

THE UNIVERSITY OF HULL

The Experiences of people with Diabetes Mellitus and Hypoglycaemia
Unawareness

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by

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Overview

This portfolio thesis contains three separate parts: a systematic literature review, an empirical study and a set of associated appendices.

Part one is a systematic literature review which synthesises published literature which explores the experiences of those who care for an adult who has hypoglycaemia. A systematic database search identified nine articles which were included in the review. The synthesis resulted in four overarching themes: emotional impact on the caregiver, effect on the partnership, restricting activities and seeking knowledge and support. Overall results are discussed in terms of their quality and their implications for future research and clinical practice.

Part two is an empirical paper exploring patient experiences of having both diabetes mellitus and hypoglycaemia unawareness. A qualitative methodology was used to explore lived experiences. Six participants shared their subjective experiences which were analysed using Interpretative Phenomenological Analysis. Three overarching themes were identified: 'I call my diabetes the beast because it just doesn't do as it's told,' 'It's like waking up every day with a giant above your bed saying right; you've got to look after me today' and 'I've got this condition and it's ruining my life. I just want to be normal.' The findings are considered within the context of existing literature and clinical implications are discussed.

Part three includes appendices from both the systematic literature review and the empirical paper. An epistemological statement and a reflective statement outlining the research process are also included.

Total word count: 10232 (excluding references and appendices)

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Part One: Systematic Literature Review

The psychosocial impact of hypoglycaemia on caregivers of adults with diabetes: A Systematic Review

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This paper is written in the format ready for submission to the Journal of Diabetes Care.
Please see Appendix A for the Guideline for Authors

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Abstract

Background: There is literature which suggests that being a caregiver for an individual with hypoglycaemia can be challenging, however the majority of the literature focuses on caring for a child with diabetes.

Purpose: This review aimed to explore the impact of hypoglycaemia on caregivers of adults with diabetes in order to identify any care or support needs for this population.

Data Sources: An electronic systematic search of the literature was conducted utilising the following online databases; PsycInfo, Medline, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Academic Search Premier and Psyc Articles.

Study Selection: 9 studies were selected in accordance with the inclusion and exclusion criteria.

Data Extraction: A data extraction form was used to collate all the relevant data

Data Synthesis: A narrative synthesis was conducted across the findings of the studies. Four overarching themes were identified: emotional impact on the caregiver, effect on the partnership, restricting activities and seeking knowledge and support.

Limitations: A limited number of studies were available for inclusion and the review and the studies had differing methodologies.

Conclusions: The review provides insight into the experiences of caregivers of adults with hypoglycaemia and the unmet care and support needs present in this population. The review identifies service needs and implications.

Introduction

Diabetes Mellitus is a lifelong medical condition, which affects around 3 million people in the UK (1). In diabetes, the pancreas is unable to produce enough insulin, meaning that the body's blood glucose level is too high. There are two types of diabetes; type one diabetes mellitus and type 2 diabetes mellitus. In type 1 diabetes mellitus the pancreas is unable to produce any insulin, resulting in the need for insulin injections and the need to ensure that levels of glucose in the blood stay balanced (2). Type 2 diabetes occurs when the body does not produce enough insulin. In 2013, over 3.2 million adults were diagnosed with diabetes, with prevalence rates of 6% in England. Type 1 diabetes accounts for 10 % of the adult diabetes population, whilst type 2 diabetes mellitus accounts for 90% of adults with diabetes worldwide (3).

Hypoglycaemia is a medical emergency occurring in diabetes that requires the patient to promptly recognise and treat symptoms (4). Hypoglycaemia has a number of associated symptoms ranging from behavioural changes and reduced cognitive function in the short term, to coma, cardiovascular dysfunction and even death in the long term (4, 5).

Living with hypoglycaemia requires the individual to self-manage and undertake behaviours to raise their blood glucose level. Self-management is a lifelong process which enables an individual to develop skills and make choices in order to manage their diabetes (6). However, if the patient is unresponsive or does not recognise their symptoms of hypoglycaemia, then another person would be required to take on a caregiving role and administer treatment in order to increase the levels of glucose in the blood and prevent the person with diabetes from losing consciousness.

Family members are important in assisting diabetic individuals with self-management and research has suggested that support from family members may improve treatment adherence (7). Whilst this may have a positive impact on the health of the person with diabetes it can negatively affect the wellbeing of family members. Research focused on families of children with type 1 diabetes, has suggested that sometimes the child's illness may affect a family system, and as a result, other needs may go unmet within the family (8). Literature into type 2 diabetes suggests that family members may perceive diabetes as having a greater impact on daily life than the individuals with diabetes themselves (9).

Existing literature reviews have primarily focused on the impact of caring for a child with diabetes (10) or on the interaction between individuals with diabetes and their family members (11). However, there has been little emphasis on the impact of being a caregiver for an adult spouse or family member with diabetes.

This review therefore aimed to explore the psychosocial impact of hypoglycaemia on caregivers of adults with diabetes to provide a greater understanding of the support needs of this population and may also inform service provision to ensure that these support needs are met. This is in line with the NHS Outcomes Framework for 2016-17 (12) which highlights that current areas for improvement within long term conditions are to ensure that people are supported to self-manage and to enhance quality of life for carers.

Method

Data Sources and Searches

An electronic systematic search of the literature was conducted utilising the following online databases; PsycInfo, Medline, CINAHL (Cumulative Index to Nursing and

Allied Health Literature), Academic Search Premier and Psyc Articles. A range of databases were searched in order to scope the literature and maximise the number of relevant articles obtained. The databases were selected to include comprehensive literature from different research and healthcare specialities; as people with diabetes typically have contact with a variety of healthcare and medical professionals.

Search Strategy

The search of electronic databases was conducted in March 2017. The search terms employed were selected to maximise the likelihood of finding literature relating to the research question. Key studies and systematic literature reviews were read and search terms were adopted from these studies and utilised in the current literature review. The search terms can be seen in Table 1.

Table 1: Search terms used in final search

Component One	Component Two [AND]	Component Three [AND]	Component Four [AND]
Diabetes	Hypoglycaemia OR Hypoglycemia OR Hypo*	Fami*OR Care* OR Partner OR Spouse OR Relat* OR Marri*	Meaning OR Experience* OR Perspective OR view

The truncation symbol [*] was used to capture variable endings of the search terms in order to maximise the amount of relevant literature found.

The Boolean operator [AND] was used to connect the search terms and the operator [OR] was utilised to optimise the inclusion of search terms which may be variable,

therefore ensuring that all literature which was relevant to the review question was returned.

Search terms were applied to the abstract and title fields only in order to reduce the amount of irrelevant literature and increase the amount of relevant literature returned.

Reference lists of the relevant studies returned were hand-searched for any further studies which would be eligible for inclusion. Relevant authors were also contacted to ensure that all available studies were included in the final review, however no further papers were identified as a result of this.

Inclusion and Exclusion Criteria

Studies were selected in accordance with the inclusion and exclusion criteria. The inclusion criteria were as follows:

- Participants were aged 18+ given the focus on adults.
- The participant was the caregiver and not the person living with diabetes.
- Caregiver met the following definition ‘the caregiver is any person who cares for the person with diabetes in his/her own environment on a regular basis and is a relative of the person with diabetes. The caregiver is not acting in a professional capacity. The caregiver cares for an adult with either type 1 or type 2 diabetes mellitus. This definition was modified from the definition used in a previous systematic literature review focusing on caregivers (13).
- Papers included were view studies (14). View studies focus on people’s views and experiences. They are non-intervention studies which can be qualitative, quantitative or mixed in design.

- Only papers published in peer review journals were included to enhance scientific rigour.
- Only studies published in the English language were included, this is because limited resources were available to translate and interpret papers in a language that was not familiar to the researchers. If papers were translated then this could potentially lead to a loss of meaning through translation.

The exclusion criteria for articles in the systematic literature review were as follows:

- Papers that were not from the perspective of the caregiver.
- Papers that could not discriminate between data for the caregiver and the person with diabetes were not included as the focus of the review was on caregiver perspectives.

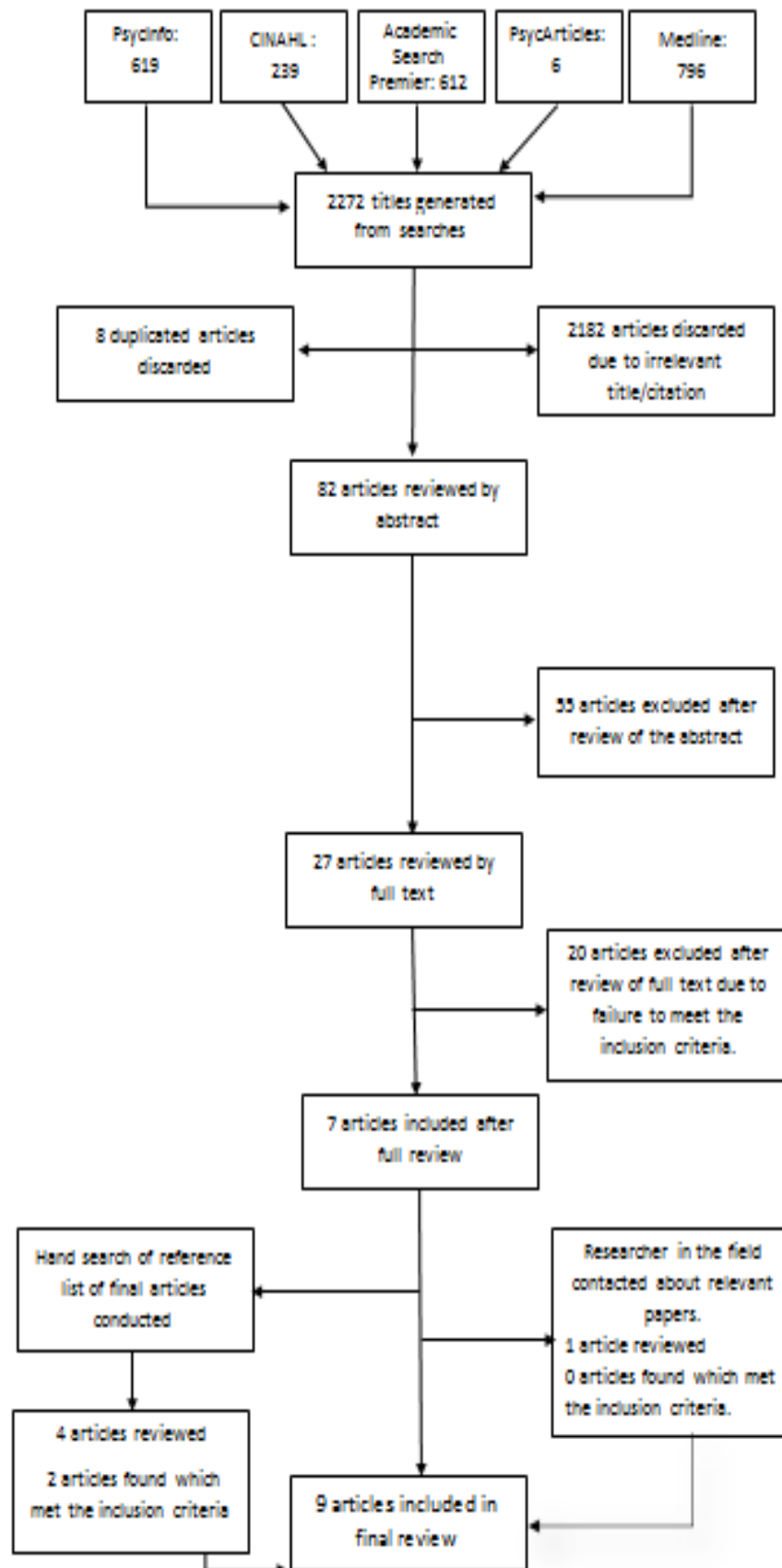


Figure 1: Flowchart outlining article selection

Quality Assessment

The Mixed Methods Appraisal Tool (MMAT; 15) was used to assess the quality of the included papers. The MMAT was chosen as it has been designed for use with qualitative, quantitative and mixed methods studies and assesses the methodological quality of studies included in a systematic review. The quality of each included paper was assessed by the first author (JG). All studies were awarded a percentage score based upon their methodological quality. All included papers were quality assessed by a peer researcher in order to assess inter-rater reliability. Inter-rater reliability was high with assessors being in agreement on 96% of the scores awarded. Where differing ratings were awarded, a discussion between markers was held, and the criteria were jointly re-evaluated. Papers were not excluded based on their quality; instead the purpose of the quality assessment was to assess the methodological quality of the included studies to inform the findings of the review.

Data Synthesis and Analysis

Papers were synthesised using a narrative synthesis methodology (16). This was deemed the best approach as the included papers are heterogeneous in their methodology. Narrative synthesis allows the findings from both qualitative and quantitative studies to be summarised through text, allowing their findings to be integrated. The process of narrative synthesis was conducted in accordance with the four key stages as set out by Popay, 2006 (16, p.12):

- 1) Developing a theoretical model of how the intervention works, why and for whom
- 2) Developing a preliminary synthesis of findings of included studies
- 3) Exploring relationships in the data
- 4) Assessing the robustness of the synthesis

Study Selection

A total of 2272 articles were generated by the initial search. The process of selecting studies for inclusion is outlined in Figure 1. A reference search of included papers identified one paper which met the criteria and was included in the review. A total of 9 papers were included in the final review.

Table 2: Included studies and their characteristics

Author (Date) (Country)	Aims	Caregiver Characteristics	Type of Diabetes	Design	Data Collection	Method of Analysis	Quality Score	Findings
Gonder-Frederick et al. (1997) (USA)	To examine the impact of severe hypoglycaemia episodes in IDDM patients on their spouses	Spouses 23 wives 38 husbands Mean age = 39.3 years	T1	Quantitative	Standardised Questionnaires. 1.Beck Depression Inventory 2.Spielberger Trait Anxiety Inventory 3.Conflict subscale of Spanier's Dyadic Adjustment Scale 4.Hypoglycaemia Fear Survey	Comparison using T-tests	100%	-Spouses of patients with recent history of hypo reported a significantly greater fear of hypoglycaemia. -Marital conflict relating to diabetes issues and sleep disturbance caused by concerns about nocturnal hypoglycaemia.
Jorgensen et al. (2003) (Denmark)	To compare patients and relatives assessments of rates of hypoglycaemia and explore the influence on involvement and concern of relatives.	284 cohabitants 55% of sample were female	T1	Quantitative	Non standardised Questionnaires	Comparisons of independent samples performed by t test or Mann Whitney U test	75%	Cohabitants of patients recall significantly more episodes of severe hypoglycaemia than the patients
Kovacs-Burns et al. (2013) (multinational study ¹)	To examine the experiences of family members of people with diabetes for benchmarking and identifying unmet needs of areas for improvement to assist family	2057 family members who were living in same household as person with diabetes. Mean age = 46 years	T1 and T2	Quantitative	Non standardised Survey	Cronbach's alpha coefficient and regression models	75%	-Supporting a relative with diabetes was perceived as a burden by 35.3% of sample. Distress was high. 61.3% of sample worried about hypoglycaemia. -Respondents did not know how best to support the person with diabetes and wanted to be more

¹ Algeria, Canada, China, Denmark, France, Germany, Italy, India, Japan, Mexico, The Netherlands, Poland, Russia, Spain, Turkey, UK, USA

	members and those with diabetes to effectively self-manage.	65% of sample female						involved in their care.
Lawton et al. (2014) (UK)	To explore the impact of hypo unawareness on family members lives.	18 partners 3 parents 3 adult children Mean age= 45.9 years 77% of sample were female	T1	Qualitative	Interviews	Thematic Analysis	75%	-Family members (FM)described restricting own activities in order to be available and vigilant to hypoglycaemia. -FM concerned about the safety of their relative. -Some FM reported being physically afraid of their partner during episodes of hypoglycaemia.
Polonsky et al. (2016) (USA)	To investigate the prevalence and sources of diabetes distress in spouses and partners of those with type 1 diabetes.	11 partners Mean age = 43.4 years 49.2% of sample were female	T1	Quantitative	Non standardised questionnaire	Exploratory Factor Analysis	75%	Diabetes related distress is common amongst partners, particularly distress relating to hypoglycaemia.
Ritholz et al. (2013) (USA)	To examine the impact of continuous glucose monitoring on diabetes management and marital relationships of adults with type one diabetes and their spouses.	13 spouses 1 partner Mean age= 48.75 years	T1	Qualitative	Focus Group	Thematic Analysis	75%	Continuous glucose monitoring seen as positively influencing hypoglycaemia management by decreasing spouses' anxiety, vigilance and negative experiences.
Stahl et al. (1998) (Switzerland)	Aim is not explicitly stated.	Spouses	T1	Quantitative	Non standardised Questionnaire	Not stated- percentages used	25%	-When partner is late, 20% of sample concerned about hypoglycaemia. -Partners had severe concerns

								about hypoglycaemia and perceived the possibility of hypoglycaemia as a burden.
Trief et al. (2003) (USA)	To learn from couples who deal with diabetes daily, what is support?	32 spouses Mean age = 49 years 41.2% of sample were female	T1 and T2	Qualitative	Interviews	Grounded Theory Approach	75%	-Spouses need support in order to effectively support their partners. -Helpful behaviours include support with dietary control and non-helpful behaviours include nagging and poor communication.
Trief et al. (2013) (USA)	To gain a better understanding of the psychosocial challenges of adults living with type one diabetes and its impact on partner relationships.	14 partners (must have been married or partnered for more than one year.) Mean age= 45.6 years 35.7% of sample were female	T1	Qualitative	Focus Group	Constant Comparison	75%	4 domains identified: (1) Impact on relationship (2) Understanding the impact (3) Stress of complications (4) Benefits of technology

Key

T1- Type 1 diabetes mellitus

T2- Type 2 diabetes mellitus

IDDM- Insulin Dependent Diabetes Mellitus

Results

Characteristics of Included Studies

A detailed overview of the characteristics of included studies is outlined in Table 2.

Most studies used samples from Westernised countries. One included study drew their sample from 17 different countries (17).

Seven studies included spouses or long term partners only. A further two studies broadened out their definition of caregiver to include adult children or parents whom assisted with care (17, 18). A total of 2479 caregivers were included across the studies. They had a mean age of 46.98 years (range 20-72) and 54.3% of the sample was female.

Four of the included studies utilised qualitative methods and gained their data through either interviews or focus groups. For studies of a quantitative methodology (n=5), the preferred method of data collection was through surveys.

Methodological Quality

One study achieved the highest possible rating of 100% (19) and one study achieved a low quality score of 25% (17).

When considering the qualitative literature, there was little included about reflexivity. All included qualitative studies failed to discuss the researchers' own influence, providing no information on how the researchers' stance has affected the findings. Reflexivity is considered to be important in qualitative research (21) and the lack of reference to it in the included qualitative studies can be considered a weakness.

Quantitative studies showed low quality when discussing their response rates. There was a lack of clarity and detail regarding how many participants had been approached to

take part in the studies and what percentage of these responded. Three of the included quantitative studies failed to provide this information (17, 20, 22).

Overall, the researcher deemed included studies to have findings which were relevant to the aims of the review. Strengths of the included studies include their clear rationale, detailed literature reviews and clear explanation of relevant findings.

Further details relating to quality assessment can be found in Appendix C.

Data Synthesis

Overview Quantitative Papers

Across quantitative papers (19,20, 23) a source of fear arose if partners were late for pre-arranged events. For some caregivers, their initial concern if their partner was late was that it was due to an episode of hypoglycaemia (20) with one study reporting that this was the case for 59% of cohabitants (23). Unsurprisingly, for spouses who had recently witnessed a severe episode of hypoglycaemia, there appeared to be greater levels of worry (19).

Multiple quantitative papers discussed the emotional impact of hypoglycaemia (17, 22, 23), with one reporting that the greatest negative effect of diabetes management on caregivers is on their emotional wellbeing (17).

Two papers reported that caregivers felt unsure of their role and did not know how involved they should be in their partner's diabetes management (17, 22). This lack of defined role could lead to feelings of distress and not knowing how best to support their partner (22). In one study (17), almost half of the sample (45.8%) reported that they would like to help the person with diabetes address their feelings about their condition,

however only 23.1% of the sample had participated in any diabetes educational programmes. This suggests that there is a clear lack of knowledge and education available for caregivers, which leads to them feeling unequipped to help manage their partner's condition.

Several studies found that sleep disturbance was an issue for caregivers (18, 19, 23). In one study (23), 44% of the sample reported having sleep disturbance due to the fear of their partner having an episode of severe hypoglycaemia whilst asleep. In this study, sleep disturbance was more commonly reported by females. This is in contrast with another study included in the literature review, which reported significantly higher levels of sleep disturbance in males (19).

Across the quantitative papers (17, 22) low levels of emotional support were reported, with one study identifying that only 20.5% of the sample felt somewhat supported (19). The lack of emotional support extended to family, friends and professionals.

Qualitative Analysis

Theme: Emotional Impact on the caregiver

A common finding across studies was the level of fear and concern felt by caregivers. Caregivers reported being concerned about the possibility of future episodes of hypoglycaemia. For some, this appeared to stem from having witnessed hypoglycaemia previously and recalling how these episodes were stressful and at times frightening.

'We've had a lot of bad experiences... but a couple of times I had to call 911' (23)

The review highlighted that the behavioural changes which occur during hypoglycaemia were distressing for caregivers. Some caregivers described being fearful of their partner (18,23) and in some instances, caregivers were afraid of their partner becoming

physically aggressive, referring to them as being ‘*very aggressive*’ and ‘*violent*’ (18). In some instances, hands off strategies were developed in an attempt to avoid being injured.

‘I used to find it easier to just put a pillow behind him and a pillow in front of him and roll him into the middle of the bed so that I’d know he was safe and then I used to just wait at the door’ (18, p.111).

Some caregivers discussed how after the episode of hypoglycaemia had ended, the person with diabetes had little awareness of how distressing the incident had been to witness as they had little recollection of the event (18, 23).

‘I would want my partner to understand how scary it is to be the person watching, not the person going through it.’ (24, p.2486).

Caregivers often made emotional statements about how hypoglycaemia left them feeling e.g. ‘*I feel aggravated,*’ (25) ‘*sometimes I get mad because he doesn’t notice it*’ (18) and ‘*I feel guilty*’ (18).

Caregivers appeared to find it difficult to manage strong emotions and this could lead to personal distress.

Theme: Effect on the partnership

In some instances, spouses reported that managing diabetes had a negative influence on their relationship (18, 24)

‘We have grown further apart in the 16 years we have been married.. I can’t say it’s all because of the diabetes, but that’s a big issue’ (24, p.2485).

Some spouses also reported a sense of resentment as hypoglycaemia affected the dynamics of their relationship (18). Whilst caregivers generally felt that the person with

diabetes was not to blame for their condition, they sometimes felt that they were used as a safety net, meaning that their partner may not self-manage as effectively as possible as they knew their partner would assist them if necessary (18). Spouses of patients who had recently had a severe episode of hypoglycaemia reported greater marital conflict than those who has not recently had a hypoglycaemic episode (19). A minority of individuals within the literature reported positive effects of hypoglycaemia on their relationship (17, 24) describing how the illness had brought them closer together and had given them a shared experience (24).

'we connect so much, it's like us against the world' (24, p. 2485).

A further sub group of participants in the literature described how they had willingly taken on the caring role.

'It's my calling in life to look after [partner]' (18, p.112).

Four studies focussed on how hypoglycaemia can affect the role of a spouse (18,23,24). One study reported how caregivers sometimes had to take on a parental role in order to persuade their spouse to monitor their glucose levels.

'I end up shouting until he pays attention. It's horrible because I feel like I've a third child' (18, p.112).

The sense of taking on a parental role was also described by another person, who stated that:

'I'm not the kind of character that finds joy in mothering another adult that I loved and respected as a male.' (18, p.112).

One paper reported caregivers' frustration at trying to manage hypoglycaemia and plan ahead for episodes (24) There was also a focus on what helpful behaviours could be applied in order to avoid nagging and taking on a parental role (25).

'saying something nicely to him. That basically helps and still makes him feel like a person' (25).

Theme: Restricting own activities

Being vigilant to signs of hypoglycaemia was a theme within the literature. One study identified how caregivers may neglect their own needs in order to be in a position to take prompt action to treat hypoglycaemia if an episode occurred.

'I feel hypo unawareness does take over because you've always got to be thinking about someone else other yourself.' (18, p.112).

This need to be hyper vigilant could lead to systems being put into place in order to ensure that the person with diabetes was safe. This included texting or call systems or encouraging the family member to buy a property nearby.

In some cases, the need to be hyper vigilant meant caregivers restricting or curtailing their own activities in order to put the needs person with diabetes before their own (18, 25). This included postponing medical procedures, going into work late or giving up recreational activities:

'I just don't have a social life.' (18, p.110)

It was evident within the literature that the use of technology decreased the need to be vigilant.

‘Both the pump and continuous glucose monitoring have been a godsend for us.

Initially, I looked at it more as it was good for her, but in reality it is for me..... It was nice for me to have some way of knowing what was going on.’ (26, p.51)

As was reported in quantitative studies (19, 23), one qualitative study (15) described how family members reported very poor sleep due to being vigilant to potential hypoglycaemia at night time.

‘I would wake up just because he has turned strangely or changed his breathing and then I’m secretly trying to make sure he’s alright.’(18, p.112)

Theme: Seeking knowledge and support

Many papers included in the review commented upon levels of diabetes related knowledge (17,18, 22, 25, 26). An area of concern for caregivers appeared to be that their family member may not pass on adequate information and

‘might not have relayed everything.’ (18).

A lack of formal education on how to use diabetes related equipment lead to caregivers feeling unsure on how best to support the person with diabetes (18, 26).

‘I don’t know why it’s (continuous glucose monitoring) doing what it’s doing. Whether it just wants to be calibrated or whether there’s something going on’ (26,p.53)

A further qualitative study included in the review (25) focused on helpful behaviour and highlighted how some spouses were able to utilise their diabetes related knowledge in order to support their partner.

‘I’ve gone into the store and have turned over every package, every vegetable thing, seeing how many carbohydrates are in what he has to eat and that is what I do.’ (25, p.61.)

As with the included quantitative studies, support appeared to be a key concept in the included qualitative studies (18, 25, 26) with one partner stating that

'No, nobody has ever asked me anything. I feel disappointed.' (18, p.112).

In one study (18) 19 out of the 24 participants interviewed described the desire to obtain feedback and support from others in a similar position in order to utilise support from other caregivers in a similar situation (18). Interestingly, there was a minority of participants who did not acknowledge their own need for support.

'I still very much feel like the person who has the illness is the person who needs the most support.' (18, p.113).

As well as identifying support needs for themselves, caregivers also reported wanting to know how to provide support for their partner (18, 25, 26). Studies highlighted the desire to be better informed in order to offer their partner emotional support (25, 26)

'I just think letting her talk to someone about it, or discuss it is helpful.' (25 p.62).

Not knowing how best to offer support could lead to anxiety and uncertainty and tension or conflict within the relationship (25).

Peer support was suggested as a method to help caregivers overcome negative feelings (18). It appears that caregivers are often left with difficult feelings with no outlet to share these or access support.

It is clear that there is some overlap in the themes of seeking knowledge and support and relationship dynamics and that one can affect the other.

Discussion

Overview of Findings

This review synthesises the literature relating to the impact of hypoglycaemia on caregivers of adults with diabetes and suggests that caregivers face many challenges and difficulties and often feel that their needs go unmet.

It is clear that becoming a caregiver can be associated with complex emotions and a period of loss and adjustment. These negative emotions can lead to a sense of guilt for caregivers. Literature which explores the transition into caregiving in other chronic illnesses suggests that such emotional reactions are common, and yet health services often fail to adequately recognise and manage this (27). Caregivers of those with diabetes could benefit from having the opportunity to express these feelings and have them validated and normalised through interventions such as one to one talking therapy. In the current NHS climate it is however unlikely that such interventions will be offered to all and therefore it is more likely that only those caregivers with a clinical need will be able to access talking therapy.

It is clear that caregivers have needs which are not currently being met. It is well documented that there can be a significant negative impact of chronic illness on caregivers (28). Literature in oncology has suggested that although couples may share the same illness experience, their patterns of adjustment may differ (29). This difference in adjustment can be detrimental to relationships. However, despite evidence to support this, there is still a tendency in healthcare to focus support solely on the person with the illness rather than taking a relationship centred approach. Literature into relationship focussed healthcare (30) suggests that whilst a clinician's first priority is to prevent illness, they must also be mindful of the relationships that promote wellbeing. Rather

than the focus being on the individual patient only, clinicians must be aware of the impact of their interventions on the patient's family and caregivers also. In other healthcare populations, couples therapy has been utilised in order to address this gap in support. Research into couples work in oncology has demonstrated positive effects on emotional wellbeing for couples living with cancer (31,32) whilst studies focusing on couples managing coronary heart disease have demonstrated significant improvements in quality of life for both patients and their partners (33). This highlights both the clinical need and potential benefits for offering dyadic interventions to those with diabetes. Relationship focussed healthcare specifies that individuals must not be done to but instead should be part of an interactive process with their therapist (30). Clinical psychologists could utilise their skills in collaborative agenda setting in order to ensure interactive ways of working. A further key role for therapists in relationship focussed care is to have an awareness of interventions on the patient's family and caregivers also. This is where psychologist could utilise their skills in systemic working in order to provide insight and understanding on how interventions which affect the person with diabetes can also affect the systems around the person. This could be informed by family systems theory (34).

It is evident that caregivers feel that they are in need of more support and advice in order to benefit both themselves and the individual they care for. It appears that an increase in knowledge and support would not only benefit caregivers in terms of making them more informed but could also decrease levels of conflict within their relationships. The NHS Mandate for 2016/17 (12) has set an objective for achieving safe and quality care. As part of this objective it is proposed that carers should be routinely identified and given access to information and support to create safe and high quality care. It is evident from this review that this may be lacking in diabetes care. It is positive that steps have been taken by the NHS to ensure that this occurs, however it is possible that

the population in this review may not be viewed as caregivers by medical professionals. As hypoglycaemia is not present at all times family members are not always viewed as being in a caring role and thus their need for information and support is not necessarily acknowledged. It is also worth noting that the NHS Mandate applies only to those living in the UK who receive NHS care. It is also clear from the review that caregivers may require different levels of support at different times. A recurring theme throughout was that caregivers support needs are more apparent after witnessing severe episodes of hypoglycaemia. Healthcare professionals have a key role in identifying times of change or difficulty and offering support. A further investigation could be carried out investigating what caregivers classify as knowledge and support and when they feel this would be most helpful.

Clinical Implications

Family members of adults with hypoglycaemia have care needs which are not being met. Healthcare services need to acknowledge the important role of caregivers and take a more relationship centred approach when planning diabetes care. Professionals should also be aware of the potential for caregivers to have their own healthcare needs. If and when caregiver distress does occur then therapy and support should be easily accessible and available for the caregiver. If such interventions are not feasible in the current NHS climate due to cuts in mental health funding and pressures on services due to waiting times (35) then caregivers should be signposted to other agencies such as self-help groups as per the NICE guidelines (36) which may be able to offer support.

Strengths and Limitations

This review draws literature together to identify clinical implications for a population who have unmet needs and are often overlooked. This review highlights that caregivers

have needs as well as people with diabetes and brings this into the forefront. Clinical implications were identified which can be explored further. A limited number of studies focussing on the impact of hypoglycaemia on caregivers were available to be included in the review and the included studies used diverse measures and methodologies, making it difficult to draw firm conclusions. A limitation of this review is that search terms were applied to the abstract and title fields which may mean that some papers were missed. This was however deemed essential in order to provide focus to the review.

In terms of the methodological quality of the reviewed papers, a strength is that both qualitative and quantitative papers were included, providing a wider overall perspective. A further strength is that a broad range of respondents were captured in the review meaning that the perspectives caregivers of different cultures and ages were considered. A limitation is that one of the included papers (17) was of particularly low quality. It is possible that quality impacts on the findings and therefore the findings of low quality papers should be treated with caution.

Conclusions

The review provides insight into the challenges of caring for an adult with hypoglycaemia. The findings remind us that caregivers are as much in need of psychological support and intervention as people who themselves have diabetes, but that this need is currently unmet. The review identifies service need and identifies implications for clinical practice within the NHS.

References

1. National Institute for Health and Care Excellence. Type 2 diabetes in adults: management. Retrieved 25 September 2017 from <https://www.nice.org.uk/guidance/ng28/resources/type-2-diabetes-in-adults-management-pdf-1837338615493>
2. NHS Choices (2013). Diabetes, type 1. Retrieved July 2, 2014 from <http://www.nhs.uk/Conditions/Diabetes-type1/Pages/Introduction.aspx>
3. NHS Choices (2014). Diabetes, type 2. Retrieved 15 June 2014 from <http://www.nhs.uk/Conditions/Diabetes-type2/Pages/Introduction.aspx>.
4. Shafiee, G., Mohajeri-Tehrani, M., Pajouhi, M, & Larijani, B. (2012). The importance of hypoglycemia in diabetic patients. *Journal of Diabetes & Metabolic Disorders*, 11, 1-7.
5. White, J.R. (2008). The Contribution of Medications to Hypoglycemia Unawareness. *Diabetes Spectrum*, 20, 77-80
6. Funnell, M.M. (2006). The Diabetes Attitudes, Wishes, and Needs (DAWN) Study. *Clinical Diabetes*, 4, 154-155.

7. DiMatteo, M.R. (2004). Variations in patients' adherence to medical recommendations: A quantitative review of 50 years of research. *Medical Care*, 42, 200-209.
8. Whitehead, A. L, Dimmock,M., & Place,M. (2013). Diabetes control and the influence of family functioning. *Journal of Diabetes Research and Clinical Metabolism*,2, 2-16.
9. White, P., Smith,S.M., & T. O'Dowd. (2007). Living with type 2 diabetes: a family perspective, *Diabetic Medicine*, 27, 796–801.
10. Whittenmore, R., Jaser, S., Chao, A., Jang, M., & Grey., M. (2012). Psychological Experience of Parents of Children With Type 1 Diabetes. *Diabetes Education*,38, 562–579.
11. Rintala, T.M., Paavilainen, E. and Åstedt-Kurki, P. (2013), Everyday life of a family with diabetes as described by adults with type 1 diabetes. *European Diabetes Nursing*, 10, 86-90.
12. Department of Health. (2016). *The Government's Mandate to NHS England for 2016/17*. Department of Health: London.
13. Schoenmakers. B., Buntinx, F., & Delepeleire, J. (2010). Factors determining the impact of care-giving on caregivers of elderly patients with dementia. A systematic literature review. *Maturitas*, 66, 191-200.

14. Harden, A., Garcia, J., Oliver, S., Rees, R., Shepherd, J., Brunton, G., & Oakley, A. (2004). Applying systematic review methods to studies of people's views: an example from public health research. *Journal of Epidemiology and Community Health*, 58, 794-800.
15. Pluye, P., Gagnon, M. P., Griffiths, F., & Johnson-Lafleur, J. (2009). A scoring system for appraising mixed methods research, and concomitantly appraising qualitative, quantitative and mixed methods primary studies in Mixed Studies Reviews. *International Journal of Nursing Studies*, 46(4), 529-546.
16. Popay, J., Roberts, H., Sowden, A., Petticrew, M., Arai, L., Rodgers, M.,... Duffy, S. (2006). *Guidance on the conduct of narrative synthesis in systematic reviews*. Results of an ESRC funded research project (unpublished report): University of Lancaster.
17. Kovacs-Burns, K., Nicolucci, A., Holt, R.I.G., Willaing, I., Hermanns, N., Kalra, S., ...Peyrot, M. (2013). Diabetes Attitudes, Wishes and Needs second study (DAWN2): Cross-national benchmarking indicators for family members living with people with diabetes. *Diabetic Medicine*, 30, 778-788.
18. Lawton, J., Rankin, D., Elliott, J., Heller, S.R., Rogers, H.A., De Zoysa, N., ... Amiel, S. (2014). Experiences, Views and Support Needs of Family Members of People with Hypoglycaemia Unawareness: Interview Study. *Diabetes Care*, 37, 109-115.

19. Gonder-Frederick, L., Cox, D., Kovatchev, B., Julian, D., & Clarke. (1997). The Psychosocial Impact of Severe Hypoglycaemic Episodes on Spouses of Patients with IDDM. *Diabetes Care*, 10, 153-1546.
20. Stahl, M., Berger, W., Schaechinger, H., & Cox, D.J. (1998). Spouses Worries Concerning Diabetic Partner's Possible Hypoglycaemia. *Diabetic Medicine*, 15, 619-620.
21. Finlay, L.(2002). Negotiating the Swamp: the opportunity and challenge of reflexivity in research practice. *Qualitative Research*, 2, 209-230.
22. Polonsky, W.H., Fisher, L., Hessler, D & Johnson, N. (2016). Emotional Distress in the Partners of Type 1 Diabetes Adults: Worries About Hypoglycaemia and Other Key Concerns. *Diabetes Technology and Therapeutics*, 5, 292-297.
23. Jorgansen, H., Pedersen-Bjergaard, U., Rasmussen, A.k, & Borch-Johnsen, K. (2003). The Impact of Severe Hypoglycaemia and Impaired Awareness of Hypoglycaemia on Relatives of Patients with Type 1 Diabetes. *Diabetes Care*, 4, 1106-1109.
24. Trief, P.M., Sandberg, J.G., Dimmock. J.A., Forken, P.J., Weinstock, R.S. (2013). Personal and Relationship Challenges of Adults with Type 1 Diabetes. *Diabetes Care*, 36, 2483-2488.

25. Trief, P.M., Sandberg, J., Greenberg, R.P., Graff, K., Castronova, N., Yoon, M., ... Weinstock, R.S. (2003). Describing Support: A Qualitative Study of Couples Living with Diabetes. *Families, Systems and Health, 1*, 57-67.
26. Ritholz, M.D., Beste, M., Edwards, S.S, Beverly, E.A., Atakov-Castillo, A., & Wolpert, H.A. (2013). Impact of continuous glucose monitoring on diabetes management and marital relationships of adults with Type 1 diabetes and their spouses: a qualitative study. *Diabetic Medicine, 31*, 47-54.
27. Adams, K.B. (2006). The Transition to Caregiving: The Experience of Family Members Embarking on the Dementia Caregiving Career. *Journal of Gerontological Social Work, 47*, 3-29.
28. Reich, J. W., Olmsted, M. E. & Van Puymbroeck, C. M. (2006). Illness uncertainty, partner caregiver burden and support, and relationship satisfaction in fibromyalgia and osteoarthritis patients. *Arthritis & Rheumatism, 55*, 86–93.
29. Northouse, L., Mood, D., Templin, T., Mellon, S., George, T. (2000). Couples patterns of adjustment to colon cancer. *Social Science & Medicine, 50*, 271-284.
30. Beach, M.C. (2006). Relationship-centred Care. *Journal of General Internal Medicine, 21*: 3–8.
31. Baik, O. M. & Adams, K. B. (2011). Improving the Well-Being of Couples Facing Cancer: A Review of Couples-Based Psychosocial Interventions. *Journal of Marital and Family Therapy, 37*, 250–266.

32. Badr, H., & Krebs, P. (2013). A systemic review and meta-analysis of psychosocial interventions for couples coping with cancer. *Psychooncology*, 22, 1688-1704.
33. Reid, J, Ski, C.F., & Thompson, D.R. (2013). Psychological Interventions for Patients with Coronary Heart Disease and Their Partners: A Systematic Review. *PLOS ONE*, 8.
34. Bowen, M. (1966). The use of family theory in clinical practice. *Comprehensive Psychiatry*, 7, 345–374.
35. Docherty, M., & Thornicroft, G. (2015). Specialist mental health services in England in 2014: overview of funding, access and levels of care. *International Journal of Mental Health Systems*, 9, 1-8.
36. National Institute for Health and Care Excellence. (2012). Patient Experience in Adult NHS services. Retrieved 15th May 2017 from <https://www.nice.org.uk/guidance/qs15/chapter/quality-statement-6-shared-decision-making>.

Part two: Empirical Paper

The Experiences of people with Diabetes Mellitus and Hypoglycaemia Unawareness

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This paper is written in the format ready for submission to the Journal of Diabetes
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Please see Appendix D for the Guideline for Authors

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Abstract

Aims

The objective of this study was to explore patient experiences of hypoglycaemia unawareness; which to date have been given very little attention within the literature. A qualitative study was therefore conducted to explore the personal experiences of this population.

Methods

Six adult participants who had a diagnosis of diabetes mellitus and hypoglycaemia unawareness took part in semi-structured interviews. The results were analysed using Interpretative Phenomenological Analysis.

Results

The analysis identified three overarching themes: 'I call my diabetes the beast because it just doesn't do as it's told,' 'It's like waking up every day with a giant above your bed saying right; you've got to look after me today' and I've got this condition and it's ruining my life. I just want to be normal.' These themes highlighted the psychological and social challenges faced by participants.

Conclusions

Living with hypoglycaemia unawareness raises significant psychosocial consequences which need to be addressed by healthcare professionals. There is a need to explore psychosocial interventions which may be of benefit to this group.

Keywords: Diabetes, hypoglycaemia, hypoglycaemia unawareness

Hypoglycaemia Unawareness

Most individuals with diabetes experience warning symptoms indicating that they may be experiencing hypoglycaemia. However, there is a population of people who do not experience such warning symptoms [1]. Hypoglycaemic unawareness is the term used to describe this. Hypoglycaemia unawareness is proposed to result from recurrent episodes of hypoglycaemia; as individuals experience more episodes of hypoglycaemia, their autonomic, symptomatic and counter-regulatory hormonal response to any subsequent episodes is reduced [2]. Hypoglycaemia unawareness can be extremely dangerous as patients are unable to recognise symptoms and therefore do not undertake the necessary treatment to increase their blood glucose levels. Whilst this is recognised as a medical emergency, the psychological implications for individuals are less well understood, but are likely to include increased levels of fear, hyper-vigilance and embarrassment [3,4].

Whilst hypoglycaemia has clear medical underpinnings [2], its diagnosis relies heavily on clinical judgement. Currently, there is no definitive test or assessment which can be used in the diagnosis of hypoglycaemia unawareness, instead clinicians are required to take a full history and ask patients about their past experiences of hypoglycaemia. It is also helpful for clinicians to speak to family members as part of their assessment, as often they detect symptoms of hypoglycaemia unawareness before the person with diabetes has begun to notice them. Scoring systems have been developed which can be used clinically. These are not diagnostic but can be used to aid the assessment [5].

The lack of clear cut guidelines on how to assess hypoglycaemia unawareness and the reliance on retrospective data means that ascertaining specific figures of those affected remains problematic (6). Prevalence rates vary within the literature; however it is

estimated to affect between 20-40% of those with type one diabetes (6,7,8). There is very little literature reporting on hypoglycaemia unawareness in type two diabetes mellitus as it is much less prevalent and therefore prevalence rates are not reported on within the literature. People with type two diabetes are relatively protected from hypoglycaemia unawareness in comparison to those with type one diabetes. Unawareness in type two diabetes is more likely to occur as the disease progresses, however even then, unawareness only occurs in less than 10% of those with type 2 diabetes who take insulin [8].

Psychological Wellbeing

Research suggests that people with diabetes are at an increased risk of developing psychological disorders. The prevalence of depression in both type 1 and type 2 diabetes is nearly twice as high as the general population [9,10]. Higher incidences of anxiety disorders are also recorded for both types of diabetes [11,12]. There does not appear to be any existing literature which has explored the prevalence of such disorders in those with hypoglycaemia unawareness.

Little is known about the specific issues associated with the experience of hypoglycaemia unawareness and the impact on an individual's psychological wellbeing. However, research has suggested that beliefs about self-management predict wellbeing in people with diabetes [13]. Psychological wellbeing was also predicted by the degree to which individuals could control the onset of complications [13]. For those individuals who found that their daily activities were affected by their diabetes, and as we might expect for those living with hypoglycaemia unawareness, psychological wellbeing was found to be worse [13]. Literature by Hart and Grindell [14] found that illness perceptions influenced the effectiveness of coping, self-care and health outcomes in this

population. Those who perceived that they had greater individual control over their treatment were better able to cope.

Aims and Rationale

There is a gap in the literature relating to our understanding of the care and support needs for people with both diabetes and hypoglycaemia unawareness.

Diabetes presents a major financial challenge to the NHS [15] and the emphasis on self-management models means that those who are unable to self-manage may be left with negative feelings. There is a need to understand the experience of living with hypoglycaemia unawareness in order to identify the potential unmet psychological and support needs of this population.

This study therefore aimed to explore the experiences of individuals with diabetes mellitus and hypoglycaemia unawareness.

Research Design and Method

The current study is an exploratory study of patients' meaning and experience of having both diabetes mellitus and hypoglycaemic unawareness. Semi structured face to face interviews were conducted in order to generate qualitative data.

Subjects

Participants were identified through purposive sampling in two ways; either by being identified and approached by clinical staff at a diabetes unit in the North of England (n=4) or via social media advertisements (n=2). Those who expressed an interest were assessed for their eligibility and were provided with further information about the study.

Participants were eligible for inclusion if:

- They had a diagnosis of either type one or type two diabetes mellitus
- They had a secondary diagnosis of hypoglycaemia unawareness
- They were over the age of 18
- They were sufficiently fluent in the English language and able to take part in an interview

Participants were excluded if:

- They had pre-existing or current cognitive impairment which would make giving informed consent difficult.

Participant Demographics

Six participants were recruited to the study overall. Five of these had type one diabetes and one had type two diabetes. Three participants were male and three were female.

Participants ranged in age from 20-82 years (mean age= 53.6 years). All participants used insulin injections as a way of managing their diabetes. Two participants lived alone, one lived in shared housing and three lived with a spouse. Demographic details are provided in table 1.

Table 1: A summary of participant demographics

Pseudonym	Gender	Age	Type of Diabetes (Type 1 diabetes= T1) (Type 2 diabetes= T2)	Self-reported time (years) since unawareness
Frank	M	80	T2	5
John	M	82	T1	6
Julie	F	52	T1	2
Mike	M	33	T1	15
Emily	F	20	T1	2
Carol	F	55	T1	5

Procedure

Ethical approval was obtained through the NHS ethics committee prior to the commencement of the research (Appendix E). All participants were required to give their informed consent to taking part (Appendix G) and a brief demographic questionnaire was then completed (Appendix H). This was followed by the semi structured in-depth interview lasting on average 40 minutes (range 30-59). All interviews were audio recorded and transcribed verbatim. Interviews were conducted either at the diabetes unit (n=3), in the participant's home (n=1) or over the telephone (n=2).

The interview schedule included open ended questions about participant's views on the consequences of their unawareness. See Appendix I for the complete interview schedule.

Data Analysis

The data was analysed using Interpretative Phenomenological Analysis (IPA) [16]. IPA seeks to understand the individual meanings attributed to individual experiences [16] and as this was the focus of the current study, it was therefore considered the most appropriate methodology. The analysis took place in three broad stages:

- 1) Transcripts were subject to line by line analysis. The researcher noted exploratory comments and began to take note of any emergent themes within the data.
- 2) In order to develop an interpretative understanding of the data, the researcher explored the data in terms of its content, language and understandings. Each transcript was read several times to ensure meaningful interpretation.
- 3) The researcher identified commonalities across transcripts and data was collated together to produce overall themes. Each theme was compared across participants' accounts to ensure that it reflected a meaningful interpretation of their speech. Themes were discussed with the research team in order to reach an overall consensus.

A reflexive attitude was adopted during the analysis process. The researcher held an outsider position in terms of not having a diagnosis of diabetes, but had insight into being diagnosed with another health condition. It was important for the researcher to recognise these perspectives as they may have had some influence over how the researcher interacted with the participants.

A credibility check of the themes was carried out by another research familiar with IPA methodology in order to ensure that themes were of a high quality and were grounded within the data.

Results

Three overarching themes resulted from the analysis as shown in table 2.

Table 2: Themes identified from analysis

Overarching Theme	Subtheme
(1) I call my diabetes the beast because it just doesn't do as it's told.	Trying to get this under control I do try and overcompensate It's my condition, I'll deal with it
(2) It's like waking up every day with a giant above your bed saying right; you've got to look after me today.	
(3) I've got this condition and it's ruining my life. I just want to be normal	When hypo unawareness happens you need somebody

Overarching theme one: 'I call my diabetes the beast because it just doesn't do as it's told.'

Across participants' accounts, an ongoing battle for control emerged, consequently resulting in participants taking measures in an attempt to regain some of this loss of control. Whilst all individuals with diabetes are required to self-manage and monitor their glucose levels, it is assumed that most of them are able to gain a sense of control if they follow medical advice; however for those with hypoglycaemia unawareness even when adhering to advice, they have little or no control over their bodies. The overarching theme title suggests that 'the beast' (diabetes) is so large, and in the case of hypoglycaemia unawareness so far beyond control, that it cannot be conceptualised as

part of the self. Instead it is described as a separate entity which is untouchable and cannot be controlled.

Subtheme one: ‘Trying to get this under control.’

This subtheme highlights the distress that participants felt in relation to their perceived lack of control over hypoglycaemia unawareness. Participants demonstrated that even when trying to self-manage and take the necessary steps, control is not always gained. In describing their battle for control and their longing for answers, participants’ sense of uncertainty and frustration was reflected in their questioning;

‘If it’s high I can sense it’s high but when it’s low I couldn’t sense anything. Why is that?’ (Frank, 332-333)

‘How careful do I have to be? What do I watch? I’m doing what I can do and I can’t really do much more.’ (Julie, 679)

‘I can’t find out why. I don’t know it’s happening... I just go into a coma.’ (John, 19)

Participants also talked about how they attempt to follow the correct steps in order to manage their glucose levels but that does not always lead to control. There appeared to be a tension for individuals between being told what is ‘correct’ by medical professionals but also knowing that adhering to these measures doesn’t appear to be helping and therefore isn’t correct for them.

‘I do check my bloods. I do this, it doesn’t make no odds. I’m trying so hard and then I feel disappointed.’ (Julie, 173).

Participants spoke of the sheer frustration in trying to adhere to advice and still not achieving the desired goal which could lead to a sense of hopelessness.

There was a general feeling that some factors were completely outside of all control which could lead to a sense that there was no hope in being able to control unawareness;

'I find the weather can affect it a lot. So if I'm too hot or too cold this can cause me to hypo but obviously that's a lot harder to control.' (Emily, 148-150)

Mike, who was one of the younger participants, appeared to be more hopeful about the future, although this suggestion that he would only be able to live once he had his illness under control highlights his despair with his current situation:

'I do like to think that one day I'll get it under control and I'll be able to live.' (Mike, 287)

Subtheme two: 'I do try and overcompensate.'

This theme highlights how the consequences of hypoglycaemia unawareness can be so catastrophic to individuals that becoming 'fixated' (Carol) on trying to avoid low glucose levels can become a way of life.

Participants described having so little control over their bodies that at times they use potentially harmful strategies in an attempt to regain some control. The decision to undertake these strategies appeared to be driven by the fear of the extreme

consequences which could occur as a result of hypoglycaemia unawareness. As Mike describes;

'the struggles for lows is the biggest problem, because you don't want to be seen to be collapsing in the middle of the street.' (Mike, 27-328)

Therefore in an attempt to avoid such feared or embarrassing consequences participants described undertaking knowingly risky actions;

'So when I exercise I was always told to have a bit more carb or reduce the insulin but I find I do both to try and avoid it.' (Emily, 72-73)

'I'll go to bed with my levels a bit too high for fear of having a night time hypo.' (Carol, 30-31).

Participants were fully aware that utilising such strategies and having high glucose levels could cause serious health problems in the long term, however they still resorted to these strategies because of the need to try and gain control and avoid unawareness;

'Yes it does concern me that it could cause additional problems, because when I was first diagnosed I was running in the 30's... I was really high in ketones so I was worried if I ever run high I'm going to cause more complications and get ketones and be really ill again' (Emily, 217-219)

Many individuals described their decision making here using tentative language and also tended to discuss these measures later on during the interviews when they appeared

to be more at ease with the researcher. There seemed to be a sense that participants were fearful about disclosing that they do not always strictly follow the measures set out by professionals. There appeared to be a dilemma between wanting to adhere to strict medical advice whilst also being aware of the reality of having to live with unawareness on a daily basis;

'I tend to ride higher than I normally would have done because obviously I don't want to hypo and fall into a coma.' (Mike, 69)

'I kind of over anticipate.' (Emily, 202).

It was also apparent that due to the fear of hypoglycaemia unawareness some individuals could become fixated or obsessed with behaviours in order to try and take back control;-

'But I got obsessed. I'd be pricking them every hour.' (Julie, 442-443)

'I get fixated by it.' (Carol, 497)

Subtheme three: 'It's my condition. I'll deal with it.'

Participants spoke about the conflict between needing help to manage their hypoglycaemia unawareness whilst also being resistant to receiving help. It appears that because hypoglycaemia unawareness feels so out of control, individuals are keen to take back control of their diabetes wherever possible.

Participants were able to recognise the important role their partners play in assisting them with their unawareness;

'She [wife] has kept me alive.' (John, 105)

'My boyfriend is a really good help. He'll help me check and he'll sort things out.'

(Emily, 193-194)

'He's [husband] learnt to administer it [glucagon injection] whereas before he used to always have to call the paramedics out.' (Carol, 21-22)

However on the contrary, participants also shared their desire to take personal control for their unawareness and appeared to be of the view that no one else could ever understand what life is like for them;

'It's narking and very irritating because you're doing the best you can do.' (Julie, 570)

'I know my signs, I know my body. I know what's happening. Just because I'm slightly grumpy doesn't mean my blood sugar is out of balance.' (Emily, 88-89)

'I'll be the judge of whether I'm managing it. I don't want him to because he's not diabetic.' (Carol, 391)

Overarching theme two: 'It's like waking up every day with a giant above your bed saying right; you've got to look after me today.'

Participants emphasised the amount of mental energy and the level of responsibility required in order to try and avoid episodes of hypoglycaemia. It was evident that there are not only physical consequences of hypoglycaemia unawareness but additional implications for mental wellbeing. Participants conveyed in their language that they were tired and resigned to the fact that they have to focus so much energy on their unawareness. There was also a sense that they were stuck in their thoughts with no release;

'It takes a lot of energy to concentrate on what you're doing... it takes a lot out of you mentally as well as physically.' (Mike, 373)

'It's the hard work in constantly thinking about it.' (Emily, 290)

'You can't have a day off. You can't just think I won't be diabetic today.' (Carol, 130)

This sense of being unable to have a break appears to be all consuming and can lead to feelings of being hopeless or stuck;

'It (hypoglycaemia unawareness) does rule my life in the sense that I can't walk away from it.' (Carol, 136)

Not only was there a huge level of personal responsibility in order to avoid the much feared personal consequence of hypoglycaemia unawareness, but participants were also aware that hypoglycaemia unawareness could be dangerous for others, with driving being one example of this. In order to avoid potential harm to others, participants described the significant amount of preparation that is required before any journey;

'I have to stop, check my levels before I carry on driving. You've got to constantly think.' (Carol, 66-67)

'The long distances. You have to stop and check, I add at least 45 minutes onto any journey time.' (Emily, 206).

'Obviously that's a massive thing if you have a hypo behind the wheel of a car, you're dead.' (Mike, 300)

Participants' accounts showed that in order to try and reduce the likelihood of an episode of hypoglycaemia, food becomes a significant consideration. Whilst this would be an issue for any person with diabetes, the focus on food appears greater in those with hypoglycaemia unawareness due to the extreme consequences of not keeping their blood glucose levels within the desired range. A lot of time and energy has to go into trying to achieve the correct diet in order to avoid lows, with this focus leading to a lack of spontaneity for one participant;

'I eat at three distinct times a day. I've got his pattern.' (Frank, 65)

At times when eating cannot be monitored as closely, such as at social events, participants described how they can become fearful;

'Through the hours I was getting agitated and I said "but I've got to have carbohydrates."' (Carol, 432-433)

For some participants it was clear that the lack of flexibility around mealtimes as well as the constant mental energy needed to focus on diet, led to food being viewed differently;

'food doesn't interest me one bit now.' (Julie, 634)

Julie's quote highlights the dangerous paradox of losing interest in something which needs to be monitored closely.

Overarching theme three: 'I've got this condition and it's ruining my life. I just want to be normal.'

This theme focuses on participants' perceived view of not being 'normal.' For some, this view led to them questioning why they have hypoglycaemia unawareness and resulted in a sense of self blame, feelings of inadequacy and guilt.

Within this theme participants differed in their attitudes to having being diagnosed with hypoglycaemia unawareness. Frank put having hypoglycaemia unawareness down to bad luck;

'Well it's no good thinking about my rotten luck is it? Because my rotten luck compared to some people is nothing.' (Frank, 176-177)

Whilst Emily stated that *'It's [hypoglycaemia unawareness] what you get given and you just have to get on with it.'* (Emily, 286)

Other participants attributed their hypoglycaemia unawareness to a failing or inadequacy within themselves;

'I don't know if it's just me, do you know what I mean. If I'm one of these people that will just not handle things well or what.' (Mike, 273-274)

'I still beat myself up because I'm thinking well it shouldn't be like this.' (Julie, 679-680).

Participants described how hypoglycaemia unawareness and its consequences threatened important roles.

This ranged from wanting to maintain independence and carry out the role as a parent;

'if he [husband] had his own way, I wouldn't work. I would just you know sort of potter at home... but I need work to keep me. You know I like my own financial independence.' (Carol, 332-333)

'My family say "why aren't you sat down?... but that's what bothers me because that's my little thing of motherhood, and you know being a wife and cooking meals.' (Julie, 700)

to more serious statements questioning the purpose of being alive and reinforcing the sense of being hopeless;

'It just makes me feel as though, what am I doing here? You need a purpose but sometimes you can't get it.' (John, 88-89)

Subtheme: 'When hypo unawareness happens you need somebody.'

Due to the nature of hypoglycaemia unawareness, participants discussed how they often had to rely on family members to assist them with managing their hypoglycaemia. For

some, this dependence on others could add to feeling inadequate and further reinforce that they are different to others. This reliance led to feelings of guilt.

Throughout his interview John frequently referred to his wife's role in keeping him well and often discussed how he is dependent on her in order to keep him alive. John made reference to the fact that he cannot be left alone due to the consequences of his unawareness:

'I'd like to be on my own to be honest but when these things happen you need somebody and if it wasn't for my wife who knows what would happen.' (John, 65-66)

Such is the level of John's dependence on his wife that he frequently alluded to how he may not still be alive without her input;

'my wife has often called the paramedics out at 2 and 3 o'clock in early Sunday morning at the weekend. And if it wasn't for her like, I don't think I'd be here.' (John, 34-36)

This reliance on family members could lead to feeling of inadequacy and guilt with two female participants discussing how the impact of hypoglycaemia unawareness in the night can affect their husbands:

'My husband's making me feel worse now because I feel so guilty for him. He's up early for work.' (Julie, 549).

'I feel guilty because he worries and he's lost sleep and then I feel guilty because it's my problem but he's had to deal with it.' (Carol, 401-402)

This subtheme has links with the earlier mentioned subtheme ‘it’s my condition, I’ll deal with it’ in that both focus on the involvement of family members. However the themes differ in that one depicts how participants want to try and be independent in order to remain in control and one links with the difficult feelings associated with relying on family members for support. It is evident that whilst family support is necessary when living with hypoglycaemia unawareness it can lead to negative feelings.

Discussion

This study is novel in that it explored individual’s experiences of living with diabetes mellitus and hypoglycaemia unawareness. The study provides an insight into the experience of daily life with hypoglycaemia unawareness and suggests that there may be a psychological impact of living with unawareness.

For participants in this study hypoglycaemia unawareness and a lack of diabetes control led to feelings of inadequacy and self-blame. Participant’s narratives suggested that there was a ‘correct’ way to manage blood glucose levels and when undertaking these measures did not lead to control, individuals often felt helpless and not good enough. It is possible that these negative attributions result from the idea that those with hypoglycaemia unawareness are failing to self- manage. The term self-management is frequently used in diabetes care and whilst the term may be empowering for some individuals, there are arguably negative implications for those who fall short of being able to self-manage. Language and terminology can construct the way we view ourselves [17] and within self-management literature those who are unable to self-manage their diabetes are referred to using terms such as ‘non-compliant’ [18] which

may cast judgement. This may be perceived by individuals as them failing. The current study suggests that internalising these feelings can result in people viewing themselves as being not good enough.

Whilst there is currently no literature critically examining the concept of self-management in diabetes, similar findings have been found relating the psychological implications of the terminology and discourses surrounding the notion of survivorship within oncology literature [19]. This literature proposes that using one term is not always helpful for all and that self-recrimination can occur if individuals feel that they are failing to live up to the standards [19]. Healthcare professionals may need to consider the power of diabetes self-management discourses and the implications for those who are unable to self-manage. Not considering the impact of such discourses may inadvertently reinforce negative ideas and feelings.

A lack of control resulted in feelings of helplessness and hopelessness for participants. Beck's theory of hopelessness [20] suggests that individuals become hopeless when they are anticipating that undesirable situations will occur which are outside of their control. As participants in the current study described being constantly hypervigilant to the possibility of potentially life-threatening outcomes outside of their control, the implications of this anxiety and hyper-vigilance on their long-term psychological wellbeing must be considered. Participants' experiences suggested that they may be likely to encounter psychological consequences which are not routinely monitored in this population. Participants' experiences highlighted that they may be at an increased risk for developing low mood and anxiety and therefore there is a need to routinely monitor mood in this population. Healthcare providers should consider offering talking therapy to those whose lives are affected by low mood and anxiety in order to offer

them space to explore their negative feelings. This therapy should be offered as it has a good evidence base for health related emotional issues as per the NICE guidelines [21]. The NICE guidelines [21] also state that individuals with diabetes and low mood may benefit from being signposted to support groups and other local and national resources whereby they can share their experiences with those in a similar position.

Whilst National Institute for Health and Care Excellence policy [22] states that for adult patients in the NHS, decision making must be a collaborative process between patients and professionals, the current study suggests that individuals with hypoglycaemia unawareness may not feel able to discuss their decision making with clinicians. Participants in this study often felt that they had no other option but to undertake risky, compensatory behaviours which may not be advocated by professionals. This was the case for participants across the lifespan and with differing living circumstances. As a result of this, participants seemed particularly tentative when discussing these behaviours and also tended to only disclose these risks toward the end of the interviews. Whilst it is unlikely that healthcare professionals will have the same amount of time to spend with individuals in clinical practice compared to in research interviews, attention must be paid to how ongoing relationships can be established so that individuals feel that can be open and honest about their management of hypoglycaemia unawareness without fear of judgement.

The current study highlights how hypoglycaemia unawareness presents challenges not only for patients themselves but also for their caregivers. Individuals wish to take control for their own wellbeing but are also aware that at times they have to rely on others. In the current study this was the case for those participants who cohabited with their partners, as reliance led to feelings of guilt and inadequacy. A recent literature

review [23] highlights that caring for someone with hypoglycaemia can have an impact on the psychological wellbeing of the caregiver as well as the individual. Clinicians working in this field should therefore be aware of the impact on both patients and caregivers and should consider employing a relationship centred healthcare model. Such models have been utilised with long term conditions such as dementia and place emphasis on not just the individual and their personal needs but also on their interactions and relationships with others [24]. Relationship centred models stipulate that caregivers should be offered an assessment of their needs and offered education and support to help them understand the individual they are caring for. The use of such models for those with hypoglycaemia unawareness could be beneficial, however the desire to manage unawareness alone must also be acknowledged. Healthcare professionals must recognise the individual needs of those with unawareness, their caregivers and also the interplay between the two.

Across participant accounts there were some commonalities and some differences of experience. This seemed to reflect the different life stages of participants due to the wide ranging ages of participants included within the study. Participants appeared to have differing levels of awareness of their own mortality. This fits with literature which focuses on the awareness of mortality at different stages of development [25]. The younger participants in the study made references to being hopeful about the future. Literature suggests that awareness of mortality is ignored in early adulthood as at this stage there is a quest to establish identity and to build relationships for the future [25]. The middle aged participants appeared to be aware of the ageing process and thus were more fearful about potential consequences of hypoglycemia and how the complications may impact their lives and the lives of their family members. This links with literature which suggests that by midlife individuals become more aware of death due to a decline

in their health and through experiencing the death of peers [25]. The oldest participant in the research spoke openly about death and how his wife ‘kept him alive.’ It is likely that managing a chronic illness for many years and having many incidences where he required medical intervention had accelerated his awareness of mortality and therefore made him feel that his passing is inevitable.

It was also evident that individuals related to their families in different ways. The youngest participant voiced her frustration when her family and boyfriend tried to intervene in her management of hypoglycaemia. This is likely because she is trying to strive for maturity and independence. This links to developmental research by Erikson [26] who proposed that at this stage in life, individuals are striving for independence and seeking out meaningful intimate relationships. Erikson proposed that in the later stages of life, individuals reflect back on life and reflect upon their successes and their regrets [26]. This fits with the oldest participant included in the study who questioned his purpose.

Limitations

The way in which individuals were recruited for the current study may have led to recruitment bias, with only those who had particularly poignant experiences volunteering to take part. A further limitation is that some interviews which were conducted over the telephone may have impacted upon the discussions due to the researcher being unable to interpret visual cues. However it is also possible that this method may have led to individuals being more open as they were not face to face with the researcher. The sample could have been more homogenous; however the topic of investigation defined the sample. It appears that despite participants’ differences over

the lifespan, their experiences are similar and have not been defined by characteristics such as age and gender. The current study focussed only on individual's experiences and it is clear that there is a wider impact on caregivers which was not captured. Future research could interview individuals and their caregivers as dyad in order to better understand their individual and dyadic needs.

Conclusions

Patient experiences of hypoglycaemia unawareness have often been neglected within diabetes research. The findings of this study suggest that this population face many challenges which could affect their psychological wellbeing and relationships. This suggests that healthcare providers should consider employing routine psychological assessments and offer interventions to address feelings of hopelessness and low mood as and when they arise. There is scope for psychologically informed interventions for this group. Further work is necessary to understand which interventions could be of benefit to this population and their caregivers.

References

- [1] Cryer, P.E., Davis, S.N., & Shamoon, H. (2003). Hypoglycaemia in Diabetes, *Diabetes Care*, 6, 1902-1912.
- [2] Macleod, K.M. (2000). Hypoglycaemia Unawareness: causes, consequences and treatment. *Journal of the Royal College of Physicians of London*, 34, 245-250.
- [3] Anderbro, T., Amsberg, S., Adamson, U., Bolinder, J.Lins, P.E.,...Johansson, U.B. (2010). Fear of Hypoglycaemia in Adults with Type One Diabetes. *Diabetic Medicine*, 27. 1151-1158.
- [4] Hayes, M. (2008). Management of hypoglycaemia unawareness in type 1 diabetes: A review. *Journal of Diabetes Nursing*, 12, 234-238.
- [5] Kenny, C. (2014). When hypoglycaemia is not obvious: Diagnosing and treating under- recognised and undisclosed hypoglycaemia. *Primary Care Diabetes*, 8, 3-11.
- [6] Geddes, J., Schopman, J., Zammitt, N.N., & Frier, B.M. (2008). Prevalence of impaired awareness of hypoglycaemia in adults with Type 1 diabetes. *Diabetic Medicine*, 4, 501-504.
- [7] Martin- Timon, I., & Carizo- Gomez. F. (2015). Mechanisms of hypoglycemia unawareness and implications in diabetic patients. *World Journal of Diabetes*, 6, 912-926.

- [8] Kalra, S...& Ramachandran, A. (2013). Hypoglycemia: The neglected complication. *Indian Journal of Endocrinology and Metabolism*, 5, 819-834.
- [9] Ali, S., Stone. M., Peters, J., Davies, M., & Khunti, K. (2006). The prevalence of comorbid depression in adults with type 2 diabetes: A systematic Review and meta-analysis. *Diabetic Medicine*, 23, 1165-1173.
- [10] Anderson, R. J., Freedland, K. E., & Clouse, R. E. (2001). The prevalence of comorbid depression in adults with diabetes: A meta-analysis. *Diabetes Care*, 24, 1069–1078.
- [11] Li, C., Barker, L., Ford, E. S., Zhang, X., Strine, T. W., & Mokdad, A. H. (2008). Diabetes and anxiety in US adults: Findings from the 2006 behavioral risk factor surveillance system. *Diabetic Medicine*, 25, 878–881.
- [12] Lin, E. H., Korff, M. V., Alonso, J., Angermeyer, M. C., Anthony, J.,& Bromet, E.(2008). Mental disorders among persons with diabetes – Results from the World Mental Health Surveys. *Journal of Psychosomatic Research*, 65, 571–580.
- [13] Eiser, J.R., Riazi, A., Eiser, C., Hammerley, S., Tooke, J.E. (2001). Predictors of psychological well-being in types 1 and 2 diabetes. *Psychology and Health*, 16, 99 -110.
- [14] Hart, P. L., & Grindel, C. G. (2010). Illness representations, emotional distress, coping strategies, and coping efficacy as predictors of patient outcomes in type 2 diabetes. *Journal of Nursing and Healthcare of Chronic Illness*, 2(3), 225-240.

- [15] Hex, N. N., Bartlett, C. C., Wright, D. D., Taylor, M. M., & Varley, D. D. (2012). Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabetic Medicine*, 29, 855-862.
- [16] Smith, J., Flowers, P., & Larkin, M. (2009). *Interpretative Phenomenological Analysis: Theory, Method and Research*. London: Sage.
- [17] Ristovski-Slijepcevic, S., & Bell, K. (2014). Rethinking Assumptions about Cancer Survivorship. *Canadian Oncology Nursing Journal*, 24, 166-168.
- [18]
- [19] Shrivastava, S.R., Shrivastava, P.S., & Ramasamy, J. (2013). Role of self-care in management of diabetes mellitus. *Journal of Diabetes and Metabolic Disorders*, 12, 12-14.
- [20] Bell, K., & Ristovski-Slijepcevic, S. (2013). Cancer survivorship: why labels matter. *Journal of Clinical Oncology*, 31, 409–411.
- [21] Beck, A. T. (1967). *Depression – Clinical Experimental and Theoretical Aspects*, New York: Harper and Row.
- [22] National Institute for Health and Care Excellence. (2012). Patient Experience in Adult NHS services. Retrieved 15th May 2017 from <https://www.nice.org.uk/guidance/qs15/chapter/quality-statement-6-shared-decision-making>.

[23] Gleeson, J.R, Alexander, T., & Wolverson, E. (2017). *A systematic Literature Review of the impact of hypoglycaemia on caregivers of adults with diabetes*. The University of Hull: Unpublished manuscript.

[24] National Institute for Health and Care Excellence (2006). Dementia: supporting people with dementia and their carers in health and social care. Retrieved 20th May 2017 from <https://www.nice.org.uk/guidance/cg42>.

[25] Doka, K.J (2015). The Awareness of Mortality: Continuing Kastenbaum's Developmental Legacy. *Journal of Death and Dying*, 70, 67-78.

[26] Erikson, E. H. (1968). *Identity: Youth and Crisis*, Norton, New York.

Part Three: Appendices

Appendix A

Journal of Diabetes Care: Instructions for Authors

General Guidelines

Original Articles. Original Articles should be arranged in the following order: title page, structured abstract, introduction (no heading), “Research Design and Methods,” “Results,” “Conclusions,” “Acknowledgments,” “References,” tables, and figure legends.

A **structured abstract** is required for all Original Articles. Abstracts for an Original Article should not exceed 250 words. (This is not to be confused with abstracts submitted to the Annual Scientific Meeting, for which the word limit is higher.) The abstract must be self-contained and clear without reference to the text and should be written for a general journal readership. The abstract format should include four sections: “Objective” (the purpose or hypothesis of study), “Research Design and Methods” (the basic design, setting, number of participants and selection criteria, treatment or intervention, and methods of assessment), “Results” (significant data found), and “Conclusions” (the validity, limitations, and clinical applicability of the study and its results).

The **Conclusions** section should discuss the findings of the study in the context of past research concerning the topic of the article, in particular highlighting how these findings add new information. Also, this section should, where possible, assess the possible clinical relevance of the findings avoiding any claim or terminology of superiority, especially when statistically significant but quantitatively modest differences are found.

The **word count limit** for Original Articles is 4,000 words, excluding words in tables, table legends, figure legends, title page, acknowledgments, and references. In addition, an original article is limited to a combination of 4 tables and figures. **References** are limited to 40 citations. A conflict-of-interest statement for all authors must be included in the Acknowledgments section of the main document, which should follow the main text and precede the references. If there are no relevant conflicts of interest to disclose, authors should indicate as such in the Acknowledgments section.

In the case of **multicenter studies**, authors should provide a list of participating investigators in an appendix to the paper. Papers will not be reviewed if this information is not included. Where appropriate, **clinical and epidemiological studies** should be analyzed to see if there is an effect of sex or ethnicity. If there is no effect, it should be stated as such in the “Results” section.

Randomized Clinical Trial reporting: Authors of reports on randomized controlled trials are required to use the instructions and checklist in the Consolidated Standards of Reporting Trials (CONSORT) Statement. The instructions and checklist are designed to ensure that information pertinent to the trial is included in the study report. CONSORT information may be included in a supplemental material online-only file so that it does not affect word count limitations.

All **clinical trials** submitted to *Diabetes Care* for consideration of publication must be registered with a clinical trial registry approved by the International Committee of Medical Journal Editors (ICMJE). Please see Section 2.5 for more information.

5.2. Novel Communications in Diabetes. Novel Communications in Diabetes are designed to provide new and exciting findings in clinical research or clinical care in one or more of the following areas:

the feasibility of a “proof of concept” principle or idea

a novel or innovative finding considered as a pilot study when planning for a larger trial

results from early phase human investigation from a small number of subjects including “first in human” studies

new technical advances (i.e., early research on artificial pancreas, glucose monitoring) or advances in diagnostic testing
studies defining a novel molecular target
studies that challenge current thinking for clinical management or novel approach to behavioral management
case report/case studies that represent a unique or novel finding on disease presentation or treatment effects
Novel Communications are not intended to be short reports on studies that are not powered for larger trials or to simply confirm findings from other studies.

A **structured abstract** of no more than 150 words is required. The abstract must be self-contained and concise, without reference citations, and written for a general journal readership. The abstract should be followed by a short introduction (two to three sentences) and four concise sections: Research Design and Methods, Results, Conclusions, and References. **References** are limited to no more than 15. In addition, Novel Communications may contain only one table or one figure.
The format of the title page, margins, text, table, figure, and font size for Novel Communications is the same as for Original Articles. Manuscripts should be double spaced, written in Arial or Times New Roman 12 point font, and saved as a .doc, .txt, or .rtf file. See Sections 6.2 and 6.3 of Manuscript Format and Style.

The **word count limit** for Novel Communications is 1,350 words, including the 150 word abstract. Tables, figures, legends, the title page, acknowledgments, and references are not included in the word count.

Author contributions, statement of guarantor, and conflict-of-interest disclosures for all authors must be included in the Acknowledgments. If authors have no relevant conflict of interest to disclose, it should be indicated as such.

Novel Communications in Diabetes are freely accessible to readers upon publishing.

Epidemiological integrity. *Diabetes Care* receives a large number of submissions with an epidemiological foundation. These largely, but not exclusively, come from hospital clinics, with data derived from electronic medical records or long-established population-based studies. The populations available for these studies may not truly represent the city/area from where they are derived or national demographics. The socio-economic status of the population, different models of health care (for example state funded or private), and ethnicity are some of the factors that need to be taken into consideration. Submissions from existing records or databases should discuss whether the findings and conclusions are applicable only to that population or can be extrapolated to a more general population, perhaps on a national basis. Authors prospectively planning studies, who would like the results to be relevant outside of their clinic, for example, should take care to include a proportion of subjects who are representative of the ethnicity, socio-economic demographic, and health care systems in that area or nation.

Letters. All Letters are published only in the online version of *Diabetes Care*. Letters are listed in the table of contents of the print version and are assigned an "E" page number. Each letter is assigned a unique DOI (digital object identifier); when citing a letter, include the DOI (e.g., 10.2337/dcXX-XXXX).

Letters do not have abstracts, should not exceed 500 words (excluding a maximum of 5 references). As with all submissions, letters should be double-spaced and include a title page. *Diabetes Care* accepts three types of letters:

Comment Letters comment on a recently published article and should include the cited paper as reference 1 in the reference list. It should be submitted within 3 months of the article's printed publication. Comment letters do not have tables or figures.

Response Letters are an invited letter from the cited author that replies to the comment letter and should include the comment letter as reference 1 in the reference list. Response letters do not have tables or figures.

Observation Letters comment on a relevant finding related to clinical care or research or present a case report/case study. Observation letters are allowed either one table or one figure. All letters require a signed Manuscript Submission Form from the author(s). A conflict-of-interest statement for all authors must be included in the Acknowledgments section of the main document. If there are no relevant conflicts of interest to disclose, authors should indicate as such in the Acknowledgments section.

All letters are freely accessible to readers upon publishing.

Commentaries. Commentaries normally accompany an original article and are invited by the editors. Instructions will be provided at the time of solicitation.

Clinical Images in Diabetes. “Clinical Images in Diabetes” are intended to provide modern views on the pathogenesis of diabetes or its complications, with the aim of linking the clinical course of diabetes and related pathologies with their underlying physiological mechanisms. By presenting *highly novel* clinical summaries regarding one to no more than three patient descriptions per article, “Clinical Images in Diabetes” serves as a valuable educational tool to better understand the pathophysiology of diabetes, enhance disease diagnosis, and offer guidance for optimized clinical treatments.

Importantly, although often presented within the context of a case(s), the “Clinical Images in Diabetes” section is not intended as a primary vehicle for traditional brief/case reports where novel insights and the use of cutting edge diagnostic/treatment tools are lacking. All submissions must include original images or videos as well as useful insight. Images may include, but are not limited to, histopathological specimens, MRI or CT scans, or other radiological imaging techniques.

All submissions will be subjected to rigorous peer review, with novelty and reader interest a high priority for editorial decisions. All submissions will also be evaluated based on how the contribution adheres to the intent of “Clinical Images in Diabetes” by judging how it advances understanding of underlying pathophysiological mechanisms.

Submissions should include 1–2 figures or videos. All figures must meet the quality standards outlined in section 6.11. **Figures.** Video submissions are encouraged and may be submitted in any of the standard formats (e.g., .avi, .mov, etc.). Please submit a separate still image for each video file. More information on video submissions can be found in section 6.12. **Video.** Figures, videos, and still images should be uploaded as separate files.

Note: Any information that might identify a patient or hospital, including a date, should be removed from the image or video. Written permission from the patient, or parent or guardian of a minor child, is required for publication of recognizable images in all forms and media.

The written portion of the submission should include the following:

A standard title page with no more than four authors

A bulleted summary of 5–10 points (125 words or less) summarizing the main narrative and including information such as diagnosis, patient characteristics, biological markers, etc.

A main narrative of 900 words or less

A standard Acknowledgments section

A reference list with 10 or fewer citations

A legend for each figure and video

All authors should consent to the standard ADA copyright and authorship form ([Manuscript Submission Form](#)). Standard page charges and fees for color figures will be applied.

5.6. Review Articles and Meta-analyses. Please read the [criteria and formatting guidelines for meta-analyses and systematic review articles](#). A meta-analysis may be submitted to the journal without prior approval from the editors. Please query the journal's interest and provide a proposal (as detailed below) if you wish to submit an uninvited review article.

The proposal should include the following: 1) why this is an important topic to review, why it is best suited for *Diabetes Care*, and why the review would appeal to the readership; 2) the article's focus; 3) major issue(s) to be addressed; 4) source of original literature to be summarized (including from X year to Y year inclusive); 5) method used; and 6) all author bios including the background of the author(s) and a description of expertise in the area to be

discussed in the review. It is anticipated that the author(s) will have worked and published in the area covered by the review.

Lastly, the authors must disclose whether they propose to write the entire article themselves, whether they received any form of sponsorship or honorarium for the material, and whether a pharmaceutical company, or its representative, was involved in the funding or authorship. In addition, the authors must point out any potential conflict of interest with a company whose products will be discussed in the review.

All proposals should be emailed (as Word document attachments) to Lyn Reynolds (lreynolds@diabetes.org) in the Editorial Office. Review Articles submitted without prior approval or invitation will be returned. All Review Articles (whether invited or by query) are subject to peer review.

Once approved, guidelines will be sent to the authors.

Editorials. Editorials are generally by invitation. If you wish to submit an unsolicited editorial, please query first and provide an outlined proposal that includes the following: 1) cover letter explaining why author(s) are suited to write the article and their area of expertise and bios; 2) brief background of the topic/problem; 3) major issue to be discussed; 4) strengths and weaknesses; 5) why this is an important topic for the journal; and 6) potential future directions. Please send the proposal to Lyn Reynolds (lreynolds@diabetes.org) in the Editorial Office. Guidelines will be provided if approved for submission.

Perspectives. Perspectives are invited or approved for submission after proposal query. A Perspective highlights recent exciting research, not primarily that of the author(s), and may provide context for the findings within a field or explain potential interdisciplinary significance (similar to that of a Review Article).

Please follow the proposal outline described in section 5.6 Review Articles and Meta-analyses. Please send the proposal to Lyn Reynolds (lreynolds@diabetes.org) in the Editorial Office. Guidelines will be provided if approved for submission.

Supplemental issues. Supplemental issues must be approved prior to submission. A proposal for a supplemental issue should first be submitted to the Publications Department of the ADA (ckohler@diabetes.org) and must specify the following:

The name of the organization(s) sponsoring and funding the supplement (not merely the name of the public relations agency handling its publication).

If the supplement is based on a symposium, where and when the symposium was held and how the speakers and papers were selected.

Whether authors will be paid and, if so, how much.

If the proposal is approved, it will be forwarded to the Editor of *Diabetes Care*. Initial approval by the ADA does not commit the Editor to accept a proposal in whole or part. All manuscripts are subject to the same peer review as other manuscripts in the journal.

For complete instructions on submitting a supplement, please contact the Editorial Office.

MANUSCRIPT FORMAT AND STYLE

Articles must be in clear and understandable English. Non-native English authors are encouraged to seek the assistance of an English-proficient colleague, or a communications agency, such as American Journal Experts, to help improve the clarity and readability of a paper before it is submitted to the journal.

For specific information on the parameters and limits for various manuscript categories (e.g., section headings, word limits, etc.), see Section 5, Manuscript Categories.

Title Page. All submissions, regardless of article type, require a title page. The title page should include the following: full title; a short running title (less than 47 characters and spaces combined); the first name, middle initial, last name, and highest academic degree of each author; each author's affiliation (in English) during the time the study was conducted; contact information of the corresponding author (name, current address, telephone number, fax number, and e-mail address); and the word count and number of tables and figures.

If two authors have equal authorship, it may be noted by * under the author list.

Main Document. The main document file includes the title page, abstract, main text, acknowledgements, figure legends, references, and tables, in that order. Please do not use headers, footers, or endnotes in your paper.

The Main Document should be in Word document format (not as a PDF). This will allow our Editorial Office to verify word count and our production staff to convert your paper (if accepted) into an article.

Text Composition. Articles should be written in clear, concise English following the recommendations for scientific writing found in *Scientific Style and Format*, the Council of Science Editors (CSE) style manual (7th ed., 2006, Reston, VA, Council of Science Editors). All accepted manuscripts will be edited according to the CSE style manual and *The Chicago Manual of Style* (16th ed., 2010, Chicago, IL, The University of Chicago Press) by ADA professional publications staff. The authors are responsible for all statements made in their articles or editorials, including any editing changes made by staff. Proof pages will be sent to the corresponding author and should be read carefully.

The designations *type 1 diabetes* and *type 2 diabetes* should be used when referring to the two major forms of diabetes. Abbreviations for diabetes, such as T2D for *type 2 diabetes*, should not be used. The term *diabetic* should not be used as a noun.

All manuscripts should be double-spaced, in Arial or Times New Roman 12-point font, and saved as a .doc, .txt, or .rtf file. In addition, please do not "lock" or "page protect" your document, and avoid using footnote and endnote functions.

Abbreviations and Units. Abbreviations should be used only when necessary, e.g., for long chemical names (HEPES), procedures (ELISA), or terms used throughout the article. See the [list of abbreviations](#) that need not be defined; all others must be defined at first use. Abbreviate units of measure only when used with numbers. Abbreviations may be used in tables and figures. The CSE style manual contains lists of standard scientific abbreviations. Clinical laboratory values and units should be in Système International (SI) form. Kilocalories should be used rather than kilojoules. HbA1c values should be dually reported as “% (mmol/mol).” Please use the NGSP’s HbA1c converter at <http://www.ngsp.org/convert1.asp> to calculate HbA1c values as both % and mmol/mol.

6.5. Font. Text, including title and author names, should be in 12-point Arial or Times New Roman. Please avoid using boldface font. Text in tables should be no smaller than 10-point font.

6.6. Margins. Margins should be 1" at the top and bottom and 1" on the left and right sides.

Acknowledgments. The acknowledgments are located after the main text and before the reference list. Acknowledgments should contain the author contributions paragraph, brief statements of assistance, the guarantor's name (person[s] taking responsibility for the contents of the article), funding/financial support, conflict of interest statement, and reference to prior publication of the study in abstract form, where applicable.

References. Please place the reference list after the main text and acknowledgments (if applicable). Original Articles are limited to 40 references. Letters are allowed 5 references. Review Articles are allowed 60 references, and meta-analyses should have no more than 40 references.

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References: minimum 40, maximum 60 citations

Tables and figures: Any combination of 4 tables and/or figures will be accepted—Include a flow diagram that depicts search and selection processes, along with evidence tables

Appendix B
Quality Appraisal Checklist- MMAT

Types of mixed methods study components or primary studies	Methodological quality criteria	Responses Yes	No	Can't tell	Comments
Screening questions (for all types)	Are there clear and quantitative research questions (or objectives*), or a clear mixed methods question (objective*)? Do the collected data allow address the research question (objective)? E.g. consider whether the follow-up period is long enough for the outcome to occur (for longitudinal studies or study components). <i>Further appraisal may not be feasible or appropriate when the answer is 'No' or 'Can't tell' to one or both screening questions.</i>				
1. Qualitative	1.1. Are the sources of qualitative data (archived, documents, informants, observations) relevant to address the research question (objective)? 1.2. Is the process for analysing qualitative data relevant to address the research question (objective)? 1.3. Is appropriate consideration given to how findings relate to the context, e.g. the setting, in which the data were collected? 1.4. Is appropriate consideration given to how findings relate to researchers' influence, e.g. through their interactions with participants?				
2. Quantitative randomized controlled (trials)	2.1. Is there a clear description of the randomization (or an appropriate sequence generation)? 2.2. Is there a clear description of the allocation concealment (or blinding when applicable)? 2.3. Are there complete outcome data (80% or above)? 2.4. Is there low withdrawal/drop-out (below 20%)				
3. Quantitative non-randomized	3.1. Are participants (organizations) recruited in a way that minimizes selection bias? 3.2. Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes?				

	<p>3.3. In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls) are the participants comparable, or do researchers take into account (control for) the difference between these groups?</p> <p>3.4. Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow up)?</p>				
4. Quantitative descriptive	<p>4.1. Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)?</p> <p>4.2. Is the sample representative of the population under study?</p> <p>4.3. Are measurements appropriate (clear origin, or validity known, or standard instrument)?</p> <p>4.4. Is there an acceptable response rate (60% or above)?</p>				
5. Mixed methods	<p>5.1. Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)?</p> <p>5.2. Is the integration of qualitative and quantitative data (or results*) relevant to address the research question (objective)?</p> <p>5.3. Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative data (or results*) in a triangulation design?</p> <p><i>Criteria for the qualitative component (1.1 to 1.4), and appropriate criteria for the quantitative component (2.1 to 2.4, or 3.1 to 3.4 or 4.1 to 4.4), must also be applied</i></p>				

* These two items are not considered as double-barrelled items since in mixed methods research, (1) there may be research questions (quantitative research) or research objectives (qualitative research), and (2) data may be integrated, and/or qualitative findings and quantitative results can be integrated.

Appendix C

Quality Ratings for Included Studies

	Screening Question 1	Screening Question 2	Question 1	Question 2	Question 3	Question 4	Total
Gonder-Frederick et al. (1997)	✓	✓	✓	✓	✓	✓	100%
Jorgensen et al. (2003)	✓	✓	✓	X	✓	✓	75%*
Kovacs-Burns et al. (2013)	✓	✓	✓	✓	✓	X	75%
Lawton et al. (2014)	✓	✓	✓	✓	✓	X	75%
Polonsky et al. (2016)	✓	✓	✓	✓	✓	X	75%
Ritholz et al. (2013)	✓	✓	✓	✓	✓	X	75%
Stahl et al. (1998)	✓	✓	✓	X	X	X	25%*
Trief et al. (2003)	✓	✓	✓	✓	✓	x	75%
Trief et al. (2013)	✓	✓	✓	✓	✓	x	75%

As per the MMAT guidance (Pluye, Gagnon, Griffiths & Johnson-La Fleur, 2009) screening questions do not contribute to an overall score but are used as a guide as to whether further appraisal of quality is possible. If the answer to both screening questions is a no then further appraisal may not be feasible (Pluye et al, 2009).

Questions 1-4 differ depending on the methodology of the paper being appraised. If the paper is qualitative then questions 1.1-1.4 are selected, if quantitative then 2.1-2.4 are selected, if the paper is quantitative non randomised then questions 3.1-3.4 are used, if the paper is quantitative descriptive then questions 4.1-4.4 are selected and for mixed method papers, questions 5.1-5.4 are used. (Please see appendix B for the list of questions).

Each of the four questions was awarded 25% if the criteria were met.

*Denotes final score awarded when there was a discrepancy between the first and second marker.

References

Pluye, P., Gagnon, M. P., Griffiths, F., & Johnson-Lafleur, J. (2009). A scoring system for appraising mixed methods research, and concomitantly appraising qualitative, quantitative and mixed methods primary studies in Mixed Studies Reviews. *International Journal of Nursing Studies*, 46, 529-546.

Appendix D

Journal of Diabetes Research and Clinical Practice: Guidance for authors

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Appendix E
Confirmation of Ethical Approval

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Appendix F
Participant Information Sheet
Information Sheet

I would like to invite you to take part in my research study. Before you agree to take part, I would like you to understand why the research is being done and what you will be asked to do if you choose to take part. The researcher will be happy to go through this sheet with you and answer any questions you may have. Please talk to others about the study if you wish.

Purpose and aims of the research

This research study is being conducted as part of the Doctorate in Clinical Psychology programme at the University of Hull.

The aim of the study is to gain information on what it is like to experience both diabetes mellitus and hypo unawareness.

How the research will be carried out

This research study will involve you taking part in an interview which will be about 1 hour long and will be audio-recorded. During the interview, you will be asked to talk about your diabetes mellitus and hypo unawareness and how they have affected how you feel and your life. The data collected during the interview will be transcribed, which means that the information audio-recorded from the interview will be changed into a written format. This information will then be analysed along with other people's information, to see the main things that people say about how their diabetes and hypo unawareness has affected how they feel and their lives.

If you agree to take part in the research study, you will be asked to sign a form that you consent (agree) to take part. All of the personal data and information obtained about you during the study will be made anonymous and will be kept confidential. This means that the information about you will not be shared with other people. However, in the event that you disclose a criminal offence, intent to harm yourself or others, I will have to share this information with appropriate others. This will be discussed with you if this occurs. You have the right to withdraw from the study at any point. You have the right to withdraw your personal information and data from the study, up until the point of transcription, if you wish to. This would not affect the standard of care that you receive.

Why have I been asked to take part in the study?

You have been asked to take part in the study, because you have diabetes mellitus and hypo unawareness. Your diabetes nurse at the clinic has identified you as a potential participant of the study. You are receiving information about the study so that you can decide if you would like to take part. It is completely your decision as to whether you decide to take part in this study.

What will happen?

If you are unsure or would like the chance to ask some more questions about the study then please contact the researcher either by email on XXXXXXXXXXXX or by telephone on XXXXX. If you decide at this point that you would like to take part in the study then please leave your details with the diabetes team. The researcher will then contact you and a date and time to take part in the interview will be agreed with you.

On the day that you come to take part in the study, before the interview begins, you will be asked to sign a form to consent (agree) to take part. The interview will last for about 1 hour.

You will be asked to talk about your diabetes and hypo unawareness and how they have affected how you feel and your life.

Once the interview has finished, you will be asked if you would like to be informed of the findings of the study. If you decide that you would like to be informed, you will be asked to provide an address for the findings to be sent to you in writing.

How will the research be used?

This research is being carried out as part of a Doctorate in Clinical Psychology course at the University of Hull. The research submitted will be anonymised to ensure the confidentiality of the information provided.

You are free to withdraw your data from the study, up until the point of transcription. After this, information is completely anonymous. This research will be submitted to be published. If the research is published then it will be accessible to anyone who may be interested in reading it, although no-one will be able to be identified from it in any way.

Potential advantages and disadvantages of taking part in the study

A potential disadvantage of you taking part in the study is that it is possible that you could experience some distress whilst discussing how your diabetes and hypo unawareness is affecting you. If this happens, then you are free to stop the interview at any time.

If you do choose to take part in this study, your experiences could help to provide a greater understanding of how having diabetes and hypo unawareness can affect lives. If your experiences are better understood, then it is hoped that healthcare professionals will be able to provide better services to meet people's needs. Additionally, you may feel that discussing your diabetes and hypo unawareness is helpful.

What will happen if concerns/problems arise?

If you experience any problems whilst you are taking part in the study, please feel free to contact me on the details provided below. I will do the best that I can to answer any questions that you have. If you wish to make any formal complaint during the course of the study, you can do this by contacting the NHS Patient Advice and Liaison Service (PALS).

How is this research funded?

This research is funded by the University of Hull, as part of the Doctorate in Clinical Psychology course.

Who is reviewing this research study?

Research that is carried out within the NHS must be approved by a Research Ethics Committee. This is in order to protect the interests of anyone taking part in the research.

What happens now?

We would like to know if you would be interested in taking part in this study. If you wish to take part then please leave your details with your diabetes nurse so that the researcher can contact you, or alternatively, you can contact the researcher either by email or by telephone using the details below.

If you decide that you would like to take part in the study, a date, time and place for interview will be agreed.

Thank you for your time.

If you wish to contact me at any point, please do not hesitate to do so using any of the contact details below:

Researcher: Jessica Gleeson

Telephone Contact Number: XXXXX

Contact Address: Department of Clinical Psychology and Psychological Therapies, Hertford Building The University of Hull Cottingham Road Hull HU6 7RX

Email: XXXXXXXXXX

Appendix G

Participant Consent Form

CONSENT FORM

Title of Project: **The experiences of people with diabetes mellitus and hypoglycemic unawareness.**

Why have I been asked to take part in this research?

You have been asked to take part in this study, as you have been identified by clinical staff as having diabetes mellitus and experiencing episodes where your blood sugars drop and you do not experience the usual warning symptoms associated with this. This is sometimes referred to as hypo unawareness. We would like to explore your experiences of this.

Name of Researcher: Jessica Gleeson

Please initial all
boxes

I confirm that I have read and understand the information sheet (version 3, 9/6/2016) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

☐

I agree to a Diabetes Specialist Nurse in the diabetes clinic being informed of any concerns that arise regarding my well-being so that they can best support me and provide me with advice.

☐

I agree to the interview being audio-taped and to the use of verbatim quotation from my interview.

☐

I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Person

Date

Signature

taking consent.

Appendix H

Demographic Information Form

Participant number:

Age:	
Type of Diabetes	
When was diagnosis of diabetes made?	
When did you first become hypo unaware?	
Treatment:	
Who do you live with?	

Any additional details:

Appendix I

Semi structured Interview Schedule

- 1) Please could you give me a brief history of your experience of having hypo unawareness?
- 2) What happens after an episode of hypo unawareness?
- 3) How do you feel after an episode of hypo unawareness?
Prompt: physically, emotionally, mentally.
- 4) How does hypo awareness affect your everyday life?
Prompt: work, interests, relationships
- 5) Does hypo unawareness affect how you see yourself?
- 6) How do you find talking about your hypo unawareness with others?
Prompt: friends, family, professionals
- 7) On a day to day basis how do you deal with hypo unawareness?
- 8) Do you think much about the future?
- 9) Is there anything I haven't asked or you haven't mentioned which you feel is important?

*Please note that questions were used only as a guide

Appendix J

Worked Example of Analysis

Descriptive & exploratory comments	Transcript	Emerging Themes
Balance between needing support from others vs wanting to manage things by self.	S2 Yes. I like to be in control of my condition and I want help, not as in help...I can't really (pause).... I want perhaps him to be...take notice and be knowledgeable about my condition, but I don't want him interfering with it. It's odd. It's my condition, I'll deal with it. But, I want him to understand the consequences and the, what could happen. But, I mean, like my husband suffers with psoriasis and so I've looked it up on the internet and, you know, what triggers sometimes flare-ups and what have you, but I perhaps want him to look into diabetes and know the consequences, but I don't in a way, because I know he'll read more and maybe not quite...not let me do things because of my diabetes and but....	Control
Feels like husband doesn't understand.		Others don't understand
Others can't understand and therefore shouldn't offer their input. Perceived as nagging?	S1 And that causes more tension and...? (Overlapping Conversation) S2 Yeah, that I'm not managing it properly. And, I'll be the judge of whether I'm managing it. I don't want him because he's not a diabetic. S1 That sounds difficult S2 Yes, that's right, yeah. S1 Do you find sort of if he's had to give support in the night, does that cause	Needing input from others but not wanting it. Control

<p>Feeling of guilt due to the impact on husband.</p>	<p>kind of a row or more tension?</p> <p>S2 Yeah. I mean, he laughs...we laugh about it. You know, it's sort of...it's dealt with at the time and then, you know, he'll get up, go to work, and then, you know, we'd sort of in the evening "Oh I'm shattered, because someone was hypo in the night so I only got two hours' sleep," and I'll say, "Look, you know, I'm sorry, I don't mean it." And then, I feel guilty because he's worried and he's lost sleep and then I feel guilty because it's my problem, but he's had to deal with it.</p>	<p>Guilt Impact on others</p>
<p>Fear for the future and consequences</p>	<p>S1 I guess he doesn't understand that you've lost sleep and then you've felt very unwell after the hypo. You know, you've had that, although you've come around, you felt.... (Overlapping Conversation)</p> <p>S2 That's right, yeah. But again, sometimes I've wanted to ring in sick at work because of this hypo I've had, but I don't. I drag myself into work. I feel, you know, very lethargic, but I won't let it defeat me in that respect, you know. I mean, touch wood, I've never had time off work as a result of my diabetes. I've been ill, but it's never a direct result of my diabetes, you know. So, I just...so that's why I'm fearful that this hypo unawareness is going to creep into my waking hours.</p> <p>S1 Yes.</p> <p>S2 And, that does really scare me.</p>	<p>Fear Wanting a 'normal' life</p>

Driving- constant time and energy needed to manage	S1 Yeah, somewhat it would affect.... (Overlapping Conversation)	Driving- sense of responsibility
Sense of responsibility	S2 Yeah, you know, driving. Again, that's my...you know, I got up this morning about half past seven to check my sugar levels and I had to make an adjustment dose. I checked them again before I came out because, by law, well, driving law, you're supposed to check before you actually get behind the wheel of a car. So, I have, you know, a slice of toast, check my levels just to make sure I was okay to drive. So, yeah. You sort of do it without thinking, but you've always got to stop and think about if you know what I mean?	
Lack of spontaneity and flexibility. Everything has to be thought through	S1 Yeah. S2 I can't just think, "Oh gosh, I'm meeting Jessica, I'll grab my bag and go.	Constant effort/time needed to self-manage

Appendix K

Theme/Subtheme	Example of how participants map onto each theme
<p>Theme one</p> <p>Subtheme one: 'Trying to get this under control.'</p>	<p>'If it's high I can sense it's high but when it's low I couldn't sense anything. Why is that? (Frank)</p> <p>'How careful do I have to be? What do I watch? I'm doing what I can do and I can't really do much more.' (Julie)</p> <p>'I can't find out why. I don't know it's happening... I just go into a coma.' (John)</p> <p>'I do check my bloods. I do this, it doesn't make no odds. I'm trying so hard and then I feel disappointed.' (Julie).</p> <p>'I find the weather can affect it a lot. So if I'm too hot or too cold this can cause me to hypo but obviously that's a lot harder to control.' (Emily)</p> <p>'I do like to think that one day I'll get it under control and I'll be able to live.' (Mike)</p>
<p>Subtheme two: 'I do try and overcompensate.'</p>	<p>'So when I exercise I was always told to have a bit more carb or reduce the insulin but I find I do both to try and avoid it.' (Emily)</p> <p>'I'll go to bed with my levels a bit too high for fear of having a night time hypo.' (Carol)</p> <p>'I tend to ride higher than I normally would have done because obviously I don't want to hypo and fall into a coma.' (Mike)</p> <p>'I kind of over anticipate.' (Emily).</p>
<p>Subtheme three: 'It's my condition. I'll deal with it.'</p>	<p>'I get fixated by it.' (Carol)</p> <p>'Sometimes you do things you shouldn't to try and alleviate the risk., (Frank)</p>

<p>It's like waking up every day with a giant above your bed saying right; you've got to look after me today.'</p>	<p>She [wife] has kept me alive.' (John)</p> <p>'My boyfriend is a really good help. He'll help me check and he'll sort things out.' (Emily)</p> <p>'He's [husband] learnt to administer it [glucagon injection] whereas before he used to always have to call the paramedics out.' (Carol)</p> <p>'It's narking and very irritating because you're doing the best you can do.' (Julie)</p> <p>'I know my signs, I know my body. I know what's happening. Just because I'm slightly grumpy doesn't mean my blood sugar is out of balance.' (Emily)</p> <p>'I'll be the judge of whether I'm managing it. I don't want him to because he's not diabetic.' (Carol)</p> <p>'It takes a lot of energy to concentrate on what you're doing... it takes a lot out of you mentally as well as physically.' (Mike)</p> <p>'It's the hard work in constantly thinking about it.' (Emily)</p> <p>'You can't have a day off. You can't just think I won't be diabetic today.' (Carol)</p> <p>'It's like waking up every day with a giant above your bed saying right; you've got to look after me today.' (Mike)</p> <p>'It (hypo unawareness) does rule my life in the sense that I can't walk away from it.' (Carol)</p> <p>'I have to stop, check my levels before I carry on driving. You've got to constantly think.' (Carol)</p> <p>'The long distances. You have to stop and check, I add at least 45 minutes onto any journey time.' (Emily).</p>
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	<p>‘I’d like to be on my own to be honest but when these things happen you need somebody and if it wasn’t for my wife who knows what would happen.’ (John)</p> <p>‘My wife has often called the paramedics out at 2 and 3 o’clock in early Sunday morning at the weekend. And if it wasn’t for her like, I don’t think I’d be here.’ (John)</p> <p>‘My husband’s making me feel worse now because I feel so guilty for him. He’s up early for work.’ (Julie)</p> <p>‘I feel guilty because he worries and he’s lost sleep and then I feel guilty because it’s my problem but he’s had to deal with it.’ (Carol).</p> <p>‘Managing unawareness on your own... well you can’t. When hypo unawareness happens you need somebody.’ (Mike)</p>
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Appendix L

Reflective Statement

Choosing an area of research

From a young age, I have always been very interested in those who manage long term health conditions and when I began my doctorate I was clear that I wanted to conduct health related research. It is likely that this is the case as I myself have several rare health conditions which I am required to manage on a daily basis and I also have several family members who have a diagnosis of diabetes. When I was initially looking for an area to research it was very important to me to find a supervisor who shared my passion for giving those with health conditions a voice. Initially I had considered carrying out research into my own health condition; however after much consideration I realised that this may result in some bias and also some strong emotional reactions and therefore I decided to put some distance between my own personal circumstances and the research.

After exploring other potential areas I felt that due to the link with diabetes in my family this was something I would like to pursue. I also felt strongly that those with hypo unawareness are underrepresented in the literature and therefore I was passionate about giving them the opportunity to share their experiences.

Method and Design

As part of my undergraduate degree I had conducted quantitative research and therefore I was keen to try something different, further my skillset and conduct qualitative research as part of the doctorate. I felt strongly that meeting with people and hearing their voices would keep me motivated and engaged. I did however have some

reservations as qualitative research was alien to me and I had concerns about the analysis process and how I would go about this. In the early stages I had never heard of Interpretative Phenomenological Analysis (IPA), however once I had read up on it and realised that it was all about individual's personal experiences I realised that this was the method for me.

I had initially considered carrying out research with individuals and their caregivers as a dyad, however several people involved in the research persuaded me to decide against this due to feasibility issues. Having now heard how important caregivers are to those with hypo unawareness I sometimes wonder whether I should have pursued this avenue and not been so easily put off. I am however proud of the research I have conducted and feel it is very meaningful and has real life implications so perhaps I did make the right choice!

Recruitment

Throughout the whole process I was aware that recruitment was likely to be challenging and had heard horror stories from previous trainees, however nothing could have prepared me for the difficulties I would encounter and the battles I would face.

Initially I had decided upon recruiting those with type two diabetes only, however after some months of trying hard to recruit it became evident that I had chosen an area that was too specific and that it was not going to be achievable within the timescale.

Difficulties with recruitment coupled with my original research supervisor leaving and my recruitment site falling through left me feeling hopeless and questioning why I had picked such a topic. There were many times when I regretted my decision and felt that if

only I had done a quantitative or questionnaire based study then this wouldn't have happened. There were many times where I genuinely considered leaving the course because the stresses of research became too great and began to impact upon my health and wellbeing.

After many months of amending my proposal, going through the ethics process again and building relationships with a new recruitment site, I cannot put into words the feelings I had when I was told that staff had identified a participant who wished to take part in the research. Such was the relief and joy I felt in that moment that I rung several friends and family members to share the good news.

Interviews

Having put so much effort into finding a participant who wished to take part in the research I was looking forward to finally getting started and hearing their story. I was however also nervous, after such a wait and I felt pressure to make the most of the opportunity and to say and do the right things.

My first interview did not go how I had anticipated. I felt that I had struggled to keep the participant on track and they appeared to find it difficult to stay on topic and provide detail. After the interview I felt a sense of despair again. I began questioning why nothing was going right and began to feel that the research wasn't going to be interesting in any way or add anything. In hindsight I feel that I was too self-critical. I think my eagerness to get off to a positive start after such a wait had set me up to fail and I began to lose sight of the bigger picture and the overall goal.

Subsequent interviews rebuilt some of the confidence I had lost after the initial interview. I began to settle into the process and began to relax. When participants were discussing their experiences with such honesty and emotion I began to feel very privileged to share the moment with them. Several participants told me that taking part in the research had been helpful and therapeutic for them and this made me see the worth in the research. I once again remembered why I had been so passionate about conducting qualitative research and began to see the benefits of choosing such a method.

Looking back on interviewing overall, I feel that I made many mistakes. I was new to the process and at times I think I summarised too much or used questions which were too closed. In hindsight there are times when I feel I should have asked more questions and gained more information rather than asking another question and moving on. However, there were times when participants shared such meaningful and poignant moments with me that I felt I must have done something right and I hope that such moments are represented within the analysis.

Analysis and Findings

I found the process of transcribing very laborious. Due to difficulties with my own health it was often difficult to concentrate for prolonged periods of time and it often felt like a thankless task. However upon reading the transcripts back I began to realise the depth of what had been covered within the interviews and this began to spark excitement for the analysis process.

When imagining what the analysis process would entail prior to carrying out the research I was often filled with a sense of dread and anxiety about how I would go about this. I was completely surprised to find that when it came to it, I really embraced and enjoyed the analysis process. When the themes began to take shape I felt like all the challenges and self-doubt about I had encountered were laid to rest and I began to see the worth in the research and felt genuine excitement about the impact it could have.

The thing I found most difficult about the analysis was condensing what I had found to come up with just a few overarching themes. I had worked so hard to gain participants that I wanted to share everything they had said. At times it felt like I was doing them a disservice by gaining so much information and then only sharing snippets of it within the main body of the research. My passion for the research meant that I found it hard to pick out key themes and at times found it difficult to leave out certain quotes which I had become attached to. Throughout this process, discussion with my supervisors was invaluable as they helped me clarify what the key issues were and were able to make me see when I was perhaps steering away from the key themes.

I am very proud of the overall analysis section. I feel it captures the difficulties faced by this client group in an open and honest way.

Systematic Literature Review (SLR)

I found choosing an initial topic for the SLR very difficult. I would often conduct literature searches and then feel very overwhelmed with the number of articles which met my search terms. I felt pressure to choose an area which would be meaningful and useful and began to question whether I would ever get there. On reflection I believe that I lacked confidence in my abilities as a researcher and this doubt made making

decisions difficult for me as I was fearful of committing to a topic which was then not helpful in any way.

Once I had decided on my area for the SLR I began to feel very passionate about the role of caregivers and began to feel that this area had very important implications for clinical work. Upon seeing that my SLR and empirical findings tie in well together, I feel confident that I made the right decision to explore this topic area.

My relationship with the research

My feelings towards the research have changed throughout the process. Initially I was very excited about the process and things seemed to be moving along well, however major challenges with recruitment alongside personal health issues meant that I did not complete the research at the same time as my peers which at times made me feel frustrated and inadequate. I seriously considered walking away from the course at one point because the mountain of research seemed too big to tackle and there were major negative implications for my physical and mental wellbeing.

With support from peers and input from a therapist I have come to the realisation that due to reasons beyond my control I have been on a different path to my peers. I realise now that this is okay and that the delay in completing the research does not in any way detract from the sense of personal achievement that I feel. In many ways these difficult feelings echo those of the participants who took part in this research and this has allowed me to empathise with their experiences.

Due to extreme fatigue and health issues this research has been stop start at times. This made it difficult to keep myself engaged and motivated. In the end I made the decision to take a few months out of work to focus solely on this research. This was a positive decision and has allowed me to immerse myself in the research. I have found this period far more enjoyable and rewarding than I ever could have anticipated and now realise that much of my difficult relationship with the research was due to having too many ongoing demands at the same time.

Final Thoughts

This process has been the most challenging of my life. It has tested me in ways I could have never imagined and has made me think a lot about my limitations. However I feel incredibly proud of the research and feel that the project gives a voice to those who do not always feel heard. Completing this project is a huge personal achievement for me and I look forward to taking everything I have learnt into my future career.

Appendix M

Epistemological Statement

It is important for researchers to be aware that the way in which they experience the world will have an influence on how they conduct research. The underlying assumptions which I hold about reality will inevitably have influenced the ways in which I have conducted the research. The epistemological and ontological assumptions which have led to the development of the current research will be explored within this epistemological statement.

Epistemology refers to how we come to know about reality and how we believe things to be true (Barker, Pistrang & Elliot, 2002) and ontology refers to the study of existence and attempts to answer questions relating to whether entities are real ((Doucet, Letourneau & Stoppard, 2010). Such assumptions will have had an influence on the approach and methodology selected for use within this research and this is explored below.

One stance considered by the researcher was the positivist stance. This is typically used in quantitative research and adheres to scientific methods of conducting research and suggests that independent truths exist. This stance assumes that the researcher and participants exist independently (Ponterotto, 2005), thus meaning that researcher bias does not occur and that the results are not influenced in any way. This approach can therefore be deemed reductionist and would not capture the subjective accounts and the richness of experiences captured in this study. This stance was therefore rejected.

In contrast to the positivist stance, constructivism assumes that there is no objective reality and believes that an individual's reality is constructed by their personal experiences and perceptions of the world. This stance suggests that interpretations are constructed in our minds and are influenced by our experiences of culture, relationships and language. (Burr, 1995; Ormston, Spencer, Barnard, & Snape, 2013; Ponterotto, 2005) Such methodology is often used in qualitative studies. In this position, researchers are active in collating and analysing data and cannot be seen as detached observers from the research.

The researcher considers her position to be between somewhere between the extreme positivist and constructionist stances and the current research was therefore approached from a position of critical realism (Blaike, 2007.) This position assumes that truths do exist in the world but that these cannot be objectively measured and can only be gained through exploration of individual's subjective interpretations (Cook & Campbell, 1979.) This approach suggests that individuals can have differing perspectives on one reality. As the current research aimed to explore experiences of diabetes from different perspectives, this was therefore deemed suitable and adopted by the researcher.

The aim of the current study was to explore patient experiences of having both diabetes and hypoglycaemia unawareness. In order to understand participants' subjective experiences a qualitative methodology was employed. Having decided upon a qualitative methodology, the researcher had to carefully consider which approach to use. Several methods were therefore explored. Thematic or content approaches of qualitative data group themes together to develop categories (Pistrang & Barker, 2010). This method does not have a focus on individual accounts and lacks interpretation. As

this study aimed to gain an understanding of individual experiences rather than just describe them, this approach was not deemed appropriate for the study. A grounded theory approach (Strauss and Corbin (1994) was also considered. This approach aims to generate theories which are grounded within analysed data. This theory considers both positivist and interpretative perspectives. Whilst the current research involves interpretation, the researcher was not aiming to generate theory but instead understand experiences and this stance was therefore rendered inappropriate and rejected by the researcher.

After spending a considerable amount of time exploring potential methodologies for use within the study, Interpretative Phenomenological Analysis (IPA) was considered the most appropriate. This is due to the focus being on exploring lived experiences of having hypoglycaemia unawareness. IPA seeks to understand the individual meanings attributed to individual experiences and this was key in the current study (Smith & Osborn, 2008).

IPA is informed by three theoretical underpinnings; phenomenology, hermeneutics and idiography (Smith, Flower & Larkin, 2009) which appeared to be of value in the current research. Phenomenology refers to the study of personal experience. This was important in the current study as the focus was on lived experience. Hermeneutics refers to the theory of interpretation. IPA recognises that individuals make interpretations about their experiences as a way of gaining meaning and acknowledges that this will be reflected in their personal accounts (Smith et al, 2009). Within IPA researchers are seen as being engaged in a double hermeneutic process, whereby they attempt to make sense of how participants make sense of the phenomena. It is recognised that the researcher's own

perspectives will influence the analysis process (Smith et al, 2009). This was something the current researcher was aware of. Due to her own experiences of having a health condition this could have impacted upon the analysis and resulted in bias, however steps were taken to minimise this by using open questioning and using the participants own words to inform themes. Finally, idiography deems that individual experiences are unique and thus a deeper understanding is required as a way of understanding them, rather than by developing generalised predictions. The researcher therefore tried to ensure that the analysis in the current study represented the participants' lived experiences and was conscious to avoid making generalisations.

For the reasons outlined above, IPA was considered the most appropriate methodology for the study in order to understand the lived experiences of those with both diabetes and hypoglycaemia unawareness. The theory behind IPA in terms of exploring lived experience was relevant to the phenomena being explored in the current study.

References

- Barker, C., Pistrang, N., & Elliott, R. (2002). *Research methods in clinical psychology* (2nd ed.). Chichester: John Wiley & Sons.
- Blaikie, N. (2007). *Approaches to social enquiry: Advancing knowledge*. Cambridge: Polity.
- Burr, V. (1995). (Eds) *An Introduction to Social Constructionism*. London: Routledge
- Cook, T.D. & Campbell, D.T. (1979). *Quasi-experimentation: Design and analysis issues for field settings*. Chicago: Rand-McNally.
- Doucet, S. A., Letourneau, N. L., & Stoppard, J. M. (2010). Contemporary paradigms for research related to women's mental health. *Health Care for Women International*, 31(4), 296-312.

- Ormston, R., Spencer, L., Barnard, M., & Snape, D. (2013). The foundations of qualitative research. In J. Ritchie, J. Lewis, C. Nicholls, & R. Ormston (Eds). *Qualitative research practice: A guide for social science students and researchers* (pp.1-26). London: Sage.
- Pistrang, N., & Barker, C. (2010). Scientific, Practical and Personal Decisions in Selecting Qualitative Methods. In M. Barkham, G.E. Hardy & J. Mellor-Clark (Eds.). *Developing and Delivering Practice-Based Evidence*. (pp. 65-89). New York: John Wiley & Sons, Ltd.
- Ponterotto, J. G. (2005). Qualitative Research in Counselling Psychology: A Primer on Research Paradigms and Philosophy of Science. *Journal of Counselling Psychology*, 52, 126-136.
- Smith, J. (2008). *Qualitative Psychology. A practical guide to research methods* (2nd ed.). London: Sage Publications.
- Smith, J. A., Flowers, P., & Larkin, M. (2009). *Interpretative Phenomenological Analysis: Theory, method, research*. London: Sage Publications.
- Strauss, A. & Corbin, J. (1994). Grounded Theory methodology: An overview, In N. K. Denzin, and Y.S. Lincoln, (Eds): *Handbook of Qualitative Research*. Sage Publications, London, 1-18.