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Hvidoere Smiley Faces: International Diabetes Quality of Life assessment tool for young children

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Running Title Page

Smiley Faces: Diabetes Quality of Life

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Abstract

Background: Few diabetes-specific Quality of Life (QOL) tools are available for young children.

Objectives: Design and evaluate, a new age specific QOL questionnaire and its associations with treatment regimens and metabolic control.

Methods: Clinical, demographic data and centrally analysed HbA1c were collected on 1133 children <11 years (girls 48%; mean $\pm$ SD age 8.0 ± 2.1 years; diabetes duration ≤ 1 year) from 18 centres (Europe Japan and North America and Australia). Children completed the 10-item Smiley Faces QOL questionnaire constructed for the study, and children ≥ 7 years also completed the KIDSCREEN-10 Index.

Results: 1035 children completed the new Smiley Faces questionnaire which was well understood by 993 (70% ≥ 4 and 96% ≥ 5 years old, respectively). Internal consistency and reliability were good (Cronbach's $\alpha = 0.73$). Inter-item correlation ranged $r=0.047-0.451$ indicating each item measures separate aspects of children's satisfaction construct.

Convergent validity assessed by comparison to the HrQOL KIDSCREEN-10 Index showed moderate correlation coefficient 0.501. Factor analysis revealed 3 factors explaining 51% of the variance. Children reported good QOL with most items positive, mean values between 1-2 on a 5-point scale (lower scores indicating greater QOL). Diabetes satisfaction was unrelated to age, diabetes duration, HbA1c, or severe hypoglycaemia. Girls were more satisfied than boys. Children on intensive regimens reported better QOL ($P<0.02$). Main dissatisfaction related to insulin injections and blood sugar testing.

Conclusions: The Smiley Faces questionnaire enables QOL assessment in young children

and identification of areas of dissatisfaction and other clinically relevant items relating to diabetes management.

Introduction

The assessment of Quality of Life (QOL) is now a recommendation in the care of children and adolescents with diabetes (1), and the American Diabetes Association recently released a position statement on the psychosocial care of people with diabetes. Included is a recommendation that clinicians should “Consider assessing youth with diabetes for generic and diabetes related distress starting at about 7–8 years of age.”(2). Whilst the American Diabetes Association guidelines also recommend a number of measures for specific issues and population groups, no self report measures are recommended for children under 7 years of age. This is possibly due to the fact that there are few quality of life or related tools available for young children.

Available tools for children include the KIDSCREEN generic HrQOL and the DISABKIDS Diabetes Module (3). However these are suitable for children aged 8 to 12 years and require the administration of 2 separate questionnaires to children (4-6). Tools for under 8 years are limited and include the PedsQL for 5-7 year old children which has a 23 item diabetes specific questionnaire which needs to be completed along with an additional separate generic questionnaire which makes it impractical for regular use in clinical contexts (7). The DISABKIDS-Smileys is available for 4 to 7 years and is a brief questionnaire to assess health

related quality of life and the levels of distress caused by a chronic disease, but it is not a diabetes specific tool.

Parent proxy measures are also available for young child including KIDSCREEN and PedsQL measures however it is known that proxy and self-report QOL assessments differ between parents and children (8, 9).

To our knowledge when commencing the study in 2009 there was no available diabetes QOL self-report measure for children less than 8 years that is comprehensible for young children and assesses both generic and diabetes specific issues. Our major aim to develop and test a single short questionnaire to address both diabetes and generic QOL issues that could be used in the clinical context. This type of assessment is difficult in very young children where we rely on verbal responses from children with limited and varied cognitive abilities. A pictorial scale was developed, whereby a child is presented with a series of faces, ranging from a happy smiling face to a sad tearful face, as this provides a format that seems more appropriate for this younger age group. This approach has been shown to be effective for assessments of painful medical procedures and events (10,11) and has been used as a tool for assessment of quality of life in this age group (12).

Therefore, the purpose of this Hvidoere study 2009 was to determine, in a large international cohort of young children with Type 1 Diabetes (T1D) aged under 11 years, metabolic control and QOL, and to develop a brief, easy to complete clinically useful diabetes specific QOL questionnaire. The aim is to enable the development and provision of an individually tailored

and precise treatment based on knowledge regarding the challenges the individual child has to overcome.

Methods

Full details of the methodology have been reported previously (13,14). Clinical and demographic data were collected on 1133 children (girls 48%) under 11 years of age and their parents from 18 Centres in Australia, Europe, North America and Japan with diabetes for more than one year. The mean age was 8.0 years $\pm$ 2.1 years (range 1.8 -11 years), diabetes mean duration 3.8 years $\pm$ 2.1 (mean $\pm$ SD). Insulin regimens comprised of conventional <3 injections/day (CT) 36.5%; conventional premix (CT Premix) 6.3%; (CT+) 2 injections of free-mix + rapid analogue as necessary) 7.5%; Insulin pump (CSII) 32.8%; Intensive (ICT) e 3 injections/day 16.9% (14). HbA1c was analysed centrally at Steno Diabetes Center in Denmark (DCCT aligned normal range 4.4-6.3% (24.6-45.4 IFCC mmol/mol)). Overall 93.7% of eligible patients participated in the study.

Invitation letters and accompanying information sheets were sent to parents and the child one week in advance of their clinic appointment. At the clinic the child and accompanying adult(s) were provided with the documents. The children aged 4 years and older were asked to complete the Smiley Faces Diabetes Specific QOL questionnaire and those aged 8 years and older were asked to also complete the KIDSCREEN 10 generic HrQOL questionnaire (15), which is designed and used for healthy and chronically ill children with normative data available in many European countries. Children completed the questionnaire independently of parents, either in the absence of or at a distance from parent(s) and accompanied by an instructed health professional who explained the questionnaire and read the items if necessary following written guidelines. These health professionals also rated whether the child understood the questions from: not at all, only some parts, most parts and completely, and also assessed the length of time it took for the child to complete the questionnaire. In addition the Kidscreen-27 proxy questionnaire was presented to the primary caregiver to assess his/her child's Health related QoL (3). The Questionnaire consists of 27 items combined to 5 dimensions, physical well-being, psychological well-being, autonomy and parent relation, social support and peers, and school/kindergarten.

Diabetes Quality of Life Questionnaires for children

The new 10 item QOL questionnaire includes the four quality of life domains as identified in the major review of this area: disease state and physical symptoms, functional status, psychological functioning and social functioning (16). Items relate to: well-being, diabetes, food, injections, blood sugar, diabetes clinic, parents, school, friends and general health perception on a 5 point scale. These issues were identified from literature review and multidisciplinary clinical discussion as the most concern to children, families and professionals. Items were scored 1-5; a lower score indicated greater satisfaction. The instrument was first developed in English, and then translated into 15 languages. Translation of the questionnaires was performed by a forward translation from English followed by an independent backward translation which was endorsed by the originators of the first English version see Figure 1.

INSERT FIGURE 1 ABOUT HERE

Analysis

Data were all double entered at a central administration center. Ambiguous data on the CRF were resolved by direct contact with participating centers. Factor analysis was undertaken using principal components analysis of the covariance matrix, using an oblique rotation. Factor number and structure was determined by identification of the point of inflection on the scree plot, and simple structure in the factor loadings. Statistical analysis was performed using analysis of variance, Spearman's rank correlation coefficient, Cronbach's alpha coefficient value and principle component factor analysis.

The study was performed according to the criteria of the Helsinki II declaration, and ethical approval was obtained from the relevant regulatory or institutional Ethics Committee in each country and centre.

Results

Details of the whole sample have been characterized above and published elsewhere (13).

From 1133 participants from 18 centres, in 17 countries overall, 1035 children 4 years or older answered the Smiley Faces Questionnaire. Mean age of this subgroup was 8.3 ± 1.8 years (range 4-11 years), 47.3% female, mean duration of diabetes 3.4 ± 2.1 years, 49.7% on infusion pumps or basal bolus regimens, mean HbA1c 8.0 ± 1.0 % ($\pm$ SD) (64 ± 8 mmol/mol). As previously reported, glycaemic control was not associated with age, diabetes duration, gender, family, co- morbidity, severe hypoglycaemia or DKA (13).

The questionnaire was understood completely or in most parts by 70% of 4 year olds but by more than 96% of children $\geq$ 5 years as rated by health professional (See fig 2). Only data of children that were rated as completely or in most parts understanding the task and answering all items were included in the following analyses ($n = 993$).

INSERT FIGURE 2 HERE (Understanding of Smiley Faces Questionnaire by Children)

The mean time needed to complete the Smiley Faces questionnaire was 6.21 ± 4.0 minutes. The frequency of responding for each item is shown in Table 1. All ten items had each response option endorsed by at least 1% of the responses, with 6 of the 10 items having all response options endorsed by at least 4% of the children. All items responses showed marked skewness towards the more positive end of the scale.

INSERT TABLE 1 HERE

Factor analysis of the items identified the point of inflection to be at three factors, accounting for 51% of the variance. Examination of the factor loading in the pattern matrix indicated a simple structure with 9 items loading greater than 0.4 on only one factor and no double loadings, see Table 1. The first item (at the moment I feel very happy) and last item (I feel good and healthy) loaded on a single scale, referred to as **Well-being**. Four items (feel about diabetes, blood sugar tests, insulin and clinic) loaded on the second factor, referred to as Diabetes, which had adequate internal consistency, with a Cronbach's alpha of 0.69. The parent, school and friends items all loaded on a third factor, referred to as Social, with a relatively poor internal consistency, $\alpha = 0.44$. The diet item did not load on any factors above 0.4, and if the items were treated as one, unidimensional scale the internal consistency was good, Cronbach's $\alpha = 0.73$, with inter-item correlation ranging from 0.047 to 0.451, indicating each item measures separate aspects of children's happiness. **For the subgroup of children aged 4-8 years internal consistency was also good, Cronbach's $\alpha = 0.71$.** The three factors and a total item score were calculated, by simple summation. The three factors were strongly correlated with the total score and the Diabetes scale has the highest

correlation, 0.88 (0.6 and 0.66 for the other two scales). Between factor correlations were moderate (0.30 -0.36), indicating they are assessing distinct aspects of children's happiness.

Convergent validity was explored through exploring associations within the cohort of children over 8 years, who completed the Diabetes Smiley Quality of Life Questionnaire and KIDSCREEN-10 Index. Children's response to the KIDSCREEN-10 was similar to European norms 53.90 ± 10.71 vs. sample 54.22 ± 10.10 ($p=0.626$). For the 737 children who completed both measures there was strong correlation between the total score of the Smiley Faces questions and the KIDSCREEN-10 ($r=0.501$), with the factors all correlating moderately with the KIDSCREEN (Well-being $r=0.491$, Diabetes $r=0.392$, Social $r=0.349$). The associations of SMILEY total score with all 5 dimensions of the parents' Kidscreen 27 proxy questionnaire on Health related Quality of life were significant but small ranging from 0.247 (psychological well-being) to 0.191 (social support and peers).

The mean sum score of the Smiley Faces measure was 19.2 ± 5.5 (range 10-41), with girls reporting a significant lower value (=happier) compared to boys (18.8 ± 5.3 vs 19.5 ± 5.7 ; $p=0.038$).

Children's response to the Smiley Faces measures, subscale or total, was not related to their age, duration of diabetes, HbA1c, frequency of hypoglycaemia or DKA. Children on intensive insulin regimens (ICT / CSII) scored lower (= happier) on the total score on the Smiley Faces Measure (ICT/CSII 18.6 ± 5.4 vs Conventional Therapies 19.9 ± 5.9 , $p=0.001$) and on the

Diabetes Factor (ICT/CSII 9.08 ± 3.4 vs Conventional Therapies 10.1 ± 3.7 , $p = 0.001$, but there was no difference for the **Well-being** ($p > 0.75$) or Social ($p > 0.11$) factor scores (See fig 3).

INSERT FIGURE 3 HERE (Child QOL sum score by insulin regimen)

Discussion

A new diabetes specific QOL questionnaire appropriate for young children with diabetes was developed and analysed based on the data of 993 participants from 18 paediatric diabetes centers in four continents. The scale is comprised of both disease specific and generic items. When used as a full scale in an international setting, the questionnaire showed good evidence of feasibility, internal consistency and validity even in the youngest aged 4-8 years. It enables the identification of clinically relevant aspects relating to the practical management of diabetes in young children in a busy clinical setting. The psychometric adequacy and acceptability indicates its value as a QOL assessment tool for young children which is brief, easy to administer and score, and may be used also to facilitate communication between child, parent and health professional. The questionnaire is translated into 16 languages and provides an international resource for clinicians and researchers to assess and compare diabetes specific QOL-related issues in an economic and child appropriate way. Possible limitations of the study include that due to the cross-sectional study design no data on retest-reliability are available and should be assessed in another study, furthermore further research is required increase our understanding and justify cut-off values for structured educational, psychosocial, or therapeutic interventions in the future.

In this international study we found that the majority of young children with diabetes have a good QOL not different from the background population of the same age. This may reflect the fact that at this age their parents take most of the responsibility and burden of diabetes management. Young children's cognitive ability to understand the chronicity and severity of

the disease and the future perspective is limited and might be one reason for their subjective positive well-being (17). On the other hand it is known from many cross-sectional studies with older diabetic youths that glycemic control and QOL are related to each other with better QOL observed in patients with lower hemoglobin A1c (18,19,20). Some current longitudinal studies have observed that poor QOL predicted less frequent blood glucose measurement and adherence along with poorer diabetes control (21,22). This is another argument to screen regularly for impaired QOL in order to identify individual burdensome psychosocial issues even in the youngest cohort of children with diabetes.

In a previous study we reported that adolescent females were more worried, had less satisfaction with life and had poorer health perception compared to adolescent males (18). Surprisingly girls in this younger age group, unlike adolescent females, are more satisfied than boys. The finding of a good QOL in the majority of children in this young age group nevertheless highlights the importance of assessing and repeatedly monitoring the health related QOL in children with diabetes in order to identify those vulnerable boys and girls with particular difficulties even at an early stage. As the course of future acceptance of diabetes is set very early in childhood, child specific interventions to reduce stress and burden are crucial for their long term physical and emotional well-being. A holistic approach including psychosocial support is required, endeavouring to prevent the development of poorer QOL and metabolic control at a later age particularly in girls (23-25).

The main area of **diabetes-specific** dissatisfaction detected in this study **in addition to having diabetes** was related to insulin injections and blood sugar testing. However, children on intensive insulin regimens **in this sample** had generally a better QOL than those on conventional regimens. This may reflect the better blood **glucose** control and freedom associated with **intensive regimens despite additional insulin injections and blood sugar testing (24,26)**. With currently increasing acceptance of continuous glucose monitoring (CGM) and other new technologies it is important to focus not only on metabolic outcome but also on the consequences of children's emotional well-being and diabetes-specific QOL (27,28). Identifying indicators of poor QOL and psychosocial factors in young children is important in relation to their ongoing QOL and diabetes care. The Smiley Questionnaire provides a first step in this process and creates a basis for a tailored child appropriate treatment for diabetes.

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Table 1. Smiley Faces Satisfaction Responses: Distribution of answers

Factor 1 Diabetes (feel about diabetes, blood sugar tests, insulin and clinic; Factor 2 Social (parent and school friends); Factor 3 (Wellbeing) (item 10)

Items	1 very happy	2	3	4	5 very unhappy	Factor 1 Diabetes	Factor 2 Social	Factor 3 Well being
1. Overall happiness	549 (55.3%)	302 (30.4%)	118 (11.9%)	14 (1.4%)	10 (1.0%)			.53
2. Diabetes	219 (22.1%)	249 (25.1%)	280 (28.2%)	113 (11.4%)	132 (13.3%)	0.72		
3. Eating and drinking	501 (50.5%)	271 (27.3%)	157 (15.8%)	45 (4.5%)	19 (1.9%)			
4. injections/pump	302 (30.4%)	229 (23.1%)	217 (21.9%)	126 (12.7%)	119 (12.0%)	0.83		
5. Blood sugar testing	305 (30.7%)	285 (28.7%)	276 (27.8%)	75 (7.6%)	52 (5.2%)	0.71		
6. Diabetes Clinic	398 (40.1%)	282 (28.4%)	203 (20.4%)	64 (6.4%)	46 (4.6%)	0.51		
7. Parents	778 (78.3%)	126 (12.7%)	61 (6.1%)	14 (1.4%)	14 (1.4%)		.62	
8. School/ Kindergarten	569 (57.3%)	223 (22.5%)	118 (11.9%)	38 (3.8%)	45 (4.5%)		.63	
9. Friends	831 (83.7%)	121 (12.2%)	29 (2.9%)	6 (0.6%)	6 (0.6%)		.77	
10. Feel good and healthy	387 (39.0%)	455 (45.8%)	70 (7.0%)	63 (6.3%)	18 (1.8%)			.86

Figure Legends

Figure 1.

Hvidoere Smiley Faces Diabetes QOL Questionnaire for young children

Figure 2.

Understanding of Questionnaire by children and age group

Figure 3.

Mean sum score and 95% CI on Questionnaire for Individual on Different Insulin

Regimens (regimes characterized in detail in (14))

(Low scores indicate greater QOL)

(Insulin regimens: Conventional <3 injections/day (CT); Conventional premix (CT Premix);

(CT+) 2 injections of free-mix + rapid analogue as necessary; Insulin pump (CSII); Intensive

(ICT) e 3 injections/day.

Figure 1.

1. At the moment I feel ...

2. About my diabetes I feel ...

3. About the food I eat and drink I feel ...

4. About having my insulin injection / insulin pump I feel ...

5. About blood sugar testing I feel ...

6. When I go to the Diabetes Clinic/Centre I feel ...

7. When I think about my parents I feel ...

8. About my school / play school I feel ...

9. When I play with my friends I feel ...

10. I feel good and healthy...

all the time/ most of the time/ half the time/ sometimes/ not often

Figure 2.

Figure 3.

Appendix Authors

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Review 1

1. In the introduction, the currently available quality of life measures should be cited (e.g. PedsQL). In addition, there is an omission of parent report measures for QOL. There are parent report versions of many of these measures for younger children, including those ages 2-5 with diabetes. What does a child report measure add for the younger ages beyond a parent report?

We assume that the basics of assessment of quality of life are familiar to most readers of Pediatric Diabetes. We are aware that there are established measures for generic QOL (PedsQL in US, Kidscreen/Disabkids in Europe) and for disease-specific questionnaires all as proxy and self-report questionnaires. We adjusted the text and cited both series of questionnaires in the section "Introduction" as suggested. When commencing the Hvidoere Study in 2009 to our knowledge the only missing questionnaire was a diabetes-specific QOL self-report measure that is understandable for young children. This was the main target of our study published here.

It is known from several publications that proxy and self-reports QOL assessments clearly differ between parents and children, e.g. (Samardzic M [J Pediatr Endocrinol Metab](#). 2016 Jun 1;29(6):663-8 or Davis, E., Nicolas, C., Waters, E., Cook, K., Gibbs, L., Gosch, A., & Ravens-Sieberer, U. (2007). Parent-proxy and child self-reported health-related quality of life: using qualitative methods to explain the discordance. *Quality of Life Research*, 16(5), 863-871 or [Eiser C¹, Varni JW](#). Health-related quality of life and symptom reporting: similarities and differences between children and their parents. [Eur J Pediatr](#). 2013 Oct;172(10):1299-304.

As the children are affected with diabetes, they are our main focus and we strongly promote their inclusion in the management of their diabetes. Due to their cognitive developmental level they experience and understand diabetes differently from their parents as parents answers are influenced by their future fears including knowledge of late complication.

For us, it was most important to develop an instrument to directly assess children with diabetes rather than by proxy alone. Therefore the children were not assisted by their parents but by a trained health professional assessing the child's competence to understand the task and the questions.

2. In the Methods, please provide the dates of data collection. There is a particularly high percentage of youth on conventional regimens. Further, it is unclear why a conventional regimen is less than 3 injections a day, as the standard conventional regimen of N and R insulin is typically 3 injections/day and intensive (ICT) is typically ≥ 4 injections/day.

The data were collected in 2009 and we have included this in the manuscript. It was a reality even in many developed countries, that young children used CT. Our sample was not selected as in many clinical studies, but included all children of the defined age-groups in the 18 centres worldwide. Our real life data showed us, that there was a less clear understanding of the types of insulin therapy in many countries. This was published and critically discussed by A. Neu et al. 2015. We cited this manuscript in the first paragraph of the methods section. The special value of our data is now that we included many children with CT and can compare them with children on CSII and other new devices. In addition we have now referred to this in the discussion section.

3. The demographic information for the larger study sample is unnecessarily presented both in the methods and the results. It is suggested that the larger study sample can be presented in the methods but the results section should focus specifically on the demographic characteristics of the study subsample $n=1048$ who completed the questionnaire of interest for the current study.

We have reviewed our data and have removed the demographic information for the larger study sample from the results section as recommended. We have now focused specifically on the demographic characteristics of the subsample who completed the questionnaire. Relevant changes have been made to the results section including table 1.

The subsample of children who tried to answer the smiley questionnaire were 1049 (including even very young children to test the limits), Finally 1035 children completed the questionnaire and of them 993 were able to understand the items (either read by a study assistant or reading by themselves) and answered all items. Their data are the final basis for the factor analyses. The abstract and the results section were changed accordingly

4. The analysis plan needs to address how missing data was handled. Based on the n 's presented in Table 1, it appears that all 1048 participants did not complete all 10 items of the scale.

1035 children completed the questionnaire which was well understood by 70% of 4 year olds and 96% ≥ 5 years. Only data of children who were rated as completely or in most parts understanding the task and answering all items were included in the following analyses ($n = 993$). We have revised Table 1 and included figure (2) to demonstrate this.

5. Given the large age range of the sample, it would be helpful to break down the measure characteristics by age brackets to demonstrate reliability in both younger and older ages rather than the overall sample.

Many thanks for this suggestion. In addition we calculated Cronbach's alpha for the subsample of the 4-8 years old. Internal consistency and reliability for the whole group studied were good (Cronbach's alpha = 0.73) and for the children aged < 8 years internal consistency was also good, Cronbach's alpha = 0.71. We have added this within the results section

6. The time frame for the current QOL measure is unclear and it appears to measure current (e.g. in the moment) quality of life rather than over a specified time period (e.g. 2 weeks). This is different than other QOL measures, and the authors should justify the time frame chosen when designing the questionnaire. Information on test/retest reliability would be helpful in evaluating the measure and stability in QOL over time.

We discussed this topic when designing the questionnaire based on the background of developmental psychology. It is well-known that the understanding of time in the youngest age group is very limited: Time is for them is an “ongoing now”. The simple wording “in the moment” is based on their understanding.

As the Hvidoere study was a cross-sectional study there are no data available to assess the retest reliability. This could be done in another follow-up study with a smaller sample.

7. The total score, factor scores, and standard deviations for the Smiley Faces questionnaire should be presented for the total sample before presenting the mean scores by regimen.

We have now included these scores in the results section of the manuscript before presenting the mean scores by regimens.

8. QOL seems to vary by regimen; however, other studies using this sample have found that center location accounted for differences rather than regimen (e.g. de Beaufort et al., 2013). Were center effects examined in this study? If not, it would be helpful to look at differences by participant location, particularly as perceptions of QOL may vary across cultures.

In the first publication HbA1c was related to centre and independent of insulin regimen. This dependency of centre (country) and type of insulin therapy is described in the 2013 publication in detail. QOL when adjusted for insulin regimen showed no centre difference. Whilst funding and the approach towards diabetes care is quite different between countries, however, after adjusting for type of insulin therapy there were no significant centre differences between the 18 centres according to the QOL data (SMILEY Scale) and the intensified approach was associated with better QOL.

9. The discussion notes that the main areas of dissatisfaction related to insulin injections and blood sugar testing; however, looking at Table 1, it appears that the highest dissatisfaction was with diabetes in general. This should be addressed.

Many thanks to the reviewer. We have now reflected this in the discussion section.

10. The discussion requires a more sophisticated discussion of the clinical implications of this work. The items assessed by this measure are broad and it is unclear how a clinician would use this measure to inform intervention or care for youth with diabetes. Do the authors have specific suggestions for what to do with this measure in clinical care? Are there clinical cut-offs to identify those with poor QOL or is that an important future direction? Further,

the concluding sentence refers to the importance of assessing QOL because of associations with metabolic control, yet no associations were found in this sample. What is the benefit of routinely assessing QOL in younger children who are not taking on daily responsibilities for management of diabetes?

We reconsidered and discussed this query and reformulated the discussion section. We have now focused on the results of this study in young children including the clinical implications and limitations of using the SMILEY scale. Following this we have discussed the relevance of QOL assessments throughout childhood in paediatric diabetes care.

Reviewer: 2

Attention to several minor issues will strengthen the contribution of this manuscript:

1. On page 10, the authors state that “The questionnaire was understood completely or in most parts by 70% of the 4-year-old children....” it is not clear whether the word “understood” means that the 4-year-old children read the items on the questionnaire or whether they understood the items that were read to them? How many of the 4-year-old children were able to read the text of the questionnaire? And how many had to have the items read to them?

All 4-year-olds and all 5-year-olds were read the questionnaires by study assistants in a structured way (written instruction). All children were instructed by assistants and not by their parents. We have now included this information in the manuscript

2. The factor “Health” perhaps could more appropriately be called “Well-being” as it is composed of 2 items: emotional health (happiness) and physical health.

We appreciate this suggestion and have included it in the manuscript

3. Were the instructions protocolized for the individuals who administered the questionnaire to the children, such things as prompts, how to answer questions from the children, how to handle a child who could not engage with the questionnaire.?

Written instructions and a written protocol were provided for health professionals. Core elements included: ‘telling us about life with diabetes’ and no wrong or right answers. One question was included for the health professional to give the child prior to presenting the questionnaire in order to check whether the child understands the scale, followed by questions with no influence or comment from the assistant, all children to be praised for their cooperation; children who could not understand the task to colour the smileys, paint a picture and also be praised. We have made some additions to the methods sections to describe this.

4. It would be helpful for the authors to provide a more detailed description of the KIDSCREEN-10

We have included a brief description of KIDSCREEN-10 which is a well-known validated European Questionnaire free of charge in nearly all European languages
<https://www.kidscreen.org>

5. I believe there is a typo on page 10 line 2. When the age range is reported as “1.8 – 11 years”. Given that the lower age range reported in the Methods is 4 years, possibly the 1.8 should be 4.8?

Whilst all children participating in the overall study were offered the questionnaire in order to test the age range. Only the data of children who were rated as completely or in most parts understanding the task and answering all items were included in the following analyses (n = 993). We have revised Table 1 and added fig (2) to reflect this. In addition we present the demographic data of this subsample in the results section.

6. The authors report that children on intensive insulin regimens reported higher quality of life on the overall score and the Diabetes subscale than did children on conventional therapies. It would be of interest to readers to know how self-reports of diabetes quality of life differed between children using contemporary diabetes technologies, pumps and CGM, and those using syringes and pens, and blood glucose monitors.

This is a very important and interesting topic which requires further research. We were able to compare children with pumps against the others. There were no differences among children with ICT whether using CSII or MDI (Figure 3); but all children on ICT reported better QOL compared to those treated with either type of CT. In 2009 there were only 2 children using CGM, and no child using it continuously. Our “old data” are important to compare QOL in young children in relation to new technologies.

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