Title

Development of an acceptable and feasible blood glucose management intervention for children, young people and families living with type 1 diabetes.

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Funding

This project was funded by a grant from the DRWF (check on award letter title of the grant)

Acknowledgement

We would like to thank the young people and families that took part in the development of the intervention and participated in the focus groups. We would also like to thank Dr Hannah Duncan, Madeline Harris, Louise Potts, Emily Storr and Laura Rose for helping to run the groups.

Additional Journal details required to be inserted here

Abstract

Hypoglycaemia is the commonest adverse event associated with insulin treatment in both type 1 (T1DM) and type 2 diabetes (T2DM). Fear of hypoglycaemia potentially leads to reduced quality of life underpinned by anxiety and 'hypoglycaemia avoidance behaviours'. Little has been published on interventions that specifically address fear of hypoglycaemia in parents or children and young people in order to improve glycaemic control. We therefore undertook a programme of work aimed at 1) developing an acceptable and deliverable programme that is age-appropriate and addresses the self-identified needs of children and young people with T1DM and their parents in relation to hypoglycaemia and blood glucose management; and 2) assessing the acceptability and feasibility of delivering the programme in a pilot undertaken within a clinical service.

Introduction

Hypoglycaemia is the commonest adverse event associated with insulin treatment in both type 1 diabetes (T1DM) and type 2 diabetes (T2DM) diabetes (Wild et al., 2007). Children and families *'learn quickly that hypoglycaemic episodes are physically aversive, potentially dangerous and a source of possible social embarrassment'* (Brouhard, 1987). Fear of hypoglycaemia (FoH) potentially leads to two problems. One being reduced quality of life underpinned by anxiety about frequent monitoring, the relentless nature of daily management and lack of confidence that others are able or willing to provide appropriate care (Barnard et al., 2010). The second is 'hypoglycaemia avoidance behaviours' (Wild et al., 2007) which lead to persistent hyperglycaemia in an attempt to prevent hypoglycaemia. Anxiety and hypoglycaemic avoidance behaviours are seen in both parents and young people with diabetes.

Whilst such fears may be rational, the subsequent rise in glycated haemoglobin (HbA_{1c}) as a consequence of these short term coping responses worsens the risks of long-term complications (Wild et al., 2007). The development of interventions to support children with T1DM is important to overcome this clinical challenge (Barnard, Thomas, Royle, Noyes, & Waugh, 2011). Although there is an extensive literature on proposed psychological and psycho-educational programmes designed to address general regimen adherence to improve overall metabolic control in children and adolescents with T1DM (Delamater, 2009; Hampson et al., 2001), little has been published on interventions specifically for parents of children with T1DM that improve glycaemic control. Recently evaluated structured educational programmes have focused on increasing knowledge and skills offering practical ways to reduce HbA_{1c} and hyperglycaemia; however, behaviour change strategies or focus on FoH are not specifically addressed (Christie et al., 2009; Gregory et al., 2011)

In a recent systematic review (Patton, Dolan, Henry, & Powers., 2008), no interventions were found that focus specifically on reducing parental FoH that might mediate or moderate the ability of parents to put education and knowledge into practice. Blood glucose awareness training, one of most well documented training programs for adults (BGAT-2; Cox et al., 1995) and an online version BGATHome.com (Cox et al., 2008), had positive results for adults improving hypoglycaemia awareness and glucose management. However, such programmes are focused on individuals who do not test or do not know that they are hypoglycaemic, and are not necessarily applicable to parents and children who are actively making a choice to avoid hypoglycaemia and who are likely to be regularly recording and adjusting their blood glucose (Nurick and Johnson, 1991).

We therefore undertook a programme of work aimed at 1) developing an acceptable and deliverable programme that is age-appropriate and addresses the self-identified needs of children and young people with T1DM and their parents in relation to hypoglycaemia and blood glucose management; and 2) assessing the acceptability and feasibility of delivering the programme in a pilot undertaken within a clinical service.

Methodology

We undertook our study in three phases, the first two developing and refining the intervention and the third evaluating a pilot of the intervention.

Development

Semi-structured interviews were conducted with members of the research or medical team. Interviews were conducted with a Diabetes Nurse Specialist, a Health Psychologist who has a child with diabetes, a Clinical Psychologist working in a Diabetes team, and a Professor of Diabetes. These ideas were integrated with themes identified in the literature and the current UCLH clinical structured education programme. The suggested intervention was a 4 session family programme run once a month that would focus on managing hypoglycaemia.

Five children and young people attending the Child and Adolescent UCLH Diabetes clinics (median age 10 years, range 9-16; median years living with T1DM 4, range 2-13) and their parents were approached and asked to comment on the proposed intervention and what changes they would want to make.

Refining the intervention

Children, young people, and families (including those who had been previously interviewed) were then invited to review the draft intervention. Three focus groups were run with different age groups, one group for four adolescents (14-16 years old) and four mothers, one group for three children (10-11 years old), two mothers, one father, and one brother, and one group for four children (8-10 years old), four mothers, and one sister. Transcriptions were made from audio recordings of the three groups. Feedback was discussed by the clinical intervention team (DC, LC and AC) and further amendments were made.

Delivery of the Pilot study

Families with children and young people aged between 8 and 16 years old with T1DM were contacted by phone or approached in clinic. Families who agreed to participate were offered a group based on the young person's age and gender. Reasons for non-participation were recorded in order to learn about barriers to participation and ensure equitable access. We used a mixed models approach to evaluate the feasibility of delivery, recruitment rates, interest in participation and effectiveness of the intervention and generate data to inform a full RCT.

The intervention

Feedback from the development interviews indicated that families wanted a single group run over a day and that the content should not be too new or complicated. Young people did not want to think only about FoH but rather annoyance and practicalities of diabetes getting in the way of things. The intervention content and structure was redesigned using these ideas. We incorporated evidence based techniques designed to engage young people in wanting to change their behaviour (Christie & Channon, 2014; George, Iveson, & Ratner, 1999). The workshops were delivered by two clinical psychologists, a diabetes clinical nurse specialist and an assistant psychologist. The workshop included family group sessions on: a) how insulin and food affect blood glucose; b) potential impact of long term high HbA_{1c}; c) effects of hypoglycaemia and hyperglycaemia on daily living; d) self-management techniques; and e) talking to people about diabetes with confidence. **Table 1** shows a summary of the different activities that were included in the day.

Table 1 A summary of the different activities included in the workshop

Time (mins)	Activity	
15	'Like' Boards	Ice breaker with flip charts for parents and children in two groups facilitated by staff discussing favourite foods, music, hobbies and activities
10	Introductions	In a large group each person says one true thing and one not true thing about themselves and kids have to guess which is the true thing
15	Questions you want answered	Parents and children and young people in separate groups with facilitator thinking about if the day went well what questions they would want answered. Questions are read out and placed on a flip chart.
25	Blood Glucose and Insulin	A game to show how insulin works as a key to allow glucose to enter cells and what happens if insulin not present. Kids play the role of the cell, the door, the insulin and blood glucose. Worksheet given out to take home
10	Break	
30	Factors influencing blood glucose levels	Parents and kids in different groups with a facilitator. Each group given a number of cards describing different factors that affect Blood glucose levels and have to decide if they make blood glucose go up down or both. Facilitator goes through the different cards encouraging young people to give reasons for their choices. Worksheet with correct answers given out to take home
10	HbA_{1c} – DCCT trial	Workshop leader talks through what HbA_{1c} stands for (using developmentally appropriate language) and shows the DCCT complications chart to illustrate why HbA1c is given such importance by parents and clinic staff.
40	Hypoglycaemia and Hyperglycaemia	Young people are interviewed as a group by the workshop leader about hypo and hyper symptoms, what the effects on at home and in school and what they need to do to manage both situations.
10	Parents reflections	Parents are interviewed and asked what struck them listening to the young people, what they have learned and what they might do differently
	Lunch	

60	Parents / 8-12 age group	Young people meet on their own with 2 workshop leaders. The specific activity is designed by the psychologist during the lunch break and depends on the developmental and cognitive level of the group. The aim is to invite kids to identify their strengths abilities and resources and think about ways to answer back questions other people have about diabetes. A variety of media are used during this session Parents are offered a group session facilitated by a workshop leader (qualified psychologist). Parents are invited to use the session to discuss whatever topic they would like to so each session is always different. They are also reminded of the questions they raised at the beginning of the day to see if any of these have been answered
15	Bring back for feedback	Parents return to hear about the output the young people have designed
10	Break	
30	Question Time	Based on the BBC programme format young people make up a panel and answer the questions that were identified at the beginning of the day. Parents act as the audience
30-40	Blueprint for success - Going to do differently	Young people are interviewed about what they enjoyed, what they learned what they will do differently as a result of attending the workshop and what they have appreciated about each other. The answers are written on certificates called a Blueprint for success. Parents are then invited to reflect on what they heard their children talk about and asked what they were struck by and what they will be doing differently and asked to contribute their appreciations of the young people
5	Evaluation Post it notes	Participants are invited to say in a scale of 1 to 10 whether they would recommend the day to other families with diabetes.

Most of the day young people and parents worked together. In the session after lunch the young people and parents were in separate groups each facilitated by a qualified clinical psychologist. The underlying philosophy of the intervention approach came from systemic theories which assume families are aware of what they ‘need’ to do, however, are not willing, able or ready to put this knowledge into practice. ‘Scaffolding’ questions help ‘draw information out’ (Vygotsky, 1987). Learning is a collaborative effort between family and provider reducing the sense of an expert imposing knowledge, which is presumed to be missing, moving towards a shared venture. This active rather than passive approach is effective at eliciting behaviour change in other areas (Albarracin et al., 2005).

Participants

Eligible participants were between 8-16 years old, at least 6 months post diagnosis with no additional co-morbid illness and sufficient spoken English to participate in the groups. The Paediatric and adolescent diabetes service at University College London Hospital (UCLH) has approximately 400 children with T1DM, of whom approximately 300 were eligible to participate in the pilot. 25 participants were required to achieve pilot and feasibility objectives. Estimating a dropout rate of 20%, we aimed to recruit 32 participants.

Outcome measures

Primary outcomes were acceptability and feasibility of delivery of the intervention. Acceptability was assessed using qualitative and quantitative evaluation scores. After each workshop was completed, young people and parents were asked to indicate on a scale, from 1 to 10, how likely they would be to recommend the programme to other young people and families living with diabetes. Feasibility was measured by collecting data on a) the uptake of the programme b) final attendance and drop-out rate and c) potential barriers to participation.

In addition to the feasibility and acceptability data, participants' mean HbA_{1c} over a period of 12 months before for the pilot study was used as baseline HbA_{1c}. The first available HbA_{1c} provided 2 – 6 months after the group was completed was used as the follow up HbA_{1c}.

One month after the workshop families were contacted and invited to complete follow up questionnaires and asked how useful they had found the day, how much they enjoyed the activities, and how comfortable they were speaking about diabetes since participation. They were also asked if they had changed anything in their diabetes management and asked what benefits they perceived from participating in the program and for feedback on the intervention content, design and delivery.

Number of hypoglycaemic events. Parents were asked how many times their child has experienced an episode of hypoglycaemia in the past month.

Hypoglycaemia Fear survey (HFS). The Hypoglycaemia Fear Survey (HFS)-II Behaviour and Worry subscales were developed to measure behaviours and anxiety related to hypoglycaemia in diabetes (Gonder-Frederick, Nyer, Shepard, Vajda, & Clarke, 2011; Gonder-Frederick et al., 2013). The HFS behaviour scale records inappropriate behaviour related to fear (maintenance of high blood glucose) as well as appropriate behaviours involving avoidance of hypoglycaemic risks by other behaviours. FoH is classified as high if participants scored ‘often’ or ‘all the time’ on at least one of the items in the worry scale (Hajos, Polonsky, Pouwer, Gonder-Frederick, & Snoek, 2014).

Additional questionnaires. Three questionnaires were given to families and young people before and after the groups to see if they would be acceptable and could be easily completed. The three measures used were the diabetes module from the Paediatric Quality of Life Inventory (PedsQL 3.0; Varni et al., 2003) The Diabetes family Responsibility Questionnaire (Anderson, Auslander, Jung, Miller, & Santiago, 1990) and the Self-Care Inventory (La Greca, 1992)

Results

Feasibility

Recruitment. Between 28 July 2014 and 9 December 2014, a total of 89 eligible families (44% females; mean age 12.4 years, range 8-16) were sent study information either prior to attending or during their clinic appointment. They were then approached to take part during clinic or were called on the telephone. Both mothers and fathers were invited to participate in sessions along with their children.

Uptake of the programme. Of the 89 contacted 34 (33%) consented to participate (41% female; mean age = 11.8, range=8-16)

Attendance and drop-out rate. The 34 families were contacted to arrange a convenient date to attend a group. The groups were based on the young person’s age (separated into 8-10 year olds, 11-12 year olds, and 13-16 year olds). Four (or five) families were assigned to each group. Single and mixed gender groups were available. Some families requested groups run in the school holidays. This was arranged where possible. All participants were rung the week before the group to remind them of the arrangements. The median number of times families were contacted to recruit them into the study was 4 (range 1 – 8). Families took between 0 to 63 days before agreeing to take part in the study.

One participant withdrew from the study after giving consent with an additional 11 cancelling the week before or on the morning of the group. The final 22 families participated in seven groups (2 – 4 families per group) delivered by 2 qualified clinical psychologists, an assistant psychologist and a diabetes clinical nurse specialist. One group that had been arranged in the half term holiday was cancelled due to insufficient participants for that session (see **table 2).**

Table 2 Number of participants in each group

	Number of children/young people		Number of Parents		Age range
Group	Boys	Girls	Dads	Mums	
1	2	1	0	3	8-9
2	4	0	0	4	8-9
3	0	4	2	4	9
4	1	1	0	2	11
5	3	0	0	3	13-14
6	1	1	1	2	13-16
7	3	1	1	4	14-16
8 (Cancelled)	0	1	0	1	15

Barriers to participation. The main reason given for declining to take part was being unwilling to miss school (N=35). Other reasons included being busy and not having time (N=10), general disinterest in the study (N=7), and living too far away (N=2) or transportation issues (N=1).

Baseline data collection. A median of 3 (range 1-15) attempts were made to contact people in order to collect baseline data. Baseline data were collected a median of 19.5 days (range 1-115 days) before the group began.

Follow up data. Follow up data were collected in clinic (3 young people, 6 parents), over the phone (14 young people, 9 parents) or via post/email (1 young person, 4 parents). A median of 5.5 (range 1-20) attempts were made to contact people in order to complete the follow up data. It took a median of 45 days (range 22-109) to collect follow up data. One family was unwilling to complete the follow up questionnaires and three families could not be contacted. **Table 3** describes the baseline demographics for people approached, consented, and finally participated.

Table 3 Demographic characteristics data and HbA1c for the 89 approached, the 33/34 that consented and completed the baseline questionnaire, and the 22 that participated

	Approached (N=89)	Completed baseline questionnaire (N= 33)	Actual participants (N=22)
Female, n (%)	39 (44%)	19 (48%)	8 (36%)
Age (years), mean (SD)	12.4 (2.5)	11.8 (2.7)	11.2 (2.8)
Ethnicity			
White, n (%)	72 (81%)	33 (83%)	17 (77%)
Asian/Asian British, n (%)	8 (9%)	4 (10%)	3 (14%)
Black, n (%)	6 (7%)	2 (5%)	1 (5%)
Other, n (%)	3 (3%)	1 (3%)	1 (5%)
Time since diagnosis (years), mean (SD)	6.3 (3.4)	6.1 (3.4)	6.2 (3.2)
Time since enrolled at clinic (years), mean (SD)	3.6 (2.8)	3.6 (2.6)	3.91 (3.0)
HbA$_{1c}$ % , mean (SD)*	8.5 (1.4)	8.0 (1.0)	8.2 (1.1)
HbA$_{1c}$ mmmol/mol, mean (SD)	69.4 (11.4)	63.9 (8.0)	65.6 (11.6)
Number of hypoglycaemic episodes in the last month Median (IQR)	Not available	9.0 (7.0)	9.0 (6.8)
Number of children and young people with High FoH (%)	Not available	17/33 (52)	15/22 (61)
Number of Parents with High FoH (%)	Not available	31/33 (94)	20/22 (91)

* The median number of recorded HbA$_{1c}$ values for each participant was 3 (range 1 -5)

Acceptability

Parents and young people recommended the day highly both on the day and at follow up, found the day useful and enjoyed it (see **table 4**)

Table 4 Qualitative evaluation

	Child Mean (Range)	Parent Mean (Range)
Recommendation of the day		
On the day*	9.0 (6.5-10)	9.6 (7.5-10)
Follow up (22-109 days later)	9.1 (8-10)	9.4 (5-10)
Usefulness of the day	8.6 (5-10)	8.9 (7-10)
Enjoyment of the day	8.9 (3-10)	9.1 (5-10)
Comfort speaking about diabetes		
Before participation	6.0 (1-10)	8.5 (1-10)
After participation	7.4 (3-10)	8.8 (1-10)

*N=22 for evaluation on the day; 21 completed the follow up qualitative evaluation

Participants were unanimously enthusiastic and positive about the workshop. **Table 5** summarizes the themes that emerged form a thematic analysis of the quotes.

Table 5 Themes from qualitative evaluation

Theme 1	General enjoyment of the day
Theme 2	Parents listening to their children
Theme 3	Comfort with sharing and speaking about diabetes
Theme 4	Recognizing personal strengths

Theme 5	Learning about diabetes
Theme 6	Improving self-management

Quotes are also given below in order to illustrate the themes. Quotes from young people are identified by gender and age.

> *"I enjoyed the day because we got to explain how we feel and share what we are going through."* (Girl, 9)
>
> *"The day has boosted my child's confidence. She was very apprehensive about attending but was made to feel relaxed and valued during the day. She was able to talk in front of new people and share her knowledge which was a huge achievement for her."* (Parent)
>
> *"My son used to have a negative attitude towards hospitals, but this was much more fun and engaging."* (Parent)

Parents enjoyed listening to their children talk about their diabetes knowledge.

> *"It was good to see that she can manage it, and understands what affects her blood sugar and see her confidence grow from sharing her knowledge with others and feeling comfortable with talking to others."* (Parent)
>
> *"It was nice that he realized he is very knowledgeable. It also made me see how wonderful and amazing he is."* (Parent)
>
> *"I will allow her more freedom and not be the one making all the decisions, because she clearly knows what is going on and what she needs to do when she's high or low."* (Parent)

Both young people and parents liked sharing ideas and meeting others with diabetes. Young people also indicated that they felt more comfortable speaking about diabetes after participation as opposed to before

> *"It was amazing to realize that others felt the way I did."* (Girl, 11)

> *"It was interesting to see how other people are affected differently by low or high blood sugar."* (Boy, 13)

> *"It's good to know that others are going through with the same situation, it makes you feel connected. Otherwise you think you're the only one. You don't get many opportunities like this."* (Parent)

Other themes from the feedback were recognizing personal strengths, learning about diabetes, and improving self-management. Parents and young people identified how working in the group had helped them see they were doing well.

> *"I know more about diabetes than I think and know how to look after myself."* (Boy, 15)

> *"I realized that we're all coping quite well, even when we think we're not, and our worries are all quite similar."* (Parent)

> *"I realized that I deal quite well with pressure and we're not falling apart—I can pat myself on the back for that."* (Parent)

Even though many participants had extensive education on diabetes, they still found that the day enabled them to learn more about diabetes.

> *"I learned what HbA1c means and stands for."* (Girl, 9)

> *"The insulin game showed me what things affected blood glucose, and how one thing can make it go either way."* (Boy, 13)

> *"I've learned more about diabetes today than I did in three years!"* (Parent)

Participants also identified how the day improved their self-management.

> *"I will be more aware of what happens when I'm high or low, and pay more attention to what my body is telling me."* (Boy, 14)

> *"My son managed to do a cannula change with confidence—this has proved challenging in the past so it is a huge step forward."* (Parent)

In the young people's session a leaflet was developed called 'What you need to know about T1 Diabetes'. This is available on the UCLH diabetes website (https://www.uclh.nhs.uk/OurServices/ServiceA-Z/CYPS/PDIAB/Documents/What%20young%20people%20would%20like%20everyone%20to%20know%20about%20Type%201%20Diabetes.pdf)

Quantitative results

Table 6 shows the number of children and young people and parents identified as having high FoH. The first two columns were the 33 families that signed up to take part; the final columns are those that attended the groups

Table 6 Number of children, young people (YP), and parents with high FoH

	All YP N=33	All parents N=33	Baseline YP N=22	Baseline parent N=22	Follow-up YP N=18	Follow-up parent N=19
Low FoH (%)	16 (49)	2 (6)	7 (32)	2 (9)	9 (50)	0 (0)
High FoH (%)	17 (51)	31 (94)	15 (68)	20 (91)	9 (50)	19 (100)

Table 7 shows the number of hypoglycaemic episodes in the month preceding completion of baseline date. The number in the follow up column is the number in the month preceding collection of follow up data which was at least a month after the group.

Table 7 Number of hypoglycaemic episodes

	Baseline (N=22)	Follow up (N=19)
No. of hypoglycaemic episodes (in the last 1 month) Median (IQR)	9.0 (2.3-9.0)	4.0 (2.0-9.0)

HbA_{1c} * Mean (SD)	N=22	N=22
%	8.2 (1.1)	8.1 (1.2)
mmol/mol	66.0 (11.6)	65.0 (13.3)

* Data collected from clinic database therefore N=22 at both baseline and follow up

Table 8 shows the HFS behaviour and worry scores at baseline and follow up.

Table 8 HFS

OPTION 1 Baseline and follow up data on the HFS for young people (YP) and parents identified as having High FoH at baseline (higher scores indicating higher FoH).

	YP Baseline	Parent Baseline	YP Follow up	Parent Follow up
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Outcomes	(N=15)	(N= 20)	(N=13)	(N=17)
Behavior score I (maintenance of high blood glucose)	39.7 (20.8)	42.9 (22.2)	29.5 (18.1)	43.1 (12.3)
Behavior score II (avoidance of hypoglycemic risks)	64.3 (17.9)	68.5 (14.1)	61.5 (32.1)	78.5 (17.1)
Worry score	39.7 (18.9)	53.6 (20.0)	32.1 (20.2)	49.1 (20.7)

OPTION 2 Baseline and follow up data on the HFS for all young people (YP) and parents (higher scores indicating higher FoH).

	YP Baseline	Parent Baseline	YP Follow up	Parent Follow up
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Outcomes	(N=22)	(N= 22)	(N=18)	(N=19)
Behavior score I (maintenance of high blood	35.2 (18.6)	41.7 (22.4)	28.0 (17.0)	41.7 (12.7)

glucose)				
Behavior score II (avoidance of hypoglycemic risks)	53.2 (23.5)	67.0 (18.3)	59.2 (12.8)	79.5 (16.6)
Worry score	29.9 (21.5)	50.6 (21.5)	26.0 (20.1)	49.7 (20.0)

As the study was primarily to assess the acceptability and feasibility of the intervention the data from the other questionnaires are not given.

Discussion

An acceptable and deliverable programme that is age-appropriate and addresses the self-identified needs of children and young people with T1DM and their parents in relation to hypoglycaemia and blood glucose management was developed by working with young people and their families. All of the focus group participants were clear that it was essential to include a number of aspects of glucose management and not to only focus on FoH. It therefore included activities identified by young people and parents to have the potential to improve blood glucose control, which were delivered alongside diabetes education material. In addition, young people and families preferred for the intervention to be delivered as a one-day programme, and include a one-hour session with separate discussions for young people and parents.

Families were happy to complete the questionnaires that were used in the study; however the small sample size meant that statistical comparison of the baseline and follow up data is not appropriate. Parents had much higher FoH than their children with little suggestion that this changed following the intervention, though there was a small reduction in the number of hypos reported by the families without apparently compromising HbA1c levels which remained steady. Families also reported a number of positive changes in relation to the day, such as being able to listen to and understand each other more, feeling more comfortable speaking about diabetes, learning more about diabetes, recognizing personal strengths, and improving self-management. For example, young people appreciated being listened to and felt their knowledge was valued and respected, and commented on how the activities helped them pay more attention to their bodies and how to recognize symptoms of hypo- or hyperglycaemia.

In clinic families repeatedly request additional support, yet the research assistant had to call up to eight times in order to discuss the project with families and the time that it took for families to decide to take part ranged between 0-63 days (median=8.5 days). The amount of time this would take a member of the clinical team to complete would impact significantly on the ability of most services offering the programme. Despite over 90% of parents scoring as high FoH on the HFS scales, only 33% initially agreed to participate with an additional third of these families dropping out at the last minute bringing the final recruitment rate to 25%. Last minute cancellation and drop out has an impact on clinical delivery – it is much harder to run a group if only 1 or 2 participants turn up on the day (Christie et al., 2014).

The main reason given for declining to take part was being unwilling to miss school (N=35); however for the 2 groups offered during the school holiday 3 dropped out at the last minute which meant one of the groups had to be cancelled. Although there were very few demographic differences between the eligible and final participant samples, our clinical impression was that families with children in year 7 or above were less willing to miss school. However, the group offered in the holidays for a group of young people in year 9/10 was the one that had to be cancelled. There is thus a sense of ambivalence where in clinics families ask for psychological support alongside practical glucose management advice, yet when it is offered there is limited take up. Future groups could test out weekend sessions to better accommodate the schedules of young people and parents.

Moreover, we found practical difficulties collecting data with significant variation in the time between recruitment and collection of baseline data and when groups began with up to 15 attempts (median = 3) to recruit families and up to 115 days to collect the baseline data (median=19.5). There were also practical difficulties collecting follow up data a month after the group finished. Up to 20 attempts (median of 5.5) were made to contact people in order to collect follow up data. We attempted to collect data in clinic but the majority had to be collected over the phone if people didn't attend clinic appointments until 3 months after the end of the group. A small amount was collected by post/email (1 young person, 4 parents). This would need to be carefully thought about in the design of a RCT and more importantly in collection of outcomes for a clinical service. For the study this was only possible with a dedicated research assistant and even with the ability to keep chasing families we only achieved 80% follow up.

Nevertheless, the study showed that it was possible to design an intervention that was taken up by 25% of eligible families and that all of the families, children, and young people found the groups enjoyable and useful. There is a suggestion that there was a reduction in hypoglycaemic episodes without compromising overall metabolic control. The qualitative feedback suggests that the group had an impact on how parents perceived their children's ability to manage their diabetes and on young people's ability to communicate with others about diabetes. The programme offered families the chance to learn diabetes-related information from each other, and to reflect on and acknowledge each other's strengths, experiences, and abilities. This had an impact on parent-child relationships and communication, as well as on how they feel about diabetes and how to manage it in the future.

Conclusions

In summary, we have developed an intervention to help children and young people with T1D and their parents/cares better manage blood glucose levels and decrease FoH. By involving patients and families in the development process helped ensure high acceptability and usefulness of the final programme. However, the study also identified certain challenges regarding recruitment and organization of the groups due to last minute cancellations. The current study also identified practical difficulties with collecting baseline and follow-up data, such as the number of attempts needed to contact families and the expected drop-out rate. All these factors are informative and should be considered when a future RCT.

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