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**AN EXPLORATION OF PARENTS' VIEWS OF MANAGING THEIR
CHILDREN'S TYPE ONE DIABETES WITH INSULIN PUMPS: A
QUALITATIVE STUDY AND CLINICAL RESEARCH PORTFOLIO**

VOLUME I

(Volume II bound separately)

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**Submitted in partial fulfilment of the requirements for the degree of
Doctorate in Clinical Psychology (DClinPsy)**

Institute of Health and Wellbeing

College of Medical, Veterinary and Life Sciences

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July 2015

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Finally, this thesis is dedicated to my sister Sadhbh, whose compassion, strength and logic has both kept me grounded and given me wings.



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Chapter 1: Systematic Review

Parents' experiences of the insulin pump: A systematic review of qualitative literature

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Abstract

Background: Intensive insulin regimens place great demands on caregivers of children with type 1 Diabetes (T1D). Challenges associated with caring for a child with T1D can impact parental health, quality of life (QoL) and glycaemic control. Although insulin pump use is rapidly increasing, there have been no qualitative reviews conducted to synthesise studies of parents' views about the insulin pump.

Objectives: To explore and synthesise qualitative studies of parents' views of using the insulin pump to manage their child's T1D.

Method: Systematic searches of Embase, Medline, Cochrane, CINAHL, and PsycINFO were conducted. This search was augmented by hand searching selected journals, reference lists and Google Scholar. Seven articles from six studies met inclusion criteria. Quality assessments were completed using the Critical Appraisal Skills Programme criteria. Synthesis was completed using the meta-ethnographic method.

Results: All of the included studies were of "acceptable" standard or above. Five themes common to the included articles were identified: adjusting to the pump; concerns regarding child wearing the pump; freedom and flexibility; responsibility sharing; and support for the pump.

Conclusions: Although parents face challenges and experience anxiety in certain areas of pump therapy (carbohydrate counting, cannula changes, the constancy of the pump), these challenges are commonly accepted for the increased freedom and flexibility offered by the pump. Further studies aimed at understanding parents' experiences of caring for a child with T1D using the insulin pump at different developmental stages would support tailored guidance for parents at each stage.

Key Words

Qualitative Research; Meta-ethnography; Parents' Perspectives; Diabetes Mellitus; Insulin Pump

Introduction

T1D is one of the most common chronic childhood illnesses¹. The number of children under 15 years diagnosed with T1D in Europe has been increasing, with incidence rates trebling over the last 30 years. Those under 5 have the largest relative increase in T1D. If current trends continue, it has been predicted that between 2005 and 2020 prevalent cases younger than 15 years will rise by 70%, with incidence rates for those under 5 doubling².

Following a diagnosis of T1D, the patient may be expected to integrate intensive insulin regimens into their daily routine. The treatment regimen for T1D may be demanding, often requiring frequent blood glucose monitoring and insulin administration (at least 4/day), control of carbohydrate intake, and altering insulin dose to match diet and activity patterns³. It is unsurprising that the use of complex routines can often result in poor glycaemic control which can cause serious and life threatening health complications for the patient⁴, and incurs great healthcare costs⁵. Management of T1D in children can be especially difficult given the unpredictability of their food intake and activity levels, as well as the need to negotiate management responsibilities at each developmental stage⁶.

Insulin pumps

The improved development and design of insulin pumps over time offers an alternative method of insulin therapy to the more commonly used multiple daily injections (MDIs). Insulin pumps are small devices weighing around 400 grams worn outside the body, which contain insulin- filled cartridges which continuously deliver insulin through a thin tube or cannula inserted subcutaneously around the abdominal wall^{4,6}. Systematic reviews have suggested that insulin pumps may improve glycaemic control for children and young people^{4,7,8}. Poor glycaemic control has been associated with increased prevalence of mental health difficulties, and subtle neuropsychological deficits⁹. Better

glycaemic control may therefore lead to improved cognition, behaviour and emotions for this group⁹. Furthermore, insulin pumps may offer improvements to a young person's QoL compared to MDIs through facilitating a greater sense of control over diabetes, more independence, fewer physical complaints¹⁰, and more flexibility with diet and schedules^{10,11}.

On the other hand, some studies have found no significant difference in cognitive functioning and behaviour between insulin pumps and MDIs¹². Moreover, a number of factors associated with insulin pump use which may negatively impact QoL have been reported. These include: the need for appropriate supervision of pump therapy in young children¹³; school related issues¹⁴; visibility of the pump¹⁴; infections at the cannula site and pump malfunctions^{14,15}. In 2007, a systematic review was carried out to synthesise the literature on the impact of insulin pumps, and to ascertain whether pumps yielded QoL benefits for people with T1D. Their findings were inconclusive due to a number of poor quality studies in this field, and inconsistency in the assessment of QoL¹⁶. Although the evidence base for insulin pumps is ambivalent, pump use in the pediatric population is rapidly increasing⁶, with some governments investing heavily to increase the availability of insulin pumps for children and young people^{17,18}.

The impact of T1D on parents

Intensive insulin regimens place great demands on caregivers of children with T1D. Numerous factors associated with carer burden, stress and anxiety have been reported including: the need to be constantly accessible to other caregivers, strain in the relationship between the family and the child's school¹⁰; fear of hypoglycaemia¹⁹; engaging in anxiety provoking nocturnal blood glucose monitoring²⁰; variability of food intake and monitoring activity levels²¹. These factors are associated with parental QoL¹⁹, diabetes self-efficacy^{22,23} and parental health²⁴.

When considering the impact of the insulin pump on parenting a child with T1D, quantitative studies have suggested that insulin pumps reduce: overall parenting stress, worries about hypoglycaemia, problems with nutrition management²¹; anxiety^{25,26}; and the frequency of parental contact with health services²⁷. Similarly, a systematic review comparing insulin pump use to MDIs indicated that parents are more satisfied with the insulin pump⁷. Results from a randomized controlled trial (RCT) found that they may also experience improved QoL and less stress using the pump to manage their child's T1D²⁸. In contrast, a meta-analysis exploring the psychosocial impact of insulin pump therapy amongst adults, adolescents and children reported no consistent differences in anxiety, depression, QoL, self-esteem, and family functioning between MDIs and insulin pump therapy²⁹.

Marshall and colleagues³⁰ have argued that the majority of studies attempting to explore parents' perceptions of caring for a child with T1D have used questionnaires with few studies adopting rigorous qualitative methods. Marshall and colleagues stated that a study could be considered rigorous if it provided "attention to detail at all stages of the study (from design through to presentation of findings)"³⁰ (p. 1705). It has been suggested, particularly in diabetes research, that qualitative methods are especially useful in helping clinicians to answer questions that quantitative methods may not be able to. Specifically, qualitative methods have been described as being ideal for exploring patients' motivations, perceptions, expectations and experiences³¹. Understanding patients' experiences and beliefs are crucial to clinical care as they have a profound impact on health seeking behaviour and adherence to treatment³¹.

Qualitative research has helped to improve our understanding of the experience of diabetes and its management from both the perspective of children and parents³¹. Previous qualitative studies have shown that young people often report their parents as

being anxious³², and overbearingly concerned about their diabetes management³²⁻³⁴. Alsaleh and colleagues³⁵ carried out a systematic review to evaluate the contribution of qualitative studies to understanding parents and /or children and young peoples' experiences of using the insulin pump for managing T1D. They searched a number of databases for qualitative studies published between 1970 and 2009 and found six studies which described the experiences of using the insulin pump from the perspective of children and/or their parents. Of these studies, five were reported as exploring parents' views of the insulin pump. Upon closer inspection, two of these five studies may have been constrained by the methods they used. Specifically, one study used postal self-complete questionnaires³⁶, and one administered the Schedule for the Evaluation of Individual Quality of Life (SEIQoL) over a telephone interview³⁷. Additionally, a third study in this review failed to provide illustrative quotes and detail on method of qualitative analysis used. This made it difficult to understand the results and judge the quality of this study³⁸. Qualitative studies that provide mainly descriptive data and fail to report qualitative method used and /or analysis offer few insights to the synthesis of qualitative literature³⁹. Studies from this systematic review³⁵ were described in detail, however findings from the studies were not synthesised.

In light of the increasing rates of T1D in children and adolescents, and the increasing use of insulin pumps, it is important to systematically review the literature to explore parents' views of the insulin pump. Although Alsaleh and colleagues³⁵ provided a thorough review of experiences of the insulin pump from both parents and young people until 2009, only two of the studies within this review looked at parents' experiences of caring for their child with T1D using the insulin pump using qualitative methods. The inclusion of studies using structured questionnaires and clinical interviews may have occurred due to the limited number of qualitative studies in this area at the time of review. To date, there have been no systematic reviews focusing purely on qualitative studies of parents' experiences of the

insulin pump. A greater understanding of parents' views of the insulin pump is needed to support parents in managing their child's T1D, and to allow healthcare providers to offer appropriate supports.

Aims

To synthesise and discuss emerging themes from qualitative literature, exploring parents' experiences managing their child/young person's T1D using the insulin pump.

Research Questions:

- 1) What is known about parents' views of the insulin pump from qualitative studies?
- 2) How many studies have been published in this field?
- 3) What is the quality of these published studies?

Methods

Search Strategy

A systematic search of published studies related to parents' experiences of using the insulin pump to manage their child's T1D was performed using the following databases: Embase (OVID), Medline (OVID), Cochrane Library, PsycINFO (EBSCO), and Cinhal (EBSCO). Databases were searched for published journals from 1974 to 13th October 2014. Key words used included "insulin pumps", "CSII", "experiences", "narratives", "patient satisfaction", "patient attitude", "parent", "mothers", "fathers", "child", "adolescent". The results of searches using these key words were combined using "AND" and "OR" Boolean operators. As index terms vary across databases, individual search strategies were developed for each database based on the initial Embase search strategy (Appendix 2). The same key search words and terms were entered in Google Scholar to search for additional papers and relevant grey literature.

Reference lists of the included journals were also reviewed to obtain additional relevant

papers. In addition, articles from the *European Diabetes Nursing* and *Pediatric Diabetes* journals published in the last five years were hand searched to identify further papers. These journals yielded the highest number of relevant articles from the search strategy.

New evidence published after 13th October 2014 will be described in an “updated research” section in the discussion of this paper; this will allow consideration of changes that may have occurred during this research period.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Peer reviewed studies using qualitative methods and analysis to explore parents' experiences of using insulin pump therapy to manage their child/young person's T1D
- Studies published in English language

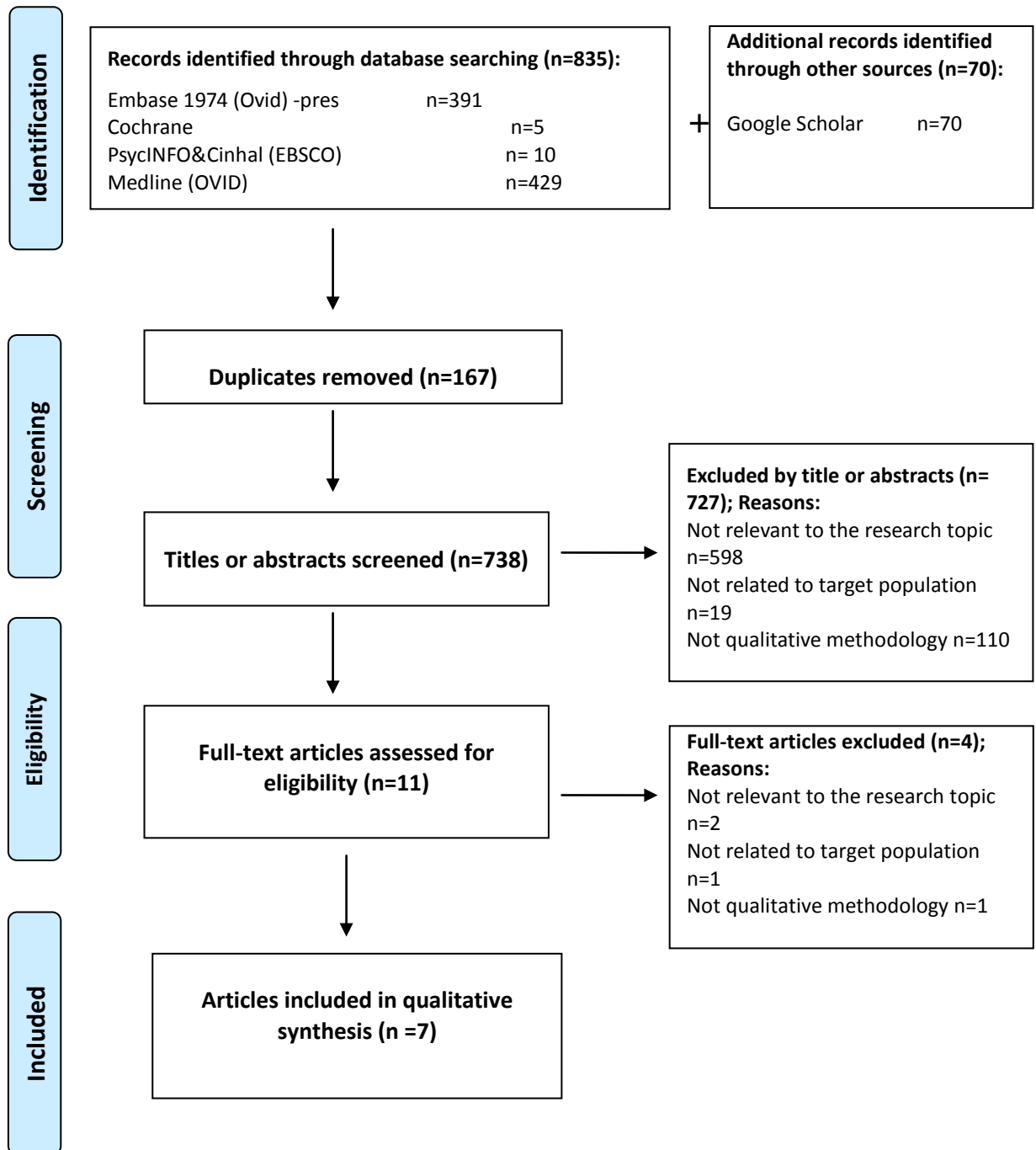
Exclusion Criteria:

- Studies describing experiences using implantable insulin pumps/closed loop systems/sensor augmented pumps
- Studies exploring experiences of adult pump users
- Studies about Type 2 Diabetes (T2D)
- Studies using quantitative methods
- Case studies
- Studies not published in English
- Unpublished research
- Studies that have not undergone the peer review process
- Studies failing to describe a recognised approach to qualitative analysis or those that fail to provide illustrative quotations.

Search Results

The search strategy produced 905 citations. Citations were screened for duplicates; 167 were removed. The titles of the remaining 738 citations were screened and 640 were excluded. It was clear from the titles that these articles were either: not related to the target population (e.g. pregnant mothers, nurses, adults); not related to the insulin pump (e.g. closed loop systems, glucose monitoring systems); or were not qualitative studies (e.g. reviews, feasibility studies, questionnaire development studies). Abstracts of the remaining 98 articles were read, and 87 were excluded. Excluded articles were either: quantitative studies; review studies; case studies; or not related to the target population. Full texts were obtained for the remaining 11 articles. Of these, 4 were excluded for employing quantitative methods, or for not being related the topic of interest. References of the final 7 articles were screened but no new articles emerged. No new articles were obtained from hand searching the last five years of both Pediatric Diabetes and European Diabetes Nursing journals. A flow chart of this process is provided in Figure 1. Table 1 provides detail on the seven articles included in this systematic review.

Figure 1: Flow chart of systematic search process and study selection



Data Synthesis

Meta-ethnography was chosen to synthesise the studies from this review and to generate new insights from the results. This method was chosen because it is, arguably, the most well-developed method for synthesising qualitative data⁴⁰, and it has been successfully used for synthesising diabetes research^{41,42}. Meta-ethnography involves selecting studies aimed at answering a specific research question to be synthesised, reading them repeatedly, and recording key concepts from these original studies. These key concepts, interpretations, and explanations from the original studies then become the raw data for the synthesis⁴¹. Noblit and Hare (p. 26-29)⁴³ described a seven step process for carrying out a meta-ethnography to allow for new interpretations through synthesising findings from individual interpretative accounts. The seven steps are as follows:

- 1) *Getting started* - deciding on a research question that is worth answering and one that could be informed by qualitative research
- 2) *Deciding what is relevant to the initial interest*- deciding what would be of interest to your audience, including defining the focus of the synthesis, finding relevant studies, and making decisions about what should be included
- 3) *Reading the studies*- becoming familiar with the content and detail of the included studies and noting emerging themes or metaphors
- 4) *Determining how the studies are related*- creating a list of themes or metaphors, juxtaposing them, and determining how they are related
- 5) *Translating the studies into one another*- comparing metaphors and concepts from each study with other included studies
- 6) *Synthesising translations*- higher order interpretation of comparisons from step five leading to a line of argument synthesis
- 7) *Expressing the synthesis*- presenting the results which is usually done through writing a paper for publication.

In keeping with the meta-ethnographic approach, summaries of original findings, using the

authors' terms and concepts, were compiled for each of the studies. Lists of these summaries were noted side by side, on a single sheet of paper to facilitate comparison of relationships between concepts in studies. After identifying key concepts from each study, a systematic search was completed to identify whether or not these concepts were present in the papers to be synthesised. This synthesis began with the earliest study, Sullivan-Bolyai⁴⁴, and continued by considering the presence or absence of each concept from this study within each of the other studies. Britten and colleagues explain that in a synthesis studies can relate to each other in one of three ways⁴⁰. First, they may be directly comparable as reciprocal translations. Second, they may stand in opposition to one another as refutational translations. Finally, they may be taken together to represent a line of argument.

Quality Assessment

Authors in the field of qualitative research are divided on the issue of quality assessment; specifically whether poorer quality studies should be included or not, and which appraisal criteria to use³⁹. A number of assessment tools for systematic qualitative reviews exist⁴⁵⁻⁴⁹. The 10 quality criteria outlined by the Critical Appraisal Skills Programme (CASP)⁴⁸ was used to assess study quality in this review. This tool was chosen as it has been used previously for assessment in meta-ethnographies^{41,50}, and specifically in the field of diabetes⁴¹. The CASP assessment tool requires the author to answer 'yes', 'partially' or 'can't tell/no' to 10 questions to assess the rigour, credibility and relevance of each qualitative study. As is common practice when using quality criteria⁴⁵, the tool was modified to allow a scoring system to be superimposed, this did not affect the validity of the CASP tool in itself as questions within the tool were not modified (see Appendix 3).

Although authors in this field⁴¹ have used quality assessment to screen studies for inclusion in their meta-ethnography, it was decided *a priori* that every study meeting the

inclusion criteria of this systematic review should be included in the final analysis. This decision is in keeping with the third research question, specifically to understand the quality of studies published in this field.

Scoring

Studies were given 2 points if they provided enough detail to answer the quality question detailed in the CASP tool, 1 point if they partially answered the question and no points if they did not, or if it was not clear whether they had answered the question. Studies scoring >15 were classified as 'good', 10-15 as 'acceptable', and <10 as 'poor'. Studies were assessed by the author and a second independent researcher.

Table 1: An overview of articles included in the review in year order

Author(s) and Year	Country	Aims	Methods	Duration of pump use	Themes	Quality Score /20	Areas of Potential Bias
Sullivan-Bolyai et al, 2004⁴⁴	Massachusetts, USA	To describe the experiences of parents managing the type 1 diabetes of their young children using insulin pump.	Interviews with 21 mothers and fathers of 16 children (2-11 years old with a mean age of 7) Content analysis was used to analyse the data.	3-36 months	<ul style="list-style-type: none"> • Introduction to the pump • Decision making process • Transition from MDI to pump • Day to day management with the pump • QoL with the pump 	17	<p>Participants may have felt under pressure to take part as they were contacted by the PI directly</p> <p>More detail needed on bias from the researchers role</p>
Low et al, 2005¹⁴	Maine, USA	To use qualitative and quantitative methods to explore psychosocial issues related to insulin pump use in youth.	Interviews with 18 adolescents (11-18 yrs) and their parents about their experience of using insulin pumps. Content analysis was used to analyse the data.	Mean =1.4. yrs	<ul style="list-style-type: none"> • Pump therapy-expectations and benefits • Adjustments related to pump therapy • Social issues; liabilities associated with the pump • Wearing an insulin pump • School-related issues 	14	<p>Not enough detail on recruitment strategy</p> <p>Data saturation not discussed</p> <p>No respondent validation</p> <p>No reflective diary use reported to allow the researcher to assess bias from their role</p>

Table 1: An overview of articles included in the review in year order (*continued*)

Author(s) and Year	Country	Aims	Methods	Duration of pump use	Themes	Quality Score /20	Areas of Potential Bias
Pay, 2011⁵¹ with additional information from Pay, 2009 (Doctoral thesis provided in italics)⁵²	Queensland, Australia	To gain an understanding of children and adolescents' and their parents' experiences of making the transition to insulin pump therapy.	Questionnaires, diaries and interviews (before and 3 months after transitioning to the insulin pump) with 12 children/adolescents (3-16yrs) and 11 parents. Content analysis was used to analyse the data.	0-3 months	<p>The meaning of diabetes</p> <ul style="list-style-type: none"> • Planning • Constancy of Diabetes care • Worries/concerns • Hypoglycaemia • Long term health <p>Transition to insulin pump therapy</p> <ul style="list-style-type: none"> • Starting over • Effort <p>The meaning of insulin pump therapy</p> <ul style="list-style-type: none"> • Fewer needles • Freedom <i>and flexibility</i> • Better control of blood glucose levels • Being attached • Feeling normal • Infusion Cannulas • <i>Education</i> 	18	<p>No reflective diary use reported to allow the researcher to assess bias from their role</p> <p>Data was not coded by a second researcher</p>
Olinder et al, 2011⁵³	Sweden	To gain insight into and generate theoretical knowledge about the processes involved when insulin pump treated adolescents take or miss taking their bolus doses.	Interviews with 12 adolescents (12-19 yrs); 4 parents and 1 diabetes nurse. 2 adolescents and 2 parents were re-interviewed after 10 months. Grounded theory used to analyse the data.	At least 3 yrs.	<ul style="list-style-type: none"> • Distribution of responsibility • Transfer of responsibility • Clarification of responsibility 	14	<p>No reflective diary use reported to allow the researcher to assess bias from their role</p> <p>No respondent validation</p> <p>More justification on sampling needed</p>

Table 1: An overview of articles included in the review in year order (*continued*)

Author(s) and Year	Country	Aims	Methods	Duration of pump use	Themes	Quality Score /20	Areas of Potential Bias
Alsaleh et al, 2013⁵⁴	London, UK	To determine the views and experiences of parents and children regarding the training and services they received at a London teaching hospital when the child commenced insulin pump therapy; and to inform future services.	Face to face interviews with 38 parents and 34 children (5-17 yrs). A mix of framework analysis and grounded approach was used to analyse the data	5m-7yrs	<ul style="list-style-type: none"> Initial worries and concerns regarding using the insulin pump Participants' views about the structured multidisciplinary insulin pump programme Recommendations for future services 	13	<p>No reflective diary use reported to allow the researcher to assess bias from their role</p> <p>No respondent validation</p> <p>Not enough detail on method (sampling and analysis)</p> <p>No detail on how this study relates to Alsaleh et al 2014⁵⁵ and why they were written as two separate papers- author contacted but no response was given to this query.</p>
Alsaleh et al, 2014⁵⁵	<i>As above as these articles are from a single study of enquiry</i>	To examine the experiences of children/young people and their parents when switching to insulin pumps	<i>As above</i>		<ul style="list-style-type: none"> Pump therapy and glycaemic control Adapting to pump technology Home and social lives 		<i>As above</i>

Table 1: An overview of articles included in the review in year order (*continued*)

Author(s) and Year	Country	Aims	Methods	Duration of pump use	Themes	Quality Score /20	Areas of Potential Bias
Forsner et al, 2014 ⁵⁶	Sweden	To determine parents' experiences of caring for a child less than two years old who had diabetes mellitus and was being treated with the insulin pump.	Three sets of parents were interviewed twice. The second interview occurred 6 months after the first. Content analysis was used to analyse the data.	6-7 months	Overarching theme: <ul style="list-style-type: none"> “The diabetes disease was threatening our baby's life, but then the insulin pump came as a rescuing, though challenging, angel” <i>1st interview:</i> <ul style="list-style-type: none"> Having your whole life turned upside down Facing fears and obstacles Being vulnerable yet confident Regaining control <i>2nd interview:</i> <ul style="list-style-type: none"> Being in control nearly all the time Being challenged Life goes on 	14	No reflective diary use reported to allow the researcher to assess bias from their role No discussion of discrepancies between authors

Results

Quality Appraisal

Five of the seven articles received the same score by the assessors (see Appendix 4). Discrepancies occurred because of different interpretations of some appraisal questions and were resolved through discussion. All of the articles were of 'acceptable' standard or above. As all studies fell above 'acceptable' standards based on quality ratings, findings were not weighted based on quality score. Quality scores did not appear to have made any real difference on the findings in this meta-ethnography as themes were similar between studies irrespective of the quality of the paper.

Synthesis

Table 1 provides an overview of the studies, emerging themes from each study, the CASP quality score, and areas of potential bias worth considering. Synthesis of the studies identified that the themes translated onto one another. Key concepts emerging from the analysis included:

- Adjusting to the pump
- Concerns regarding child wearing the pump
- Freedom and flexibility
- Responsibility sharing
- Support for the pump

Adjusting to the pump

Adjustment to the pump was frequently discussed. Some parents described feeling surprised at how difficult it was to adjust to the pump, the extra work that was involved initially⁵², and the potential for difficulties to arise^{14, 52}.

"He had lots of things happen on the pump, practically everything that can go wrong" ¹⁴ (p.24)

The process of transitioning and adjusting to the pump was described as anxiety provoking^{14,56}, tiring^{14,52}, frustrating¹⁴ and “scary”^{44,56}. Some reminisced that this experience felt like “starting over”; similar to when their child was first diagnosed with diabetes^{44,52}. Parents reported being preoccupied caring for their child with T1D on the pump, with siblings feeling pushed aside⁵⁶. Particular areas of difficulty reported included: cannula changes^{44,52}; carbohydrate counting^{52,56}; night time testing^{14,52,56}; programming the pump and problem solving when something goes wrong⁵⁵.

*“I don't have a clue really what to bolus for something from the bakery like that's what the dietician said. I remember the dietician saying have a guess if it's something like a sweet dessert, have a guess and you can correct more on the lower side than on the higher side. When I do that, when I correct the next time the correction doesn't seem to count up for what it should have been and so then he'll go high again after that.”*⁵² (p.51)

Sullivan-Bolyai and colleagues⁴⁴ described that the transition from MDI to the pump involved re-education of the child, the parents themselves and other caregivers. They reported that parents had to “rethink” the way they managed their child's diabetes including learning to sleep through the night again. Interestingly, in other studies parents reported that they were challenged adjusting to pump therapy because initially they needed to check blood sugars frequently including during the night and were “very, very tired”¹⁴ from sleep deprivation^{14,55}. Parents described that the timing of moving from MDIs onto the pump may be crucial as one programme which may be suitable for a week at school would be different to Easter holidays when lots of chocolate is consumed⁵⁵. The adjustment process varied in length for parents; however studies reported that parents felt confident with the pump from between 6 weeks⁵¹ and 6-9 months^{44,56}. This did not differ between parents of very young children⁵⁶ and parents of older children⁴⁴. Parents

reported that the initial adjustment to pump therapy had a great impact on their working lives with one parent reporting giving up work for six months⁵⁵.

“Yes the beginning of insulin pump therapy was terrible, so we actually did not work for 6 months. We did not do anything, we stopped everything.”⁵⁵ (p.5)

Concerns regarding child wearing the pump

A number of parents expressed concerns about having their child hooked up to a “mini life support system” when making the decision to begin pump therapy⁴⁴. These parents worried that the pump would malfunction giving the child too much insulin, or that the cannula would fall out. Parents also worried that their children would be stigmatised or bullied because of the insulin pump, or that other children would curiously press buttons, putting their child in harm’s way. Similarly, a father worried that the pump would be “an albatross” constantly reminding his child had he had diabetes⁴⁴. Similar pre pump initial worries were reported by parents by Alsaleh and colleagues⁵⁴. Parents most frequently worried about having a cannula constantly inside their child’s body, and worried that the pump might interfere with their child’s daily activities due to its size and shape⁵⁴.

Parents of younger children expressed concerns about the size and weight of the pump, and described having to sew pouches onto their child’s clothing to keep the pump from falling off⁴⁴. Similar concerns about the size of the pump were expressed by parents with children under two years of age; one parent commented that the pump looked like a “ghetto blaster” on her tiny baby. Parents in this study also commented that the pump was always there, getting in the way when trying to care for their baby, for example when changing diapers⁵⁶.

Alsaleh and colleagues⁵⁵ reported that although parents often worried that wearing a

pump would make their child more self-conscious of having diabetes and may render them vulnerable to being bullied. Some parents in this study also reported that the pump had a tendency to fall off or get in the way during sports. It is important to note that, when Low and colleagues¹⁴ compared parents with their teenage children they found parents tended to overestimate how uncomfortable their children were when responding to questions about the pump. Other parents reported that the pump appeared to have no effect on their child at all, except at meal times or physical activity¹⁴. Some parents said it could be hard to secure the pump to clothing without waistbands¹⁴.

Similarly, Pay reported a theme in the data of *“being attached”*; parents reported that having their child *“attached”* to the pump was a disadvantage⁵². These parents worried about how their child would manage to sleep with the pump. Although most children adjusted to wearing the pump, one parent reported that her child stopped using the pump because she felt abnormal being hooked up to a machine.

“K has told us that she no longer wants the pump because she feels that she is hooked up to a machine and does not feel like a normal kid” ⁵² (p.47)

Freedom and flexibility

Although glycaemic control was often cited as the main reason for initiating pump therapy, flexibility in terms of diet and meals (timing and size) was the most frequently mentioned benefit^{14,44}. Parents mentioned that a big advantage of the pump was allowing their child the freedom to eat when they wanted^{14,52,55}, to have a lie in if they wanted⁵², and to *“vacation without a schedule”*¹⁴. In addition to QoL benefits offered by this flexibility, parents said that this led to better nutrition management of their children⁴⁴. Parents described the pump offered them freedom from the *“slavery”* of diabetes management.

*“My husband said [we had] to leave because our son had to eat and it was close to dinnertime, and I said, “You know, we don’t have to go.” And it was such a liberating moment.....”*⁴⁴ (p. 321).

Parents reported benefits for the family too. They reported family life was less time driven and more spontaneous⁴⁴, and that it was easier to eat out as a family without having to be so regimented about food⁵⁵. Although generally parents reported that the flexibility with pump use enhanced social opportunities for their children, some parents reported specific social difficulties for their children such as attending “pool parties” and being outside in freezing temperatures which can impact pump functioning¹⁴.

In contrast to other parents interviewed about the pump, parents of children under 2 years of age reported feeling pressure to be on top of things with the pump. They reported living in a “*world of routines*” but commented that the routines were both a strain and a source of security, and felt that even with a lot of routines they preferred the pump as MDI could not deliver the small amounts of insulin their baby needed⁵⁶.

*“God! The pens they’re like trying to fix a watch with an axe.”*⁵⁶ (p.10)

Responsibility sharing

Generating theoretical knowledge around the theme of responsibility for management of the insulin pump was the focus of Olinder and colleagues’ paper⁵³, and was mentioned under other themes in most of the studies in this review. Olinder and colleagues interviewed parents and adolescents to understand the distribution of responsibility for diabetes management on the pump. The three themes exploring responsibility in this study were: *distribution of responsibility*, *transfer of responsibility*, and *clarification of responsibility*. Some parents in this study reported a struggle between helping their

adolescent child to become independent whilst also taking responsibility for their diabetes management. Parents said they offered more practical support to their adolescent children around the filling of the pump; changing infusion sets and reminding their child to bolus, however, they described a decline in such support once adolescents assumed more responsibility. Parents reported that the level of support from active to passive could shift back if the adolescent forgot to bolus at any point. Some parents said they wanted their adolescent children to know they were there to help when he/she was at home so that their adolescent child could relax knowing they were supported. This paper discussed the transfer of responsibility between the parents and adolescent as a gradual process which started when their child was very young, with more support being offered by parents when the adolescent is unwell, stressed, or when they have poor control. Parents described feeling frightened of relinquishing control with their adolescent child for fear of acute and late complications from poor diabetes management. This fear can be difficult for parents as they can feel stuck between wanting their adolescents to take more responsibility, and be more autonomous and being scared to let go of control of their adolescent child's diabetes management.

*“Well, I’m really scared. Which I don’t tell S. I’m afraid she will end up in a situation where nobody understands that she needs help...”*⁵³(p. 1552)

Parents discussed the need to clarify responsibility for diabetes management to allow necessary prompting of their adolescent child in aspects of management, such as bolus administration, without their adolescent child feeling that they are being constantly pestered by their parents. Similar discussions of parents and adolescents sharing responsibility for diabetes management on the pump were reported by Low and colleagues¹⁴, with parents assisting in aspects such as reminding to bolus, set changes and troubleshooting mechanical problems.

In keeping with Olinder and colleague's⁵³ discussion of a gradual transfer of responsibility for diabetes management, parents in Sullivan-Bolyai et al.⁴⁴ reported that the pump empowered their children (those above age six) to become more involved in managing aspects of their diabetes such as: helping to insert the catheter, counting carbohydrates, and learning the mechanics of the pump.

In addition to considering responsibility sharing between the parent and child/young person, responsibility sharing with other adults was discussed in a number of studies. Parents reported having to re-educate others who care for their children in managing diabetes with the pump, and reported that sharing diabetes management between adults was easier on the pump compared with MDI, because of the historical log which allowed parents to see whether insulin had been bloused⁴⁴. Similarly, fathers were more involved in diabetes management because the mechanical aspects of the pump were perceived as a "guy thing"⁴⁴. Parents also reported that it felt easier to get a babysitter to care for their children on the pump, as pump management was perceived as easier than MDI^{44,52,55}.

In contrast some parents reported experiencing difficulties sharing responsibility for their child's diabetes on the pump with others. Parents reported difficulties getting schools to assist in pump management¹⁴; and some felt that difficulties explaining complex pump management were a barrier to leaving their child with others^{55,56}. Parents also reported that their children received fewer social invitations from others and wondered whether other parents felt frightened to take responsibility of the pump⁵⁵. Similarly, parents of children less than two expressed anxieties about leaving their child with someone else on the pump and reported feeling isolated⁵⁶.

*"Of course we felt very alone. Very alone.... There wasn't anyone else."*⁵⁶ (p.9)

Support for the pump

The need for continued support, extra education sessions, and discussions about pump malfunctions were commonly mentioned in interviews with parents. Although most reported pump training by diabetes clinics as really helpful^{54,56}, parents often commented that additional education would allow them to discuss some of the more complex management concepts of the pump⁴⁴, and offer them additional practical tips for managing the pump⁵². Parents reported finding 24 hour support 7 days a week particularly helpful when learning how to use the pump, with additional contact details and further support also necessary⁵⁴. Opinions regarding support provided to schools were mixed; some parents reported that support helped schools to feel more equipped to manage emergencies with the pump, whilst others said that information provided to schools was excessive⁵⁴.

Parents spoke about feeling vulnerable and dependent on Diabetes nurses in the initial period after beginning pump therapy with their very young children. When these parents were followed up six months later, however, they reported increased confidence in managing pump therapy alone⁵⁶. Other parents reported that support from diabetes clinics helped them the feel like they could cope⁴⁴.

Pump malfunctions were mentioned in some interviews^{14,44,55}, with "*liabilities associated with CSII*" being a theme to emerge in one paper¹⁴. Some parents reported having problems with site infections⁴⁴, the pump freezing⁵⁵, difficulties with air bubbles⁵⁵, static interference impacting pump functioning¹⁴, and problems with the cannula^{44,55}. Although pumps are often equipped with alarms to indicate potential difficulties, some parents reported that these alarms made their children feel nervous¹⁴. Parents reported pump malfunctions as very anxiety provoking but accepted that it was part of pump therapy¹⁴.

“When something malfunctions, it is a disaster... and we have had many a sleepless night because of that. But, you know it kind of comes with the territory”¹⁴(p.27)

Parents mentioned that it was helpful to have support, and a quick response from pump manufacturers when a problem arose^{14,44}.

Discussion

This systematic review synthesised qualitative studies exploring parents' views of the insulin pump to gain a better understanding of these views and experiences. There were few studies in this field. Of the seven articles included in this review, two were specific in their focus; exploring parents views of insulin pump training in a hospital in London⁵⁴ and looking at a theoretical understanding of responsibility sharing around missed boluses⁵³. Despite these articles with specific foci it was possible to identify five key themes amongst the research: 1. adjusting to the pump, 2. concerns about a child wearing the pump, 3. freedom and flexibility, 4. responsibility sharing and 5. support for the pump.

Many parents described challenges involved in adjusting to the pump which were frequently referred to as anxiety provoking. As part of this adjustment, parents often engaged in anxiety driven nocturnal testing, had concerns about having their child hooked up to a pump, worried about how others would react to the pump, and had to overcome challenges of finding ways to keep the pump attached to their child. The paediatric transactional theory⁵⁷ emphasises the importance of gaining an understanding of these stressors and experiences of a parent caring for a child with chronic illness as these factors are associated with the child's health and behaviour. In addition, these factors have been associated with parental health²⁴, QoL¹⁹, and diabetes self-efficacy^{22,23}.

Although the two aforementioned themes (*adjustment to the pump; concerns regarding child wearing the pump*) are centered around some of the more challenging aspects of pump experience, parents often commented that these difficulties were worth it for the freedom and flexibility the pump offered their child. Interestingly, qualitative research exploring young people's experiences of the pump has mirrored this finding; even though there can be negatives to pump use (for example, being bullied); there are also positives to pump use (for example, greater freedom to socialise), with young people generally preferring the pump in comparison to MDI¹¹.

Parents of older children commented that the pump made it easier for them to share the responsibility of diabetes management with their child's other caregivers^{44,52,55}, however, parents of children aged two and under felt that it was sometimes difficult to get support caring for their child and felt isolated⁵⁶. Different challenges caring for a child with T1D depending on the child's developmental stage are in keeping with guidance from the American Diabetes Association on standards of care for children and adolescents with T1D⁶. Although numerous quantitative studies exist on glycaemic benefits on the insulin pump, it is interesting to note that QoL benefits such as increased freedom and flexibility are more frequently mentioned in the studies than glycaemic control. These findings may lend support for studies indicating improved QoL for parents and children on the insulin pump compared with MDI²⁹. This observation merits further exploration in future studies on parents' experiences with the insulin pump. Similarly, positive support from parents allowing their child to take on more responsibility has been associated with increased adolescent adherence to treatment regimens⁵⁸. Parents felt that the pump facilitated sharing of responsibility with children above six years of age⁴⁴.

Parents acknowledged that the pump is a machine and like other machines is complex and can malfunction, therefore it was felt that ongoing support is needed to help them to

cope when these difficulties arise. This finding is in keeping with Weissberg-Benchell and colleagues' meta-analysis²⁹. They reported that pump malfunctions and technological difficulties were commonly reported problematic situations for families with adolescents using the insulin pump. Studies have suggested that difficulties using the insulin pump are a common reason for children or adolescents discontinuing pump therapy⁵⁹. Guidance on caring for a child with T1D generally (regardless of method of insulin delivery) has highlighted the importance of continued support and education⁶; this may be particularly useful for families encountering pump-related difficulties.

Quality of studies in this meta-ethnography

Most of the articles received high scores for quality questions related to the aims of research, the appropriateness of method for research aims, and for detailing the value of the research. Studies commonly failed, however, to adequately consider the relationship between the researcher and the participants, with consideration of researcher-participant reflexivity often absent from studies. Articles also received lower scores for not providing enough detail on data analysis, specifically why they chose a particular method, and steps taken to allow the reader to consider whether this was appropriate and sufficiently rigorous. Word limits imposed by journals might have impacted on the level of detail provided, thus lowering quality scores. This was evident when comparing Pay's published study⁵¹ with her doctoral thesis⁵². The level of detail provided in the thesis increased the quality score from "acceptable" to "good".

When considering bias in the studies, a method of respondent validation was often absent which impacted on the reader's ability to determine how accurately the themes reflected participants' experiences. It was often unclear how authors decided when they had enough data to answer the research question as sample size considerations or saturation of data were not mentioned in some studies^{14,53-55}.

Strengths and Limitations

Of the seven articles included in this meta-ethnography, five articles^{14,44, 52, 55,56} translated into each other well with similar concepts emerging from parents' experiences in each paper. The more focused studies by Alsaleh et al⁵⁴ and Olinder et al⁵³ did not synthesise as well with the other papers. For example, although responsibility sharing was the focus of Olinder and colleagues' study and therefore synthesised well with other studies also addressing responsibility sharing, concepts common to these other studies^{14,44,52,55,56} could not be mapped onto this study because the focus was restricted to responsibility sharing. In retrospect, perhaps if there had been a greater number of qualitative studies that explored parents' views of the insulin pump more generally then these studies would have been excluded because their specific aims may impact on the understanding of wider issues for parents caring for a child on the insulin pump. Similarly, it is also worth noting that although the two papers by Alsaleh and colleagues^{54,55} focused on different aspects of parents' experiences of the insulin pump they were from a single study of enquiry.

A limitation of this review is that sampling bias may have impacted on the findings presented. It is likely that parents who took part in the studies were highly motivated to share their experiences, whereas those who decided not to participate may have had different perceptions and experiences of the pump. It is important to consider that the studies were carried out in a range of geographical areas from America, Australia, Sweden and the UK. Different healthcare systems and provisions may also have impacted on the findings presented. Similarly, it was not clear from these studies whether different cultures and ethnicities were represented in the research. Limiting the search to studies published in English language meant that studies in different cultural contexts may have been missed. The age ranges of children parented were often very wide in the studies included e.g. 2-11 years⁴⁴, 3-16 years⁵¹, and 5-17 years⁵⁴, it was therefore difficult to analyse differences in parents' experiences based on the age of their child throughout this

meta-ethnography. Given these limitations it is likely that this review is limited in understanding parents' views of the insulin pump; however the intention of this review was not to generate generalisable findings but to gain an in depth understanding of parents' experiences of using the insulin pump.

A recent systematic review highlighted that qualitative research is rarely published in high ranking journals⁶⁰; this finding combined with the exclusion of unpublished research from this review may have limited our understanding of the topic area. Although the studies included in this review spanned a ten year period and covered experiences of parenting children across the developmental range from two to nineteen years of age, common experiences could be identified between studies. More qualitative studies in this field could allow for a stratified analysis to be carried out which may capture the different care needs for each developmental stage.

Updated Research

Since this review was carried out, Rankin and colleagues⁶¹ published a qualitative study exploring 19 parents' experiences of managing their children aged 12 or younger, with T1D on the insulin pump. In keeping with this review, parents reported benefits from the pump in terms of more freedom and flexibility at mealtimes and with life generally. Similarly, responsibility sharing was also discussed by these parents within the theme "*more work for parents and other caregivers*". Other themes from this study that did not emerge in the present review included: "*benefits of bolus advisors*", "*more work to address perceived risks of hypoglycaemia*", and "*more work because parents can do more to manage their child's diabetes*". Further qualitative studies in this field may allow for more convergence with themes from this study that did not emerge from the meta-ethnography.

Reflexivity

This review was completed while the author carried out research into parents' experiences of caring for a child with T1D using the insulin pump. These experiences may have influenced the author's secondary interpretation of the papers.

Clinical Implications

This review suggests that parents of children with T1D using the insulin pump can experience difficulties with the change from MDI management. These initial difficulties can be around cannula changes or anxieties about their child constantly being attached to a pump. The majority of parents reported benefits of the insulin pump for family flexibility and for sharing the responsibility of diabetes care with others, however, a number of parents indicated that they would like more information and education on using the pump over and above the support already received. More knowledge on some of the more difficult aspects of the pump and how to manage these could help normalise parents' experiences, decrease anxieties, and increase adherence to pump therapy. Some parents identified that the process of adjusting to the pump was very anxiety provoking; more guidance on supporting parents with anxiety related to diabetes management at this time could ensure that parents' psychological needs are better supported, which may impact on the parent and child's level of distress, and subsequent glycaemic control⁶.

Research Implications

The care needs and levels of support required by children differ according to the child's developmental stage⁶. More research focusing on parents' experiences of the pump for children at different developmental stages could provide greater understanding of the challenges and support needs at each stage. Similarly, only two studies included in this review looked solely at only parents' views. Being involved in a study whereby the parent is aware that their views will be examined alongside their child's may have impacted the data provided. Furthermore, as the findings from this review were based on studies conducted in four countries with different health care systems in operation, more research

across different countries, cultures and ethnicities is warranted to gain a better understanding of experiences for specific population groups.

Conclusion

Parents play a pivotal role in supporting their child with T1D using the insulin pump, however few qualitative studies exist to understand parents' experiences of this insulin management process. This review emphasises that although parents face challenges and experience anxiety in certain areas of pump therapy, these challenges are commonly accepted for the increased freedom and flexibility offered by the pump. Further studies aimed at understanding parents' experiences of caring for a child with T1D using the insulin pump at different developmental stages could help to tailor support offered to parents at each stage.

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Chapter 2: Major Research Project

An exploration of parents' views of managing their children's type one diabetes with insulin pumps

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Plain English Summary

Background

Type 1 Diabetes (T1D) is an illness that usually starts during childhood and requires treatment with a combination of insulin injections, blood sugar tests, dietary control and exercise. Traditionally, insulin was delivered by multiple daily injections; however, the development of insulin pumps which deliver insulin through a small tube inserted under the skin has resulted in another method of diabetes management. Insulin pumps may offer benefits to people with T1D, e.g. improved blood sugar control, quality of life (QoL), thinking skills and behaviour. Although parents play a lead role in helping their children manage their diabetes using the insulin pump few studies have looked at the impact of the insulin pump on parental quality of life.

Aims

To explore the views of parents who manage their children's T1D with insulin pumps with a particular focus on the impact of the insulin pumps on their quality of life.

Methods

Following ethical approval and informed consent, seven parents of children aged 12 or younger with T1D, and who had used the insulin pump for nine months or more, were invited to participate in this study. The researcher carried out interviews lasting about 50 minutes each, these were digitally recorded, typed out word for word, anonymised and analysed to gain an in-depth understanding of what it is like to care for a child with T1D using the insulin pump.

Main Findings and Conclusions

Four themes described parents' experiences caring for their child using an insulin pump: life before the pump, transition to the pump, life on the pump, and the perceived impact for their child. On the whole parents were happy with the pump, although parents explained that there were both positive and negative aspects to using the pump. This study may help to inform the care that parents of a child with T1D receive from their diabetes team.

Abstract

Background: Insulin pumps have the potential to improve glycaemic control and health in childhood type 1 diabetes (T1D) but they require intensive monitoring and their impact on parental quality of life (QoL) is less well understood.

Aims: To explore the views of parents who manage their children's T1D with insulin pumps, with a particular focus on the impact of this method of insulin delivery on parental QoL.

Method: A qualitative, cross-sectional study was conducted. Seven parents with a child aged 12 or younger with T1D, who have used the insulin pump, were recruited using purposive, volunteer sampling. Semi structured interviews were carried out and analysed using interpretative phenomenological analysis (IPA).

Results: Four super-ordinate themes describe parents' experiences adjusting to caring for their child using an insulin pump; 'life before the pump', 'transition to the pump', 'life on the pump', and the 'perceived impact for their child'. Each super-ordinate theme comprised several sub-themes, and a concept that crossed all themes was 'fluctuating feelings of control'.

Conclusions: Parents were generally positive about using the insulin pump to care for their child with T1D, and most wished to continue with this method of insulin delivery. Parents faced challenges at particular times with the pump, but with support regained control over difficult aspects of pump use. Understanding parents' experiences will assist diabetes teams to implement care practices centred on the needs of the family.

Key words: Insulin Pumps; Type 1 Diabetes; Children; Young People; Parents

Introduction

T1D is one of the most common chronic childhood illnesses with incidence rates rising rapidly in the last ten years in Europe, Australia and the United States of America (USA)¹. Management of T1D requires continued attention to a number of factors which can each impact glycaemic control including: insulin administration, blood glucose monitoring, physical activity, and meal planning². Complications in glycaemic control may affect the eyes, kidneys, nerves and cardiovascular system and in some cases may lead to coma and even death³. Recommended treatment of T1D includes intensive insulin replacement therapy to try to achieve near optimal glycaemic control; this is often a challenge for children, young people, and their families⁴.

Insulin pumps

Insulin pump therapy offers an alternative to the more traditionally used multiple daily injections (MDIs). Insulin pumps are small devices worn outside the body, which continuously deliver insulin through a thin tube or cannula inserted subcutaneously. The insulin can be delivered at a set rate or increased when needed, for example at meal times. It is advised that the cannula be replaced and repositioned every three days⁵.

A Cochrane review of 23 randomised controlled trials (RCTs) (including seven with participants below 18 years of age) comparing insulin pumps with MDIs reported that insulin pumps may result in improved glycaemic control compared with MDIs³. Guidelines recommended the use of insulin pump therapy for children and young people who present with either: recurrent severe hypoglycaemia, suboptimal glycaemic control, microvascular complications and/or risk factors for macrovascular complications, or for those who have good glycaemic control but whose insulin regimens compromise their lifestyles⁶.

Insulin pumps and QoL

Studies about insulin pump therapy tend to focus on clinical effectiveness and medical

outcomes from this method of insulin delivery^{7,8}. It may be the case that benefits occur over and above good glycaemic control. For example, improved glycaemic control is associated with benefits in cognition, behaviour and emotions⁹. A number of clinical specialists, patient experts and studies have indicated that the use of insulin pumps yield a number of QoL benefits, including: greater flexibility in routines and diet, less physical burden^{6,10}; autonomy, spontaneity, socialisation, improved sleep¹⁰; and decreased fear of hypoglycaemia¹¹. In contrast, factors associated with pump use have also been reported which may negatively impact QoL such as: cannula site infections¹¹; pump malfunctions^{11,12}; supervision requirements of pump therapy in young children^{12,13}; school related issues¹²; and the visibility of the pump^{10,12}. A systematic review which explored the literature, and tried to ascertain whether pumps yielded QoL benefits for people with T1D stated that their findings were inconclusive due to poor quality studies in this field, and inconsistency in QoL assessment¹⁴.

The impact of the insulin pump on parenting a child with T1D

The task of managing T1D in young children rests almost completely on adult carers. A wide variety of carer burden, stress and anxiety has been reported including: food intake variability, activity level monitoring¹⁵; having to be constantly available to other caregivers, tension in the relationship between the family and the child's school⁶; carrying out anxiety provoking nocturnal blood glucose monitoring¹⁶; and fear of hypoglycaemia¹⁷. These factors have been shown to affect both parental health¹⁸ and QoL¹⁷.

Some studies have suggested that insulin pumps allow parents of children with T1D greater flexibility, spontaneity and freedom in their lives⁶; reduced parental stress and worry regarding their child's overall care⁶ and glycaemic control¹⁵; and greater confidence and independence in managing their child's diabetes¹⁹. Similarly, a Scottish qualitative investigation of the effect of the insulin pump on young people's QoL found that they

reported less parental burden and more parental support with the insulin pump compared to MDIs¹⁰. A meta-analysis investigating the psychosocial impact of insulin pump therapy found no consistent differences in QoL, self-esteem, anxiety, depression, and family functioning between insulin pump therapy and MDIs²⁰.

Gaps in the knowledge base

In conclusion, studies about the impact of insulin pump therapy on QoL in T1D yield conflicting results. A recent systematic review emphasised that there is limited qualitative data examining experiences of parents caring for children with T1D using insulin pumps²¹. This review and individual studies focusing on parents' experiences of caring for children with T1D have underlined the scarcity of research in this area; authors in this field have concluded that further investigations of parent QoL are warranted^{16,22}. These gaps in the evidence base are particularly relevant within the Scottish context, given the increased provision of insulin pumps amongst the Scottish paediatric population²³, driven by Government investment²⁴.

Aims

This study aimed to explore parents' views of managing their children's diabetes with insulin pumps compared to MDIs.

Objectives

- (I) To explore the views of parents managing their children's T1D with insulin pumps
- (II) To investigate the perceived impact of the insulin pump on parents' QoL*

*There is a lack of agreement on the definition of QoL, or how best to measure this within health and social research. In keeping with the work of Joyce and colleagues²⁵, and for the purpose of this study, QoL will be what the participant chooses it to be; they "alone can define it and assess its changing personal significance" (p.121).

Methods

Design

The present study was an exploratory qualitative study and used Interpretative Phenomenological Analysis (IPA). IPA aims to explore flexibly and in detail how the research participant makes sense of their experiences, while acknowledging that the analysis of this exploration of experience is influenced by the researcher's interpretation of these views²⁶. The IPA approach has been commonly used to explore experiences with illness²⁷.

Participants

In keeping with IPA principles, a purposive, well defined homogeneous sample²⁶ of parents of children with T1D, attending a Scottish paediatric diabetes clinic was recruited for this study. The intention of this study was not to provide a generalisable account of parent's experiences managing T1D using insulin pumps, but to provide an in-depth account of each individual's experience of their child's diabetes management, whilst also allowing exploration of similarity and difference of experiences within the sample.

Consistent with developmental stages²⁸, research into children with T1D is often divided into age bands of 12 years or younger, and above 12 years of age²⁹. This study focused on the experiences of parents with children aged 12 or younger with T1D who use, or have used the insulin pump, because parents will play a crucial role in helping their children to manage their diabetes during these younger years. It can take parents six weeks to nine months to feel confident using the insulin pump after initializing pump therapy³⁰; to prevent initial confidence issues from influencing the data, parents with less than nine months experience using the pump were excluded. Due to the exploratory nature of this study, both genders of parents were included; this is consistent with other research in this field^{30,31}.

Inclusion criteria

- Has a child aged 12 or younger with a diagnosis of T1D and has used (current or past use) an insulin pump for at least nine months
- Child (and siblings) has/have no additional major chronic health conditions requiring hospital attendance
- Fluent in English
- Has a child attending the recruiting hospital

Recruitment Procedure

Recruitment packs were sent to a random sample of 25 parents identified as meeting inclusion criteria. Posters were also put up in the waiting room of the Diabetes outpatient department to invite eligible parents to take part. Interested participants were contacted, and an appointment was arranged to conduct the interview within the diabetes clinic. Written informed consent was obtained prior to conducting the interview. See appendices 6-10 for forms used during recruitment.

Of the 25 parents invited to take part in this study, nine made contact with the researcher and seven agreed to be interviewed. Six were mothers, one was a father, their children were between seven and twelve years old at recruitment; all were from two parent families (see Table 2). By the seventh interview, it was observed that similar themes and experiences were being spoken about in the interviews, with no new themes arising; data had therefore reached saturation within this sample. A number of sample sizes for IPA have been suggested^{26,32}. This sample size is consistent with the recommendation of between four and ten participants for a professional doctorate (p.52)³².

Table 2: Summary of participant demographics

<i>Parent</i>	<i>Mother/Father</i>	<i>Age and Sex of child at recruitment</i>	<i>Age at T1D diagnosis (yrs)</i>	<i>Duration on the pump (yrs)</i>
1	Mother	10 F	5	4.0
2	Mother	12 M	6	1.6
3	Mother	9 M	4	2
4	Mother	7M	1	3.4
5	Mother	10 F	7	1.1
6	Mother	9 F	4	2.5
7	Father	12M	4	1.2

Research Procedures

An interview schedule was developed based on the existing literature and through discussion with the principal researcher and supervisors (Appendix 11). The interview was semi structured using the interview schedule as a starting point but allowing for areas that arose spontaneously to be explored. It was piloted on the first three interviews, judged to be effective and, therefore, was not modified for subsequent interviews. Interviews were carried out in September and October 2014. Interviews lasted between 35-70 minutes, and were recorded using a digital voice recorder, transcribed verbatim and anonymised. In keeping with other qualitative research³³, at the end of each interview the participant was asked to summarise the main points discussed, and to rank summary points in order of importance, as a form of respondent validation.

Analysis

Interviews were analysed consistent with IPA guidance (p. 79-107)³⁴. Each transcript was read a number of times and annotated in detail to identify interesting or significant points raised. Comments were recorded which connected or summarised significant discourse within each transcript, and to identify at a higher level of abstraction the essence of the text. Preliminary themes reflecting the participant's experience were then identified for

each transcript, followed by the identification of emerging themes. Emerging themes for all participants were then charted. During charting, a number of themes appeared to cluster together, this allowed grouping of these themes as super-ordinate themes. Within each theme it was possible to identify similarities of experience, and areas of difference. Restructuring and regrouping of themes occurred throughout the analysis process. Extensive note taking and use of a reflective journal by the principal researcher throughout data analysis allowed the interpretative thought process to be recorded for transparency, and helped to facilitate the identification and minimisation of researcher bias.

An adaptation of Kreuger and Casey's³⁵ long table approach was used to sort data. This involved cutting, sorting and arranging data into categories, on a long table. Each quote in the transcript was given a unique identifier; data were copied and pasted into groups and subgroups based on the emerging themes. This approach is recommended for a novice qualitative researcher rather than using qualitative analysis software since the long-table approach involves visually sorting information which facilitates data familiarity³⁵. Validity criteria for promoting rigour in qualitative research were followed³⁶. A transcript was independently analysed by a second experienced researcher supervising this project to assess inter-rater reliability. Agreement was achieved in terms of the content of salient themes, although wording used to describe the themes differed slightly.

This study was approved by NHS Greater Glasgow and Clyde Research and Development Team and The North of Scotland Proportionate Review Research Ethics Committee approved the study (appendices 12-13).

Reflexivity

The IPA approach acknowledges explicitly that the researcher's beliefs and experiences will influence their understanding of the participant's experience³². The principal researcher, a trainee clinical psychologist, did not have prior clinical experience, personal

experience, or in-depth knowledge of diabetes before commencing this project. This study was however carried out whilst the author was also completing a meta-ethnography exploring parents experiences of the insulin pump. To prevent bias from results of this meta ethnography from influencing this study, the author referred back to parents summaries of important points from the interview during the analysis process (appendix 14), and a transcript was independently coded by a second experienced researcher.

Results

The focus of this study was to explore parents' experiences of managing their children's T1D with insulin pumps. During the interviews parents also spoke about their experiences of having a child with T1D more generally. To remain focused on the study aims only the shaded themes specifically related to parents' experiences with the insulin pump will be discussed. Super-ordinate themes are presented in keeping with the temporal sequence of parents' lived experience, starting with life before the pump, transitioning to the pump, and life on the pump including considering the impact for their child.

Table 3: Super-ordinate and emergent themes

Super-ordinate themes	Emergent themes
Initial diagnosis	<ul style="list-style-type: none"> • Noticing symptoms • Seeking help • Emotional adjustment to diagnosis
Life before the pump	<ul style="list-style-type: none"> • Control/ helplessness • Anxiety associated with rigidity of meals
Transition to the pump	<ul style="list-style-type: none"> • Getting a pump • Upheaval • Finding own way with the pump • Support

Life on the pump	<ul style="list-style-type: none"> • More effort • Parents' emotional well-being • Perceptions of glycaemic control
Perceived impact for their child	<ul style="list-style-type: none"> • Developing autonomy- benefits and challenges • Child's emotional well-being

Life before the pump

The super-ordinate theme 'life before the pump' involved parents looking back and considering what life was like on MDI to provide a context for their experiences using the pump. Key emergent themes when reflecting on this time were issues of control and feelings of helplessness, and anxiety.

Control / helplessness

Parents spoke about their perceptions of control using MDI. Although most parents reported feeling helpless on MDI, describing that no matter how hard they tried, they struggled to get good glycaemic control for their child, two parents felt MDI allowed them good glycaemic control, with one parent highlighting that she felt more secure using MDI with her son. This mother had experienced multiple pump malfunctions, and struggled to get the right support to help her feel like she understood the pump:

"I can work out the needles, I can work out when he's on the pens, I know exactly what I'm doing, I just find this (the pump) very stressful." (Parent 2, line 152)

Half of the parents described constantly having to "*feed insulin*" carrying out up to six injections a day to get their child's blood sugar under control, and frequently being sleep deprived as a result of correcting their child's blood glucose levels throughout the night:

"The night times particularly were very hard you know..... we caught many of his

really severe lows when he was sleeping which he never woke up from, and regularly we were catching highs which we were correcting for throughout the night, em you know so it was very, we got what was classed as a reasonably good HbA1c but to get that we were sacrificing a huge amount” (Parent 4, line 78)

One mother spoke about having her sense of hopelessness on MDI confirmed and reflected by her GP:

“ Her HbA levels started going up, the doctor basically said to us “there’s no more answers”, you know we had tried them all, nothing worked, nothing brought her levels down” (Parent 1, line 125)

Feelings of helplessness seem to be particularly acute when parents were unable to intervene with rising blood glucose levels:

“I felt so helpless when he was sitting there after injections and his blood sugar was 12, 14, 16 and all you can do was sit, there’s nothing you could do, and I just felt so helpless watching him stew in syrup” (Parent 7, line 310)”

Anxiety associated with rigidity of meals

Most parents described feeling anxious and panicked at having to stick to rigid ways of eating whilst using MDI. This impacted on the whole family’s routines.

“We did get a bit panicky, even within the very set routine we had, we started to get a bit panicky or nervous about getting (dinner) at exactly six o’clock, exactly at this time, everything perfect... we had to also modify our diet, there was less sugar, less treats, less cakes..” (Parent 7, line 148)

"It was hard you know having to do injections if we were out somewhere, having to find somewhere private to do injections....having to find a toilet and having to go in and inject, and I don't like doing that in toilets". (Parent 6, line 442)

One mother described having to engage in parenting behaviours that seemed paradoxical, such as force feeding her daughter chips in a restaurant if her daughter had ordered them and then no longer wanted them. Similarly, she described a range of anxiety provoking imagined scenarios, which were outwith her control, where she worried her daughter would not be able to eat what she had injected for:

"I was writing on her lunch box "this is your carb count for the day", so she would dutifully put that number of units, inject it, and then she could throw her sandwiches in the bin, and it did, it really did worry me sick". (Parent 5, line 451)

Another mother described how upsetting it was not being able to give her son the same treats as his brothers, feeling stressed when she could hear the ice cream van outside, and having to come up with elaborate reasons why her son's smaller treat was better. This mother described how other adults' lack of understanding of diabetes and food caused additional stress and tension for her family:

"Other people's understanding was awful at times, coming up and waving something in front of his face and saying "can he have this?".... we left family parties and we left things half way through, we thought "this is too hard, let's just go home". You know it wasn't fair on him, it wasn't fair on the other kids, it created tensions between the adults". (Parent 4, line 59)

Transition to the pump

The super-ordinate theme 'transition to the pump' contained emergent themes which described parents' struggles to get their child on a pump, a sense of upheaval when first using the pump, how they adjusted at this time, and the support that was needed to allow this adjustment in many cases.

Getting the pump

Parents commonly heard about the pump through diabetes support groups or through friends of their families. Most parents felt that they needed the pump because they were not getting good glycaemic control on MDI. Five parents spoke about approaching their health care team for the pump but were told that either there was no funding for the pump, or that they were not eligible for it. Three of these parents described the sense of frustration and anger which had led them to fight for a pump through contacting local papers, threatening to contact their minister of parliament (MP), or through moving hospital with their child.

"We had to go to six injections a day because they weren't working, and that's when we had to fight to get the pump... we had to go to the local papers to get the pump... we were told that it was the only thing that would help because there was no money for funding" (Parent 1, line 112)

"He (endocrinologist) kind of mentioned the pump although was aware that our hospital didn't support it at that point... We kind of felt we weren't getting anywhere, we couldn't move forward so we asked for a referral, we had to kind of fight to get the transfer of hospital" (Parent 4, line 114)

One mother pointed out the injustice of feeling that she was being punished for all the effort she was putting into getting her daughters diabetes under control:

"I said "so because were managing (daughter's) diabetes well we're being

punished for it”, and I said “look this has to stop, this cannot be”, and I said which I probably shouldn’t have said “well I can get (daughters) count up and down like a yoyo” but what parent would do that because that’s her health..... so I did say “well I’ll be going to my MP because this is not good enough.” (Parent 5, line 84)

Upheaval

Struggling to adjust especially in the first days after going live on the pump was a common narrative amongst parents. Areas of difficulty included learning how to programme the pump, adjusting the pump to intervene for high or low blood glucose counts, worries about the cannula, and watching their child answer questions about the pump. These experiences of learning to adapt to the pump mirrored some experiences of adapting to diabetes when first diagnosed:

“I think had she been given the pump on diagnosis I think it would have been much different. You know because all the questions around diabetes would have happened at the start and she would have been used to it, whereas it was like we were diagnosed for three years and then it was like back to square one for her a wee bit” (Parent 1, line 458)

Recalling difficult experiences on MDI helped to reframe difficulties adjusting to the pump in a more positive light:

“It was kind of an upheaval, but we had been in such a bad place and so worried before with injections that it was kind of a fresh start in a way” (Parent 6, line 214)

Similarly, peer support from other parents about difficulties they may encounter in the early days of pump therapy was identified as helpful for allowing experiences to be normalised:

"I remember one mum saying to me "you know you will want to throw the pump out of the window within the first week", and I remember that- wanting to throw it out the window". (Parent 4, line 289).

Finding own way with the pump

Parents spoke about the process of finding their own way with the pump, including determining pump roles between parents, figuring out which pump programmes and functions were helpful for their child, working out when is best to change their child's cannula and trying out different types of cannulas to find one which suits their child.

"Initially she was on silhouette cannulas and they were horrendous because they left dreadful marks on her tummy... so for the first while changing the cannulas were a nightmare because they were big needles, she was terrified of getting it done.... But since we moved to the mio (cannula) it's like night and day." (Parent 6 line 219)

A process of "trial and error" was often described until parents had adjusted to using the pump in a way which suited their family:

"I made the mistake of changing the cannula at night and I'll never do that again. Do not change the cannula after dinner because you're setting yourself up for a sleepless night." (Parent 3, line 505)

Parents described a process of growing confidence where they would first get used to basic functions of the pump, and then challenge themselves to use more advanced pump features once they comfortable with the more basic functions:

“you’re playing about with it all the time, and initially you’re just trying to get the basal right, and then you start to get a bit braver, you know you play around with the temporary basals and things like that” (Parent 4, line 336)

Different roles and responsibilities parents shared with their spouse in relation to pump use were often described. Parents in this study described shouldering most of the responsibility for managing the pump. They reported that their spouse either: struggled to understand the pump, lacked confidence in cannula changing, or struggled to put a needle in their child. Some parents stated that their spouse could take a leading role in uploading data from the pump on to the computer which allowed the couple to feel that they were sharing the responsibility of diabetes to a greater extent compared with MDI use:

“Well (husband), he’s got his thing, he puts it on the computer, I hate the computer, so he, he’ll upload it onto the computer a couple of times a week so that means we can share the load of that you know because...whereas as before (on MDI’s) I did everything, whereas now he does that role, he feels he’s doing much more than he had been doing”.(Parent 1, line 705)

One parent described a degree of conflict and tension related to how the couple preferred to use the pump:

“I was really keen to tinker with it, but I think because she hadn’t been on the training, she was suspicious of me” (Parent 7, line 282)

Support

Support parents received for transitioning to, and managing the pump was mostly perceived as excellent. Parents felt that the training for starting the pump was comprehensive and well-timed. They felt the diabetes team were constantly available to

advise on queries or problems encountered:

“The consultant gave us his personal email to use if we had a problem, and if he was working that night he would check that email, and em, we didn’t need to use it, but it was just knowing that he was there.” (Parent 1, line 350)

“The level of support was super.... I remember a nurse phoning us at nine o’clock at night, you know every night for the first three or four nights, and you know they are phoning you from home... (Parent 4, line 421)

“We could phone the diabetes ward and email them 24/7. In fact email anytime and (nurse on the ward) got back to us, he was absolutely brilliant” (Parent 5, line 212)

This constancy of support was important for allowing parents to grow in confidence using the pump:

“So every day I would email and say “this is what I think”, and they would say “right go ahead and do that”, and then it got to the stage where I would say “so I’ve done....”and they would say “that’s absolutely fine, that’s exactly what we would have done” (Parent 7, line 298)

One parent struggling with the pump felt that she would have benefitted from more training days specifically for parents of children who had been on the pump for around a year and had questions about aspects of the pump encountered during that time:

“I think the problem with the pump is you do the four (training) days and there is a lot to learn, and you take it all in, but it’s only until afterwards that you think “oh

what do I do about this”..... I think they need to have more workshops for kids that have had diabetes and they’re on the pump for maybe a year and it is things they’ve identified (that are difficult)”. (Parent 2, line 617)

In addition to support from the diabetes medical team, two of the mothers had requested psychology support for their daughters as they were aware of the emotional difficulties that are often associated with diabetes generally, as well as body image issues surrounding pump use. They felt it would be important to normalise talking to a psychologist for their daughters.

Life on the pump

The super-ordinate theme ‘life on the pump’ incorporates key emergent themes where parents reflected on the increased effort often required when using the insulin pump, the impact of pump use on their own emotional well-being, and their perceptions of, and reflections around glycaemic control using the pump.

More effort

Parents often felt that the pump required more effort than MDI, with insulin pump management being a more complex process with more variables to manage (cannula, pump batteries, pump programmes, back up MDI kit in case of pump failures etc):

“It’s not as easy as people think, em I suppose if you are not going to be vigilant and check and change things and be on top of things, you could try a profile and just sit back, but we are not that type of parents (laughs), so we make changes all the time...(Parent 3, line 197)

“Ultimately, it’s a lot more work than MDI” (Parent 3, line 713)

“For me it’s more difficult on the pump, for me, but not for (daughter), because I’ve done the cannulas, we’ve worked out the ratios, all she has to do is physically put it in the pump”. (Parent 1, line 173)

This additional effort was often accepted, however, for the lifestyle flexibility it afforded the family, and in some cases improved glycaemic control:

“She has a great H1BC, the consultant said it’s a fabulous, fabulous result which is great, but he sort of hit the nail on the head when he said “you don’t get that without all the effort you put in “ (Parent 6, line 5)

The ability to make changes to pump programmes helped parents to feel less helpless when their child’s glycaemic control was poor, although adjusting the settings sometimes required more effort in the form of frequent basal tests and sleepless nights. One mother felt that the pump allowed her to feel that she was doing the best for her child, but recognised that striving for the best glycaemic control possible had to be balanced with managing anxiety associated with these targets:

“You don’t want to be upset about it, but get it as accurate as you possibly can, and the pump allows you to do that so you feel your being truer to your child, you know, you don’t want in 20 years’ time to say “well I could have done better, but it was too much effort you know”. (Parent 4, line 155)

Parents’ emotional well-being

Most parents described feeling a sense of relief at being able to treat their child ‘normally’ on the pump. They recalled no longer having to worry about sticking to rigid ways of eating, they could parent their children more fairly, and had more flexibility when choosing to make changes to the pump, which allowed more time to meet the attention needs of

their other children:

“I always feel like I’m throwing (non T1D child) her cereal in, you know because you’re not measuring it, so there is an element of (daughter with T1D) does get more attention... it’s hard as a mum to try to balance it all, because you need to do all that for (daughter with T1D).. It’s much better on the pump, because all I have to say to (daughter with T1D) at lunch time is “your blood sugar is 7.5, you’ve had 50 carbohydrates, go do your pump” and she can go and do it.”
(Parent 1, line 651)

Similarly, they perceived that they could manage poor glycaemic levels more easily:

“There’s definitely less stress because whatever her bloods are doing we can fix it, whereas previously we couldn’t fix it, and I think that was really difficult for us. There was a friction because no matter what we did we couldn’t fix it” (Parent 1, line 698)

Although generally the pump was perceived as having a positive impact on the parents’ well-being, times of increased anxiety included: when changing cannulas, when considering the potential for, or dealing with pump malfunctions, and when their child was unhooked from the pump for certain activities:

“You’re just thinking “what if doesn’t come back soon” (T1D daughter had pump off whilst swimming) ...and I had to find her and say “you need to come back and sit for a wee bit”, and that was quite hard, that’s another drawback of it, that she can only take it off for an hour and a half and it’s got to be that way”. (Parent 5, line 312)

Only one mother described having a very difficult time with frequent pump malfunctions,

she reported that there did not seem to be any reason why, but often her son's pump would not deliver insulin. She recalled feeling panicked and frustrated when trying to get support from the pump manufacturers, which was exacerbated by difficulties encountered with the manufacturers not understanding her Scottish accent:

"So I had to phone America.... I went on the phone and I was honestly, I was tearing my hair out because she was struggling to understand me and I was struggling to understand her... the frustrating thing with insulin delivery, why would it three times not work, and then on the fourth it works". (Parent 2, line 197).

It seemed that these difficulties impacted on this mother's confidence using the pump which may have had a knock on impact on her willingness to try out different pump settings with her son. She reported that it was easier to just go back to injections during school holidays as her son's activity levels would not be in keeping with what his pump was programmed for:

"Any holidays we have now I put him back on injections because I know now because he's not doing all these sports the pump is programmed for....it's easier during the holidays going back to injections" (Parent 2, line 319)

Another parent whose son suffered from urticaria, and therefore had experienced difficulties with her son scratching off his cannula, seemed to feel ashamed of admitting that she found the pump more stressful:

"I just feel much more stressed on the pump, I do, it's a terrible thing to admit"
(Parent 3, line 555)

Only one mother who had experienced difficulties with pump malfunctions reported

that she wanted to return to MDI use. On the whole, most parents reported that the pump has had a positive impact on their lives and the lives of their families:

“it’s easier to say to others, “don’t worry the pump will work that out, the pump will work out the correction doses”, not having to do things like (correcting with MDI) that does take the stress out you know, and it’s easier to plan things as well”
(Parent 4, line 217)

“Without sounding dramatic, it has been life changing for us, and for (son). I mean it really has changed the way we live our life, it’s changed the quality of our lives hugely” (Parent 4, line 143)

Perceptions of glycaemic control

Opinion was split as to whether the pump improved their child’s glycaemic control. Four parents reported that the pump gave better control; they felt the numerous settings allowed more exact and tailored insulin delivery matched to the child’s needs, and therefore felt that their child experienced more consistent control:

“She (daughter) was just tested, it was 49 her HbA1c, so that’s fantastic, that’s really good; they said (diabetes team) they are absolutely delighted with that, so that’s great” (Parent 6, line 391)

“There’s a lot less highs and lows, it’s a lot more consistent, a lot more constant now on the pump... you can be a lot more exact with what she’s eating and what gets punched into the pump. (Parent 5, line 279)

Three parents reported that their child’s control had either improved slightly, or had not changed:

“Most importantly don’t expect a great level, I think that’s number 1, don’t expect, to go from an A1C of 10 to an A1C of 5, that’s not going to happen”. (Parent 3, line 752)

Two of these parents reported that their children had experienced ketones for the first time on the pump. Interestingly, one father explained that even though his son had experienced some of the “*worst highs*” on the pump, he felt the pump functions gave him more control to manage these incidents without having to call the diabetes team:

“If he had ketones (on MDI) like he’s had on the pump we probably would have called the hospital... but now we just fiddle with the pump and eventually get it right and it comes back normal” (Parent 7, line 353)

This father still felt that the pump offered the opportunity for the best glycaemic control he could give his child despite experiencing ketones. Most of the parents considered QoL in relation to glycaemic control. Parents often described feeling that good glycaemic control superseded any QoL benefits afforded by the pump, as anxiety regarding long term health complications or fatal incidents resulting from hypoglycaemia were their greatest concerns:

“It wasn’t necessarily about what would suit (daughter with T1D) at the time; it was about the long term goal of keeping her as healthy as we could” (Parent 1, line 724)

Perceived impact on their child

In this super-ordinate theme ‘perceived impact on their child’ parents reflected on how the pump had afforded their child more developmentally appropriate freedoms, the challenges

encountered with this increased autonomy, and their perception of their child's emotional well-being whilst using the pump.

Developing autonomy- benefits and challenges

Parents felt that the pump allowed their children to be 'normal', in that the flexibility afforded by the pump allowed them more independence:

"As soon as she was diagnosed her social life changed because mum was everywhere, and mum had to be everywhere, whereas I definitely think with the pump, I would have the confidence that she just had to type, you know "I'm having a chomp", she just had to type 15, you know at her friend's house and away she went. It gives her a lot more freedom." (Parent1, line 527)

With this developing independence came some of its own challenges. Three parents described situations where their children had not bolused properly, with one child developing ketones as a result. These parents described either having to increase the amount of supervision their child had for bolusing as a result of these errors, threatening that the pump would be removed if they mismanage, or having to spell out the long term complications of diabetes to teach their child about the seriousness of mismanagement:

"Well we had a situation when we were away where he had ketones because he forgot to bolus.. , I don't know if it's good or bad parenting or not, but I'm quite harsh on him when he forgets. I've also eh, I think it's time now, he's old enough now that we need to start laying down the line of potential long term effects are of Diabetes, and how crucially important it is to keep his blood sugars under control"(Parent 7, line 398)

Struggles between feelings of relief that the pump offered more developmentally

appropriate freedoms for children had to be balanced with parents own anxiety regarding whether the pump was being used properly:

*“They keep telling us in here that it should be a normal conversation of “how is your day? What did you do, blah blah blah...” but you do get round to “did you bolus today?”, you can’t not ask the question because you need to know”.
(Parent 5, line 428)*

“It’s very difficult, because you know, they (other adults) don’t realise how important it is ... we’ve had (son with T1D) come back where maybe he’s been at a sleep over and his readings have been through the roof” (Parent 2, line 454)

There appeared to be anxiety associated with being solely responsible for their child’s diabetes. Allowing their child more responsibility also came with its own anxieties. Promoting pump independence was described as a process of helping children to take responsibility for certain aspects of pump use, with supervision increasing if the child forgot to bolus, if glycaemic control was poor, or for aspects of the pump which remained challenging like cannula changes.

Child’s emotional wellbeing

Most parents mentioned that their children appeared to be “*perkier*”, “*happier*”, had “*more of a spark*” and were “*less upset*” and less “*grumpy*” on the pump compared with MDI:

“I remember saying to my husband “ I really feel like she’s a lot happier in herself”, em, and I really did notice a big difference when she went onto the pump... the only way I could describe it was that she wasn’t as flat... a wee bit more of a spark, a wee bit more perky and happier”, (Parent 6, line 559)

One mothers wondered if herdaughter was less upset as her minds was allowed more distance from diabetes, without the constant reminder that came from having to inject throughout the day:

“I think Diabetes isn’t at the front of her mind all the time, and because she was doing all these injections....She doesn’t get as upset on the pump as she did on injections. (Parent 1, line 565)

One mother also wondered whether her daughter felt less anxious knowing that basal insulin doses protected her from low glycaemic levels. Another mother spoke about how heart breaking it was having her daughter explain how hard diabetes was for her, but expressed a sense of relief that these conversations had not occurred since her daughter started using the pump:

“...she did say to me before.. “I wish you had diabetes mum just so you could feel what it feels like for one day”..... but she’s never said that since the pump, and I don’t know if it’s just like- well if life’s going to be like this than maybe it’s not as bad” (Parent 5, line 547)

Particularly, parents of girls in this study reported that the visibility of the pump had been difficult for them and their daughters to manage, especially when other people asked difficult questions such as “does that keep you alive”? One mother became tearful when describing how difficult it was watching her daughter trying to conceal her pump:

“she was looking for something to cover it up (said through tears), and I said “no we don’t do that, just put it over it”...I thought to myself, I can’t help her look for rest of her life” (Parent 6, line 323)

Parents helped their children manage self-consciousness associated with the visibility of the pump through modelling humorous responses to difficult pump related questions, and by finding ways to wear the pump that reduced self-consciousness. Some parents expressed worries about how their children would cope with wearing the pump as they approached adolescence which is often a time of increased self-consciousness.

Discussion

To the author's knowledge, this study is the first qualitative study employing IPA to explore parents' views of managing their children's T1D using insulin pumps, and the impact of this method of insulin delivery on their QoL. To this end, parents described their experiences of the insulin pump across four super-ordinate themes, specifically 'life before the pump', 'transition to the pump', 'life on the pump', and the 'perceived impact for their child', which facilitated an understanding of their journey adjusting to life on the pump.

A concept occurring across all themes was control, with parents describing fluctuating perceptions of control across their experiences managing their child's T1D. Parents commonly felt that they had little control on MDI, with efforts to gain control through rigid ways of eating and frequent injections being described as stressful and anxiety provoking. Fighting to get a pump appeared to have been a practical way to try to regain some control over feelings of helplessness encountered on MDI. Similarly, using supports appeared to help parents gain control using the pump after the initial upheaval that came with changing to this method of insulin delivery. Although parents reported that the pump required more effort, the ability to make changes to pump settings again helped parents to feel like they could do more to control their child's diabetes. Perceptions of control fluctuated, particularly during difficulties encountered with the pump, and when allowing their children more responsibility for managing aspects of their pump use, or to take on more developmentally appropriate freedoms. Models of parental uncertainty when caring for a child with chronic illness may be theoretically useful for conceptualising fluctuating

feelings of control, as illness uncertainty is associated with perceptions of control³⁷. In keeping with these findings, Cohen and colleagues³⁸ proposed that triggers of heightened uncertainty occurred for parents around changes in therapeutic regimens, when disease control was poor, and with new developmental demands of the child. Similar feelings of fluctuating control have been emphasised by other parents using the insulin pump³⁹.

Adjusting to the pump was particularly challenging for parents. In keeping with other qualitative research^{12,30,39,40}, support from the diabetes team and pump manufacturers helped parents to grow in confidence using the insulin pump, with support being particularly important for managing pump malfunctions^{12,30}; with the necessary support in place, pump malfunctions can be accepted as a normal part of pump therapy¹². This study emphasises that when a parent experiences difficulties with the pump, and does not feel supported in resolving these, then adjustment to the pump, and subsequent confidence with the pump can be impacted. Families may wish to discontinue pump therapy as a result. A study of pump-related adverse events reported for young people by the Food and Drug Administration over a 10 year period identified that a third of adverse events reported were as a result of pump malfunctions, and 82% of cases of insulin pump adverse events resulted in the young person requiring hospital care⁴¹. These figures underscore the importance of ensuring adequate provision of support to families using the insulin pump, particularly at times of pump malfunction. These findings also lend support to quantitative studies showing that difficulties using the pump are common reasons for discontinuing pump therapy⁴².

A recent systematic review identified that freedom and flexibility were more commonly reported benefits of the pump by parents than glycaemic control²¹, and quantitative research has found that lifestyle flexibility and QoL was deemed more important for parents than improved glycaemic control⁴³. In contrast, parents in this study stressed that

the potential to achieve better glycaemic control superseded any QoL benefits afforded by the pump, with some parents reporting that they would sacrifice flexibility afforded for good glycaemic control, as ultimately their child's health was the most important concern.

Parents in this study reported that the pump required more effort than MDI, but this additional effort in the form of programme alterations, frequent basal tests and sleepless nights was accepted as parents felt like they were helping their child to achieve the best glycaemic control they could. This is interesting, because parents reported similar experiences of "feeding insulin", and sleepless nights correcting insulin on MDI but appeared less accepting of the effort put in using this method, as this was not rewarded by resulting improved glycaemic control. This finding of parents putting more work into insulin management with the pump because they perceive that they can do more to control their child's diabetes is in keeping with recent qualitative findings⁴⁴. As one mother pointed out in this study, efforts for optimal glycaemic control need to be balanced with parents managing their own anxiety associated with these targets, as studies have shown that behaviours such as nocturnal blood glucose monitoring may have an impact on parental health¹⁸ and QoL¹⁷.

Generally, parents reported that the pump had a positive impact on their emotional well-being and QoL, reporting feeling relieved that their children appeared happier; that they could treat their child 'normally' and parent fairly; and feel that their child is safer with basal doses of insulin being delivered on the pump. Interestingly, in addition to the increased effort required on the pump than MDI, parents also reported anxiety associated with certain aspects of pump management including: their child being unhooked from the pump; cannula changes; pump malfunctions and difficulties encountered watching their children manage self-consciousness associated with the visibility of the pump. Therefore there appeared to be both positive and negative aspects of pump use which impacted on parents' QoL to a greater or less extent across participants. These findings help to

highlight the complexity in understanding perceptions of QoL for parents using the pump, which is reflected in the literature which has not found consistent differences between family functioning and psychosocial measures on MDI versus the pump²⁰. Qualitative studies highlighting complexities in understanding QoL for parents using the insulin pump may help to support the development of more robust quantitative measures to further understand this aspect of pump use.

Findings from the super-ordinate theme 'perceived impact for the child' support other qualitative studies where parents have noticed an improvement in their child's mood on the pump compared with MDI^{30,45,46}. Improved glycaemic control has been associated with improvements in cognition, behaviour and emotions⁹, however improvements in mood could also be as a result of increased developmentally appropriate freedoms afforded by the pump, which many parents reported in this study and throughout studies in this field^{10,12,30,46}. This potential benefit of children having more independence and freedom on the pump, including taking some responsibility for aspects of T1D management is particularly important when considering psychosocial development. Erikson's psychosocial theory of development⁴⁷ suggests that children must develop feelings of competence and belief in their skills in their years before adolescence (age 5-11), with their task during adolescence being to develop their sense of independence from their parents. Diabetes can impact on a child's ability to complete these tasks successfully⁴⁸ which can result in the development of feelings of inadequacy⁴⁷. Benefits of the insulin pump in facilitating self-management and increased separation from parents are therefore significant for the child's development.

Olinder and colleagues⁴⁹ qualitative study attempted to generate theoretical knowledge to explain the transfer of responsibility for T1D self-management on the pump with adolescents. Findings from this study lend support to processes involved in responsibility sharing elucidated by Olinder et al⁴⁹, with young people in this study self-managing some

aspects of pump use and parents increasing supervision when mismanagement occurred. Almost half of the parents in this study reported difficulties encountered with their children not bolusing properly, with one child developing ketones as a result. Research has shown that missed meal boluses were the main reason for suboptimal control, with more than a third of young people missing a bolus per week⁵⁰. Pump alarms may help to reduce the frequency of missed boluses and support young people to self-manage their diabetes more accurately. Struggles for parents in this study between feeling relieved that their child could be more independent with the pump, and managing their own anxieties around relinquishing control have been emphasised in earlier research⁴⁹. Health care providers should assess where families are in the process of parent management to adolescent management of diabetes and support, and facilitate the gradual sharing of responsibility as appropriate⁵¹.

Watching children manage the visibility of their insulin pump through answering questions from others about the pump, or through finding clothes to cover the pump was difficult for parents in this study. Although some studies have shown that parents tend to overestimate the impact of the pump on their child's level of self consciousness^{12,45}, other studies have shown that young people can find the visibility of the pump distressing, particularly when encountering negative reactions from peers¹⁰. Sex differences regarding body image and social acceptance using the insulin pump have also been reported in other qualitative research⁵². The need for further research aimed at understanding differences between those who struggle with the visibility of the pump, versus those who do not has been identified^{10,52}. Further research in this area of pump use may help parents to support their children to manage issues of self-consciousness.

Strengths and Limitations

To the author's knowledge this study is one of the few qualitative studies exploring parent's experiences of the insulin pump in the United Kingdom (UK)²¹, and the second of

its kind to be carried out in Scotland⁴⁴. Findings from this study are particularly relevant within the Scottish context, given the increased use of insulin pumps amongst the Scottish paediatric population²³ driven by clinical guidelines¹¹ and recent Government investment²⁴.

Use of Whittemore et al's³⁶ four primary validity criteria; credibility, authenticity, criticality and integrity improved the validity of this study. Credibility refers to the assumption that the results reported are an accurate representation of what the parents discussed. Having a record of what parents deemed were important points from their interview facilitated constant reflection during analysis to ensure that findings emerging from the raw data were credible. Authenticity is concerned with ensuring that findings reported actually reflect the experiences of the participants. Use of a semi-structured topic guide allowed parents to explore topics that were salient to them, while also allowing the research question to be addressed, which arguably improved authenticity. Criticality refers to the extent to which the researcher is critical of their findings. To maintain a critical view point, the author searched for alternative themes in the raw data and discussed these with an experienced qualitative supervisor who also had access to the raw data. Attention was paid to divergent opinions within each theme. Finally, integrity refers to the extent that interpretations of raw data are truthful and not biased towards the researcher's own agenda. Double coding of a transcript by an experienced qualitative researcher and use of a reflective diary helped to maintain integrity.

In keeping with the design and analysis of this study this sample is intended to be homogenous, and therefore findings are not generalisable. Parents in this study were mostly mothers from two parent families who freely gave up their time to discuss their experiences parenting their children with T1D using the insulin pump. Similarly, parents described their experiences of parenting children between the ages of 7 to 12. Therefore an understanding of experiences of what it is like to parent children using the insulin pump at other developmental stages was not determined in this study. Consistent with the

qualitative literature on parents' experiences using insulin pumps²¹, only one father was interviewed in this study, thereby findings were unintentionally largely based on mothers' experiences. Further research may benefit from exploring fathers' views of the insulin pump, and its impact on their QoL. Similarly, as 31% of families in Scotland are single parent families⁵³, research exploring single parents' experiences of the insulin pump may also be warranted.

Although care was taken to highlight that the researcher was not connected to the diabetes team, the research did take place at a diabetes clinic, and was supervised by a Clinical Psychologist working within the diabetes field. These factors may have had an influence on what parents chose to discuss.

Clinical Implications

Findings from this study illustrating experiences transitioning to the insulin pump, and life thereafter on the pump may be helpful for other parents when deciding whether to start insulin pump therapy with their children. Similarly, these findings showing the complexity of QoL issues surrounding insulin pump use are useful for health care providers to understand when supporting families with diabetes management. Although parents in this study reported that they were mostly well supported caring for their child's diabetes using the insulin pump, an awareness of fluctuating feelings of control parents may experience around different stages of pump use, whilst supporting their children to be more independent, may also be helpful for health care professionals to be aware of. This may allow support to be increased for families at times of uncertainty. Similarly, it may be important to explore with parents anxiety associated with striving for optimal glycaemic control, and the lengths parents may be going to for this control, as this may have an impact on parental well-being.

Support is fundamental for helping parents to adjust to the pump. In addition to support

received from health care teams and pump manufacturers, peer support from other parents using the pump has been identified as particularly helpful for normalising frustrations during adjustment to the pump. Parents may therefore benefit from the provision of a list of local diabetes peer support groups from their health care provider to augment support received from the health care team. Health care providers should also be aware that support should be increased for parents experiencing pump malfunctions. Parents may experience pump mistrust and dissatisfaction with the pump, impacting their adjustment to pump use if they do not receive adequate support at this point. This may lead to pump discontinuation.

Research Implications

Research into parents' experiences caring for their child using the insulin pump at different developmental stages may further our understanding of their support needs. Similarly, research focusing on fathers' and single parents' experiences using the insulin pump may help to understand how best to support these parents using this method of insulin management. Quantitative research exploring some of the complex factors influencing parental QoL caring for a child on the insulin pump may help to determine how generalisable these findings are, and may allow differences to be explored across different populations.

Conclusions

To conclude, parents in this study were generally positive about using the insulin pump to care for their child with T1D, with all but one parent wishing to continue with this method of insulin delivery. Parents faced challenges at particular times with the pump, but with support they often regained control over difficult aspects of pump use. Although the insulin pump offered increased freedom and flexibility for families, parents felt that the insulin pump required more effort than MDI; this was, however, accepted because parents felt the insulin pump provided them with the best method of achieving good glycaemic control for

their child. Understanding the unique challenges parents face adjusting to caring for a child using an insulin pump and strategies they found helpful to overcome these challenges, will assist diabetes teams to implement care practices centred on the needs of the family.

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Chapter 3: Advanced Practice 1- Reflective Clinical Account Abstract

The perils of being too goal focused in therapy

This reflective account describes, from a developmental perspective, my experiences of being too goal focused in therapy. Rolfe et al's (2001) framework for reflexive practice was used to structure my reflective account which describes complex clinical cases which increased my awareness of being too goal focused, and factors which influence this tendency from the client, from within myself and from wider political and organisational influences on the profession. This reflective account enabled me to consider the strengths and weaknesses of being goal focused, and the importance of striking a balance between structured goal focused therapy and a clear understanding of the distress behind the clients goals. I conclude by considering on how these reflections have shaped my view of how I wish to progress post qualification as a Clinical Psychologist who is mindful of these issues in my own clinical work, in supervision of others, and in promoting clinical governance.

Chapter 4: Advanced Practice 2- Reflective Clinical Account Abstract

“To MDT or not to MDT - that is the question”- A reflection on my experiences of multidisciplinary team working

Reflective practice is a key skill for Clinical Psychologists for self and professional development. This reflective account describes my experiences of working within multidisciplinary teams (MDT). I have used Gibb's (1988) reflective model to structure my reflections of an experience of MDT working that went well, and one that was more challenging. Within these reflections I consider factors that have helped, and hindered my effective contribution to MDT working, considering both my own development and wider systemic issues. I consider the role of the Clinical Psychologist in bringing about change in an MDT, and in promoting a voice for Psychology and Psychologically informed care. I have considered the influence of policy including the British Psychological Society policy, New Ways of Working for Applied Psychologists (BPS, 2007), as well as the Psychological Therapies Matrix (The Scottish Government, 2011) on the evolving role of Clinical Psychologists within MDTs. I conclude by considering ways in which I aim to improve my current practice within MDTs, and how I hope to develop skills for bringing about positive change within MDT working post qualification.

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Appendix 1: Author Guidelines for submission to Pediatric Diabetes

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Appendix 2: Search Strategy

#	Embase Search Strategy
1	insulin pump/
2	Insulin pump*.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
3	1 or 2
4	experience.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
5	experience/
6	personal experience/
7	experience\$.mp.
8	narrative/
9	qualitative research/ or qualitative analysis/
10	patient satisfaction/ or patient attitude/
11	parent/ or adolescent parent/ or adoptive parent/ or divorced parent/ or father/ or mother/ or separated parent/ or single parent/
12	(parent\$ or mother\$ or father\$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
13	CSII.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
14	3 or 13
15	4 or 5 or 6 or 7 or 8 or 9 or 10
16	14 and 15
17	limit 16 to yr="1974 -Current"
18	limit 17 to (child <unspecified age> or adolescent <13 to 17 years>)
19	child.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
20	child/
21	adolescent/
22	20 or 21
23	17 and 22
24	18 or 23
25	11 or 12

26	17 and 25
27	24 or 26
28	limit 27 to English language

Appendix 3: CASP Quality Assessment Rating Scale (CASP, 2003) and Scoring Criteria

Quality Questions	Yes (2 points)	Partially (1 point)	"Can't Tell"/ No (0 points)
<p>1. Was there a clear statement of the aims of the research?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • What was the goal of the research? • Why it was thought important? • Its relevance 			
<p>2. Is a qualitative methodology appropriate?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants • Is qualitative research the right methodology for addressing the research goal? 			
<p>3. Was the research design appropriate to address the aims of the research?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • If the researcher has justified the research design (e.g. have they discussed how they decided which method to use)? 			
<p>4. Was the recruitment strategy appropriate to the aims of the research?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • If the researcher has explained how the participants were selected • If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study • If there are any discussions around recruitment (e.g. why some people chose not to take part) 			
<p>5. Were the data collected in a way that addressed the research issue?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • If the setting for data collection was justified • If it is clear how data were collected (e.g. focus group, semi-structured interview etc.) • If the researcher has justified the methods chosen • If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews were conducted, or did they use a topic guide)? • If methods were modified during the study. If so, has the researcher explained how and why? • If the form of data is clear (e.g. tape recordings, video material, notes etc) • If the researcher has discussed saturation of data 			

<p>6. Has the relationship between researcher and participants been adequately considered?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • If the researcher critically examined their own role, potential bias and influence during <ul style="list-style-type: none"> (a) Formulation of the research questions (b) Data collection, including sample recruitment and choice of location • How the researcher responded to events during the study and whether they considered the implications of any changes in the research design 			
<p>7. Have ethical issues been taken into consideration?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained • If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study) • If approval has been sought from the ethics committee 			
<p>8. Was the data analysis sufficiently rigorous?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • If there is an in-depth description of the analysis process • If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data? • Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process • If sufficient data are presented to support the findings • To what extent contradictory data are taken into account • Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation 			
<p>9. Is there a clear statement of findings?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • If the findings are explicit • If there is adequate discussion of the evidence both for and against the researchers arguments • If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst) • If the findings are discussed in relation to the original research question 			

<p>10. How valuable is the research?</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • If the researcher discusses the contribution the study makes to existing knowledge or understanding e.g. do they consider the findings in relation to current practice or policy? or relevant research-based literature? • If they identify new areas where research is necessary • If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used 			
<p>Comment on bias that may have impacted on the study.</p> <p>HINT: Consider</p> <ul style="list-style-type: none"> • Selection bias • Influence from the researcher • Contradictory themes taken into account? • Credibility of findings 			

Appendix 4: Assessor agreement in quality ratings

Study	Assessor 1- Quality score	Assessor 2- Quality score	Area of disagreement (CASP Questions that differed)	Agreed quality score
Sullivan-Bolyai et al, 2004	17	17		17
Low et al,	13	14	Q3	14
Pay et al, 2011 with additional information from Pay, 2009	18	18		18
Olinder et al, 2011	14	14		14
Alsaleh et al, 2013	14	12	Q5; Q6; Q9	13
Alsaleh et al, 2014	13	13		13
Fosner et al, 2014	14	14		14

Appendix 5: Major Research Project Proposal

Title: An exploration of parents' views of managing their children's type one diabetes with insulin pumps

Abstract

Background: In 2011, the Scottish Government committed to substantially increasing the availability of insulin pumps across Scotland; with the aim of ensuring that a quarter of young Scots with type 1 Diabetes (T1D) would have access to insulin pumps by March 2013. Research into the impact of the insulin pump on quality of life has yielded conflicting results, and although parents play a central role in managing their child's diabetes, few studies have looked at the impact of the insulin pumps on parent quality of life.

Aims: This study aims to explore the views of parents managing their children's T1D with insulin pumps, and to investigate the impact of this method of insulin delivery on their quality of life.

Method: A qualitative cross-sectional study will be carried out and analysed using Interpretative phenomenological analysis. Parents attending the Royal Hospital for Sick Children (RHSC) with a child aged 12 or younger with T1D who have used the insulin pump will be recruited using purposive, volunteer sampling. Semi structured interviews will be conducted in the RHSC.

Applications: The findings of this study may be helpful for clinicians, and for parents, deciding whether to begin insulin pump therapy with their child.

Introduction

Background

Type 1 diabetes (T1D) is one of the most common chronic childhood illnesses in the UK (Misso et al, 2010), with increasing numbers being diagnosed each year (NHS, 2013). In 2013, more than 28,849 people were registered as having T1D in Scotland, with the incidence in those below ten years of age increasing from 27 to 29 percent in 2009-2011 (NHS, 2013).

T1D is a lifelong condition of multiple aetiology, whereby pancreatic cell destruction leads to insulin deficiency, characterised by chronic hyperglycaemia. Management of T1D requires continued attention to a number of factors which impact on glycaemic control including insulin administration, blood glucose monitoring, physical activity and meal planning (Daneman, 2006). Complications in glycaemic control may impact the eyes, kidneys, nerves and cardiovascular system and in some cases may lead to coma and even death (Misso et al, 2010).

Recommended treatment of T1D includes intensive insulin replacement therapy to achieve glycaemic control; this is often a challenge to achieve. Results from the 2012 Scottish Diabetes survey indicate that more than a third of people with T1D struggle to achieve good glycaemic control (NHS, 2013).

Insulin pumps

The improved development and design of insulin pumps over a number of years has resulted in the creation of an alternative method of insulin therapy to the more commonly used multiple daily injections (MDIs). Insulin pumps are small devices worn outside the body, which continuously deliver insulin through a thin tube or needle (cannula) inserted subcutaneously. The insulin can be delivered at a set rate or increased by the push of a button when needed, for example at meal times. It is advised that the cannula be replaced and repositioned every three days (NICE, 2008).

A Cochrane review of 23 randomised controlled trials (including seven with participants below 18 years of age) comparing insulin pumps with MDIs reported that there was evidence to suggest that insulin pumps may result in improved glycaemic control compared with MDIs (Misso et al, 2010).

NICE Guidance for insulin pump use for T1D has stated that it should be recommended as a treatment option for children 12 years and above, provided that attempts to reach target haemoglobin A1c (HbA1c) levels with MDIs result in the person having 'disabling hypoglycaemia' or HbA1c levels have remained high (8.5% or above) with MDIs despite careful attempts to manage their diabetes (NICE, 2008, p.1). There were concerns over insufficient data on insulin pump therapy for those under 12. The guidelines therefore recommended the use of insulin pump therapy "as a possible treatment if treatment with multiple daily injections is not practical or is not considered appropriate" (NICE, 2008, p.1).

In 2011, in response to the emerging evidence base in support for insulin pumps, the Cabinet Secretary for Health, Wellbeing and Cities Strategy announced that NHS Scotland will commit to substantially increasing the availability of insulin pump therapy across Scotland, with the aim of ensuring that a quarter of young Scots with T1D would have access to insulin pumps by March 2013 (The Scottish Government, 2012). The Scottish Government pledged funding of over two million pounds to deliver the aforementioned commitment (The Scottish Government, 2012). A recent Scottish Government CEL 4 report indicates that insulin pump use is increasing (The Scottish Government, 2012), with 16.1% (n=466) of those with T1D below 18 years of age using an insulin pump (NHS Boards, 2013).

Insulin pumps and quality of life

The majority of studies on insulin pump therapy focus on the clinical effectiveness and medical outcomes resulting from this method of insulin delivery. However studies have emerged which suggest that greater benefits may occur beyond good glycaemic control. For example, improved glycaemic control is associated with benefits across cognition, behaviour and emotions (Ambler et al, 2006). A number of clinical specialists, patient experts and studies have indicated that the use of insulin pumps yield a number of quality of life benefits, including greater flexibility, autonomy, spontaneity, socialisation, improved sleep, improved mood, decreased fear of hypoglycaemia and less physical burden (NICE, 2008; Phillip et al, 2007; Whittaker, 2012). However, a number of factors have been reported which may impact negatively on quality of life such as infections at the cannula site, pump malfunctions, the need for appropriate supervision of pump therapy in young children, school related issues and visibility of the pump (Klingensmith et al, 2001; Low et al, 2005; NICE, 2008). In 2007, Barnard and colleagues carried out a systematic review to synthesise the literature on the impact of insulin pumps on quality of life, and to ascertain whether pumps yielded quality of life benefits for people with T1D. Their findings were

inconclusive due to a number of poor quality studies in this field, and inconsistency in the assessment of quality of life (Barnard et al, 2007).

The impact of the insulin pump on parenting for a child with T1D

The task of managing T1D in young children rests almost completely on adult carers. A wide variety of carer burden, stress and anxiety has been reported including variability of food intake, monitoring activity levels, the need to be constantly accessible to other caregivers, strain in the relationship between the family and the child's school, engaging in anxiety provoking nocturnal blood glucose monitoring, and fear of hypoglycaemia (Barnard et al, 2010; Monaghan et al, 2009; Muller-Godffroy, 2009; Phillip et al, 2007). These factors have been shown to affect both parental health and quality of life (Barnard et al, 2010; Monaghan et al, 2009).

Some studies have suggested that insulin pumps allowed parents of children with T1D greater flexibility, spontaneity and freedom in their lives, reduced parental stress and worry regarding their child's overall care, and greater confidence and independence in managing their child's diabetes (Litton et al, 2002; Müller-Godeffroy et al, 2009; Phillip et al, 2007). Similarly, a Scottish qualitative investigation of the effect of the insulin pump on young people's quality of life found that they reported less parental burden and more parental support with the insulin pump compared to MDIs (Whittaker, 2012). However, a meta-analysis on the psychosocial impact of insulin pump therapy reported no consistent differences in anxiety, depression, QoL, self-esteem, and family functioning between MDIs and insulin pump therapy (Weissberg-Benchell et al, 2003).

Gaps in the knowledge base

On the whole, studies investigating the impact of insulin pump therapy on QoL in T1D yield conflicting results. Authors of a recent systematic review highlighted that there is limited qualitative data into experiences of parents caring for children with T1D using insulin pumps (Alsaleh et al, 2012). They identified only six studies which described the experiences of children and/ or their parents with insulin pumps therapy, of these studies the majority were carried out in the United States (US). Only two studies were carried out in the United Kingdom (UK), one using structured telephone interviews (Barnard et al, 2008) and the other questionnaires (Wilson et al, 2008). Both studies failed to state the duration of pump therapy, and our understanding of parents' experiences may have been limited by the methodologies used. This review and individual studies solely focusing on parents' experiences of caring for children with T1D have highlighted the scarcity of

research in this area; authors in this field have concluded that further investigations of parent quality of life are warranted (Alsaleh et al, 2012; Monaghan et al, 2009). These gaps in the evidence base are particularly relevant when considering the increased use of insulin pumps in Scotland driven by Scottish Government investment.

Aims

This study aims to explore parents' views of managing their children's diabetes with insulin pumps compared to multiple daily injections. It is hoped that this study will provide insight into the impact of insulin pumps on parents' quality of life.

Objectives

- (I) To explore the views of parents managing their children's T1D with insulin pumps
- (II) To investigate the perceived impact of the insulin pump on parents' quality of life

Methods

Design

This study will be an exploratory qualitative study and will use Interpretative Phenomenological Analysis (IPA). IPA aims to explore flexibly and in detail how the research participant makes sense of their experiences, whilst acknowledging that the analysis of this exploration of experience is influenced by the researcher's interpretation of these views (Smith & Osborn, 2003). The IPA approach has been most commonly used to explore experiences with illness, and an exploration of experiences of diabetes has been stated as being consonant with the IPA approach (Smith, 2011).

Participants

In keeping with IPA principals, a purposive, well defined homogeneous sample (Smith & Osborn, 2003) of parents of children with T1D attending the Glasgow Royal Hospital for Sick Children (RHSC) will be recruited for this study. The purpose of this qualitative study will not be to provide a generalisable account of experiences of managing T1D using insulin pumps, but to provide an in depth account of each individual's experience of their child's diabetes management, whilst also allowing exploration of similarity and difference of experiences within the sample.

A number of sample sizes for using IPA have been suggested (Smith et al., 2009; Smith & Osborn, 2003). This study aims to recruit a sample of eight participants which is

consistent with the recommendation of between four and ten participants for a professional doctorate (Smith et al, 2009).

Consistent with developmental stages, research into children with T1D is often divided into age bands of 12 years or younger, and above 12 years of age (Devenney et al, 2011). Presumably this is because a young person has not yet reached the final stage of cognitive development, the formal operational stage, which according to Piaget is necessary for abstract problem solving (Piaget, 1953). Parents will therefore play a crucial role in helping their children to manage their diabetes during their younger years. For this reason this study will focus on the experiences of parents with children aged 12 or younger with T1D who make use of, or have used the insulin pump. It has been suggested that it can take parents six weeks to nine months to feel confident using the insulin pump after initializing therapy (Sullivan-Bolyai et al, 2004), in order to prevent initial confidence issues from influencing the data, parents with more than nine months experience of using the pump will be included. Due to the exploratory nature of this study, both genders of parents will be included; this is consistent with other research in this field (Sullivan-Bolyai et al, 2004; Wilson, 2008). Interviews will be carried out on an individual basis if both parents wish to take part.

Inclusion criteria

- Has a child aged 12 or younger with a diagnosis of T1D and have used (current or past use) an insulin pump for at least nine months
- Child has no additional major chronic health conditions requiring hospital attendance
- Child does not have siblings with major chronic health conditions requiring hospital attendance
- Fluent in English
- Has a child attending the RHSC

Recruitment procedure

A clinician from the diabetes team in the RHSC will be invited to identify parents of children attending the RHSC that meet the inclusion criteria. In August 2014, the Diabetes team will have 99 patients that meet the study inclusion criteria. A random sample of 25 identified parents will be sent an information pack about the study in the first instance. This information pack will contain a covering letter from the diabetes team explaining why they are being contacted, an information sheet about the project, and a participant

response form (appendices 7-9). Posters will also be put up in the waiting room of the Diabetes outpatient department to invite those who meet the inclusion criteria to take part (appendix 10). The principal researcher will contact interested participants via their preferred method and arrange an appointment to carry out the interview at a suitable time within the RHSC. Written informed consent will be gained prior to conducting the interview (appendix 11). Participants will be recruited until the required number of participants has been met, or until data saturation.

Research Procedures

An interview schedule has been developed based on the existing literature and through discussion with the principal researcher and supervisors (appendix 12). It will be piloted on the first three interviews and revisions made if necessary (pilot interviews will be included in the analysis). The interview schedule will guide the semi structured interviews which will last for approximately 30-45 minutes. Interviews will be recorded using a digital voice recorder and transcribed verbatim. At the end of each interview the participant will be asked to summarise the main points discussed. The researcher will record these points on cards and then ask the participant to rank summary points in order of importance as a form of respondent validation. All participant identifiable data will be deleted from the transcripts to preserve anonymity.

Settings and equipment

Interviews will take place in a private room within the RHSC. A digital voice recorder, transcription equipment and access to a University of Glasgow computer will be required for the recording, storing and analysis of the interviews.

Data analysis

Interviews will be analysed in accordance to guidance outlined by IPA developer Professor Jonathan Smith (Smith, 2007). This will involve a number of readings of the transcripts to identify interesting or significant points raised, followed by the identification of emerging themes that aim to reflect the participant's experience. Emerging themes will be charted to allow for connections to be made in the data within a participant's experience, and between participants' experiences. A reflective journal will be kept by the principal researcher throughout data analysis to facilitate the identification and minimisation of bias from her own viewpoint.

An adaptation of Kreuger and Casey's (1994, p.137) long table approach will be used to sort data according to IPA guidelines. This involves cutting, sorting and arranging data into categories on a long table. This approach will be adapted using Microsoft Word. Each quote in the transcript will be given a unique identifier, data will then be copied and pasted into groups and subgroups based on the emerging themes. Kreuger and Casey (1994) recommend this approach for a novice qualitative researcher rather than using qualitative analysis software (such as NVIVO or NUD*IST), since the long-table approach involves visually sorting information which often facilitates familiarity with the data, and specialised qualitative computer programmes may be difficult to operate.

A subset of transcripts will be independently analysed by a second experienced researcher in order to assess inter-rater reliability. Thematic interpretations will be discussed and verified by an experienced researcher.

Dissemination of results

This study will be written up for: publication in a peer reviewed scientific journal; presented as a component of a thesis for a Doctorate in Clinical Psychology; and as an internal report to the Diabetes Team in the RHSC. Participants will be asked at the interview whether they would like to have a copy of the research findings. If they do, these will be sent to them when the study is complete via their preferred method of communication.

Health and safety issues

The interviews will be carried out in the RHSC during normal working hours and will comply with standard safety procedures.

Researcher safety issues

Procedures used in this study will be similar to those used by clinical psychologists with these participants, and are not normally associated with production of significant distress.

Participant safety issues

Participants will be informed that their participation in this study is voluntary; they can opt out at any time without this affecting the quality of care their child receives from the RHSC. It will be explained prior to conducting the interviews that interviews will be recorded and all participant identifiable data will be removed from the transcripts. An opportunity will be given to have any comments removed from the transcripts after the interview. Participants will be informed that anonymised transcripts will be securely stored

on a University of Glasgow password protected computer. Written consent will be obtained, and limits of confidentiality addressed, before commencing the interviews. The clinical team will be consulted if any issues of risk arise in relation to the participant's, or their children. Similarly, the clinical team will be consulted if a participant is deemed to have psychological difficulties or experience significant distress during the interview. An option will be available for participants to be referred for psychological input if necessary, and at the end of each interview participants will be given a list of resources for additional support including confidential helplines.

Ethical issues

Permission to conduct the study will be sought from a Proportionate Review Research Ethics Committee and the local Research and Development board. Pertinent ethical issues which have been considered and addressed within this proposal include: obtaining informed consent, confidentiality procedures, anonymisation of transcripts, researcher and participant safety.

Signed consent forms will be stored in a locked cabinet, with access limited to the principal researcher.

Financial issues

Costs of stationary and stamps will be reimbursed by the University of Glasgow. The principal researcher's travel costs will be reimbursed by the NHS.

Timetable:

January 2014:	Proposal submission to university for approval
June 2014:	Apply for ethical approval
August 2014:	Recruitment
February 2015:	Transcribing and coding data
March 2015:	Analysis
April/June 2015:	Write up
July 2015:	Submit to university

Practical implications

The results of this study will provide an understanding of what is like to parent a child with T1D using the insulin pump. Additionally, this study may provide insights into the impact of the insulin pump on parents' perceived quality of life and overall family functioning. To

date, there are few studies about parents' experiences of using the insulin pump in the UK, and no studies of this nature in Scotland. Insight into the experiences of these parents may be helpful for others deciding whether or not to begin insulin pump therapy with their child, and it may provide clinicians with a greater understanding of the impact of the insulin pump on parenting. Findings from this study may identify areas for clinical intervention and may provide grounds for further research.

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Appendix 6: Covering Letter from the Diabetes Team

Women & Children's Directorate

GGC CHILDREN'S DIABETES SERVICE

Contact Details

Secretary

Main Switchboard 0141 201 0000

Diabetes Team 0141 201 0331

Web www.diabetes-scotland.org/ggc

Anne McElwaine 0141 232 1892

E-mail: anne.mcelwaine@ggc.scot.nhs.uk

Date:

Dear Parent

I am writing to you on behalf of Dr Oonagh Duffy and colleagues Dr Liz Hunter based at the Royal Hospital for Sick Children, and Dr Suzy O'Connor from the University of Glasgow. This research team is interested in exploring parents' views of managing their children's type one diabetes with insulin pumps.

The researchers have asked me to identify a random sample of parents registered with the Diabetes outpatient department who have a child aged 12 or under with Type 1 Diabetes who have used the insulin pump for nine months or more. I have not given your name and address to the researchers. Please read the enclosed information sheet for more detail on this project.

If you are willing to take part, please pass on the participant response form with details of the best way to contact you to a member of the Diabetes Team. Alternatively you can contact the principal researcher directly (Oonagh Duffy on 075 642 61705 or o.duffy.1@research.gla.ac.uk) if you have any questions about this project or if you would like to take part in this study.

Thank you for taking the time to consider this request.

With best wishes,

The Diabetes Outpatient Team

Appendix 7: Participant Information Leaflet



Title: An exploration of parents' views of managing their children's Type 1 Diabetes with insulin pumps

You are being invited to take part in a research study which will look at parent's experiences of managing their child's Diabetes using the insulin pump. This research is being carried out by Oonagh Duffy, Trainee Clinical Psychologist (main researcher), together with Dr Suzy O'Connor and Dr Elizabeth Hunter, Clinical Psychologists working within the University of Glasgow and the Diabetes team at the Royal Hospital for Sick Children. This information leaflet has been designed to let you know why this study is being carried out, and what it would involve for you. Key questions that you may have are addressed below, however please do not hesitate to contact the main researcher if anything seems unclear or you would like to discuss the project further.

Why is this study being carried out?

We are interested in hearing about parents' experiences of managing their child's Type 1 Diabetes using the insulin pump. There has been very little research carried out in the UK on this topic. Your experiences may help the hospital to gain a more in depth understanding of the impact of the insulin pump on parenting, and improve the service they provide to families attending the Diabetes clinic.

Why am I being invited to take part?

You are being invited to take part because you have a child aged 12 or under with Type 1 Diabetes who has used the insulin pump for a period of at least nine months. We are approaching a large number of people but can only interview between 8-10 people.

Do I have to take part?

No- your participation is voluntary, and deciding not to take part will not affect the care your child receives in any way. You can withdraw from the study at any point without giving a reason and without this affecting your child's care.

What do I have to do?

You will meet with the main researcher to take part in an interview in the Royal Hospital for Sick Children which is expected to last approximately 35-40 minutes. This interview will involve discussing your experiences of managing your child's diabetes with the insulin pump, and will be voice recorded.

Who will know I am taking part?

The Diabetes Outpatient Department may know that you are taking part in this study if you return the response form to a member of this team, or you are seen attending your interview in the Royal Hospital for Sick Children, but the information that you provide would be anonymised so that no one would be able to identify what you had said. The main researcher would only break confidentiality if it was believed that you or someone else is at risk of harm. In these circumstances the appropriate people would be informed, but this would be discussed with you beforehand.

What will happen to the information I provide?

Your interview will be recorded using a digital voice recorder. These voice recordings will be typed up word for word and then destroyed. If you feel uncomfortable with any comment that you have said, you will be given an opportunity to review your transcripts to have this comment removed. You will be asked if you wish to do this, and arrangements will be made for this after your interview. The information collected from you will have your name removed and will be given a code or a fake name so that the transcripts are anonymous. Anonymised transcripts will be securely stored on a University of Glasgow password protected computer. Only the research team will have access to your recordings, however, information collected about you may be looked at by representatives of the study Sponsor (NHS Greater Glasgow and Clyde) to ensure the study is being conducted properly.

A report analysing all of the participants' interviews will be submitted to the University of Glasgow as part of a Doctorate in Clinical Psychology, and for publication in a research journal. Quotes of what you have said may be used in the report to illustrate key points of your experience, but these will be anonymous. You will be asked at the interview whether you would like to have a copy of the research findings. This will be sent to you (if you wish) when the study is complete.

Are there any benefits to taking part?

We cannot promise that this study will directly benefit you or your child, but your views will help the diabetes team to gain a more in depth understanding of the impact of the insulin pump on parenting. This study may also help other parents when deciding whether or not to begin insulin pump therapy with their child. Findings from this study may also identify areas for further support for children with Type 1 Diabetes and their parents, and may contribute to the wider diabetes research literature. If you would like impartial advice about participating in research please refer to www.conres.co.uk.

Are there any down sides to taking part?

It is possible that part of our discussion may bring up thoughts, feelings or memories for you that are upsetting. You can ask to stop the interview at any point in time if you feel uncomfortable. If you wished, a referral could also be made for you to talk to a Clinical Psychologist within the Diabetes Team.

What do I do if there is a problem?

If you are unhappy about any aspect of this study then please speak to the main researcher who will do her best to address your concerns. If you remain unhappy, and wish to complain formally, then please telephone the NHS helpline on 0800 224 4888 for advice on how to proceed with a complaint.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by NRES Committees-North of Scotland (2).

How do I take part?

If you are interested in taking part then please complete the attached participant response form and pass this on to a member of the diabetes team. Alternatively please feel free to contact the main researcher directly by telephone (075 642 61705) or email (o.duffy.1@research.gla.ac.uk). The main researcher will then arrange an appointment to carry out the interview at a suitable time within the Royal Hospital of Sick Children. Before the interview begins you will be asked to sign a consent form to say that you have read and understood the information in this leaflet and that you wish to take part in the study.

Thank you for taking the time to read through this information leaflet.

Dr Oonagh Duffy (BSc PhD)

Trainee Clinical Psychologist, NHS Greater Glasgow and Clyde

Department of Mental Health and Wellbeing,

Gartnavel Royal Hospital, Administration Building,

1055 Great Western Road,

Glasgow, G12 0XH

Appendix 8: Participant Response Form



If you have read the participant information leaflet for the research study entitled “**an exploration of parent's views of managing their children's type one diabetes with insulin pumps**” and are interested in being contacted to take part, or to discuss the study further, then please complete a few details and pass this onto a member of the Diabetes Team or contact me directly.

Your name:

Your child's name:

Relationship to child (<i>please circle</i>):	Mother	Father
Preferred contact (<i>please circle</i>):	Email	Telephone

Email address:

Telephone number:

If you wish to be contacted by telephone, is it ok to leave a voice message if you are not available to take the call? (*please circle*):

Yes	No
-----	----

Thank you, I look forward to speaking with you soon.

Yours sincerely,

Oonagh Duffy (Trainee Clinical Psychologist)

o.duffy.1@research.gla.ac.uk

Tel: 075 642 61705

Appendix 9: Poster Advertising the Study



Research exploring parents' views of managing their children's Type 1 Diabetes with insulin pumps

We are a team of psychologists from NHS Greater Glasgow and Clyde and the University of Glasgow interested in understanding parents' experiences of using the insulin pump to manage their child's diabetes.

If you have a child aged 12 or younger who has used the insulin pump for at least 9 months and would like to be involved then please ask a member of the Diabetes team for more information. Alternatively you can contact me directly (details below).

Participation would involve meeting with me to take part in an interview in the Royal Hospital for Sick Children which is expected to last for 35-40 minutes.

Your views will help the diabetes team to gain a more in depth understanding of the impact of the insulin pump on parenting. This may help to identify areas for further support for children with Type 1 Diabetes and their parents.

Please do not hesitate to contact Oonagh Duffy (Principal Researcher) by email o.duffy.1@research.gla.ac.uk or telephone 075 642 61705 for more information, or if you would like to take part.

Appendix 10: Participant Consent Form



University of Glasgow,
Department of Mental Health and
Wellbeing,
Gartnavel Royal Hospital,
Administration Building,
1055 Great Western Road,
Glasgow,
G12 0XH
Tel: 075 642 61705
o.duffy.1@research.gla.ac.uk

Participant Consent Form

Title of project: An exploration of parents' views of managing their children's type one diabetes with insulin pumps.

Please initial each box if you agree with the statement.

Name of researcher: Oonagh Duffy.

I have read and understood the information sheet dated 01/07/14 version 2.2 for the above study. I have had time to think about the information given to me. I have had the opportunity to get satisfactory answers to any questions that I may have had. ☐

I understand that my participation is voluntary. I am free to withdraw from this study at any time, without giving a reason and without my child's medical care or legal rights being affected. ☐

I understand that this interview will be audio recorded but that any information that could identify me will be removed from the transcripts of this recording. ☐

I understand that some quotations from the interview may be used in the write up and future publications of the study, but that there will be no way of identifying me from these quotations. ☐

I understand that some of the data collected during the study may be looked at by Clinical Psychologists supervising the project (Dr Elizabeth Hunter and Dr Suzy O'Connor). ☐

I understand that some of the data collected during the study may be looked at by the study sponsor (NHS Greater Glasgow and Clyde) for purposes of audit only. ☐

I agree to take part in the above study. ☐

Your name Date Signature

Researcher Date Signature

1 copy for the participant and 1 copy for the research team

Appendix 11: Interview Schedule

Participants will be informed prior to commencing the interview that there are no right or wrong answers. This interview schedule is intended to guide discussions; however discussions will not be limited to this interview schedule.

Experiences of having a child with Type 1 diabetes generally:

Question: Can you tell me a little of what it's like to have a child with Type 1 diabetes?

Prompts:

- How did you find out?
- How did it make you feel?
- How did it impact on your life and your family's life?
- Have you had to make adjustments to your daily routines?
- What's that been like?
- What is most difficult?
- Are there any positives?

II) Experiences of managing child's diabetes:

Question: Can you tell me what the management of your child's diabetes has been like?

Prompts:

- Multiple daily injections first or straight to pump?
- What were/are injections like for you and your child?
- How much control do you feel the injections gave?
- How did you hear about the pump?
- How do you and your family find the pump?
- What made you decide to try the pump with your child?
- What made the clinical team decide to try the pump with your child?
- What was the change like from injections to the pump?
- What support did you get for this change? Was this enough?
- Were there any aspects of pump use which you found particularly helpful or difficult?

III) Insulin pump and quality of life:

Question: Can you tell me about the effect of this management change on your quality of life?

Prompts: What's it been like to have to change the cannula every three days? How has it/had it impacted on your child's quality of life and other family member's QoL?

VI) Perception of the impact of the insulin pump on child's well-being:

Question: How do you think the pump has/had impacted on your child's ability to cope with diabetes?

Prompts: What impact has it had/did it have on glycaemic control?
How do you think they feel/felt about wearing the pump?
How do you think the pump affects/affected their social life?
How do you think it affects/affected their emotional well-being?
How do you think it affects/affected their sleep?
How do you think it affects/affected their body image?
How do you think it affects/affected your child's future?
Does the pump stop them from doing anything they used to enjoy?
How is the pump managed in school?

V) Perception of the pump on family functioning:

Question: What has been/ was the impact of the pump on your family life?

Prompts: In terms of flexibility of routines?
Family stress?
Family arguments?
Meal planning?
Sense of control?
How are siblings coping?

VI) Perception of the pump overall:

Question: What are the advantages and disadvantages of managing your child's diabetes with the pump compared with injections?

Prompt: Overall, which would you recommend the pump or injections?
What advice would you give to a parent trying to decide which regime to start their child on?
(if currently on pump) Do you intend to keep your child on the pump?
Is there anything else you would like to tell me?

Appendix 12: NHS GG&C Research and Development Board Approval Letter



Coordinator/Administrator: JMcG/ LR
Direct Line: 0141 211 8548
E-mail: Joanne.McGarry@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

R&D Management Office
Western Infirmary
Tennent Institute
1st Floor, 38 Church St
Glasgow
G11 6NT

22nd July 2014

Dr Elizabeth Hunter
Clinical Psychologist
Paediatric Psychology Department
Royal Hospital for Sick Children
Dalnair Street
Glasgow
G3 8SJ

NHS GG&C Board Approval

Dear Dr Elizabeth Hunter

Study Title: An exploration of parent's views of managing their children's type one diabetes with insulin pumps

Chief Investigator: Dr Elizabeth Hunter

GG&C HB site: RHSC

Sponsor: NHS GG&C

R&D Reference: GN14CP310

REC Ref: 14/NS/1011

Protocol no: V8.1 dated 05/05/14

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
 - a. During the life span of the study GGHB requires the following information related solely to this site
 - i. Notification of any potential serious breaches.
 - ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

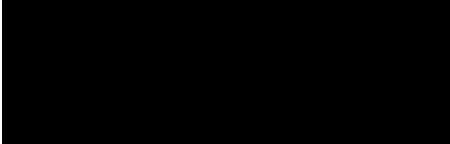
2. **For all studies** the following information is required during their lifespan.
 - a. Recruitment Numbers on a monthly basis
 - b. Any change of staff named on the original SSI form
 - c. Any amendments – Substantial or Non Substantial
 - d. Notification of Trial/study end including final recruitment figures
 - e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely



Joanne McGarry
Research Co-ordinator

CC: Dr Oonagh Duffy, Student, Glasgow
Dr Suzy O'Connor, Academic Supervisor, GRH, Glasgow

Appendix 13: North of Scotland Research Ethics Committee Approval Letter

NRES Committees - North of Scotland

Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558458
Facsimile: 01224 558609
Email: nosres@nhs.net



1 July 2014

Dr Elizabeth Hunter
Clinical Psychologist
NHS Greater Glasgow and Clyde
Paediatric Psychology Department
Yorkhill NHS Trust
Dalnair Street
Yorkhill
GLASGOW
G3 8SJ

Dear Dr Hunter

Study title: An exploration of parent's views of managing their children's type one diabetes with insulin pumps
REC reference: 14/NS/1011
IRAS project ID: 153318

Thank you for the letter dated 1 July 2014 from Dr Duffy. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 13 June 2014.

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter – Response to Ethics		1 July 2014
Covering Letter to Participant	2	1 July 2014
Participant consent form	2.1	1 July 2014
Participant information sheet (PIS)	2.2	1 July 2014

The final list of approved documentation for the study is therefore as follows:

Approved documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
Poster	1	23 March 2014
Interview schedule	1	12 April 2014
IRAS Checklist XML: Checklist 11062014		11 June 2014
Covering Letter to Participant	2	1 July 2014
Letter from Diabetes Service		29 May 2014
Participant consent form	2.1	1 July 2014
Participant information sheet (PIS)	2.2	1 July 2014
REC Application Form: REC Form 11062014		11 June 2014
Referee's report or other scientific critique report: Letter of approval		3 April 2014
Research protocol or project proposal	8.1	5 May 2014
Summary CV for Chief Investigator (CI)		13 May 2014
Summary CV for student		28 May 2014
Summary CV for supervisor (student research)		28 April 2014

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

14/NS/1011	Please quote this number on all correspondence
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Yours sincerely



Mrs Carol Irvine
Senior Ethics Co-ordinator

Appendix 14: Participants' Summary Points

Parent	Summary Points (<i>ranked in order of importance</i>)
1	<p>Better control on the pump- can change settings</p> <p>Family life is much better</p> <p>Impact on daughter- daughter struggled initially</p> <p>Adults making choices for child to give the pump a try</p>
2	<p>It's very complicated</p> <p>The pump is a constant reminder for son that he has diabetes</p> <p>Disappointed by the pump</p> <p>Ongoing training needed</p>
3	<p>It's not necessarily going to improve blood glucose levels</p> <p>It takes a while to get used to</p> <p>It's not as easy as people think</p> <p>Its more stressful for parents</p>
4	<p>Better blood glucose control</p> <p>Improved QoL (both top ranked)</p> <p>Increased freedom and independence for son</p>
5	<p>Better glycaemic control</p> <p>Better emotional wellbeing</p> <p>Positive impact on daughters social life</p>
6	<p>Recommending the pump to other parents as the way forward</p> <p>Using the supports available to educate yourself about diabetes and introducing child to range of supports including psychology</p> <p><i>Points deemed equally important</i></p>
7	<p>The opportunity for better blood glucose control</p> <p>Pump gives child freedom to live a normal life</p> <p>Parent and child need to be continuously vigilant</p>