

Health-related quality of life in children with Type 1 diabetes: an RCT of hospital-based care and hospital-based home care at diagnosis

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Introduction: When a child is diagnosed with Type 1 diabetes, it involves extensive lifestyle changes for the whole family. There is limited knowledge of the impact the initial care has for children and parents over time. The aim was to compare children's diabetes-specific health-related quality of life (HRQOL) in hospital-based care and hospital-based home care (HBHC), 12 and 24 months after the onset of Type 1 diabetes. The aim was also to compare the children's and parents' proxy-report of the children's diabetes-specific HRQOL after 12 and 24 months, regardless of the form of care.

Method: The trial took place at a university hospital in Sweden and had a randomised controlled design evaluating the hospital-based care and HBHC, referring to specialist care in a home-based setting. Children aged 5–16 and their parents answered the PedsQL™ 3.0 Diabetes Module, 12 months and 24 months after the onset of the illness.

Results: The results showed no difference regarding the children's diabetes-specific HRQOL. However, 12 months from diagnosis, the children and parents who received HBHC experienced more worry than those who had received hospital-based care at diagnosis ($p = .012$). Irrespective of the form of care, children reported more discomfort of the disease than their parents reported that the children would have ($p = .017$).

Conclusion: Overall, the result indicates that both hospital-based care and HBHC provide equivalent outcomes in terms of the children's diabetes-specific HRQOL. However, a more home-based model of care might put more strain on some families. Those families need to be identified and the routines should be flexible in order to meet each family's need.

Keywords: Children, HBHC, HRQOL, parents, Type 1 diabetes

Introduction

Diabetes Type 1 is a disease which requires self-care all hours of the day. Understanding the complex situation inflicted upon children and parents, with anxiety and increased demands, could help children and parents handle the new situation.¹ Individual care is necessary since each individual with diabetes is unique.² Furthermore, it is important to strive for good health and quality of life by providing education for children, adolescents, and parents, tailored to age.³ When a child is diagnosed with Type 1 diabetes it is a stressful event for parents, and the level of stress may vary depending on many different factors.¹ The parents are affected by their outlook on life, family resources, social networks, the child's age and personality and the support offered by the healthcare profession. The parents use different methods to minimise the child's feeling of being different, for example by focusing on the healthy aspects rather than the illness.¹

Research shows that parents of children who were treated in hospital after the onset of diabetes felt the

education about diabetes to be more about routines, and about the do's and don'ts, rather than why things should be done.² The parents expressed a need for reflection, something the healthcare system did not always give room for. Some parents reported that it could take them several months to think of and formulate questions that they wanted to discuss with the diabetes team.² Parents of children who were treated at a hospital at the onset of diabetes did not feel sufficiently prepared to deal with day-to-day life after discharge.^{4,5} Lowes *et al.*⁶ interviewed parents of children who were newly diagnosed with diabetes, and who managed the care at home with house calls twice a day, about their experience of the first year. The parents realised the seriousness of the disease and why metabolic control was important, but to be able to manage the diagnosis and the seriousness, they emphasised the importance of living a normal life. They also expressed the need for professional support, adequate information and high accessibility even outside office hours. The parents reported that even if they had been treated at a hospital, they would have to

learn how to deal with the disease at home after discharge.⁶ However, in Sweden, national guidelines for paediatric diabetes⁷ have existed for almost 40 years and they have laid a foundation for local care of high standards. The national guidelines recommend hospital-based care at diagnosis and at the time of planning this study, limited evidence existed of alternative ways of providing care at diagnosis. By measuring health-related quality of life (HRQOL), a measure is acquired of how the disorder affects children's and adolescents' experience and evaluation of their own well-being.^{8,9} A factor which could affect well-being is the metabolic control. Good metabolic control among children and adolescents with Type 1 diabetes is associated with good HRQOL and deteriorated control is associated with worse physical and psychological health, which results in an increased burden.^{10,11} Younger children with diabetes, and their parents, also experience lower diabetes-specific HRQOL due to the increased burden the disease and its treatment entails, compared to healthy children and their parents.¹²

Shortening the stay at the hospital, and offering home-based care at the time of diagnosis, is believed to be a safe and efficient alternative to conventional hospital-based care for children who are clinically stable at the time of diabetes onset.^{6,13–15} By minimising the time at hospital, to the benefit of care in a home-like environment, children and parents are given the opportunity to find day-to-day routines more quickly.

Individuals with the same disease experience different problems to a varying degree.¹⁶ It is important to evaluate how different models of care affect children and their parents from different perspectives over time. Therefore, the aim was to compare children's diabetes-specific HRQOL in hospital-based care and hospital-based home care (HBHC), 12 and 24 months after the onset of Type 1 diabetes. The aim was also to compare the children's and parents' proxy-report of the children's diabetes-specific HRQOL after 12 and 24 months, regardless of the form of care.

Methods

Design

The study design was based on the British Medical Research Council framework for development and evaluations of Randomised Controlled Trials (RCT) for complex interventions^{17,18}, and has been described in detail elsewhere.¹⁹ The study follows the Consolidated Standards of Reporting Trials (CONSORT) recommendations²⁰ and was registered at ClinicalTrials.gov with identity number NCT00804232, December 2008. Statistical power calculation included the primary outcome HbA1c two years from diagnosis. In order to show a mean difference of 10.5 mmol/mmol, 30 children were needed in each group. The randomisation was performed by an independent centre for clinical research and the researchers received two sets of coded, sealed and opaque envelopes. Randomisation was performed in

two strata: younger than eight years and eight years and above.

Participants and setting

The study took place from 1 March 2008 up to the end of August 2011 at the Skåne University Hospital, division of paediatrics at the Children's Hospital in Lund, Sweden. The study included children, aged 3–15 years and newly diagnosed with Type 1 diabetes. The follow-up of two years set the upper age limit at 15 as the transition to the adult diabetes care setting when the adolescents reach their 18th birthday. Additional inclusion criteria were that the child did not have any other difficult chronic illness, had no sibling with Type 1 diabetes, was not in social-care custody, and lived in a family who could understand and speak Swedish. When the child was medically stable, he or she received subsequent care according to the randomisation procedure: either continued hospital-based care or HBHC, referring to specialist care in a home-based setting. After the first month, all families followed the conventional care with visits to the outpatient department unit.

Hospital-based care Children randomised to hospital-based care were admitted to the hospital 1–2 weeks before they gradually spent more time in their own home. One parent could stay at the hospital during the night and both parents were encouraged to attend the information meetings with the diabetes team during the hospital stay. The paediatrician, the dietician and the social worker usually had 3–4 meetings with each family and the diabetes nurse had 4–8 meetings (30–60 min each). The information followed a checklist where each discipline was responsible for different parts of the education, for example diabetes pathophysiology, insulin treatment, self-care and nutrition. The child could leave the ward in the daytime between meetings when parents felt secure in their management of hypoglycaemia and if they had an agreement with the responsible paediatrician. Towards the end of the hospital stay, the family returned to their home for a few days with frequent telephone contact with the diabetes team until discharge.

Hospital-based home care Children randomised to HBHC left the Children's Hospital together with their parents, when the child was clinically stable, and stayed at a Family House, placed in the hospital area, until families felt confident to return home.²¹ Since Sweden has a long tradition of long in-hospital stay at diagnosis²² it was not possible to compare the traditional hospital-based care with actual home-based care. Therefore, the choice of using a Family House was made for the HBHC group in order to make the transition to home smoother. The Family House, supported by a non-profit Child foundation, offers sick children and their families a home-like environment when the child is under care at the hospital. The staff members at the family house worked daytime and were not trained in nursing. The stay included support of a diabetes nurse

during parts of the day. Information meetings with other professionals in the diabetes team were held at the Children's Hospital in accordance with the conventional care. The contents of the information given to families were the same in both groups. The active parts of the HBHC were defined as an individualised learning process through supportive interaction between the family and the diabetes nurse at the Family House. Another active part included the home-like environment which allowed families to practise the diabetes management with the concurrent support. The final active part was increased support after discharge in the form of three home and/or school visits by the diabetes nurse besides the regular diabetes check visits as well as increased telephone access to the diabetes nurse during day and evening, seven days a week. During nights, they could receive assistance from the general hospital staff.

Outcome measurements

Outcomes included data from valid and reliable instruments^{23,24}, and data were collected at 12 and 24 months from diagnosis. In the first years, a research assistant assessed the outcomes and booked appointments with families outside the hospital. Later in the study, questionnaires were sent home by mail with a return envelope to the families instead. PedsQL™ 3.0 Diabetes Module measures diabetes-specific HRQOL for children with Type 1 diabetes in the ages, both in the form of child self-reports (child 5–7 years, 8–12 years and adolescents

13–18 years) and parent proxy-reports (2–4 years, 5–7 years, 8–12 years and 13–18 years). PedsQL™ 3.0 Diabetes Module includes 28 items scored on a 5-point (0–4) Likert-type scale for the response categories, covering five dimensions; diabetes symptoms ($n = 11$), problems with treatment ($n = 4$), treatment adherence ($n = 7$), worries ($n = 3$) and communication ($n = 3$).

Statistical analysis

Analyses were conducted using SPSS™ (version 22); differences with p -values $< .05$ were considered statistically significant. The scales were lineally transformed into 0–100 scales to facilitate interpretation of the scores, and scale scores were computed as the sum of the items divided by the number of items answered. Higher scores indicate better diabetes-specific HRQOL. Continuous variables were checked for distributional characteristics, and since the data were assessed as normally distributed, Student's t -test was used to compare children's and parents merged reporting at 12 months and at 24 months in hospital-based care and in HBHC. Furthermore, the children's reporting was compared with the parent's reporting, independent of randomisation.

Ethical considerations

Ethical approval was obtained by The Regional Ethical Review Board in Lund, Sweden (LU 305/2007). Children should, whenever possible, give their own opinion in the form of written consent for a study they attend, in addition to that of the child's legal caregiver. The ability to make an independent decision is strictly connected to the process of thinking and the ability of abstract thinking which in terms of clinical research has been shown to be from the age of 12.²⁵ Therefore, parents of all children and children over the age of 12 were asked for consent and children under the age of 12 were asked for assent. Children were given age-appropriate information verbally and children 12 years or older also received age-appropriate information in writing.

Results

Child and parent background characteristics are presented in Table 1. We have previously reported on children's metabolic control, other health outcome measurements and cost-effectiveness in the two models of care up to two years from diagnosis.^{13,21,26–28} In this article, we present children's report and parents' proxy-reports of the child's diabetes-specific HRQOL. Of the total number of 60 children and 117 parents, 48 children and 71 parents responded to PedsQL™ 3.0 Diabetes Module 12 months after diagnosis and 35 children and 31 parents responded 24 months after.

Overall, there were no differences in how children and parents reported the child's diabetes-specific HRQOL of life in hospital-based care and in HBHC. The only dimension where there was a significant difference ($p = .012$)

Table 1 Background characteristics of children and parents that responded to PedsQL™ 3.0 Diabetes Module at 12 and 24 months from the child's diagnosis.

	12 months, Intervention/Control	24 months, Intervention/Control
Children		
Age 5–7, n	5/5	2/4
Age 8–12, n	12/12	9/7
Age 13–18, n	7/7	8/5
Parents		
Mothers	19/19	8/8
Fathers	18/15	8/7
Country of birth		
Born in Sweden	35/31	14/15
Born outside Europe	1/2	1/0
Education mother		
Compulsory school	19/19	8/8
Secondary school	19/17	8/8
University degree	8/11	5/6
Education father		
Compulsory school	18/15	8/7
Secondary school	18/14	8/7
University degree	9/7	4/4

Table 2 Comparison between children's and parents' estimates of the child's diabetes-specific HRQOL in hospital-based care and HBHC, 12 months after the onset of Type 1 diabetes.

Scales	Comparison hospital-based care/HBHC after 12 months			
	Mean <i>n</i> = 58/61	SD	<i>p</i> - value*	95% CI lower–upper
Diabetes symptom	66.0/68.2	14.3/ 12.9	.392	–7.099–2.802
Treatment barriers	73.7/75.8	18.3/ 15.5	.512	–8.186–4.101
Treatment adherence	84.5/82.2	13.2/ 15.3	.373	–2.853–7.550
Worry	81.4/72.4 ^b	17.5/ 20.9	.012*	1.989–16.077
Communication	77.9/79.0 ^b	20.5/ 25.0	.785	–9.516–7.208
Total scale score ^a	76.7/75.6	11.3/ 11.3	.587	–2.980–5.238

^aSummarising all items in the questionnaire.^bMissing data from one parent.**p* < .05.

between the two groups concerned worry, as children and parent reported more feelings of worry 12 months from diagnosis in the HBHC compared to children and parents who received hospital-based care (Tables 2 and 3). However, the difference did not remain 24 months after diagnosis.

When the children's reporting of their HRQOL was compared with the parents' proxy-report independent of randomisation (Table 4), there was a significant difference in how children and parents reported on diabetes symptoms (*p* = .017) 12 months from diagnosis. Children experienced more discomfort from the disease than the parents estimated that their children did. The difference did not remain 24 months from diagnosis in this comparison either (Table 5). No other differences were seen between the two groups.

Discussion

Overall, there were no differences in how children or their parents reported on the children's diabetes-specific HRQOL in hospital-based care and HBHC. However, when it came to the individual dimensions, significantly higher worry was experienced in the HBHC group after 12 months compared to hospital-based care. Furthermore, the result revealed that there was a significant difference between the children's and their parents' reports, regardless of type of care, after 12 months, showing more diabetes symptoms among the children compared to how the parents experienced the child's symptoms. This result is in line with other studies, showing that parents express feelings of security during hospital stay after the onset of the child's disease.⁴ The parents said that it felt like 'living in a bubble', which gave a sense of security. Also, Sparud-

Table 3 Comparison between children's and parents' estimates of the child's diabetes-specific HRQOL in hospital-based care and HBHC, 24 months after the onset of Type 1 diabetes.

Scales	Comparison hospital-based care/HBHC after 24 months			
	Mean <i>n</i> = 31/35	SD	<i>p</i> - value*	95% CI lower–upper
Diabetes symptom	68.7/66.8	12.5/ 12.4	.537	–4.222–8.034
Treatment barriers	72.3/72.8 ^b	17.4/ 14.6	.263	–3.452–12.434
Treatment adherence	83.3/81.9	9.0/ 11.8	.593	–3.817–6.625
Worry	80.4/73.6	16.2/ 21.9	.161	–2.770–16.380
Communication	73.7/70.2	22.1/ 23.3	.545	–7.789–14.624
Total scale score ^a	76.7/73.1	9.6/ 11.6	.181	–1.700–8.851

^aSummarising all items in the questionnaire.^bMissing data from one parent.**p* < .05.

Lundin and Hallström²⁸ showed that parents felt secure during hospital care since professionals were available all the time. Lowes *et al.*⁶ reported parents' opinions that it was important to have professional support, adequate information and high accessibility to the staff even after office hours. HBHC, as well as self-care in the home, requires a different kind of support for the children and their parents compared to the support during hospital stay concerning how to handle worries. Parents have different internal resources to deal with their worries depending on their own knowledge and self-confidence. Therefore, it is important to early identify children and parents in need of

Table 4 Comparison between children's and parents' estimates of the child's diabetes-specific HRQOL regardless of the form of care, 12 months after the onset of Type 1 diabetes.

Scales	Comparison child/parent after 12 months			
	Mean <i>n</i> = 48/71	SD	<i>p</i> - value*	95% CI lower–upper
Diabetes symptom	63.5/69.5	15.2/ 12.0	.017*	1.095–10.971
Treatment barriers	75.7/74.2	17.1/ 16.8	.633	–7.781–4.749
Treatment adherence	85.3/82.0	12.3/ 15.5	.219	–8.583–1.984
Worry	80.1/74.5 ^b	17.2/ 21.2	.131	–12.891–1.695
Communication	77.3/79.3 ^b	22.9/ 22.9	.637	–6.476–10.533
Total scale score ^a	76.4/76.0	11.3/ 11.3	.847	–4.601–3.782

^aSummarising all items in the questionnaire.^bMissing data from one parent.**p* < .05.

Table 5 Comparison between children's and parents' estimates of the child's diabetes-specific HRQOL regardless of the form of care, 24 months after the onset of Type 1 diabetes.

Scales	Comparison child/parent after 24 months			
	Mean <i>n</i> = 35/31	SD	<i>p</i> - value*	95% CI lower–upper
Diabetes symptom	65.7/66.9	12.6/ 12.0	.171	–1.862–10.251
Treatment barriers	75.8/74.0 ^b	14.4/ 18.0	.653	–9.841–6.210
Treatment adherence	84.5/80.4	8.4/ 12.3	.126	–9.356–1.185
Worry	79.8/73.4	17.4/ 21.6	.189	–15.969–3.219
Communication	70.0/73.9	21.2/ 24.3	.486	–7.272–15.121
Total scale score ^a	75.2/73.3	9.0/ 12.6	.764	–6.153–4.541

^aSummarising all items in the questionnaire.

^bMissing data from one parent.

**p* < .05.

extra support and to maintain regular follow-up contacts and visits with the family.²⁹ The fact that a child is affected by a life-long disease is experienced differently in different families due to, among other things, the structure in the family and the accessibility to a social network.³⁰

Care in HBHC requires, at the start, increased responsibility on the part of both the child and the parents when it comes to solving everyday life situations. Sparud-Lundin and Hallström²⁸ reported how parents declared that, even if they had the possibility to be together in a more home-like environment, they felt that the adaptation to their own home later on felt like a challenge.

The fact that children estimate significantly more diabetes symptoms compared to the parents' assessment could possibly be a consequence of the children's feeling that all the symptoms are affecting their body. Parent's tendency to underestimate the children's experiences is in line with a study by Jönsson *et al.*³¹, where the result revealed that fathers of children aged 8–12 years underestimated the children's experiences of the diabetes symptoms. Variation in estimation of HRQOL could be due to the parent's perception of the child's health and well-being as well as their own health and well-being.³² The child's age can affect the experiences concerning the diabetes symptoms.²⁴

Strengths and limitations

The instrument PedsQL™ 3.0 Diabetes Module is a validated and tested instrument concerning the assessments of diabetes-specific HRQOL among children with diabetes Type 1.^{23,33,34} The Swedish version was tested by Sand *et al.*²⁴, and it was shown to be sufficiently valid and reliable regarding the child and parent report.

Therefore, it is a valuable instrument for measuring diabetes-specific HRQOL among children both in research and in the clinical environment. A strength of the present study's outcome is that children and parents were cared for by the same staff during the whole period, which increased the possibility for equal and consistent conditions for both groups. At follow-up after 12 months, 80% of the children answered the questionnaire with an equal distribution between groups. The response rate among parents was lower and 61% of the total number of mothers and fathers answered the questionnaire, which still can be seen as acceptable. The response rate at 24 months was lower than at previous follow-ups, probably explained by changed routines of data collection. This might have led to greater variability in the final outcomes and thereby the results from the 24-month follow-up are less reliable. In a comparison of background characteristics of the 12 and 24 months follow-up with data from baseline²⁷, no obvious differences were observed.

When interpreting results, one must hence also take into consideration the difference that the study was powered to detect.³⁵ The fact that sample size was not chosen with the aim to detect significant differences in the outcomes reported on in this study. Thus, the results can therefore only be interpreted with caution and as direction of effects that needs to be confirmed in future studies with adequate power.

Conclusion

Few studies have provided high-quality evidence when comparing hospital-based care with different models of home-based care. Overall, the result indicates that both hospital-based care and HBHC provide equivalent outcomes in terms of the children's diabetes-specific HRQOL. However, the results of the present study indicate that when care is relocated from the hospital to the home it implies increased responsibility for the parents and thereby can influence the child's future health. Increased responsibility is likely to affect vulnerable families more negatively. Therefore, it is important to identify the families who are in need of extended support, and in a home-based model of care the routines need to be even more flexible to meet each family's need.

Acknowledgements

We thank healthcare professionals at the paediatric department and the staff at the Family House. We are most grateful to the families who participated in the study.

Funding

This study was supported by the Swedish Institute for Health Sciences and the Faculty of Medicine at Lund University, the Swedish Research Council (Dnr: 521-2013-2633 project nr: K2014-99X-22564-01-4), the

Swedish Diabetes Foundation and the Region of Skåne (Dnr: 2011/1816).

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