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**Fear of hypoglycaemia in parents of young children with type one diabetes:
A qualitative study using Interpretative Phenomenological Analysis**

And Clinical Research Portfolio

Volume 1

(Volume 2 bound separately)

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Submitted in partial fulfilment towards the degree of Doctorate in Clinical
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CHAPTER 1: Systematic Review

Parental experiences of having a child with type one diabetes:

A systematic review of qualitative literature.

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Abstract

Aim: Qualitative synthesis is increasingly being employed in health care research to enhance knowledge and understanding of a range of disorders. Whilst parents play a key role in the management of their child's diabetes, there are no systematic reviews to date, of the qualitative literature that explore parents' experiences of living with a child with Diabetes mellitus type 1 (DM1).

Method: Meta-ethnography was utilised to synthesise the published qualitative literature exploring parents' experiences of living with a child with DM1. The quality of such literature was also considered.

Results: Nine studies were included and all were deemed to be acceptable standard or better. A number of key themes emerged from the synthesis: diagnosis, short term coping, longer term adjustment, emotional and psychological impact, relationships, support networks and transitions. The findings suggest that parental experiences are dynamic and occur in the context of wider social systems.

Conclusions: This review has implications for healthcare professionals in describing the breadth and depth of parental experiences when a child has DM1. The healthcare team play a key role in supporting the family in terms of disease management but also psychosocial impact, which in turn may affect control. Limitations and directions for future research are discussed.

Introduction

Diabetes mellitus (DM) is a metabolic disorder, characterised by chronic hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. Treatment comprises a strict regimen including glucose monitoring, insulin administration as well as a closely monitored balance of diet and activity levels. The Scottish Diabetes Survey (Scottish Diabetes Survey Monitoring Group, 2010) has demonstrated that the prevalence of DM1 has continued to increase in Scotland over the past ten years. It is a major cause of morbidity both in Scotland and worldwide.

DM1 is a lifelong condition and there are different challenges associated with managing the condition at different life stages. For this reason, research into DM1 is often split into different age groups and investigates children separately from young people.

When a child is diagnosed with DM1, both they and their families face the challenge of learning about the condition and how to manage it. Many studies have investigated the role of family factors in predicting and mediating outcomes in children with DM1. For example, family functioning and adherence behaviours were found to be strongly related to a child's health status (Lewin et al., 2006) whilst DM1-specific conflict and adherence to blood glucose monitoring were found to be strongly linked to the child's glycaemic control (Anderson et al., 2002).

It seems likely that a complex bidirectional relationship exists between family factors and DM1. In addition to the role of family factors on DM1 outcomes, the

child's condition will have an impact on the family unit and may have different effects on different members within the family. Parents must monitor their child's diet, activity levels, glucose levels and insulin injections and constantly balance the short term risk of hypoglycaemia against the long term risks associated with hyperglycaemia. Faulkner and Clark (1998) found that parental life satisfaction was most affected by the burden the child's DM1 placed on the family. Furthermore, they noted a difference in satisfaction depending on the age of the child, with parents of school-aged children reporting greater life satisfaction than parents of adolescents. Parents must also liaise with other areas of the child's wider system, e.g. school, to ensure appropriate management of the condition continues when the child is not under their direct supervision. Siblings are also affected; they may feel sidelined, worry about their sibling or worry that they may develop DM1 themselves. A meta-analysis that examined the siblings of children with a chronic illness found that psychological functioning, peer activities, and cognitive development scores were lower for siblings of children with a chronic illness compared to controls. Furthermore, chronic illnesses with daily treatment regimes were associated with negative effects compared to chronic illnesses that did not affect daily functioning (Sharpe & Rossiter, 2002).

Qualitative methods are increasingly being employed in healthcare research to gain a deeper understanding of people's experiences of living with long term health conditions. Systematic review and synthesis of findings from such papers is increasingly being conducted to enhance knowledge and generate theories which are more comprehensive and generalisable (Atkins et al., 2008). A recent systematic review of qualitative studies of type 1 DM1 in adolescence found that social

relationships are a key factor in the management of DM1 and that teenagers' ability to independently manage their condition is tied in with the systems in which they live; peers, families, school and health services (Spencer, Cooper & Milton 2009). Despite the established importance of the role of such systems in the management of DM1, and the reliance of young children on such systems, it is perhaps surprising that currently there are no reviews of qualitative studies that explore parents' experiences of living with a child with DM1. A greater understanding of parents' experiences can be used to inform services and systems about how they can best support families in order to meet the needs of such children and their families. This systematic review will summarise the published qualitative literature that explores parents' experiences of living with a child with DM1 and consider the quality of such literature.

Aim

The aims of this review are:

1. To consider the quality of the qualitative literature in this area.
2. To synthesise and discuss emerging themes from the qualitative literature that explores the experiences of parents of children with DM1.

Method

Systematic Search Strategy

A systematic literature search was conducted using the following databases: Medline (Ovid), Embase (Ovid), CINAHL (EBSCO), PsychINFO (EBSCO), Web of Science (Web of Knowledge) and Google Scholar was also searched. There were no limits placed on time span to ensure comprehensiveness of the search. The search employed the use of index terms where possible (EMBASE AND MEDLINE) in addition to key terms. Boolean operators (OR and AND) were used to combine search strings. The same search terms were entered into Google Scholar to find additional papers.

The search terms and strategy used were as follows: Parents mapped to index term and exploded OR parent* or carer* or guardian* AND Child mapped to index term OR Child* or infant* or school aged or preschool or P?ediatric AND Diabetes mellitus mapped to index term OR Diabet* or IDDM AND Qualitative mapped to index term OR qualitative AND (research or method* or analys*).

The reference lists of the included papers were searched and in addition, the Journal of Pediatric Nursing and Journal of Advanced Nursing were hand searched for the past 5 years, as these were the journals that yielded the highest number of articles.

Inclusion Criteria

This review included research that:

- employed qualitative methodology and analysis to focus on the lived experience of parents
- explored the experiences of parents in relation to their child with DM1
- related to an index child aged 12 or under to focus on families where parents will still play a pivotal role in DM1 management
- was published in a peer reviewed journal
- was published in English language

Exclusion Criteria

This review excluded research that:

- employed quantitative methodology
- related to adolescents (i.e. aged>12) or adults
- related to type 2 diabetes
- was not published in a peer reviewed journal
- was not published in the English language

Results of Search

The search produced a total of 386 citations. The abstracts were read and screened for relevance which resulted in the removal of 350 citations leaving a possible 36. Duplicates were removed and full text articles were read and examined according to the full inclusion and exclusion criteria. The hand search of references yielded an additional 2 studies. The search of the Journal of Pediatric Nursing and the Journal of Advanced Nursing did not yield any further results. This resulted in a final list of 9 articles which were included in the review. For a flow chart of this process, see appendix 2.

Synthesis of Data

There are several possible approaches to synthesise the findings of qualitative studies for example: meta-ethnography, grounded theory synthesis, critical interpretative synthesis and thematic synthesis. Meta-ethnography, which was developed by Noblit and Hare (1988), is based on an integrative approach that involves the translation of studies into one another. This method was chosen as it has been suggested as a “leading method for synthesising qualitative healthcare research” (Ring, Ritchie, Mandava & Jepson, 2011, p.16) and therefore best fits with the aims of the present paper. Furthermore, meta-ethnography allows for the synthesis of research that has drawn on a variety of approaches. The process involves seven steps which should result in the production of a new interpretation by bringing together findings from individual interpretative accounts.

The seven steps of meta-ethnography (Noblit and Hare 1988) are:

1. Getting started: the search
2. Confirming initial interest
3. Reading studies and extracting data
4. Determining how studies are related
5. Translating studies
6. Synthesising translations
7. Expressing the synthesis

In this systematic review a “line of argument” synthesis was conducted whereby a new level of interpretation is offered based on a previous set of individual studies and explanations. Lines of argument are developed by comparing interpretations,

examining similarities and differences and integrating the findings within a new interpretation (Pope, Mays & Popay, 2007).

Quality Assessment

There is a lack of consensus on how best to appraise the quality of qualitative research (Atkins et al., 2008). Despite this, a number of possible critical appraisal tools exist. One such tool is the summary criteria developed by Walsh and Downe (2006) which was based on a critical review of existing frameworks. The development involved the removal of nonessential criteria making the resultant framework more practicable than earlier systems, which Walsh and Downe (2006) argued were excessively detailed. The authors recommended that their criteria should be used flexibly; however, for the purposes of the present paper a scoring system was created in order to evaluate and compare study quality. An *a priori* decision was made, to include all papers regardless of the quality score, to be as inclusive as possible, given the lack of consensus in the literature regarding the utility of applying quality criteria to qualitative research (Atkins et al., 2008). The quality criteria can be found in appendix 3.

Scoring

Studies were awarded a score of 2 for each essential quality criteria fully met, 1 if partially met and 0 if not met. Studies were then classified as 'poor' if they obtained a score of <50%, 'acceptable' if they obtained a score of 51%-75% and 'good' if they obtained a score of >75%. Each paper was scored by the author and second scored by an independent researcher. Six of the nine studies were classified the same by both scorers. Discrepancies were resolved through discussion.

Results

Quality Appraisal

All nine studies were of an 'acceptable' standard or higher. The quality criteria yielding the lowest scores across the studies were the demonstration of researcher reflexivity and whether or not the method or design was consistent with the research intent. Several studies failed to discuss the epistemological / ontological grounding for the study, or failed to state the specific qualitative method used (e.g. ethnography, grounded theory, phenomenology). Criteria such as setting the study within the context of existing research and theory were more commonly met.

One aspect of the quality assessment related to whether or not authors considered reflexivity and maintained an audit trail during their research. Whilst studies may report having considered these elements, evidence of this is often absent from the published papers. It may be that word restrictions necessitate this, however, this means that quality is being judged on what the authors' state that they have done, in the absence of any evidence. This may suggest that when assessing the quality of qualitative papers, one may be assessing the quality of the written report, in terms of explicitness and detail, as opposed to the quality of the stages and processes involved.

Table 1: Quality scores, percentages and classifications.

Author(s) and year	Quality score out of 24 (%)	Quality Classification
Hatton, Canam, Thorne & Hughes (1994)	16 (67%)	Acceptable
Buckloh et al. (2008)	18 (75%)	Acceptable
Bowes, Lowes, Warner & Gregory (2009)	18 (75%)	Acceptable
Sullivan-Bolyai, Deatrick, Gruppuso, Tamborlane & Grey (2003)	22 (92%)	Good
Lowes, Gregory & Lyne (2004)	23 (96%)	Good
Lowes, Lyne & Gregory (2005)	24 (100%)	Good
Sullivan-Bolyai, Rosenberg & Bayard (2006)	23 (96%)	Good
Marshall, Carter, Rose & Brotherton (2008)	24 (100%)	Good
Smaldone & Ritholz (2011)	20 (83%)	Good

Synthesis

Table 2 displays a list of themes from each of the papers included in the review.

Through the process of meta-ethnography, a new interpretation was developed by

bringing together findings from individual interpretative accounts. The resulting themes are presented and discussed below.

The following key themes emerged from the analysis.

- Diagnosis
- Short term coping
- Longer term adjustment
- Emotional and psychological impact
- Relationships
- Support networks
- Transitions

Table 2. Themes from qualitative literature

Author(s) and year	Country	Themes
Hatton et al., (1994)	Canada	<ul style="list-style-type: none"> ○ Nature of the experience ○ Diagnosis and hospitalisation <ul style="list-style-type: none"> ○ Emotional responses ○ Coping strategies ○ Caring for their child at home <ul style="list-style-type: none"> ○ Blood sugar levels ○ Depression ○ Long term adaptation <ul style="list-style-type: none"> ○ Growing as a family ○ Additional findings <ul style="list-style-type: none"> ○ Mothers v fathers ○ Opening up during interviews
Buckloh et al., (2008)	USA	<ul style="list-style-type: none"> ○ Parental anxiety ○ Shifting parental focus from daily management to long term complications ○ Seeking a flexible and collaborative educational approach ○ Seeking emotional support from the health care team ○ Motivating children ○ Burning out with diabetes ○ Gaining knowledge of long term

		complications
Bowes et al., (2009)	Wales	<ul style="list-style-type: none"> ○ Revisiting diagnosis ○ Triggers that evoked a resurgence of parental grief <ul style="list-style-type: none"> ○ Insulin injections ○ Illness or hospitalisation ○ Diabetes control ○ Risk of complications ○ Letting go ○ Transition from paediatric to adult diabetes service ○ Emotional Support ○ Parental differences in expressing their feelings
Sullivan-Bolyai et al., (2003)	USA	<ul style="list-style-type: none"> ○ Constant vigilance <ul style="list-style-type: none"> ○ Day to day concerns ○ Day to day management ○ Supportive resources ○ Burden of Constant Vigilance on Mothers' Physical and Emotional Health
Lowes et al., (2004)	Wales	<ul style="list-style-type: none"> ○ Events leading to diagnosis ○ The first week ○ Four months after diagnosis ○ Twelve months after diagnosis

Lowes et al., (2005)	Wales	<ul style="list-style-type: none"> ○ Diagnostic period has the characteristics of a psychosocial transition ○ The consequences of the diagnosis mirror those described for a psychosocial transition
Sullivan-Bolyai et al., (2006)	USA	<ul style="list-style-type: none"> ○ Sadness ○ Shock and awe ○ Suck it up ○ Staying in the loop ○ Partnership in care: co-parenting ○ Active participation: Staying involved ○ Mantra for living with diabetes: Child first Diabetes second
Marshall et al., (2008)	England	<ul style="list-style-type: none"> ○ Transition ○ Attachment ○ Loss ○ Meaning
Smaldone & Ritholz (2011)	USA	<ul style="list-style-type: none"> ○ Diagnostic Experiences: Frustrations, Fears, and Doubts ○ Adapting to diabetes ○ Negotiating developmental transitions

Diagnosis

Parents described a range of experiences relating to the period leading up to and surrounding diagnosis. They reported suspicions of DM1 but also alternative explanations for their child's symptoms (Lowes et al., 2005). Some parents felt that their child's non specific complaints had not been taken seriously and/or blamed their own lack of parental experience of DM1 (Smaldone & Ritholz 2011). Some parents reported that diagnosis was characterized by a gradual acceleration of concern driven by a progression of their children's symptoms (Lowes et al., 2004) while others reported that diagnosis followed an abrupt progression of acute diabetic ketoacidosis (DKA) and hospitalisation. Sullivan-Bolyai et al. (2006) found that fathers had detailed memories of diagnosis and described their feelings as very sad and painful. Lowes et al. (2004) found that parents experienced a heightened sense of urgency once their child was in hospital and that this was experienced both positively and negatively; some viewed this as good service whereas others experienced it as concerning. Although a number of parents reported relief at their child not requiring hospitalisation (Lowes et al., 2005), others were reluctant to leave the safety and security of the hospital environment due to their uncertainty about managing the DM1 at home on their own (Smaldone & Ritholz, 2011). Hatton et al. (1995) found that parents experienced misdiagnosis and had concerns that their child may die due to their extreme ill health. Being a witness to complex medical procedures and equipment contributed to the stress of this experience. Parents reported finding it difficult to accept and understand the immediate and chronic implications of the diagnosis.

Short term coping

Returning home from hospital was described as a time of survival, ruled by an inflexible management regimen (Hatton et al., 1995). The period following diagnosis was a time of gaining information and knowledge and learning the complex regimen which required them to repeatedly inflict pain on their child via blood glucose tests and insulin injections. Fathers reported being involved in the early stages of care (Sullivan-Bolyai et al., 2006). Parents focused initially on the practical aspects of DM1 management and prioritizing their children's immediate needs (Lowes et al., 2005) however, some experienced self doubt in their ability to effectively adjust (Smaldone & Ritholz, 2011). Parents developed coping strategies such as being assertive and advocating for their child (Hatton et al., 1995), taking things one day at a time, talking to other people with knowledge of DM1 and getting into a routine (Bowes et al., 2009; Lowes et al., 2005).

Parents sought support, particularly from the health care team (Hatton et al., 1995) and reported that their child's glycaemic control strongly influenced their perception of how well they were coping (Lowes et al., 2005). Consequentially, lifestyle changes and compromises were made to accommodate the DM1 and its treatment, which had further social and financial implications for the family. These were often experienced as several losses, e.g. of flexibility, spontaneity and freedom (Hatton et al., 1995; Lowes et al., 2005).

Sullivan-Bolyai et al. (2003) explored mothers' experiences and discovered a central theme in the data of "constant vigilance." Mothers described the use of hyper-vigilance to achieve daily management. They reported vigilance with regards to day-

to-day concerns and responsibilities such as monitoring tasks, which were primarily aimed at achieving appropriate glycaemic control. Parents also reported vigilance with regards to day-to-day management including both hands-on management skills (e.g. injections) and process-management skills (e.g. problem-solving). Fathers reported constant vigilance in coping with the condition, particularly when the child was younger (Sullivan-Bolyai et al., 2006).

Longer term adjustment

Time, knowledge, learning to trust others and building support systems helped parents adjust in the longer term. Parents reported an increased capacity to receive information about long term complications after a period of time and as they became more familiar with day-to-day tasks (Buckloh et al., 2008). Parents gained useful information from advocacy groups, written material, research, friends and family also with the condition and reported feeling generally pleased with these sources (Buckloh et al., 2008). Increases in confidence allowed parents greater flexibility; however, they maintained a sense of vigilance. Trigger points such as erratic blood sugar levels and a continuing fear of hypoglycaemia contributed to the recurring and enduring emotional impact of parenting a child with DM1 (Hatton et al., 1995; Lowes et al., 2005).

Parents reported 'growing as a family' and combining 'hope with realism' (Hatton et al., 1995, p. 575) as time from diagnosis lengthened. Fathers spent time ensuring that their child with DM1 was treated like any other child (Sullivan-Bolyai et al., 2006) and normality was seen as something to aspire to (Marshall et al., 2008). There is the

suggestion, however, that many parents may never fully accept the diagnosis (Bowes et al., 2009).

Emotional and psychological impact

Parents experience a range of emotions beginning at diagnosis and enduring over time (Buckloh et al., 2008; Hatton et al., 1995; Lowes et al., 2005; Sullivan-Bolyai et al., 2003). Initially parents experienced overwhelming stress and anxiety at the point of hospitalisation and diagnosis. Some parents experienced depression and considered suicide in the early weeks following diagnosis (Hatton et al., 1995).

The diagnostic period was followed by ongoing distress in relation to the pain associated with blood glucose testing and insulin injections with continuing fear and 'dips in confidence' associated with hypoglycaemia (Hatton et al., 1995; Sullivan-Bolyai et al., 2003). Other emotional responses included shock, anger, fear, grief, guilt, sadness and frustration. These are often experienced as overwhelming in intensity and accompanied with a sense of responsibility, hopelessness, loss of control and inadequacy. Some parents reported that they did not feel sad all of the time but key trigger points (e.g. illness or hospitalisation) could result in a resurgence of grief; also that stress and anxiety continued for many years after diagnosis (Bowes et al., 2009). Not all of the emotions experienced were negative, however, with parents also reporting hope and optimism for a potential cure, and stating that this provides them with motivation and strength (Buckloh et al., 2008; Hatton et al., 1995).

Parents report searching for meaning, needing there to be a cause for DM1 and seeking to understand why it happened to their child (Hatton et al., 1995; Lowes et al., 2005; Marshall et al., 2008). Some parents or relatives also had DM1; therefore the child's diagnosis was described as the realization of one of their worst fears (Sullivan-Bolyai et al., 2006). Parents blamed themselves if they held a family history of DM1 (Bowes et al., 2009). They felt they had failed to protect their child from the condition, had concerns about the future and struggled with the lack of certainty that the DM1 created (Marshall et al., 2008).

In addition to the emotional and psychological impact, parents reported experiencing physical burden, with parents feeling exhausted and drained and reporting a number of health problems including weight gain or loss, sleep deprivation and migraines. Some parents reported being hospitalized and attributed their problems to the burden and responsibility of care (Sullivan-Bolyai et al., 2003).

Relationships

DM1 affects family relationships in a variety of ways. Some parents found it difficult to communicate with each other about the DM1 (Hatton et al., 1995) whereas others turned to their spouse and other immediate family members for emotional support (Sullivan-Bolyai et al., 2003). Many parents spoke about sharing care with their partner and working together as a team (Smaldone & Ritholz, 2011). Fathers described a division of labour and co-parenting approach to DM1-related care but acknowledged that the mothers took a leadership or 'expert role' (Sullivan-Bolyai et al., 2006). Other parents spoke of being unable to establish a partnership in DM1 care and described the toll that this had taken on the marriage (Bowes et al., 2009;

Smaldone & Ritholz, 2011). Some mothers reported only communicating what they thought their partners could cope with; also some parents had not discussed their emotions about their child's DM1 up to 10 years after diagnosis (Bowes et al., 2009).

In terms of the parent-child relationship, parents reported looking for ways of increasing their child's motivation to take a greater role in self care and management of DM1. This was reported to include both positive strategies (e.g. incentives) and less positive strategies such as using scare tactics (Buckloh et al., 2008). Changes in the parent-child relationship often related to issues with how the child chose to self manage their DM1 and this could lead to tensions within the relationship (Marshall et al., 2008). It has been suggested that DM1 results in multiple losses for parents through changes in attachment, with parents often feeling that their child was dependent on them and needing to frequently check on their child to reassure themselves that their child was safe (Marshall et al., 2008).

Support Networks

Studies reported on the impact that a child's diagnosis can have on families' use of wider support networks. Some mothers found that relatives and friends initially offered help and support but did not follow through with this (Sullivan-Bolyai et al., 2003). Parents reported that grandparents found it overwhelming and difficult to accept the child's condition (Hatton et al., 1995) and as a result, relatives often withdrew both emotionally and in terms of practical help and support (Smaldone & Ritholz, 2011). As such, parents were obliged to accept a lack of support from extended family and friends and instead sought support from the healthcare team. Parents reported different experiences of this; some positive, some less positive

(Bowes et al 2009; Smaldone & Ritholz, 2011; Sullivan-Bolyai et al., 2003). For example, some parents reported that parent-paediatrician communication varied with regards to empathy and support offered at point of diagnosis (Smaldone & Ritholz, 2011). Parents reported wishing for a collaborative and flexible approach including information, sensitive and clear communication, emotional support as well as reasons to feel hopeful (Buckloh et al., 2008).

Support groups were described as a helpful resource by some parents (Smaldone & Ritholz, 2011) whereas others reported choosing not to attend or not finding them helpful (Bowes et al., 2009). Fathers described forging links with school staff, sports, and other social activities so that their child was included in activities (Sullivan-Bolyai et al., 2006).

In general, babysitters could not be found / trusted or they felt unable to cope with the responsibility of looking after DM1 (Hatton et al., 1995). Parents reported vigilance in relation to ongoing assessment of others' ability to care for their child, with some parents opting against placing children in a day care facility (Sullivan-Bolyai et al., 2003). Parents who used such resources reported staff being over-concerned with blood glucose testing or having misperceptions about the condition and its management (Sullivan-Bolyai et al., 2003). Parents described additional concerns about their children starting school, specifically relating to negotiations between parents and school staff, staff competence in providing care and their child being accepted at school (Smaldone & Ritholz, 2011).

Transitions

Lowes et al., (2005) concluded that a diagnosis of childhood DM1 leads to a psychosocial transition for parents. They argue that the concept of transition provides a framework for explaining parents' responses to loss, grieving and adaptation. They found that parents experienced sudden changes to their world, leaving them insecure and uncertain about the future. Parents reported successful adjustment and accommodation of their child's DM1 within a new model of the world as part of a dynamic process.

Other transitions, such as developmental changes in children were identified as stressful times for parents as they were often characterised by struggle and conflict e.g. regarding invasive procedures, food, power and control (Hatton et al., 1995). Transition to adolescence was a cause for concern for parents, even when their child was still young (Marshall et al., 2008). Parents reported anxieties about their child developing increasing levels of independence and other normative experiences of youth such as school trips and sleep-overs. They were concerned about whether their child could manage such activities independently and safely but acknowledged the normality and necessity of these (Marshall et al., 2008, Smaldone & Ritholz, 2011).

Discussion

Parents' experiences of caring for a child with DM1 are inevitably very personal and unique, however, qualitative research has unearthed some key themes and similarities. The time leading up to and surrounding diagnosis is an important life event for children and their parents. This is reported as being a very emotive and

confusing time for families, despite them having often held suspicions that DM1 may be present. After the initial shock, parents continue to struggle with distressing emotions and cognitions about their child, DM1 and their ability to cope. Parents search for information in order to learn about the condition and how to manage it. They are constantly vigilant because of the unpredictability of the condition and need to reassure themselves that their child is safe. Despite gaining confidence and feeling hopeful, parents report ongoing feelings of sadness and anxiety. Relationships change due to DM1, in terms of the relationship between carers as they try to co-parent, but also with their child as they negotiate transitions. Finally parents must adjust to changes in their usual support network, to include that of the healthcare team and to cope with the withdrawal of extended family and friends, in some instances. There are mixed experiences of handing over child care to nurseries and schools and parents worry about the ability of others to manage the condition.

This synthesis clearly highlights the impact that having a child with DM1 often has on parents' coping, adjustment and relationships. The intensity, range and duration of parental experiences are highlighted, as well as the key role of the health care team in educating and supporting them through this. While NICE (2004) and SIGN guidance 116 (2010) guidance acknowledge some of the potential psychosocial effects of DM1, such as the increased risk of emotional and behavioural problems in children with type 1 DM1, they neglect to fully address the extent to which the condition may affect parents. This is particularly important for younger children, given that parents adopt the primary role of management. This lack of acknowledgement of the impact on parents limits the ability of the healthcare

professionals to adequately prepare and support parents for the potential impact that the condition may have on them and their family.

While studies have evidenced the role of parental factors on the child's control, there has been a lack of focus to date on the personal experience of parents and the factors that they highlight as being important in caring for a child with DM1. This review concurred with the findings of Spencer, Cooper & Milton (2009), in that relationship and systemic factors are important when considering the management of DM1. Thus, whilst roles and dynamics of relationships may change, the systems in which they exist continue to be influential for both children and young people and therefore merit attention and research to understand how best to support such systems. SIGN guidance 116 (2010) highlights the role of maternal distress in poor control in children with DM1, however, this review included research demonstrating the role, impact and experience of fathers in caring for a child with DM1. Although the guidance advocates screening for psychological distress, this is mostly in relation to depression and anxiety and screening using structured screening tools is recommended. The focus on screening for a psychiatric construct is somewhat at odds with the findings of this review, which found that depression is just one potential and extreme example of the emotional impact experienced by parents and that the intensity of psychological distress is more likely to be a subclinical and complex combination of emotions. This review suggests that in addition to taking a psychopathological or diagnostic approach, it may also be appropriate to offer normalisation of parents' experiences in the context of the significant event and subsequent changes faced, in receiving a diagnosis of DM1 for their child.

SIGN guideline 116 (2010) recognises that children spend a large amount of time at school and that school staff may not be experienced in the management of DM1. There is limited evidence on how best to support children in this context and studies generally focus, understandably, on the impact of school interventions on the child's glucose control. This synthesis highlights variation in the extent to which schools are able and willing to support children with DM1 and the potential impact that a lack of support from school may have, not only on the child's control, but also on parents and family functioning. This may in turn impact on the child and their control. Further research is required as to how children can be best supported in school and further attention paid to the complex relationship between school staff, parents and wider social support systems. There is room for work to be done addressing the inequalities being experienced in relation to the interagency link between health and education in terms of DM1 care.

Parents repeatedly stress the importance of learning and education, in enabling them to feel confident in their management. Although NICE (2004) guidelines recommend that education is delivered in relation to aspects of the condition and its management, it does not go into detail as to what this should include or how this should be delivered. It appears that there is a lack of clarity and evidence as to the optimum method and content of such education programmes. This could result in inequalities as to the options available for parents attending different clinics.

The papers included in this review were published in a range of countries with very different healthcare systems. It is possible that such differences in health care systems impact parents' experiences of their child's diabetes as well as their

engagement with the treatment regimen and the healthcare team. Furthermore it is also possible that this may influence the perspective of the researchers, in addition to their own theoretical perspective. Indeed, three of the studies investigated the relevance of particular psychological theories or concepts in exploring parental experiences and it is again possible that this influenced their approach to their research and interpretation of data. This further highlights the importance of researcher reflexivity in acknowledging the social/theoretical context for qualitative research.

This review has implications for healthcare professionals in describing the breadth and depth of parental experiences when a child has DM1. The healthcare team play a key role in supporting the family in terms of disease management but also psychosocial impact, which in turn may affect control. Future research could assess further the effectiveness of interventions and education programmes, not only in terms of the impact on the child's glycaemic control but also in a broader sense, to more accurately capture the multitude of risk and resilience factors involved when a child is diagnosed with DM1. This review clearly demonstrates that DM1 is a community issue, affecting the child, their parents, wider family and friends and school. The resources and support available should reflect this in order to optimise the quality of life and health outcomes for all involved.

Reflexivity

Given that this systematic review is concerned with the synthesis and interpretation of qualitative research, it is appropriate to be transparent about researcher reflexivity. As a Trainee Clinical Psychologist, it is inevitable that the author will be influenced

by the dominant theories and models inherent in clinical psychology training. As such, it felt important to acknowledge the dominant model of influence on the author is that of a cognitive model, which was initially developed by Beck in the 1960s. This model explains individuals' emotional, behavioural and physiological responses as mediated by their perceptions of experiences (Beck, 1979).

Limitations

Pope et al. (2007) highlight that meta-ethnography has the same strengths and weaknesses facing all systematic reviews of qualitative evidence, for example difficulties surrounding searching for studies given that qualitative literature is not well indexed in the main electronic databases. Furthermore, like primary qualitative research, interpretation requires personal judgement which will differ depending on the influences of the person conducting the synthesis in terms of their personal values and theoretical influences. This means that the resulting interpretation will be one of several possible ways of interpreting the collection of studies. Given that this review is based on a synthesis of qualitative research and small sample sizes are inherent in this, the findings are not intended to be generalisable but rather offer insight into some of the experiences of parents of children with DM1.

Conclusions

In conclusion, parents play a key role in the management of their child's DM1 and as such, it is important to acknowledge their experiences and needs in relation to this. This review highlights the range of parental experiences including their private internal experiences but also in terms of wider systemic experiences. The findings suggest that parental experiences are fluid and dynamic from the point of diagnosis,

throughout the course of the disease. While NICE (2004) and SIGN (2010) guidelines go some way in acknowledging the psychosocial impact of the disease, more could be done to recommend evidence based interventions and service design and delivery, in terms of intra and inter agency working and with the families and communities of children with DM1.

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CHAPTER 2: Major Research Project

Fear of hypoglycaemia in parents of young children with type one diabetes:

A Qualitative study using Interpretative Phenomenological Analysis

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Lay Summary

Diabetes mellitus type 1 (DM1) is the most common form of diabetes in children. Strict glycaemic control can increase the risk of hypoglycaemia (when blood sugar levels are too low), which is characterised by a number of unpleasant and often frightening symptoms. Fear of Hypoglycaemia (FOH) is thought to contribute to psychological distress and diabetes management, however little is known about parents' experiences of FOH. The aim of this study was to explore parents' experience of FOH and its impact on their engagement with intensive insulin therapy. A sample of 4 parents took part in semi structured interviews. These were then transcribed and analysed. A number of key themes relating to parents' experiences of FOH emerged: parents' internal experiences, coping, family unit and school. FOH appears to be characterised by a range of emotional and psychological symptoms. Parents attempt to manage the condition and their experiences through a combination of different coping strategies. The social challenges of managing both the condition and FOH were apparent. The results of the study have implications for enhancing clinicians', policy makers' and health care providers' understanding of the experience and impact of parental FOH. This may contribute to improvements in delivery of care and treatment for children with DM1.

Abstract

Background: Diabetes mellitus type 1 (DM1) is the most common form of diabetes in children. Strict glycaemic control can increase the risk of hypoglycaemia, which is characterised by a number of unpleasant and often frightening symptoms. Fear of Hypoglycaemia (FOH) is thought to contribute to psychological distress and diabetes management, however little is known about parents' experiences of FOH. The aim of this study was to explore parents' experience of FOH and its impact on their engagement with intensive insulin therapy.

Methods: This qualitative study was conducted and analysed utilising an Interpretative Phenomenological Analysis (IPA) approach. Purposive, volunteer sampling was used. Semi-structured interviews were conducted with 4 parents in the hospital setting. These were transcribed and analysed.

Results: The results of this study suggest that FOH is a very salient topic for parents of children with DM1. Four super-ordinate themes emerged: parents' internal experience, coping, family unit and school. FOH appears to be characterised by a range of emotional and psychological symptoms. Parents attempt to manage the condition and their experiences through a combination of emotion-focused and problem-focused coping strategies. The systemic challenges of diabetes and FOH were highlighted by parents' worries about their child's safety when under the care of others and the burden that this places on them.

Conclusions: The results of the study have implications for enhancing clinicians', policy makers' and health care providers' understanding of the experience and impact of parental FOH. Suggestions are made for improvements in the delivery of care and treatment for children with DM1.

Introduction

Diabetes mellitus (DM) is a major cause of morbidity both in Scotland and worldwide and rising prevalence rates have been observed (Scottish Intercollegiate Guidelines Network, [SIGN], 2010). It is a metabolic disorder of multiple causation characterised by chronic hyperglycaemia as a result of defects in insulin secretion, insulin action, or both. Diabetes mellitus type 1 (DM1) is the most common form of diabetes in children. Treatment requires a strict routine that typically includes a carefully managed balance of diet, physical activity, multiple daily blood glucose tests and insulin injections. Strict glycaemic control or the maintenance of blood glucose levels, can increase the incidence of episodes of hypoglycaemia (Diabetes Control & Complications Trial Research Group, [DCCT], 1997) which is the most commonly reported adverse event in both type 1 and 2 diabetes (Wild et al., 2007). Hypoglycaemia is characterised by symptoms such as shaking, sweating, nausea, drowsiness, poor motor coordination, mental confusion and unconsciousness (Wild et al., 2007). In its extreme form it can result in loss of consciousness and death (Skrivarhaug et al., 2006). For all clients with diabetes, the acute risk of hypoglycaemia has to be balanced with the long term health complications following prolonged hyperglycaemia, such as kidney failure, coronary heart disease, stroke, blindness and amputation (DCCT, 1997).

For adults with diabetes, research has shown that fear of hypoglycaemia (FOH) is more common among those clients who have experienced severe hypoglycaemic events that have involved a loss of consciousness (Wild et al., 2007; Haugstvedt, Wentzel-Larsen, Graue, Sovik, & Rokne, 2010). FOH is thought to have a role both

in contributing to psychological distress as well as having a behavioural impact on diabetes management (Wild et al., 2007). A critical review of the literature concerning FOH in diabetic clients found that FOH is consistently related to a history of hypoglycaemia and blood glucose variability (Wild et al., 2007). Evidence has suggested that FOH can have a negative impact on diabetes management, metabolic control and health outcomes. Cox, Gonder-Frederick, Antoun, Clarke, & Cryer (1990) described a case study of an adult who experienced a severe hypoglycaemic event that resulted in hospitalization. The client presented with elevated Hypoglycaemia Fear Survey scores and HbA1c levels (an average measure of plasma glucose concentration). They acknowledged that they maintained higher blood glucose levels to avoid a future hypoglycaemic event. Behaviours aimed at reducing the likelihood of further hypoglycaemic events are likely to be negatively reinforced by anxiety reduction (Ferster & Skinner, 1957). Such strategies can have serious clinical implications for diabetes management, as they include measures such as taking less insulin or overeating (Wild et al., 2007) and could ultimately affect clients' blood glucose control and long term health outcomes.

For paediatric clients, FOH may be experienced by the child and/or their parents. It is generally accepted that childhood diabetes “affects and is affected by the entire family” (Stresand, Swift, Wielmarl, Chen & Holmes, 2005, p. 513). For younger clients, particularly those under the age of 12, their parents will likely take the lead role in the management of their condition and will therefore experience the emotions and concerns associated with this role (Marrero, Guare, Vandagriff, & Fineberg, 1997). Several studies have found that a history of severe hypoglycaemic events is positively associated with parental FOH (Marrero, et al., 1997; Patton, Dolan, Henry

& Powers, 2007; Haugsvedt et al., 2010). A positive association has been found to exist between parental FOH and children's HbA1c levels (Clarke, Gonder-Frederick, Snyder & Cox, 1998; Patton et al., 2007; Haugsvedt et al., 2010).

The evidence to date is not without limitations. Research in this field is characterised by the employment of quantitative methods. These studies tend to use a cross sectional design, which preclude the identification of causal relationships (Haugstvedt et al., 2010). Small sample sizes are also common, which are problematic in terms of generalising findings to the population (Patton et al., 2007). Existing psychometric measures have been criticised for being vulnerable to reporting bias (Patton et al., 2007) and although numerous psychometric tools are available, few have been found to meet rigorous psychometric appraisal criteria (Eigenmann, Colagiuri, Skinner, & Trevena, 2009). Finally, measures of coping have been criticised for their excessive generality and failure to account for personal characteristics, despite having demonstrated validity, reliability and applicability (Hagger & Orbell, 2003).

In a recent systematic review of FOH in parents of young children with diabetes, Barnard, Thomas, Royle, Noyes, & Waugh (2010) found that parental FOH, anxiety and depression were common and that hypoglycaemia avoidance behaviours, such as maintaining higher than desirable blood glucose levels, were employed. While these authors acknowledged that the methodological quality of the studies was generally good, there were few studies that examined FOH independently from general parental anxiety. Furthermore, the authors acknowledged that the complex issues that influence parental FOH are multifaceted and require further exploration and suggest

that “robust qualitative research is required to tease out parental attitudes in a more sensitive way than could be achieved using quantitative methods” (Barnard et al., 2010, p. 6).

There have been a number of qualitative studies that have explored clients’ and families’ experiences of paediatric chronic illness (Lowes, Lyne & Gregory 2004; Biesecker, 2006; Buckloh, Lochrie, Antal & Milkes, 2008; Collins & Reynolds 2008; Hema et al., 2008; Marshall, Carter, Rose & Brotherton 2009; Miller, 2009). Studies focused on diabetes, have examined daily stressors and coping responses of children and young people (Hema et al., 2008), parent’s perspectives of family learning and knowledge (Buckloh et al., 2008), perceptions of children and their parents of living with diabetes (Marshall et al., 2009) and parents’ experience of home management and the first year following diagnosis (Lowes et al., 2004). There is, however, no evidence to date of any qualitative studies exploring the parents’ experience of FOH, despite being identified as an important area for investigation (Barnard et al., 2010).

Aims

The aims of this study are to explore the experience of FOH in parents of young children with DM1, and the impact this has on diabetes management.

Method

Design

This study employed Interpretative Phenomenological Analysis (IPA). IPA aims to explore the research participant's lived experience from their perspective, whilst recognising that interpretation of this account is inevitably affected by the researcher's own views and lived experience, alongside the process of interaction between the researcher and the participant (Smith & Eatough, 2007). IPA is well suited to research with service users in health-related contexts because it is based on the premise of exploring how people perceive and make sense of their experiences, events and states (Smith & Eatough, 2007; Smith & Osborn, 2008).

Sample/ Participants

Research into children and young people with DM1 is often divided into young children (typically less than 12 years old) and young people (13 and over). Given that parents play a pivotal role in the management of diabetes in their young children, this study focused on parents who subjectively experience FOH. As this was an initial exploratory study, there was no specific focus on either gender of parent.

In accordance with IPA, a purposive and well defined sample of parents for whom the research question is significant was used (Smith & Eatough, 2007). IPA studies are generally conducted with relatively small sample sizes ranging from 1 to 42 with the norm being towards smaller samples (Smith & Eatough, 2007). A sample size of six was aimed for and whilst six parents agreed to take part in the study, only four

attended to be interviewed. All parents that took part were mothers, their children were all aged between nine and ten years old and all were two parent families.

Inclusion criteria:

- Has a child aged 12 or under with a diagnosis of DM1 for at least 1 year
- Child has no additional major chronic health conditions requiring hospital attendance
- Parents have subjectively experienced fear of hypoglycaemia

Recruitment Procedures

Participants were identified and given a study information leaflet by the Diabetes Team. The researcher was available, prior to interview, to answer any questions and written consent was gained prior to commencing the interviews, which were conducted in a hospital out-patient department (see appendices 5 - 8 for forms used during recruitment).

Research Procedures

An interview schedule was devised to guide the semi structured interviews (see appendix 9). This was informed by the available literature and Hypoglycaemia Fear Survey (Cox, Irvine, Gonder-Frederick, Noxacek & Butterfield, 1987). It was designed to gently approach the subject of fear of hypoglycaemia following a broader discussion of parent's experience to date. The first interview was reviewed by the author and supervising researchers, to ensure that the schedule effectively elicited the required information. The schedule was judged effective and therefore

used without modification in subsequent interviews. All interviews were recorded and transcribed with identifiers of place and person removed.

Data Analysis

The practical guidance of the stages involved in IPA was followed (Smith & Osborn, 2008, pp 53-79). To gain a holistic overview, several close readings of the transcripts were conducted and particular points of interest and significance noted. This process identified emergent themes, which captured the quality of the participants' experiences. Two of the transcripts were analysed by supervising researchers, blind to the findings of the first analyst and a comparison of themes conducted, to assess inter-rater reliability. While different language was used to describe themes, agreement was achieved in terms of the content of the salient themes. A list of themes was compiled and connections and clusters were extrapolated to create overarching themes. The overarching themes across transcripts were then compared to produce a final list of themes to be used as the basis for a narrative report, illustrated with quotes from the interviews. Finally, the author addressed reflexivity (i.e., reflection on the sources of bias that may be brought to analysis), by keeping a reflective journal, an audit trail and regular discussion within research supervision meetings.

Ethical considerations

The study was approved by the University of Glasgow, Ayrshire and Arran Research and Development Team and the West of Scotland Research Ethics Committee (see appendices 10 & 11 for approval letters). Participants had the right to withdraw at

any point, with no impact on their child's medical treatment. Consent and confidentiality were carefully and clearly managed.

Results

While the focus of the present study was FOH, it was inevitable that parents would speak more widely about their experiences having a child with DM1. Indeed this was encouraged to facilitate an open and safe environment for the discussion. Due to word limits, the narrative account below will focus on those themes and findings that relate specifically to parents' experiences of fear of hypoglycaemia.

Table 1: Table of emergent super ordinate and sub themes relating to parents' experience of hypoglycaemia.

Super ordinate Themes	Sub themes
1) Parents' Internal Experience	<ul style="list-style-type: none"> • Cognition • Emotions • Physical Impact
2) Coping	<ul style="list-style-type: none"> • Emotion-Focused Coping • Problem-Focused Coping • Control • Learning and Knowledge
3) Family Unit	
4) School	

Parents' Internal Experiences

Cognition

All four parents spoke about their thoughts and worries about diabetes and specifically hypoglycaemia. Three of the four described constant worry relating to hypoglycaemia and diabetes. There was a tendency throughout for parents to display quite a catastrophic style of thinking and all four spoke about their worst fear: the death of their child.

“You are constantly thinking have I got everything, what if this happens, what if that happens” Parent 3 (page 3 line 84)

“The main concern is (child) will die” Parent 1 (page 5 line 178)

Parents’ concerns about hypoglycaemia are present both during the day and at night and they are hyper-vigilant for their child’s individualised disease signs and symptoms which they note as ever changing and evolving. All four reported FOH at night time and two parents said their concern was finding their child unconscious in the morning. Parents described striving for a sense of control over the condition, while acknowledging the impossibility of ever fully being in control of such an unpredictable condition. It is as though parents struggle to achieve something that they feel is impossible, but try nonetheless as the alternative is to give up and risk their feared consequence.

“You can never completely manage it, you can do your best”

Parent 3 (page 4 line 148)

Separation anxiety was apparent in three of the parents along with a wish to be nearby or with the child in case of a crisis.

“I thought, something’s going to happen to (child) and even though I was only in the next town along, or couple of towns along, erm, I felt that how am I going to get back to (child) if something happens to (child)” Parent 1 (page 2 line 57)

All of the parents sought to make sense of their child's condition both in terms of aetiology and understanding hypoglycaemia or changes in blood sugar levels. They spoke about specific situations which either trigger hypoglycaemia or increase their anxiety about hypoglycaemia i.e. the impact of illness, sport and holidays. These situations seem to lessen their sense of control by introducing variability and unpredictability. Normality was referred to by parents in terms of wishing their child to have a 'normal' life and not stand out as being different to other children, the hope that their own experience as a parent is normal and looking for ways to normalise their lives. Despite the young age of their child, parents have thoughts of the future in relation to the transition to adolescence and adulthood, the lifelong nature and long term complications of the condition and hopes for a cure.

“that’s fine, so that’s normal, yes it’s not you it’s normal and just knowing that it’s normal to have that range of emotions” Parent 3 (page 20 line 772)

Self critical thoughts were evident in all four parents, ranging from self blame to minimisation of successful coping. They had concerns that they were making things worse for their child, failing as a parent, and that they had abandoned their child by not being present for hypoglycaemia.

“you don’t know if you are failing as a parent really” Parent 3 (page 14 line 525)

Parents’ memories and narratives were very rich and detailed but at times fragmented, as if they had several lines of thought at once or did not have a fully coherent narrative.

Emotions

A range of emotions were reported including sadness, panic, fear, and guilt mixed with relief and feeling thankful or lucky that things were not worse. Parents described experiencing a delayed emotional experience or suppressing their emotions to allow them to focus on supporting their child. Furthermore, they acknowledged self monitoring and attempting to mask their emotions from their children.

“Just sad, just tired, sad but relieved as well. A mix of emotions” Parent 1 (page 6 line 193)

Whilst all of the parents acknowledged feeling worried and fearful, the emotional tone of the interview felt more anxiety laden than they labelled or expressed verbally. All four parents were tearful at points during the interview but their affect was also, at times, incongruent with the content of their speech; they often laughed when describing painful memories or experiences.

Physical Impact

The physical impact on parents included feeling drained and exhausted, having migraines and feeling as though the experience had aged them. Parents acknowledged the impact that coping with FOH has on their sleep.

“once it’s done, a bit phwoar, exhausted” Parent 2 (page 6 line 266)

Coping

Emotion Focused Coping

Avoidance or attempts at thought suppression were discussed by parents. They spoke of delaying thinking about hypoglycaemia, keeping their thoughts private rather than discussing them, pushing thoughts to the back of their mind, ignoring thoughts or attempting to distract themselves from their thoughts. It seems that, whilst there is the tendency to ruminate and worry about hypoglycaemia and diabetes, parents consciously try to switch off from their thoughts at time to protect them from being overwhelmed.

“It’d be overwhelming if you thought about it all the time”

Parent 4 (page 11 line 402)

Problem-Focused Coping

Although acknowledging some attempts at emotion-focused coping, parents described a predominantly problem-focused approach to coping with diabetes and FOH. Prevention is preferable to managing hypoglycaemia, so parents describe a range of behaviours or strategies to prevent hypoglycaemia as far as possible or to detect hypoglycaemia as early as possible. They regularly test their child’s blood both during the day, at bedtime and during the night and re-test soon after, if necessary. Assessment involves weighing up signs and symptoms with blood glucose results and parents describe numerical thresholds for acceptable upper and lower blood glucose levels. Routines and rules are in place and parents reported being well prepared and organised for different situations and scenarios. Parents

ensure that they are always contactable so that they can be alerted by telephone if there are any problems when the child is under the responsibility of somebody else.

“Anything under kinda 4, if (child) is 3.9 or something we would be in hypo mode”

Parent 2 (page 4 line 169)

Once hypoglycaemia has been detected, parents described switching into problem-solving mode to quickly correct their child’s blood glucose levels. This seems to involve an internal dialogue or script about what steps they need to take with clear pre-set procedures. Parents think ahead to what their next actions might be depending on how hypoglycaemia progresses. This focus on managing the problem seems to over ride any acknowledgment of their emotional reaction at this stage as the priority is effectively to save their child, given that hypoglycaemia can lead to coma or even death.

“you just kinda become right what do we need to do, we’re doing this and we’re

moving forward” Parent 1 (page 3 line 96)

Three parents highlighted their child’s hypo unawareness or their resistance to comply with treatment when signs are apparent to others. The child’s hypo unawareness seems particularly troubling at night time, because of the risk that the child will not wake up to be treated. This seems to drive the parents’ night time testing to prevent their feared worst case scenario and this explains their experience of sleep deprivation and exhaustion.

“So when (child) doesn’t waken with a hypo and I get up to test (child), usually for that next week I get up every night because I’m too frightened not to in case I miss it” Parent 1 (page 4 line 133)

Control

The desire to prevent and treat hypoglycaemia takes place within the context of an awareness of the importance of tight glucose control for long term health. All four parents made reference to the importance of tight glycaemic control and/or an awareness of barriers to control. Two parents acknowledged that being conservative with the amount of insulin they give their child may have resulted in their child’s blood glucose level being higher than ideal but they are more comfortable with higher rather than lower blood glucose levels.

“ So maybe that’s why sometimes (child)’s a bit higher than what (child) should be, cos rather than (child) drop right down erm, I’m more likely to bolus it back down later” Parent 3 (page 9 line 347)

Learning and Knowledge

Parents highlighted the importance of learning and knowledge to allow them to prevent, detect and treat hypoglycaemia. They described the difficult position in the early stages of diagnosis, of needing to know enough to cope with disease management, but not being able to know everything. Parents described learning through being given information by medical practitioners, looking to other sources such as the internet and learning by experience. Medical terminology and jargon had been incorporated into the parents’ vernacular. They noted that there were limits to

their knowledge, that learning is a continual process and also highlighted their expertise and unique knowledge of their child.

“I spent my time just reading all this information and trying to get my head round it” Parent 4 (page 2 line 50)

Family Unit

Parents spoke about how diabetes has affected their child, their relationship with their child, the impact on siblings and family functioning in general. Three of the four parents reported either stopping work or reducing their hours. All four parents noted differences in how they and their partner experience and manage FOH. Furthermore, they identified differences in roles and responsibilities; whilst parents acknowledge the benefits of working together and having someone to share the burden with, it appears that all four mothers take on the role of main carer. The mothers all self-identify as more worried and having more responsibility or feeling a greater burden of care than the fathers. They acknowledged a degree of conflict or stress in their relationships as a result of these differences.

“I’m the one in the house with (child) all day, I’m the one that’s gonna have to deal with this big first hypo” Parent 2 (page 5 line 196)

School

Parents reported mixed experiences of the school’s approach to their child’s diabetes. Whilst some spoke of a collaborative approach involving family, school and the diabetes team, others spoke of a more conflicted relationship and school staff having

misconceptions about diabetes. Parents' key concern relates to school staff's level of knowledge about DM1. This is in terms of either lack of previous experience of managing diabetes, lack of sufficient number of formally trained staff but also a perceived lack of specialist knowledge about their child's individualised signs and symptoms of hypoglycaemia. This appears to leave parents lacking confidence that their child is safe at school.

"I did take (child) off school, erm. Just because of fear of hypo and nobody there being, knowing (child) and knowing what to look out for" Parent 4 (page 5 line 174)

Discussion

Qualitative research in healthcare enables in depth exploration of people's personal experiences, often with the aim of improving the quality of care and treatments offered. Diabetes is a chronic metabolic condition, increasing in prevalence both in the UK and worldwide with significant associated economic burden. It therefore merits and receives, increasing prominence in the research literature.

It is generally accepted that childhood diabetes affects both the child and the family (Streisand et al., 2005). A number of studies have explored parents' experiences of having a child with DM1 (Hatton, Canam, Thorne & Hughes 1994; Buckloh et al. 2008; Bowes, Lowes, Warner & Gregory 2009, Sullivan-Bolyai, Deatrick, Gruppuso, Tamborlane & Grey 2003, Lowes et al., 2004; Lowes, Gregory & Lyne 2005, Sullivan-Bolyai, Rosenberg & Bayard 2006; Marshall et al., 2009; Smaldone & Ritholz 2011). Such studies highlight important key themes in parents'

experiences including diagnosis, short term coping, longer term adjustment, emotional and psychological impact, relationships, support networks and transitions. The results from this study were in keeping with earlier findings but add to the existing literature by focusing specifically on their experiences of FOH; a need highlighted in a recent systematic review of the quantitative literature (Barnard et al., 2010)

Parents' accounts highlight the wide range of emotions and worries experienced in relation to hypoglycaemia. While parents fear the occurrence of hypoglycaemia, the catastrophic nature of their thinking means that they fear the worst possible consequence of hypoglycaemia, which is death. Parents acknowledged the excessive nature of their worry and described trying to suppress or avoid their own personal internal experience. They spoke of being hyper-vigilant for signs of threat in order to prioritise actions to save their child's life in the event of hypoglycaemia. This chronic hyper-arousal is, understandably, exhausting for parents. They recounted detailed memories, often with a fragmented narrative. Parents' emotional responses were at times incongruent from the content of their story; although tearful in parts, laughter was a frequent accompaniment to a traumatic memory. Parents' experiences can be usefully conceptualised as a trauma response. Herman, (2001) describes the complex nature of trauma reactions as an array of generalised and specific anxiety and fear symptoms, elevated levels of arousal and attention for threat, with extreme startle response to their specific feared stimuli. It is suggested that the numerous symptoms of post traumatic disorder fall into three main categories: hyper-arousal, intrusion (memories) and constriction (emotional numbing). Post traumatic stress relates not only to threats to one's own safety. It could be hypothesised that having a

child diagnosed with a lifelong chronic condition, where risk of extreme hypoglycaemia could result in death, may result in a trauma presentation in some parents. This suggests that while earlier research, such as that reviewed by Barnard et al., (2010), highlighted the presence of parental anxiety and depression it appears not to acknowledge or capture the traumatic nature of FOH for some parents.

Parents' coping was characterised by a combination of problem-focused approaches, which draw on previous experience and learning from a variety of sources, with emotion-focused strategies (avoidance, distraction, etc.). This may suggest that parents are not only striving to cope with the demands of the diabetes, but also to cope with the burden that this places on them, both emotionally and psychologically. The literature suggests that people adopt problem-focussed approaches when they feel that the problem itself can be solved, but use more emotion-focused coping when the problem is viewed as out-with their control (Lazarus & Folkman, 1987). This is in keeping with parents' accounts of the constant struggle to control their child's blood glucose levels while never really feeling that full control is achievable. It may be that parents switch between problem and emotion-focused coping strategies as their sense of control fluctuates.

Although some parents spoke of engaging in compensatory strategies to avoid FOH by maintaining higher blood glucose levels, for example, what seemed more apparent was the extent to which parents regularly test and monitor their child's blood glucose levels in order to catch the earliest signs of hypoglycaemia and respond as quickly as possible. This may be somewhat at odds with previous findings citing the use of avoidance and compensatory behaviours (Barnard et al.,

2010) and does not explain the positive association between parental FOH and children's HbA1c levels (Clarke, et al., 1998; Patton et al., 2007; Haugsvedt et al., 2010). It may be that parents did not feel comfortable during interview discussing such behaviours. Alternatively, it may be that the tendency to be conservative in administering insulin is not performed at a conscious or deliberate level.

The systemic context of diabetes and hypoglycaemia was emphasised by parents' accounts of attempting to manage the responsibility for their child not only with their partner but also within their wider systems including the child's school. Their experiences of this were mixed but concerns relating to others lack of knowledge and experience were highlighted with the result that parents are not fully confident that their child is safe under the care of others, especially at school. Although the National Institute for Clinical Excellence (NICE, 2004) guidelines for diabetes recommend that education is delivered in relation to aspects of the condition and its management, it lacks detailed recommendations regarding content and method. Despite diabetes teams' attempts to link with schools, parents' accounts suggest that this could be improved in terms of reaching a greater number of school staff and increasing general levels of awareness.

Limitations

The present study is not without limitations. In accordance with the design and analysis, the sample is homogenous and is not intended to be generalisable. Although homogeneity was intended with regard to self selection for FOH, all participating parents were further alike in that they were mothers from two parent households, with the index child aged 9-10. This narrow age band was not

intentional and it is not clear why parents of children of this age were more motivated to take part. The study would benefit from the inclusion of fathers and it would be interesting to explore experiences relating to a wider age range of children. The parents that took part in the study volunteered and were all engaged with the diabetes service. It would be important to attempt to reach a wider sample or demographic of families to gain a deeper understanding of how FOH presents in different subsets of parents.

Implications

The findings have implications for clinicians, policy makers and managers invested in providing care, treatment and support to children with diabetes, their families and wider support networks. The social nature of the condition and the greater need for inter-agency working and planning has been highlighted. Improved training and liaison with schools could have a positive impact not only on the child's health outcomes but also on parents' experiences. Furthermore, education and support could be extended from the immediate family unit to include wider family and friends, in order to enhance support networks by increasing others' knowledge and confidence in being able to care for the child. Whilst existing measures are useful tools for screening for worry and potential compensatory behaviours in relation to FOH, the findings of this study suggest that they give limited insight into the intensity of the distress experienced, the pervasiveness and wider impact that FOH has on their daily lives, relationships and family functioning. Clinical Psychologists have a valuable role in terms of being well placed to offer assessment, formulation and intervention for complex presentations, but also by offering supervision, training

and consultation to the MDT to enhance clinicians' knowledge and skills in detecting FOH and supporting families with this.

Reflexivity

Reflexivity was addressed by the author keeping a reflective log throughout the process. As a Trainee Clinical Psychologist, the analysis was noted to be influenced by cognitive models of mental health as well as models of coping. It is possible and likely that the results would be analysed differently under alternative theoretical influences. Two of the four transcripts were coded independently and discussed with supervising researchers which confirmed the super ordinate themes. This could have been further improved by checking the themes with participating parents to ensure that they represented their lived experience but due to limited time this was not practicable.

Conclusion

The results of this study suggest that FOH is a very salient topic for parents of children with DM1 and is characterised by a range of emotional and psychological symptoms. Parents attempt to manage the condition and their experiences through a combination of emotion-focused and problem-focused coping strategies. The systemic nature of diabetes and FOH was highlighted by parents' concerns regarding their child's safety, when responsibility is handed to others.

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CHAPTER 3: Advanced Practice 1 – Reflective Critical Account Abstract

The role of the Clinical Psychologist in working with complex clinical presentations.

This reflective account focuses on my experience of working with a complex clinical presentation as part of both a multidisciplinary team and the wider health and social care system. The experience pertains to the diverse and extended role of a clinical psychologist working within the current context: working with complex clinical presentations at higher tiers of care, offering consultation, engaging with ongoing clinical supervision and continuing professional development. Rolfe et al's (2001) framework for reflexive practice was employed to structure the process of reflective practice. This experience highlighted the importance of being aware of and addressing process issues within the therapeutic relationship, but also in terms of wider interpersonal and systemic dynamics. This enabled me to understand my own emotional reactions to my client and their carer and also provided further information to aid with ongoing formulation and reformulation. In turn, this fed into the delivery of an appropriate intervention and multi-disciplinary and multi agency working. It highlighted to me the importance of receiving ongoing clinical supervision and CPD. Furthermore, it highlighted the capacity of the clinical psychologist to encompass extended and diverse roles incorporating consultation and leadership in addition to direct therapeutic input.

CHAPTER 4: Advanced Practice 2 – Reflective Critical Account

The extended roles of the Clinical Psychologist: delivering consultation and training in an Older Adult Clinical Psychology Service

This reflective account relates to my experience of providing consultation and training within an Older Adult Clinical Psychology Service. Dementia is a common presenting difficulty within the older adult population. The Scottish Government has outlined the standards of care that patients with dementia, their families and carers should receive in Scotland, in relation to increasing access to evidence based psychological interventions. Cognitive Stimulation Therapy (CST) is an evidence based psychological intervention for people with dementia recommended in Scottish Intercollegiate Guidelines Network (SIGN, 2006) and National Institute for Clinical Excellence (NICE, 2011) guidelines. In accordance with the extended roles of the Clinical Psychologist and the Stepped Care approach to increasing access for psychological therapies, I was given the opportunity to provide consultation and training in order to support the development of CST groups. I used the framework for reflexive practice outlined by Rolfe et al. (2001) as I have found it to be a useful model to aid reflective practice in the past. This experience highlighted that despite there being a clear need to implement psychological interventions in accordance with government policies and guidelines, translating this into action at ground level may not be without barriers and challenges. Consultation draws on many skills inherent in therapy, which means that Clinical Psychologists are well equipped to adopt the role of the consultant within MDT teams and at a wider organisational level.

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Appendix 1: Author Guidelines for submission to British Journal of Health Psychology

The aim of the British Journal of Health Psychology is to provide a forum for high quality research relating to health and illness. The scope of the journal includes all areas of health psychology across the life span, ranging from experimental and clinical research on aetiology and the management of acute and chronic illness, responses to ill-health, screening and medical procedures, to research on health behaviour and psychological aspects of prevention. Research carried out at the individual, group and community levels is welcome, and submissions concerning clinical applications and interventions are particularly encouraged.

The types of paper invited are:

- papers reporting original empirical investigations;
- theoretical papers which may be analyses or commentaries on established theories in health psychology, or presentations of theoretical innovations;
- review papers, which should aim to provide systematic overviews, evaluations and interpretations of research in a given field of health psychology; and
- methodological papers dealing with methodological issues of particular relevance to health psychology.

1. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length

Papers should normally be no more than 5000 words (excluding the abstract, reference list, tables and figures), although the Editor retains discretion to publish

papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length.

3. Editorial policy

The Journal receives a large volume of papers to review each year, and in order to make the process as efficient as possible for authors and editors alike, all papers are initially examined by the Editors to ascertain whether the article is suitable for full peer review. In order to qualify for full review, papers must meet the following criteria:

- the content of the paper falls within the scope of the Journal
- the methods and/or sample size are appropriate for the questions being addressed
- research with student populations is appropriately justified
- the word count is within the stated limit for the Journal (i.e. 5000 words)

4. Submission and reviewing

All manuscripts must be submitted via <http://www.editorialmanager.com/bjhp/>. You may like to use the [Submission Checklist](#) to help you prepare your manuscript. The Journal operates a policy of anonymous peer review. Authors must suggest three reviewers when submitting their manuscript, who may or may not be approached by the Associate Editor dealing with the paper. Before submitting, please read the [terms and conditions of submission](#) and the [declaration of competing interests](#).

5. Manuscript requirements

- Contributions must be typed in double spacing with wide margins. All sheets must be numbered.
- Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. A template can be downloaded from [here](#).

- **Statement of Contribution:** All authors are required to provide a clear summary of ‘what is already known on this subject?’ and ‘what does this study add?’. The 2-3 (maximum) sentences for each point should identify existing research knowledge relating to the specific research question/topic and a summary of the new knowledge added by your study. Under each of these headings, please provide 2-3 clear outcome statements (not process statements of what the paper does); the statements for ‘what does this study add?’ should be presented as bullet points of no more than 100 characters each. The Statement of Contribution should be a separate file.
- Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript with their approximate locations indicated in the text.
- Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi.
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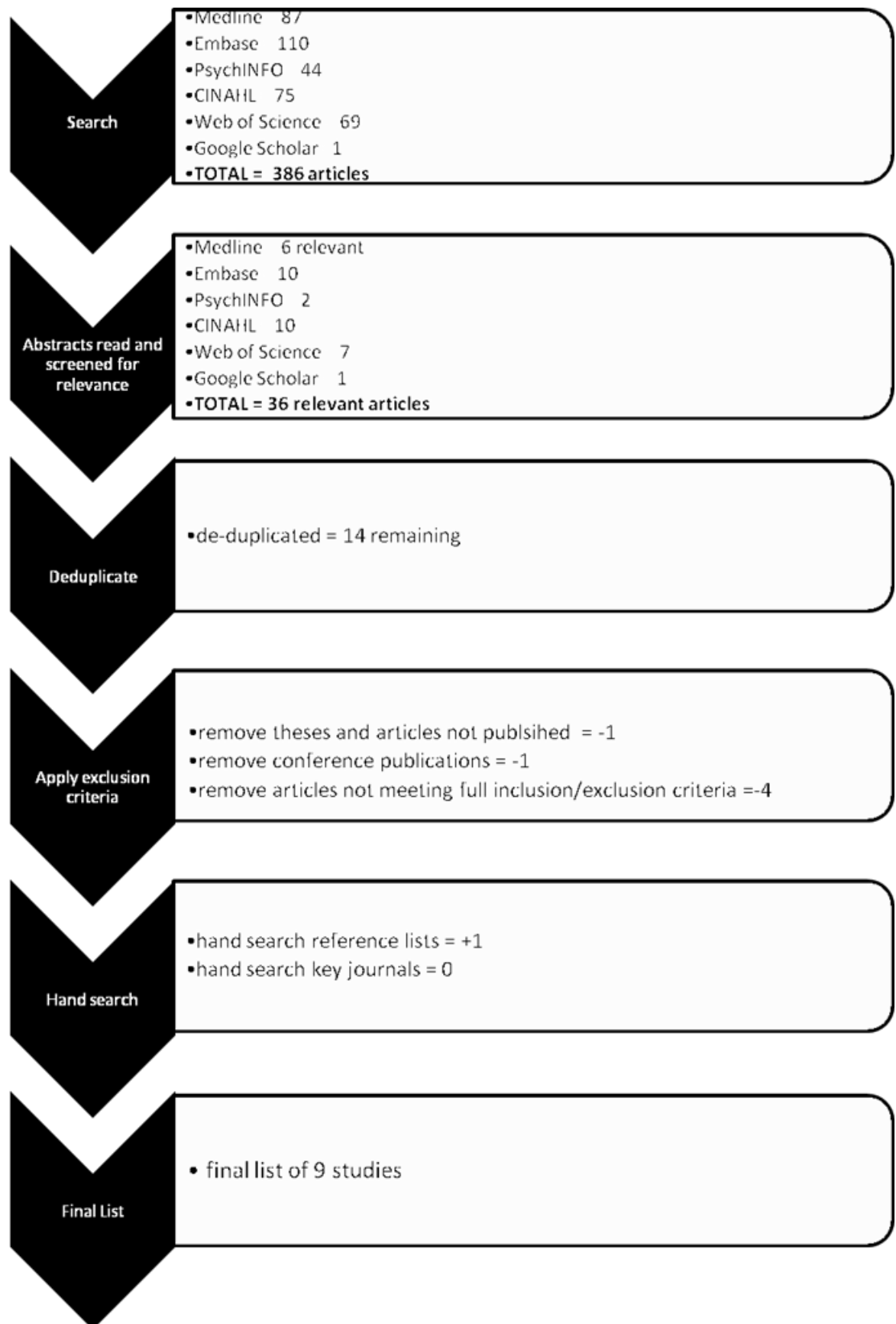
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Appendix 2: Flow Chart



Appendix 3: Quality Appraisal Framework (Based on Walsh and Downe 2006)

Scoring: For each essential quality criteria, studies awarded a score of 0 if the criteria was not met, 1 if partially met and 2 if fully met yielding a total possible score out of 24.

Stage	Essential Criteria	Specific Prompts
Scope and Purpose	<ul style="list-style-type: none"> ○ Clear Statement of and rationale for research question/aims/ purposes ○ Study thoroughly contextualised by existing literature 	<ul style="list-style-type: none"> • <i>Clarity of focus demonstrated</i> • <i>Explicit purpose given such as descriptive/ explanatory, intent, theory building, hypothesis testing</i> • <i>Link between research and existing knowledge demonstrated</i> • <i>Evidence of systematic approach to literature review, location of literature to contextualise the findings or both</i>
Design	<ul style="list-style-type: none"> ○ Method/ design apparent and 	<ul style="list-style-type: none"> • <i>Rationale given for use of qualitative design</i>

	<p>consistent with research intent</p> <p>○ Data collection strategy apparent and appropriate</p>	<ul style="list-style-type: none"> • <i>Discussion of epistemological/ ontological grounding</i> • <i>Rational explored for scientific qualitative method e.g. ethnography, grounded theory, phenomenology</i> • <i>Discussion of why particular method chosen is most appropriate/ sensitive/ relevant for research given research question/ aims</i> • <i>Setting appropriate</i> • <i>Were data collection methods appropriate for type of data required and for specific qualitative method?</i> • <i>Were they likely to capture the complexity/ diversity of experience and illuminate context in sufficient detail?</i>
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		<ul style="list-style-type: none"> • <i>Was triangulation of data sources used if appropriate?</i>
Sampling strategy	<ul style="list-style-type: none"> ○ Sample and sampling method appropriate 	<ul style="list-style-type: none"> • <i>Selection criteria detailed and description of how sampling was undertaken</i> • <i>Justification of sampling strategy given</i> • <i>Thickness of description likely to be achieved from sampling</i> • <i>Any disparity between planned and actual sample explained</i>
Analysis	<ul style="list-style-type: none"> ○ Analytic approach appropriate 	<ul style="list-style-type: none"> • <i>Approach made explicit e.g. thematic distillation, constant comparative method, grounded theory</i> • <i>Was it appropriate for the qualitative method chosen?</i> • <i>Was data managed by software package or by hand and why?</i> • <i>Discussion of how coding</i>

		<p><i>system/ conceptual frameworks evolved</i></p> <ul style="list-style-type: none"> • <i>How was context of data retained during analysis?</i> • <i>Evidence that the subjective meanings of participants were portrayed</i> • <i>Evidence of more than one researcher involved in stages if appropriate to theoretical stance</i> • <i>Did research participants have any involvement in analysis?</i> • <i>Evidence provided that data reached saturation or discussion/rationale if it did not</i> • <i>Evidence that deviant data was sought or discussion/ rationale if it was not</i>
Interpretation	<ul style="list-style-type: none"> ○ Context described and taken account of in interpretation 	<ul style="list-style-type: none"> • <i>Description of social/ physical and interpersonal contexts of data collection</i>

	<ul style="list-style-type: none"> ○ Clear audit trail given ○ Data used to support interpretation 	<ul style="list-style-type: none"> • <i>Evidence that researcher spent time dwelling with the data, interrogating it for competing/ alternative explanations of phenomena</i> • <i>Sufficient discussion of research process such that others can follow decision trail</i> • <i>Extensive use of field notes entries/ verbatim interview quotes in discussion of findings</i> • <i>Clear exposition of how interpretation led to conclusions</i>
Reflexivity	<ul style="list-style-type: none"> ○ Researcher reflexivity demonstrated 	<ul style="list-style-type: none"> • <i>Discussion of relationship between researcher and participants during fieldwork</i> • <i>Demonstration of researcher's influence on</i>

		<p><i>staged of researcher process</i></p> <ul style="list-style-type: none"> • <i>Evidence of self awareness/ insight</i> • <i>Documentation of effects of the research on researcher</i> • <i>Evidence of how problems /complications met were dealt with</i>
Ethical dimensions	<ul style="list-style-type: none"> ○ Demonstration of sensitivity to ethical concerns 	<ul style="list-style-type: none"> • <i>Ethical committee approval granted</i> • <i>Clear commitment to integrity, honesty, transparency, equality and mutual respect in relationships with participants</i> • <i>Evidence of dilemmas met and how resolved in relation to ethical issues</i> • <i>Documentation of how autonomy, consent, confidentiality and anonymity were managed</i>

Relevance and transferability	<ul style="list-style-type: none"> ○ Relevance and transferability evident 	<ul style="list-style-type: none"> • <i>Sufficient evidence for typicality specificity to be assessed</i> • <i>Analysis interwoven with existing theories and other relevant explanatory literature drawn from similar settings and studies</i> • <i>Discussion of how explanatory propositions. Emergent theory may fir with other contexts</i> • <i>Limitations /weaknesses of study clearly outlines</i> • <i>Clearly resonates with other knowledge and experience</i> • <i>Results. Conclusions obviously supported by evidence</i> • <i>Interpretation plausible and makes sense</i> • <i>Provides new insights and increases understanding</i>
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		<ul style="list-style-type: none"> • <i>Significance for current policy and practice outlines</i> • <i>Assessment of value/ empowerment for participants</i> • <i>Outlines further directions for investigation</i> • <i>Comment on whether aims/ purposes of research were achieved</i>
TOTAL SCORE		

Appendix 4: Major Research Proposal

Abstract

Background: Type one diabetes (DM1) is the most common form of diabetes in children. Treatment requires a strict routine that typically includes a carefully managed diet, physical activity, home blood glucose testing several times a day, and multiple daily insulin injections to improve short and long term health outcomes. Strict glycaemic control can increase the risk of hypoglycaemia, which is characterised by a number of unpleasant and often frightening symptoms. Fear of Hypoglycaemia (FOH) is thought to contribute to psychological distress and diabetes management. It has been hypothesised that FOH may lead to avoidant or compensatory behaviours such as elevating blood glucose levels with additional carbohydrate intake or lowered insulin dose to prevent hypoglycaemia.

Aims: To explore parents' experience of FOH and its impact on their engagement with intensive insulin therapy.

Methods: This qualitative study will be conducted and analysed utilising an Interpretative Phenomenological Analysis (IPA) approach. Purposive, volunteer sampling will be used. Semi structured interviews will be conducted in the hospital setting, with the primary caregiver. These will be transcribed and analysed.

Applications: The results of the study should enhance health care providers' understanding of the experience and impact of FOH on parents' engagement with

intensive insulin regimes and thus could improve metabolic control in children with DM1 by helping families and teams work together on this issue.

Introduction

Diabetes Mellitus (DM) is a major cause of morbidity both in Scotland and worldwide, with increasing prevalence (Scottish Intercollegiate Guidelines Network, [SIGN], 2010). It is a metabolic disorder of multiple aetiology characterised by chronic hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. Type one diabetes (DM1) is the most common form of diabetes in children. It is caused by the inability of the pancreas to produce insulin. Treatment requires a strict routine that typically includes a carefully managed diet, physical activity, home blood glucose testing several times a day, and multiple daily insulin injections. Strict glycaemic control, or the maintenance of blood glucose levels can increase the incidence of episodes of hypoglycaemia (Diabetes Control & Complications Trial [DCCT], 1997) which is the most commonly reported adverse event of both type one and two diabetes (Wild et al., 2007). Hypoglycaemia is characterised by symptoms such as shaking, sweating, nausea, drowsiness, poor motor coordination, mental confusion and unconsciousness (Wild et al., 2007).

For all clients with diabetes, the acute risk of hypoglycaemia has to be balanced with the long term health complications following hyperglycaemia. Short term risks are more salient than long term consequences and this may be further intensified if clients have experienced adverse effects such as a hypoglycaemic event. Arguably, hypoglycaemia is a significant limiting factor for strict adherence to intensive insulin

therapy goals in DM1 (Wild et al., 1997; Haugstvedt, Wentzel-Larsen, Graue, Sovik, & Rokne, 2010).

For adults, research has shown that fear of hypoglycaemia (FOH) is more common among those clients who have experienced severe hypoglycaemic events that have involved a loss of consciousness (Wild et al., 2007; Haugstvedt et al., 2010). FOH is thought to have a role both in contributing to psychological distress as well as having a behavioural impact on diabetes management (Wild et al., 2007). A critical review of the literature concerning FOH in diabetic clients, found that FOH is consistently related to a history of hypoglycaemia and blood glucose variability (Wild et al., 2007). Evidence was found to suggest that FOH may have a negative impact on diabetes management, metabolic control and health outcomes. Cox, Gonder-Frederick, Antoun, Clarke and Cryer (1990) described a case study of an adult patient where a severe hypoglycaemic event resulting in hospitalization, resulted in elevated Hypoglycaemia Fear Survey scores and HbA1c levels (an average measure of plasma glucose concentration). The client acknowledged maintaining higher blood glucose levels to avoid a further hypoglycaemic event. Behaviours aimed at reducing the likelihood of further hypoglycaemic events are likely to be negatively reinforced as they reduce the persons' anxiety. Such strategies can have serious clinical implications for diabetes management, as they include measures such as taking less insulin or overeating (Wild et al., 2007) and could ultimately affect clients' long term health outcomes.

For paediatric clients, FOH may be experienced by the child and/or their parents. It is generally accepted that childhood diabetes "affects and is affected by the entire

family” (Stresand, Swift, Wielmarl, Chen & Holmes, 2005, p. 513). For younger clients, particularly those under the age of 12, their parents will likely take the lead role in the management of their condition and will therefore experience the emotions and concerns associated with this role (Marrero, Guare, Vandagriff, & Fineberg, 1997). A positive association has been found to exist between parental FOH and children’s HbA1c levels (Clarke, Gonder-Frederick, Snyder and Cox, 1998; Patton, Dolan, Henry & Powers, 2007; Haugsvedt et al., 2010). Several studies have found that a history of severe hypoglycaemic events is positively associated with parental FOH (Patton et al. 2007; Marrero et al., 1997; Haugsvedt et al., 2010). In a recent systematic review of FOH in parents of young children with diabetes, Barnard, Thomas, Royle, Noyes and Waugh (2010) found that parental FOH, anxiety and depression were common and that hypoglycaemia avoidance behaviours such as maintaining higher than desirable blood glucose levels were employed. The evidence, however, was found to be limited. Whilst they acknowledged that the methodological quality of the studies was generally good, there were few studies that examined FOH independently from general parental anxiety. Furthermore, the authors acknowledged that the complex issues that influence parental FOH are multifaceted and require further exploration and suggest that “robust qualitative research is required to tease out parental attitudes in a more sensitive way than could be achieved using quantitative methods” (Barnard et al., 2010, p. 6).

The literature on paediatric diabetes is characterised by the employment of quantitative methods. These studies tend to use a cross sectional design, which preclude the identification of causal relationships (Haugstvedt, et al., 2010). Small sample sizes are also common, which are problematic in terms of generalising

findings to the population (Patton et al., 2007). Existing psychometric measures have been criticised for being vulnerable to reporting bias (Patton et al., 2007) and although numerous psychometric tools are available, few meet rigorous psychometric appraisal criteria (Eigenmann, Colagiuri, Skinner, & Trevena, 2009). Measures of coping have been criticised for their excessive generality and failure to account for personal characteristics, despite having demonstrated validity, reliability and applicability (Hagger & Orbell, 2003).

In terms of qualitative research, there have been a number of studies looking at clients' and families' experiences of paediatric chronic illness (Lowes, Lyne & Gregory 2004; Biesecker, 2006; Collins & Reynolds 2008; Buckloh, Lochrie, Antal & Milkes 2008; Hema et al 2008; Marshall, Carter, Rose & Brotherton 2009; Miller, 2009). With regards to diabetes, studies have examined daily stressors and coping response of children and young people (Hema, et al., 2008), parent's perspectives of family learning and knowledge (Buckloh, et al., 2008), perceptions of children and their parents of living with diabetes (Marshall, 2009) and parents' experience of home management and the first year following diagnosis (Lowes, Lyne and Gregory 2004). There is however, no evidence to date of any qualitative studies exploring the experience of FOH, despite being identified as an important area for investigation (Barnard et al., 2010).

Given the above evidence, a qualitative exploration of fear of hypoglycaemia in parents would be timely. This will give clinicians a clearer understanding of the parents' perspective and thus will be enabled to enhance the support they provide for them.

Aims

Aims: To explore the experience and impact of FOH in parents of young children with DM1 receiving intensive insulin therapy.

Questions:

1. What is parents' of children with DM1 experience of FOH?
2. What impact does this have on their engagement with intensive insulin therapy?

Plan of Investigation

Design

The study will be qualitative in design and will use Interpretative Phenomenological Analysis (IPA). IPA aims to explore the research participant's experience from his or her own perspective while recognising that exploration of this inextricably implicates the researcher's own views and the process of interaction between the researcher and the participant (Smith & Eatough, 2007). IPA is well suited to research in health-related contexts as it is based on the premise of exploring how people perceive and make sense of their experiences, events and states (Smith & Eatough, 2007; Smith & Osborn, 2008).

Sample/ Participants

In accordance with IPA, a purposive and well defined sample will be used (Smith & Eatough, 2007). The focus is not to recruit a sample that represents a sub-section of the general population, but rather “to find a closely defined group for whom the research question will be significant” (Smith & Eatough, 2007, pp.). Research into children and young people with DM1 is often divided into young children (typically less than 12 years old) and young people (13 and over), consistent with the move through developmental stages. In terms of diabetes, young people face different challenges to younger children and also to adults. For example, they are developing a sense of self with increased independence in terms of managing their condition and there is less of a focus on the role and experience of parents in relation to their child’s illness. In younger children, the parents have a pivotal role in managing their child’s condition, including monitoring and managing blood glucose levels and much of the research on clients within this age group focuses on the parents or main caregivers. For this reason, the present study will focus on parents of young children i.e. those aged 12 or younger, who experience FOH. As this is an initial exploratory study, there will not be a specific focus on either gender of parent and the study will therefore be open to both mothers and fathers.

Inclusion criteria:

- Has child aged 12 or under with a diagnosis of DM1 for at least 1 year
- Child has no additional diagnosed co-morbid chronic health conditions
- Parents have subjectively experienced fear of hypoglycaemia

Recruitment Procedures

Participants will be identified and recruited through the Outpatient Paediatric Diabetes Clinic at Crosshouse Hospital, Kilmarnock. The Diabetes Clinic consultants and nurses will be invited to identify possible participants who meet the inclusion criteria. The identified parents will then be sent an information pack about the research study. Parents will be asked to contact the researcher to indicate their interest in taking part. The researcher will contact the parent by phone to answer any immediate questions. If the parent still wishes to take part at this stage, an appointment will be arranged to conduct an interview in person at Crosshouse Hospital. Written consent will be gained prior to commencing the interview. Some parents may wish to take part in the study but be unable to attend a meeting: in such instances telephone interviews will be offered so that willing participants are not excluded. Clinicians responsible for the child's care will be informed of their parent's participation in the study. Recruitment will continue until 6-8 interviews have been completed. If parents at any time refuse to allow their interviews to be recorded it will be explained that recordings are necessary to ensure that their views can be fully noted. Recordings will be deleted once transcription has been checked.

Research Procedures

An interview schedule will be designed to guide the semi structured interviews. This will be informed by the available literature and the Hypoglycaemia Fear Survey (Cox, Irvine, Gonder-Frederick, Noxacek & Butterfield, 1987) and will be piloted on a sample of 3 participants. Interviews will then be transcribed and transcripts reviewed to ensure that the schedule is eliciting the type of information sought effectively. If the schedule is successful, the initial 3 transcripts will be incorporated

into the data set. Face-to face interviews will be conducted in Crosshouse Hospital. Interviews may be offered over the telephone for those unable to attend an appointment but who wish to take part in the study. It has been found that telephone interviews can be used productively in qualitative research and may be preferred by participants for reasons such as convenience and privacy (Sturges & Hanrahan, 2004).

Justification of sample size

IPA studies are generally conducted with relatively small sample sizes ranging from 1 to 42 with the norm being towards smaller samples (Smith & Eatough, 2007). Recently a sample size of 1 has been argued for (Smith & Osborn, 2008), but in clinical and health psychology postgraduate programmes, six to eight is often cited as an appropriate number for an IPA study (Smith & Eatough, 2007).

Settings and Equipment

Information forms and consent forms will be written for the purposes of the study. Interviews will be conducted either in person or by telephone. Recording and transcribing equipment will be required.

Data Analysis

Interviews will be transcribed according to IPA protocols. The author will follow practical guidance of the stages involved in IPA (Smith & Osborn, 2008). The transcriptions will be checked for completeness and accuracy. Any references to places or persons will be anonymised. The recordings will then be deleted. The transcripts will be stored on a password protected NHS encrypted computer.

Analysis will involve several close readings of the transcripts noting particular points of interest and significance, to gain a holistic overview which will be used to document emergent themes that capture the quality of the participants' experiences. A list of themes will be compiled, connections and clusters will be extrapolated and this will create over-arching themes. This process will be repeated for the other interviews and the overarching themes will be compared to produce a table of comparative themes. This will be used as the basis for writing up the results in a narrative report, illustrated with quotes from the interviews. A sample of the transcripts will be analysed by a second researcher (the supervising psychologist, who is experienced in the IPA research protocols) who will be blind to the findings of the first analyst. Following this, a comparison of themes between analysts will be conducted to assess inter-rater reliability. Finally, the author will address reflexivity, i.e., reflection on the possible sources of bias that may be brought to analysis, by keeping a reflective journal.

Health and Safety Issues

Researcher Safety Issues

The investigator will receive regular supervision with the supervising Clinical Psychologists. All local health and safety policies will be followed. Home visits will not be conducted.

Participant Safety Issues

Participants will have the right to withdraw from the study at any time without any impact on their child's treatment. Data will be stored on a password protected, encrypted computer. If any issues of risk arise regarding either a child or their

parents, a member of the clinical team will be alerted immediately. If any parents taking part in the study request Psychological input, they will be directed to the team's Clinical Psychologist.

Ethical Issues

The study has been verbally approved by the Paediatric Diabetes Team. Researcher and Participant safety will be carefully considered and managed according to local protocols. Ethical approval will be sought from Integrated Research Application System (IRAS). Permission will be sought from Ayrshire and Arran Research and Development Department and the local Clinical Psychology research and clinical governance committee.

All interviews will be transcribed and anonymised for references to place and person during transcription. Once the transcripts have been checked for accuracy and completeness, the recording will be deleted.

Communication about sensitive topics regarding their children may be distressing for some parents. The parents involved in the study will already be supported by the recruiting diabetes team but if additional psychological support is required, the parent can self refer or request a referral to the team's Clinical Psychologist.

Financial Issues

The financial implications of the study include travelling cost for the investigator to travel from Glasgow to Ayrshire to meet with the clinic team and to conduct the interviews, the cost of sourcing recording and transcribing equipment and the

stationary costs for posting and returning leaflets and forms. It is estimated that the financial cost of the study will amount to £32 plus travel expenses to Ayrshire.

Timetable

Application to IRAS and local R&D will take place in the summer of 2011. This should allow recruitment to begin in September 2011. Data collection will be completed by February 2012 allowing for submission in July 2012.

Practical Applications and Implications

The findings of the study should enhance knowledge of parental FOH and its impact on adherence to intensive insulin therapy in paediatric diabetes. This in turn could contribute to interventions which aim to address this issue and improve metabolic control thereby reducing the longer term risks of diabetes.

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Appendix 5: Research Study Participant Information Leaflet

Fear of hypoglycaemia in parents of young children with type one diabetes

This leaflet has been given to you by the Paediatric Diabetes Outpatient Clinic at Crosshouse Hospital, on behalf of Lesley Scott (Trainee Clinical Psychologist).

I would like to ask you to take a few minutes of your time to read over this information leaflet. My name is Lesley Scott and I am a Trainee Clinical Psychologist with the University of Glasgow. As part of my Doctorate in Clinical Psychology I am undertaking a research project in partnership with the Paediatric Diabetes Outpatient Clinic at Crosshouse Hospital, Kilmarnock.

I am contacting you to ask you to take part in a research study. This sheet is designed to give you all of the information that you will require to make this decision. I have tried to answer any obvious questions that you may have but if you would like to discuss any aspect of the study further, please do not hesitate to contact me.

What is the study about?

I am interested in hearing about parents' experiences of parenting a child with Type one diabetes. In particular I am interested in parents' experience of fear of hypoglycaemia and how they cope with this.

Why am I being asked to take part?

You are being asked to take part because you have a child aged 12 or under with Type one diabetes, attending Crosshouse Hospital.

Do I have to take part?

You do not have to take part and deciding not to take part will not affect your child's care in any way. You can withdraw from the study at any point without this affecting your child's care.

What would I have to do?

All participants will take part in an interview at Crosshouse Hospital which is expected to last for approximately 60 minutes. This interview will be recorded.

Who would know I was taking part?

The Paediatric Diabetes Outpatient Department at Crosshouse Hospital, would know that you were taking part in the study but the information that you provided would be anonymised so that no one would be able to identify what you in particular had said. I would need to know your child's name and DOB to be able inform the team that you are taking part.

I would only have to break this confidentiality if I became concerned that you or someone else was at risk of harm. In these circumstances, I would need to share my concerns but I would tell you before I did this.

What will happen to the information I provide?

The interview will be recorded. The recordings will be transcribed, anonymised then destroyed. The anonymous transcripts will be stored on an encrypted password protected computer. Only my supervisors (Psychologists working for the University) and I will have access to the recordings. The information will be analysed and

presented in the form of a report and submitted to the University of Glasgow in part fulfilment of Doctorate in Clinical Psychology and for publication in a scientific journal. Within the report, anonymous quotes of what you have said may be used. All participants will be provided with a summary of the results if they wish.

Are there any benefits to taking part?

There are no direct benefits to you or your child if you take part in this study. However, the information that you provide will contribute to our understanding of diabetes and its management, in particular parents experiences. If this study is published in a scientific journal, it would contribute to the wider research literature and could contribute to developments in the psychological care of patients and their families.

Are there any down sides to taking part?

It is possible that our discussion may trigger upsetting thoughts or feelings that may be difficult for you to talk about. If this is the case, and you wish to stop, you can end the interview at any time. If you need a break during the interview this is fine. If you wish to be referred to the Clinical Psychologist with the Diabetes Team, this can be arranged.

Who has reviewed the study?

The study has been approved by the University of Glasgow, the National Research Ethics Committee and the NHS Ayrshire and Arran Research and Development Team.

What do I do now?

If you are interested in taking part in the study, please complete the attached form and return it in the enclosed envelope. I will then contact you by telephone to answer any questions that you may have about the study and to arrange an appointment for the interview. When we meet I will ask you to sign a consent form to show that you have read and understood the information provided to you and that you agree to take part in the study.

Thank you for taking the time to read this Participant Information Leaflet and for any further input you may wish to have.

Lesley Scott

Trainee Clinical Psychologist

Contact information:

Miss Lesley Scott

Trainee Clinical Psychologist

Glasgow University Section in Psychological Medicine

Department of Psychological Medicine

Gartnavel Royal Hospital Academic Centre

1055 Great Western Road

G12 0XH

Email: l.scott.2@research.gla.ac.uk

Telephone: 0141 211 0607

Research Study Participant Information Leaflet Version 2 (11/11/2011)

Appendix 6: Participant Response Form

Please tick

I am interested in taking part in the study detailed in the *Participant Information Leaflet*. ☐

I am happy to be contacted by telephone to discuss the study further. ☐

I give consent for the researcher to leave a message if I am unavailable. ☐

Name (please print in block capitals):

Telephone Number:

Name of child:

Child's DOB:

Relationship to Child (please circle): MotherFather

Legal Guardian

Signed:

Appendix 7: Participant Consent Form

Title of study: Fear of hypoglycaemia in parents of young children with type one diabetes

Name of researcher: Miss Lesley Scott (Trainee Clinical Psychologist)

Please initial each box:

I confirm that I have read and understood the participant information sheet for the above study. ☐

I have had the opportunity to ask questions and have had satisfactory answers to these. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐

I understand that my interview will be recorded and transcribed and I give permission for this. ☐

I understand that only Lesley Scott and the supervising Psychologists (Dr Sarah Wilson and Dr Suzy O'Connor, University of Glasgow) will have access to the personal information that I provide. ☐

I understand that my medical care or legal rights will not be affected by taking part. ☐

I give permission for the researcher to inform the Diabetes Team of my involvement.

☐

I understand that discussion of some topics may be upsetting for me.

☐

I agree to take part in the above study.

☐

Name of participant

Date

Signature

Name of researcher

Date

Signature

Participant Consent Form Version 2 (11/11/2011)

1 copy to researcher, 1 to participant, 1 to hospital records.

Appendix 8: Letter to Diabetes Team

Miss Lesley Scott

Glasgow University Section in Psychological Medicine

Department of Psychological Medicine

Gartnavel Royal Hospital Academic Centre

1055 Great Western Road

G12 0XH

Email: l.scott.2@research.gla.ac.uk

Telephone: 0141 211 0607

Date:

Diabetes Team

Crosshouse Hospital

Kilmarnock

KA2 0BB

Dear Colleagues

RE: Child's Name DOB

I am writing to inform you that _____, the
Mother/Father/Legal Guardian of _____ has
agreed to take part in the research study titled *Fear of hypoglycaemia in parents of
young children with type one diabetes.*

Thank you for your assistance in recruiting participants to this study.

Yours sincerely

Lesley Scott

Trainee Clinical Psychologist

Version 2 (11/11/2011)

Appendix 9: Interview Schedule

- Can you tell me about your *experience of having a child with DMI*
 - How did you find out? (symptoms)
 - How did you react?
 - How did it feel?
 - How has this changed things for you?
 - How has this changed things for your child?
 - Is anyone else in the family affected?
 - What is the most difficult aspect of the diabetes?
 - Are there any positive aspects?
- What is your *knowledge/understanding* of diabetes?
 - What is your understanding or knowledge about the short terms risks?
 - What is your understanding or knowledge about the long term risks?
 - How can your child's diabetes be controlled?
 - Where do you get your information from?
 - How competent/confident do you feel in managing your child's diabetes?
- What concerns do you have related to your child having *diabetes*?
 - What is the main worry/worst fear?
- Has your child ever had a *hypoglycaemic event*?
 - What happened?
 - How did you react?
 - What was it like for you?
 - Frequency, severity?
 - *What concerns*, if any, do you have about hypoglycaemia?
 - Not realizing
 - The hypo symptoms themselves e.g. fainting, disorientated
 - Child losing control
 - Hypo whilst in other's care

- while asleep
 - while at school
 - while in public
 - not having food or juice
 - long term complications
 - insulin reaction
- *How do you respond* or cope with these concerns?
 - Avoid child being away
 - Run blood sugars high to be safe
 - Feed large snacks
 - Give less insulin
 - Carry fast acting sugar
 - Rest child
 - Check blood sugar often
 - Check on child during the night
- What are your thoughts on the *treatment* for diabetes?
 - Diet
 - Injections
 - Exercise
 - Do you worry about any aspects of treatment?
 - How do you cope with this?
- What are your expectations for the *future*?
 - What are you hopes?
 - What are your fears?
 - Has this changed since the diagnosis?
- What *advice* would you give families receiving a diagnosis?

Appendix 10: Approval Letters from West of Scotland Research Ethics Service

WoSRES
West of Scotland Research Ethics Service

**COPY FOR YOUR
INFORMATION**

West of Scotland REC 5

Ground Floor - Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT

Date 27 October 2011

Direct line 0141 211 2102
Fax 0141 211 1847
E-mail sharon.macgregor@ggc.scot.nhs.uk

Dr Sarah Wilson
Psychologist
College of Medical, Veterinary and Life Sciences
University of Glasgow
Academic Unit of Mental Health and Well Being
1st Floor Administration
Gartnavel Royal Hospital Academic Centre
1055 Great Western Road
GLASGOW
G12 0XH

Dear Dr Wilson

Study title: Fear of hypoglycaemia in parents of young children with
type one diabetes: A qualitative study using
Interpretative Phenomenological Analysis
REC reference: 11/WS/0080
Protocol number: 1

The Research Ethics Committee reviewed the above application at the meeting held on 19 October 2011. Thank you to Ms Scott for attending to discuss the study.

Ethical opinion

The Committee discussed this study and thought it was a very important research area. There were no major ethical issues.

There were concerns that, without a control group, the second part of the principal research question could not be answered. However, it was agreed by the majority of the Committee that this is not necessary as this is a qualitative, psychological study.

It was also noted from the application that GPs will be informed of participation. However, the Committee did not think that this was necessary as the research is not about the child's health. The Diabetes Clinic would be aware of any concerns about the parent's management of the child, otherwise they wouldn't be in the study. However, if the researchers feel strongly that they want to inform the GP about participation, this should be stated in the Participant Information Sheet and Consent form.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

1. The Committee do not believe that the GP needs to be informed of participation. However, if the researchers want to do this, this should be stated in the PIS and a new statement added to the Consent form.
2. The PIS and Consent form should also be printed on headed paper before being given to participants. The Consent form should also include the standard footer "1 copy to researcher, 1 to participant, 1 to hospital records".

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter	-	03 October 2011
Interview Schedules/Topic Guides	1	01 September 2011
Investigator CV	-	
Other: Letter to Diabetes Team	1	01 September 2011
Other: Lesley Scott's CV		
Participant Consent Form	1	01 September 2011
Participant Information Sheet	1	01 September 2011
Protocol	1	16 September 2011
REC application	-	29 September 2011

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/WS/0080

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely


for **Dr Gregory Ofili**
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers"

Copy to: ✓ Ms Lesley Scott, Gartnavel Royal Hospital Academic Centre
Dr Karen L Bell, NHS Ayrshire and Arran

Miss Lesley Scott
Trainee Clinical Psychologist
School of Medical, Veterinary and Life Sciences
Academic Unit of Mental Health and Well Being
1st Floor Administration
Gartnavel Royal Hospital Academic Centre
1055 Great Western Road
GLASGOW
G12 0XH

Ground Floor - Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT

Date 23 November 2011

Direct line 0141 211 2102
Fax 0141 211 1847
E-mail sharon.macgregor@ggc.scot.nhs.uk

Dear Miss Scott

Full title of study: Fear of hypoglycaemia in parents of young children with type one diabetes: A qualitative study using Interpretative Phenomenological Analysis
REC reference number: 11/WS/0080

Thank you for your letter of 11th November 2011. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 19 October 2011. Please note these documents are for information only and therefore won't be reviewed by the committee.

Documents received

The documents received were as follows:

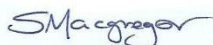
Document	Version	Date
Covering Letter		11 November 2011
Participant Consent Form	2	11 November 2011
Participant Information Sheet	2	11 November 2011
Other: Letter to Diabetes Team	2	11 November 2011

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.

11/WS/0080

Please quote this number on all correspondence

Yours sincerely



Mrs Sharon Macgregor
Committee Co-ordinator

Copy to: Dr Sarah Wilson, University of Glasgow
Dr Karen Bell, NHS Ayrshire and Arran

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Appendix 11: Approval Letters from Research & Development

Dr Sarah Wilson
Academic Unit of Mental Health
1st Floor Administration Building
Gartnavel Royal Hospital
1055 Great Western Road
G12 0XN

Healthcare Quality, Governance and Standards Unit
Research, Development & Evaluation Office
58 Lister Street
Crosshouse Hospital
Kilmarnock
KA2 0BB



Tel: (01563) 825856
Fax: (01563) 825806

Date: 6 December 2011
Your Ref:
Our Ref: CAW/KLB/AMK 2011AA071

Enquiries to: Karen Bell
Extension: 25850
Direct Line: 01563 825850
Email: Karen.bell@aaaht.scot.nhs.uk

Dear Dr Wilson

R&D 2011AA071 Fear of Hypoglycaemia in parents of young children with type one diabetes: A qualitative study using interpretive Phenomenological Analysis

I confirm that NHS Ayrshire and Arran have reviewed the undernoted documents and grant R&D Management approval for the above study.

Approved documents:

Document	Version	Date
IRAS Form	3.3	29 September 2011
SSI	3.3	22 September 2011
Protocol	1.0	16 September 2011
Interview Schedule	1.0	1 September 2011
Letter to Diabetes Team	1.0	1 September 2011
Participant Information Sheet	2.0	11 November 2011
Participant Consent Form	2.0	11 November 2011

The terms of approval state that the investigator authorised to undertake this study within NHS Ayrshire & Arran is: -

- Lesley Scott, University of Glasgow

With additional investigator(s): -

- Dr Nicola Scott, NHS Ayrshire & Arran
- Dr Scott Williamson, NHS Ayrshire & Arran

The sponsors for this study are NHS Ayrshire & Arran

This approval letter is valid until 6 January 2013.

R&D 2011AA071
Fear of Hypoglycaemia v1

Please note the following condition: the data is ours and we would prefer that if possible no personal information is held on such devices. If this is not possible however we would request that the researcher keeps the amount of personal details to an absolute minimum, that it is only held on the laptop for the least time possible and that if during transit and storage that it is kept secure at all times i.e. out of site and locked away when not in use

Regular reports of the study require to be submitted. Your first report should be submitted to Dr K Bell, Research & Development Manager in 12 months time and subsequently at yearly intervals until the work is completed.

Please note that as a requirement of this type of study your name, designation, work address, work telephone number, work e-mail address, work related qualifications and whole time equivalent will be held on the Scottish National Research Database so that NHS R&D staff in Scotland can access this information for purposes related to project management and report monitoring.

In addition approval is granted subject to the following conditions: -

- All research activity must comply with the standards detailed in the Research Governance Framework for Health and Community Care www.cso.scot.nhs.uk/publications/ResGov/Framework/RGFEdTwo.pdf and appropriate statutory legislation. It is your responsibility to ensure that you are familiar with these, however please do not hesitate to seek further advice if you are unsure.
- You are required to comply with Good Clinical Practice (ICH-GCP guidelines may be found at www.ich.org/L0B/media/MEDIA482.pdf), Ethics Guidelines, Health & Safety Act 1999 and Data Protection Act 1998.
- If any amendments are to be made to the study protocol and or the Research Team the Researcher must seek Ethical and Management Approval for the changes before they can be implemented.
- The Researcher and NHS Ayrshire and Arran must permit and assist with any monitoring, auditing or inspection of the project by the relevant authorities.
- The NHS Ayrshire and Arran Complaints Department should be informed if any complaints arise regarding the project and the R&D Department must be copied into this correspondence.
- The outcome and lessons learnt from complaints must be communicated to funders, sponsors and other partners associated with the project.
- As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collated in line with NHS Scotland IT Security Policies, until the destruction of these data. Under no circumstances should personal data be stored on any unencrypted removable media e.g. laptop, USB or mobile device (for further information and guidance please contact the Information Governance Team based at Ailsa Hospital 01292 513693 or 513694).

If I can be of any further assistance please do not hesitate to contact me. On behalf of the department, I wish you every success with the project.

Yours sincerely

R&D 2011AA071
Fear of Hypoglycaemia v1



Professor Craig A White
Assistant Director Healthcare Quality, Governance and Standards

c.c. SPONSOR Contact
Lesley Scott, University of Glasgow
Dr Scott Williamson, NHS Ayrshire & Arran
Dr Nicola Scott, NHS Ayrshire & Arran
Dr Suzy O'Connor, University of Glasgow
Lesley Douglas, Finance, Ailsa Hospital
Information Governance, Ailsa Hospital
Dr Callum Morrison, NHS Ayrshire & Arran

R&D 2011AA071
Fear of Hypoglycaemia v1

Healthcare Quality, Governance and Standards Unit
Research, Development & Evaluation Office
58 Lister Street
Crosshouse Hospital
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KA2 0BB



Tel: (01563) 825856
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Miss Lesley Scott
Academic Unit of Mental Health
1st Floor Administration
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XN

Date: 15 December 2011
Your Ref:
Our Ref: CAW/KLB/AMK 2011AA071

Enquiries to: Karen Bell
Extension: 25850
Direct Line: 01563 825850
Email: Karen.bell@aaaht.scot.nhs.uk

Dear Miss Scott

R&D 2011AA071 Fear of hypoglycaemia in parents of young children with type one diabetes: A qualitative study using interpretive phenomenological analysis

On behalf of NHS Ayrshire and Arran, I can confirm that the document below has been approved.

- Letter to Diabetes Team, version 2.0, 11 November 2011

Please contact the R&D Office if you have any further queries. On behalf of the department, I wish you every success with the project.

Yours sincerely

Professor Craig A White
Assistant Director (Healthcare Quality, Governance and Standards)

Cc. Dr Sarah Wilson, University of Glasgow