

Comparison of hospital-based and hospital-based home care at diabetes onset in children

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Introduction

Living with type 1 diabetes imposes extensive demands on a child and their family's everyday life with the constant challenge of maintaining plasma glucose levels within the near-normal range.¹ The initial management is largely a preparation phase, to help the families learn and become active participants in the diabetes care.² Conventionally, children newly diagnosed with type 1 diabetes have been admitted to hospital as part of the initial management even if the child is not acutely ill. But over the last decades there has been a trend towards shorter lengths of stay and/or exclusively outpatient management.^{3–5} Globally the duration of hospital admission at diagnosis has varied greatly from several weeks to exclusively outpatient management.^{3,6–8} Sweden has a long tradition of in-hospital care when a child is diagnosed with type 1 diabetes, in line with the Swedish national guidelines for paediatric diabetes.⁹

Diabetes management requires a practical understanding and the development of skills for integrating the treatment in everyday life¹⁰ and family functioning is closely

Summary

The aim was to compare two different regimens for children diagnosed with type 1 diabetes, hospital-based care and hospital-based home care (HBHC), in terms of the child's metabolic control, episodes of severe hypoglycaemia, the disease's impact on family and the parents' health-related quality of life, one year after diagnosis. The study had a randomised controlled design and included 60 children, aged 3–15 years old. Children were randomised to either continued hospital-based care or to HBHC. This article presents data one year after diagnosis. The results showed overall equivalence between groups. There were no differences in terms of the children's HbA1c ($p=0.804$), in episodes of severe hypoglycaemia ($p=1.0$), in insulin dose/kg/24h ($p=0.115$) or parents reported impact of the child's disease on the family ($p=0.163$). However, parents in the HBHC showed significant higher social functioning compared to parents in the hospital-based care ($p=0.006$). In conclusion, few studies provide high-quality evidence when comparing hospital-based care with different models of home-based care. The results of this study one year after diagnosis support the safety and feasibility of HBHC when a child is diagnosed with type 1 diabetes.

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Key words

quality of life; family impact; disease management; randomised controlled trial; type 1

integrated with the management of diabetes in children.^{11,12} There are various arguments as to whether in-hospital care or home management of diabetes at diagnosis is most beneficial in relation to families.¹³ Few studies provide high-quality evidence.¹³ To get closer to the goal of diabetes management, evaluations of the consequences over time for the child, for the family, and for the healthcare system, of different models of services of the initial care needs to be carried out. The aim of this study was to compare hospital-based care and hospital-based home care in terms of the child's metabolic control and episodes of severe hypoglycaemia and the disease's impact on family, one year after diagnosis.

Patients and methods

The study design was based on the Medical Research Council framework for development and evaluations of RCTs for complex interventions,^{14,15} and is described in detail

elsewhere.¹⁶ The study follows the CONSORT (Consolidated Standards of Reporting Trials) recommendations,¹⁷ with registration number NCT00804232 and was approved by the Research Ethics Committee (LU 305/2007). Statistical power was estimated on a known variation in HbA1c two years after diagnosis with a standard deviation of 14mmol/mol in individual HbA1c measurements. To show a mean difference in two groups with 10.5mmol/mol, it took 30 children in each group with the power of 0.80, at a significance level of 5%. The randomisation was performed by an independent centre for clinical research using the software R-2.6.1,¹⁸ in two strata: younger than eight years old or eight years old and above.

Setting

The trial took place at Skåne University Hospital in Lund, Sweden. Children 3–15 years old, newly diagnosed with type 1 diabetes, without any other chronic ill-

ness or siblings with type 1 diabetes, who lived in a family unit (not social care) who could speak and understand the Swedish language were included in the study. All parents and children were asked for consent. Children were age-appropriately informed verbally and children 12 years or older also received age-appropriate information in writing. After about three days with in-patient care, children received subsequent care according to their randomisation; either continued hospital-based care or hospital-based home care (HBHC) ie specialist care in a home-based setting.¹⁹ The Family House – situated in the hospital area and offering sick children and their families a home-like environment – was chosen as a home-based form of care for HBHC. In order to minimise nesting between the groups, there were different diabetes nurses who interacted with the families in each group, while the rest of the diabetes team included the same people for both groups. A flow chart detailing the phases of the trial up to the one-year follow-up in September 2012 is shown in Figure 1. After discharge, all families followed the conventional care plan with visits at the outpatient department unit.

Hospital-based care

Children randomised to hospital-based care followed the conventional care according to the national guidelines,⁹ which involved 1–2 weeks²⁰ of hospital-based care while child and parent had educational sessions with the diabetes team members. Once the family had received most of the necessary information they were able to go on short visits home, before the child was actually discharged from hospital. The diabetes nurse offered to make a school visit, with the purpose of informing teachers and school friends about diabetes and insulin treatment, over and above

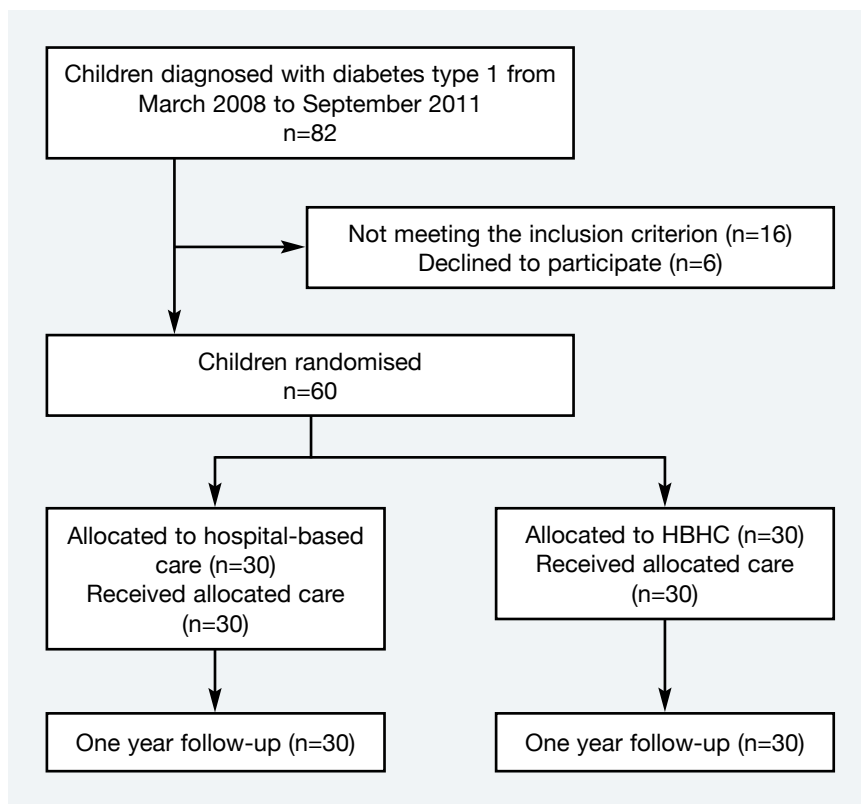


Figure 1. Flow chart of the progress through the phases of the trial one year after diagnosis

the outpatient visits that were offered by the physician.

Hospital-Based Home Care

Children randomised to HBHC left the Children's Hospital together with their parents when the child was medically stable and stayed at the Family House for up to a week.²⁰ The stay included support from a diabetes nurse during parts of the day. The child and the child's parents had information meetings with other professionals in the diabetes team at the Children's Hospital in accordance with the conventional care.⁹

The information given to families was the same in both groups. However, active parts of HBHC were defined as an individualised learning process and a home-like environment which allowed families to practice the diabetes management with the concurrent support of a diabetes nurse. Over and above

the regular diabetes check visits at the outpatient department unit, families in the HBHC was offered increased support after discharge in the form of three home or school visits by the diabetes nurse.

Outcome measurements

The assessment one year after diagnosis included episodes of severe hypoglycaemia, HbA1c, insulin units/kg/24hours and PedsQL Family Impact Module,^{21,22} designed to measure parents' reported impact of paediatric chronic health conditions on the family. The assessment also included the Swedish SF-36,^{23–26} measuring parents' reported health-related quality of life. All the HbA1c values have either been derived from capillary blood samples in a clinical setting to then be analysed at the laboratory or by the family using a prepared kit which was sent to the laboratory via post. The questionnaires were assessed by a person not

involved in the care and the family were able to choose the location for the completion of the forms. The parents were instructed to answer the questionnaires independently of each other. The PedsQL Family Impact Module consists of 36 items and the 5-point (0–4) Likert-type scales for the response categories were linearly transformed into 0 to 100 scales (higher scores indicating better functioning) as to facilitate interpretation of the scores.²⁷ The SF-36 includes 36 items, for each question raw scores were coded, recalibrated in two instances, summed, and transformed into a scale from 0 (worst possible health state measured) to 100 (best possible health state).

Statistical methods

Analyses were conducted using SPSS (version 21) where differences with p -values <0.05 were considered statistically significant. Descriptive statistics were used to present the child and parents' background characteristics. Continuous variables were checked for distributional characteristics and to compare data from two independent groups, a t -test was used since the data was normally distributed.²⁸ HbA1c values and insulin units/kg/24hours were registered every third month. For cases without recorded values at the designated time one year after diagnosis, values were weighted and interpolated between the two closest registrations.

Results

Background characteristics and medical variables at diagnosis are presented in Table 1. There were no differences in episodes of severe hypoglycaemia (defined as unconsciousness with or without cramp) with a mean of 0.03 episodes in both groups up to 12 months from diagnosis ($p=1.0$). There were no differences in

Child background characteristics	Hospital-based care n=30	HBHC n=30
Boys/girls, n	16/14	20/10
Age at diagnosis, mean (SD)	8.6 (3.8)	8.8 (3.7)
pH at diagnosis, mean (SD)	7.35 (0.08)	7.35 (0.11)
HbA1c (mmol/mol) at diagnosis, mean (SD)	87.3 (28.7)	85.7 (26.4)
Parents background characteristics	n=58	n=58
Mothers age, mean (SD)	40.4 (5.3)	40.1 (6.2)
Fathers age, mean (SD)	43.6 (6.6)	42.6 (5.7)
Country of birth, n (%)		
Parents born in Sweden	51 (89.4)*	56 (96.6)
Parents born outside Europe	6 (10.5)*	2 (6.9)
Education, n (%)		
Mothers with university degree	18 (60.0)	15 (51.7)
Fathers with university degree	13 (46.4)	15 (50.0)

*The number of parents' country of birth sum up to 57 parents of the totals 58 parents, meaning one parent was born in Europe and outside Sweden

Table 1. Background characteristics and medical variables at diagnosis in hospital based care and HBHC

insulin dose/kg/24h with a mean of 0.70 (SD 0.23) in the hospital-based care and 0.80 (0.25) in the HBHC ($p=0.115$) or in HbA1c (mmol/mol) with a mean of 48.6 (SD 7.2) in the hospital-based care and 49.1 (9.7) in the HBHC ($p=0.804$).

Of the total number of 116 parents, 103 responded to The PedsQL Family Impact Module (Table 2). Parents reported the impact of paediatric chronic health conditions on the family with a mean of 72.6 (SD 16.8) in the hospital-based care and 77.0 (15.2) in the HBHC ($p=0.163$). The SF-36 was answered by 100 parents (Table 3) and the rated physical health was mean 80.2 (SD 14.0) in the hospital-based care and mean 82.7 (12.9) in the HBHC ($p=0.344$). Parents rated mental health was mean 71.1 (SD 15.7) in the hospital-based care and 76.9 (13.4) in the HBHC ($p=0.052$). The only subscale that showed a significant difference between the groups was in social functioning with a mean of 82.2 (SD 18.7) in the hospital-based care and 91.8 (15.1) in the HBHC ($p=0.006$).

Discussion

The evaluation one year after diagnosis showed overall equivalence between groups. There were no differences in terms of the child's outcomes or parents' reported impact of the child's disease on the family. However, parents in the HBHC showed a significant higher social functioning compared to parents in the hospital-based care. In line with these results there was a direction of effect towards greater mental health for parents in the HBHC compared to parents in the hospital-based care and no differences in parents' report of their physical health. We have previously shown the effect of HBHC compared to traditional hospital-based care one month²⁰ and six months²⁹ from diagnosis. Results one month from diagnosis showed advantages in HBHC with fewer episodes of hypoglycaemia (defined as values <4 mmol/mol) and 30% lower healthcare costs. Results six months from diagnosis showed no differences in children's HbA1c or in parents' working hours six

Scale	Items	Hospital-based care			n	HBHC		p-value
		n	Mean	SD		Mean	SD	
Total scale Score ¹	36	51	72.6	16.8	52	77.0	15.2	0.163
Parent HRQOL summary score ²	20	51	72.5	19.4	52	78.0	16.7	0.124
Physical functioning	6	51	71.9	20.6	52	75.6	20.3	0.349
Emotional functioning	5	51	66.7	20.8	52	73.7	19.1	0.079
Social functioning	4	51	74.1	23.2	52	82.0	18.1	0.059
Cognitive functioning	5	51	77.2	23.3	52	80.7	19.3	0.406
Communication	3	50	78.8	21.9	52	82.2	17.2	0.388
Worry	5	51	67.0	16.8	52	73.5	17.0	0.054
Family summary score ³	8	51	72.7	18.5	52	74.1	17.4	0.683
Daily activities	3	51	73.2	22.3	52	73.9	22.9	0.880
Family relationships	5	51	72.2	18.7	52	74.4	18.4	0.545

¹Summarising all items in the questionnaire; ²summarising physical, emotional, social and cognitive function; ³summarising the scale's daily activities and family relationships

Table 2. The result shows parents report from the PedsQL Family Impact Module one year after diagnosis, in hospital-based care and HBHC

month after diagnosis. However, parents in HBHC were more satisfied with the received care both after one and six months, compared to parents who had received hospital-based care at diagnosis.

Home-based care has been suggested to enable parents, to a greater extent, to integrate diabetes management into the family's normal lifestyle from the time of diagnosis and thereby reduce the negative impact of the disease on the family.³⁰ Even though the results from this study cannot thoroughly support that suggestion, our results may indicate that parents in the HBHC are able to socialise with family and friends to a greater extent compared to parents in the hospital-based care. There were subscales of social functioning in both the instrument included in this study and even though only one of them showed significant differences between the groups, both showed the same direction of effect. However, these instruments give, to some extent, different perspectives; the child's disease impacts on the family on one hand and the parents' experience of their health-related quality of life on the other hand. Intellectual disabilities or

poor health, as well as lack of financial resources and social support affect families' level of distress and their adjustments to stressful situations.³¹ Social support is emphasised as the major protective factor against the effects of stressors, and therefore a lack of social support leads to a family being more vulnerable to stressors.³² With a randomised study design and no obvious differences in families' background characteristics at the time of inclusion, these results may indicate that the initial management matters for how parents view their situation over time and to what extent they are able to integrate the child's treatment with a social life.

A Cochrane review comparing hospital-based care and home-based care¹³ concluded that there is no strong validity of inferences from previous studies of a child's outcomes in terms of metabolic control or episodes of severe hypoglycaemia. Therefore, the findings from the present study make an important contribution and support the fact that the HBHC model of care does not seem to lead to any disadvantages in terms of metabolic control and severe hypoglycaemia up to one year after diagnosis.

In a longer perspective, most children do not reach the recommended targets of metabolic control.³³ Diabetes self-management is an ongoing process over time¹ and continued evaluation is essential in order to reach a deepened understanding of the support needed by families in their task of diabetes management. Therefore the follow-up will continue for two years from the time of diagnosis. In conclusion, there are only a few studies providing high-quality evidence when comparing hospital-based care with different models of home-based care and the results of this study one year after diagnosis support the safety and feasibility of HBHC when a child is diagnosed with type 1 diabetes.

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	Items	Hospital-based care			n	HBHC		p-value*
		n	Mean	SD		Mean	SD	
Physical health ¹	21	47	80.2	14.0	53	82.7	12.9	0.344
Physical functioning	10	47	94.4	8.3	53	93.5	11.5	0.669
Role – physical	4	47	81.4	28.3	53	86.8	24.8	0.311
Bodily pain	2	47	76.6	23.4	53	78.5	20.3	0.659
General health	5	47	68.3	16.0	53	72.1	13.0	0.196
Mental health ²	14	47	71.1	15.7	53	76.9	13.4	0.052
Vitality	4	47	57.5	22.1	53	64.6	19.8	0.090
Social functioning	2	47	82.2	18.7	53	91.8	15.1	0.006*
Role – emotional	3	47	81.6	34.6	53	84.9	32.4	0.619
Mental Health	5	47	63.2	9.4	53	66.1	6.3	0.072
Health transition	1	47	3.9	0.9	53	3.9	0.9	0.888

* $p < 0.05$; ¹summarising physical health scales; ²summarising mental health scales

Table 3. The result shows parent's health related quality of life measured by SF-36 one year after diagnosis, in hospital-based care and HBHC

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