetes. The results suggest that offering family psychological support to the child and parents together could enable these children to adapt to living with diabetes and still perceive themselves as having a normal everyday life.

At 24 months, the children and adolescents in the intervention group gave higher ratings for their communication skills than they did at six months, whereas the control group indicated that their communication skills had decreased over time. The results are encouraging, since the intervention was to a large extent based on supporting communication skills within the family and to avoid future conflicts around the diabetes management, to share the responsibility, and to have age appropriate expectations of the child's own ability, elements shown to be important in earlier intervention studies [4, 5, 10-12].

Mothers especially, but also fathers, assessed their child's HRQOL differently than the children themselves, which is line with earlier studies [21, 27]. The fathers in the intervention group had lower estimates of their child's worry than the fathers in the control group; this was true both at six and 24 months. Furthermore, the children in the intervention group perceived themselves as having less worry than the control group at 24 months after T1DM onset. It might reflect the fact that the children and adolescents in the intervention group had an opportunity to verbalize their experiences of the diabetes-specific issues that worried them. The family intervention may also have helped them to communicate with their parents and the diabetes team about their diabetes management.

At 24 months, the fathers in the intervention group estimated their child's emotional functioning to be higher in comparison to the ratings by fathers of the control group children at 24 months. They also observed that their child had fewer diabetes symptoms and overall an improved diabetes-related HRQOL, as reported by the children themselves. In the control group the fathers perceived that their child's school functioning had decreased over time.

This study found that the fathers, children, and adolescents in the intervention group estimated an improved diabetes-related HRQOL at 24 months. It was somewhat different for the mothers and generally they estimated the child's HRQOL to be lower, in line with a result reported recently [28]. It has been suggested that assessing a child's HRQOL by proxy could reflect the burden of care-giving and parental well-being [29]. There were no significant differences concerning the mothers' assessment of their child's HRQOL in the intervention group versus the control group. Earlier studies show that mothers often tend to be over-involved and internalize psychological aspects of their child's disease [30]. This fact might be reflected in our results.

There were no significant differences in the HbA1c values between the intervention and the control group at diagnosis, 6 or 24 months. Previous studies have shown significant positive correlations between a HRQOL and glycemic control [17, 31]. Therefore it will be of interest to see how these results develop over time.

There are some limitations to this study. The parents in the study sample consisted of a rather homogenous group regarding education level, with as many as 64% of the mothers and 46% of the fathers having a high level of education. Furthermore, the fact that only 7% had an immigrant background adds to the homogeneity of the sample. A more diverse sample would have added to the generalizability of the results. In randomized controlled trials, analyses are often based on intention-to-treat since there may be many drop-outs, and these may be non-differential regarding baseline characteristics and/or randomization arm. In the present study there were only six drop-outs, four in the control arm and two in the intervention arm. Therefore we consider our findings to be valid without taking these drop-outs into account.

Furthermore, the study could not demonstrate a significant difference in the change of HbA1c but there was a tendency ($P = 0.1810$). The study material

has to be enlarged by a factor 4.4, so the total number of patients equal 440, in order to give the power of 80%.

5. Conclusions

In summary, we conclude that this two-year prospective family intervention study, with a focus on supporting and strengthen in communication skills within the family after the onset of T1DM, presents promising results. The children in the intervention group presented several indications of an improved general and diabetes-specific health-related quality of life. Fathers of the intervention group estimated their child´s emotional functioning as being better and with less diabetes related symptoms.

Involving both parents, not only immediately after T1DM onset but also during two years of ongoing care had a positive impact on the children's and adolescents' HRQOL.

Acknowledgments

Key Notes

Assessment of HRQOL in a clinical setting has been recommended for children with T1DM.

The effectiveness of family interventions has shown promising results, although methodological questions have been raised, like need for larger samples in randomized controlled studies in combination with long-term follow-ups.

This RCT-study concludes that involving both parents, not only after T1DM onset but also during two years of ongoing care had a positive impact on the children's HRQOL.

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